99-0
(24)

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June 24, 2006

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r)(3). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only. If I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide.

Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

Similar to MD and DO suppliers, I am required to obtain a valid supplier number and must adhere to all of the current supplier standards. I am subject to the Stark laws and other Federal and State regulatory requirements. If CMS plans on making specific allowances for physician suppliers, podiatric physicians must be included. My use of DMEPOS items as an integral part of patient care is no different than that of my MD and DO colleagues.

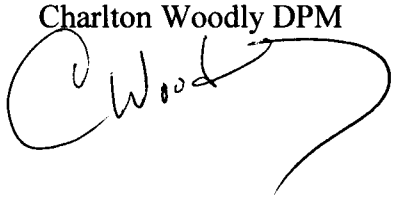
For example, if I treat a patient with an ankle injury, I may determine that an ankle brace is necessary to stabilize the ankle and crutches are necessary to limit weight bearing on

the injured extremity. If I am not a DMEPOS supplier in the new competitive acquisition program because I was unsuccessful in competing to bid to supply to the entire MSA rather than just to my patients, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

Please change the physician definition from 1861(r)(1) to 1861(r)(3) so that I am eligible to bid to supply items to my patients only and execute physician authorizations. I want to be able to continue to provide medically necessary and appropriate care to the patients I serve.

Sincerely,

Charlton Woodly DPM



Hours By Appointment

Telephone 515-576-3338
(FEET)

Rick P. Salocker, D.P.M., P.C.
PODIATRIST-FOOT SURGEON

3 N. 17th STREET
FORT DODGE, IOWA 50501

100

June 26, 2006

Mark B McClellan, MD, PhD
Administrator
Centers for medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Mr. McClellan,

I am writing to urge the Centers for Medicare and Medicaid (CMS) to revise the physician definition) used in the proposed rule that would establish a competitive acquisition program for certain medical equipment, prosthetics, orthotics, and supplies (DMEPOS) from 1861(r)(1) to 1861 (r)(3).

As a podiatric physician (DPM), I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. These individuals are my patients whom have relied on me for the past twenty-eight (28) years of practicing. My reputation is built on applying my best medical judgment and clinical skills in treating them. I use a variety of DMEPOS items. Often, the supply is needed immediately to prevent further complications therefore preventing the need for surgery, i.e. fractures of the metatarsals non-displaced. If I no longer function as a supplier, the patient is forced to travel and risk further injury to the foot. In some instances, a delay in obtaining a DMEPOS supply could actually bring on the need for surgery.

I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. DPM should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to my patients only and the right to execute a physician authorization.

I urge CMS to modify the physician definition from 1861 (r)(1) to 1861 (r)(3) before finalizing the regulations for the competitive acquisition program. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan Statistical Area (MSA), my patients will be negatively impacted.

Sincerely,

Rick P Salocker, DPM

ECP Distributors, Inc.

440 INDUSTRIAL BLVD
POST OFFICE BOX 1038
HAWKINSVILLE, GEORGIA 31036
PHONE: (478) 783-4988 FAX: (478) 783-0489

101

June 22, 2006

Department of Health & Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Re: Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies

To Whom It May Concern:

As a supplier of medical supplies to skilled nursing facilities we would like to express our concerns regarding Competitive Bidding. Previous demonstration projects have determined that it was best to concentrate on non-institutional settings and we agree with this determination. The patients in skilled nursing facilities cannot be compared to those patients cared for at home due to much more complex care plans and acuity levels.

Unlike the home health market, a supplier who specializes in skilled nursing facilities is already in a very competitive market which requires us to service our customers in an efficient and cost effective manner. As a result of this competition, the suppliers to skilled nursing facilities have already met the objectives presented in your Competitive Acquisition for DMEPOS Overview. Competitive Bidding has the potential to increase the overall cost of care in skilled nursing facilities by disrupting the patient's access to quality products and services. More importantly, if the skilled nursing facilities lose their choice of a preferred supplier or the ability to provide the products on their own, there is the potential of putting the patient's health and safety at risk.

We appreciate your consideration of our concerns when deciding this important issue.

Sincerely,

Cal Franklin
President

FOOT & ANKLE SPECIALISTS, P.C.
Specializing in Medicine and Surgery of the Foot & Ankle

102

SCOTT E. HUGHES, D.P.M.
AMY K. BALETTIE, D.P.M.
GREGORY P. VOGT, D.P.M.
CHRISTINE I. TUMELE, D.P.M.

1060 N. Monroe St.
Monroe, Michigan 48162
(734) 241-0200
Fax: 241-1961

8085 Secor Rd.
Lambertville, Michigan 48144
(734) 856-8900
Fax: 856-3615

June 22, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Electronic Comments

Dear Dr. McClellan:

A new CMS rule regarding DMEPOS used the definition of physician that excludes podiatric physicians. I urge CMS to change the definition from 1861(r)(1) to 1861(r).

I prescribe and supply DMEPOS only to my patients. I meet all the same requirements as MD and DO providers. As a physician in the Medicare program I should have the same right to dispense DME.

It improves patient compliance, is more convenient for the patient and leads to better outcomes when DME can be dispensed in the office.

Please reconsider the CMS definition of physician and change it to 1861(r), which will allow DPM's to supply DMEPOS to their patients

Sincerely,

Scott E. Hughes, DPM, FACFAS

Hand Therapy
SPECIALISTS
experienced individual care for the hand & upper extremity

103-0
(15)

Centers of Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

June 26, 2006

Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS
CMS-1270-P

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

Thank you for the opportunity to comment on a regulation that will significantly affect my quality of service to Medicare beneficiaries.

My name is Nancy Nebenzahl, and I am an occupational therapist specializing in the treatment of upper extremity disorders. I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the exam. I have been treating upper extremity patients for over 26 years, and am currently working closely with a local hand surgeon who refers acute and post-operative patients, many of whom are Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

Therapists are unique from other suppliers of DMEPOS. We work as both a provider and a supplier, and it is difficult to divide the two aspects of our profession. As a hand therapist, while orthoses are a critical component in the treatment of my patients, they are just one part of their overall management. When supplying an orthoses, we also look at the disease process, functional and ADL needs, ergonomics, precautions, future orthotic needs, etc. The provision of an orthosis is usually performed as part of a complete treatment plan, and I feel that the proposed competitive bidding system will pose a serious threat to my ability to effectively treat these patients.

Hand therapists typically treat very acute patients, and the need to be able to immediately dispense and adjust an orthosis is crucial to the final outcome of these patients. In the course of treatment of these patients, we will often see

11925 Pearl Road, Suite #202 • Strongsville, OH 44136
phone: 440.238.0300 • fax: 440.238.0750

changes in stability, edema, inflammation, and wound healing that require immediate attention. This regulation, as stated, could significantly interfere with my ability to react to these changes, putting repairs and patients at risk.

In addition, I feel that this system has the potential to place me in an untenable legal and ethical position. If a patient appears in my clinic with an inappropriate orthoses, supplied by another entity, am I to adjust this orthosis, assuming some of the liability for a device that I did not supply or charge for? Or should I let them leave my office and drive to another facility, with its possible delay, knowing that they are inadequately fitted and/or unprotected? This very possible scenario has both legal and ethical considerations.

A patient's needs are thoroughly evaluated by a therapist to determine the appropriate orthosis for beneficiary use. In many cases, a specific brand may be the only one that will appropriately meet the needs of a patient. Should this rule be enforced as written, suppliers will not be required to bid on all brands of a certain orthosis. As a result, there is no guarantee that a beneficiary will be able to find a specific orthosis in their area, potentially limiting their access to an important orthosis. As a hand therapist, I routinely stock those off the shelf orthoses that I know the beneficiary and the referring physician will require.

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

In conclusion, I request that Medicare revise the proposed regulation to allow therapists to continue to supply critical OTS orthoses unimpeded by a competitive bidding process. Thank you again for the opportunity to comment on this proposed regulation.

Sincerely,

Nancy Nebenzahl OTR/L CHT

Nancy Nebenzahl, OTR/L CHT

BOSTON MEDICAL CENTER

Foot Care, Vascular,
and Endovascular Specialists
of Boston Medical Center

Preston Building, F2
732 Harrison Avenue
Boston, MA 02118
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Gary W. Gibbons, M.D.
Executive Director
Vascular Surgery
Professor of Surgery

Geoffrey M. Habershaw, D.P.M.
Clinical Director
Chief of Podiatry
Assistant Professor of Surgery

Christopher M. Locke, D.P.M.
Attending Physician
Instructor in Surgery

Hau T. Pham, D.P.M.
Attending Physician
Instructor in Surgery

Palma M. Shaw, M.D.
Vascular Surgery
Assistant Professor of Surgery

Susan M. Walsh, D.P.M.
Attending Physician
Instructor in Surgery

104

BOSTON UNIVERSITY
SCHOOL OF MEDICINE

June 23, 2006

Mark B. McClellan, MD, PhD
Administrator
CMS - Department of Health and Human Services

RE: CMS-1270-P

Dear Doctor McClellan:

It is in the best interest of Medicare beneficiaries for the CMS to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) *from* 1861(r)(1) *to* 1861(r).

As podiatric physicians and surgeons, we prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. We are required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and are subject to the same Stark requirements that apply to MD and DO physician suppliers. Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply *select* DMEPOS items to *our patients*.

In this hospital based practice which serves an urban community, we use a variety of DMEPOS items. As an example, when a diabetic patient presents with a foot ulcer, it is imperative to off-load the affected area immediately. The patient leaves our office with a surgical boot (a DMEPOS item) on his foot. To send him walking across the hospital campus to another department or facililty to obtain this boot would completely defeat the purpose of reducing pressure on the foot which is a critical component of limb salvage.

I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r) before finalizing the regulations for the competitive acquisition program. The quality of patient care, and therefore the number of successful outcomes, will be greatly diminished if we have to send our patients out for DMEPOS items.

Sincerely,

Susan M. Walsh, DPM

105

Taylor Pharmacy
109 Fairgrounds Rd.
Hardinsburg, KY 40143
270-756-5222
1-800-522-1182

Centers for Medicare &Medicaid Services
Department of Health & Human Services
Attention:CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

June 26, 2006

RE: Proposed program on DME competitive bidding

To Whom It May Concern:

I currently work for a small DME company in a rural area in northcentral Kentucky. I have worked for the same company for nine years and have watched the customers multiply. This did not happen because of bad service. It happened because of many years of hard work and dedicated service to our patients. Our customers are pleased with our service and like the fact that we are located only miles away from their homes. They do not want to deal with a company that is from hundreds of miles away and that they have a fear of never seeing. If they did, they would have started with that company in the first place.

If we are not awarded a contract under the proposed competitive bidding process we will not be the only ones to suffer. The ones we are truely here for, our patients, will suffer as well. As I stated earlier, we live in a very rural area, 70 miles from any major city. If denied, our customers would have to wait for someone from out-of-town (who doesn't know or care about them) to deliver and maintain their equipment for them. They will simply get lost in the shuffle. What if they need a piece of equipment as soon as possible (within 1 hour or less)? No one will be able to service them because they will simply be too far away. An oxygen patient will have to go without oxygen or a person needing a nebulizer will just have to wait until someone can get to them! These are problems our patients should not have to worry about. If someone breaks their leg, they should be able to come to their friends, their local pharmacy, for crutches. Please listen to the small providers, we are the ones that service the majority of the people. We should not be overlooked just because we are in a rural area. Finally, the elderly will not understand these changes. They are already confused from all of the changes taking place regarding Medicare PartD. Do not confuse them any further.

Thank you for your time listening to what I have to say. Even small rural DME providers have a voice.

Thank You,

Kim Howell

Kim Howell

106

ELDERSBURG PODIATRY CARE

ANNETTE M. JOYCE, D.P.M.

1000 Liberty Road, Ste. 101
Eldersburg, MD 21784
Telephone: (410) 795-2155
Fax: (410) 795-2154

June 23, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Electronic Comments

Dear Dr. McClellan:

I am writing to urge the Centers for Medicare & Medicaid Services (CMS) to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) from 1861(r)(1) to 1861(r).

As a podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. These individuals are my patients and they rely on me to use my best medical judgment and clinical skills in treating them. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to my patients only and the right to execute a physician authorization.

In my practice, I offer many DME solutions for foot pain and injuries. As a DME supplier I am able to carefully select the appropriate device that will return the patient to normal activities and hopefully avoid further complications and surgery. All DME is not created equal. It is very important that DME suppliers be well trained in diagnosing and treating lower extremity disease to benefit the patient fully and to dispense the right device. For example, I recently sent a patient who was experiencing posterior tibialis dysfunction to his private insurance's DME warehouse for the casting of a UCB type semi-rigid orthotic. Properly made, this device should have helped the patient to return to normal function quickly and avoid unnecessary surgery in the future. Unfortunately, his insurance would only allow him to see a DME supplier which happened to be an athletic trainer with a high school diploma. The product was not casted properly, a nonstandard "foam" impression" was made and the device failed to help the patient recover. I had to spend several additional office visits with this patient to adjust this device and when we were unable to do so, the patient went on to surgery. I feel this could have been avoided if physicians are able to fit and dispense the proper DME device on the initial visit.

ELDERSBURG PODIATRY CARE

ANNETTE M. JOYCE, D.P.M.

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Eldersburg, MD 21784
Telephone: (410) 795-2155
Fax: (410) 795-2154

I also feel that the diabetic shoe program would suffer greatly if taken out of the hands of podiatric physicians. We are some of the few providers who are able to do a thorough and proper evaluation of the diabetic foot. We are well trained in Podiatric Medical School and residency programs to provide custom shoes for the high risk diabetic population including amputees. I feel that addressing the shoegear of these patients is critically important. With diabetic amputations on the rise, these patients have significantly higher risk of morbidity and mortality from diabetic foot infections. I have seen many patients who are wearing shoes that are too small, often sized improperly from a mail order supply company. These patients are insensate and cannot tell when a shoe is causing a problem until a wound develops. They must be carefully followed by a trained specialist to provide proper footcare and to check on the fit of a new shoe. Many of the patients are unable to travel, are homebound and live on fixed incomes. They would be unable to travel to a DME warehouse, and would simply neglect their feet or go without shoes or supplies altogether. This would be at tragedy.

I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r) before finalizing the regulations for the competitive acquisition program. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

Sincerely,

Annette Joyce D.P.M.
Eldersburg Podiatry Care

Longenecker Pharmacy, Inc.
www.longrx.com

5277 Lincoln Highway
Gap, PA 17527
(717) 442-9523
FAX (717) 442-5246

Parkesburg Shopping Center
Parkesburg, PA 19365
(610) 857-2114
FAX (610) 857-0179

104

June 23, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Re: CMS-1270-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. As a Certified Pharmacy Technician and Medicare Coordinator for an independent retail pharmacy, I offer the following comments for consideration as CMS develops the final regulation.

- **Competitive Bidding Areas**
- I strongly object to CMS' alternative proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers. This restricts beneficiaries' choice. This proposal would severely restrict beneficiaries access to needed items and supplies, and could very well compromise patient health outcomes, particularly when it comes to diabetic testing supplies.

- **Criteria for Item Selection**
- The competitive bidding program should not include common DMEPOS supplies such as ostomy supplies, incontinence supplies, and, most importantly, diabetic testing supplies. If CMS intends to centralize and consolidate the provision of DMEPOS items and supplies, the Agency should limit the competitive bidding program to those unique products that could be provided by a central supplier.

- **Opportunity for Participation by Small Suppliers**
- I urge CMS to take steps to ensure that small suppliers – which include the majority of pharmacy-based suppliers, such as my pharmacy – can participate in the competitive bidding program. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to be competitive in large metropolitan areas.
- After CMS establishes the single payment about for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier. They should not be excluded based on their initial bid.
- CMS must take these steps to preserve beneficiaries' convenient access to SMEPOS supplies and to maintain established provider/patient relationships. I feel this is especially important due to our status as an independent retail pharmacy in a small

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(610) 857-2114
FAX (610) 857-0179

town. We are trusted by our patients and want to continue serving all of their healthcare needs, not just their prescription needs.

- I currently provide diabetic testing supplies, ostomy supplies, incontinence supplies, wound care dressings, walkers, wheelchairs, and canes to patients on a regular basis. Without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients.

- In conclusion, I urge CMS to revise the regulation to:
  - Allow for patients to choose whichever supplier is most convenient to them, including small suppliers like pharmacies.
  - Exclude common DMEPOS supplies such as diabetic testing supplies, ostomy supplies, and incontinence supplies for the competitive bidding program.
  - Take measures to ensure that small suppliers can remain competitive and not be excluded from contracts based on initial bids.

Thank you for considering my view.

Sincerely,

Rebecca A Wenrich, CPhT

Rebecca A. Wenrich, CPhT
Medicare Coordinator
Longenecker Pharmacy, Inc.
108 W. 1st Avenue
Parkesburg, PA 19365
Phone: (610) 857-2114 ext. 229
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RSI Reimbursement Services, Inc. [HME billing solutions]

ADD » PO Box 2570
Greer, SC 29652

PHN » 864 877 5600

FAX » 864 877 9799

108

June 26, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

COMMENTS ON MMA – COMPETITIVE BIDDING

Under the current provisions for the MMA (Competitive Bidding) rural providers will be forced to accept low allowable rates that will be set by winning bids in urban areas. Rural providers have a higher cost structure than urban providers. Rural providers at present do not make as much from their services because of the overhead cost of fuel. They are many times required to drive long distances to service their patients. Many of these businesses will not be able to continue doing business in the proposed atmosphere. Who will be hurt the most? THE PATIENTS.

Why does this have to be so complicated and so costly to our government? Any provider of Home Medical Equipment would rather take a cut in fees than go thru this nightmare and fear of not only losing their businesses but of their patients losing out on quality care.

Sincerely,

Kay Mattox

Kay Mattox
Vice President/Owner

RSI Reimbursement Services, Inc. [HME billing solutions]

ADD » PO Box 2570
Greer, SC 29652

PHN » 864 877 5600

FAX » 864 877 9799

189

June 26, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

COMMENTS ON MMA – COMPETITIVE BIDDING

Rebates to beneficiaries will open up a new opportunity for fraud. It sounds very similar to the Stark Law in which kickbacks are illegal. Now they'll be legal? What's the difference between a rebate and a kickback anyway? There is no difference – they're both enticements for business.

Why does this have to be so complicated and so costly to our government? Any provider of Home Medical Equipment would rather take a cut in fees than go thru this nightmare and fear of not only losing their businesses but of their patients losing out on quality care.

Sincerely,

Kay Mattox

Kay Mattox
Vice President/Owner

RYAN FOOT & ANKLE CLINIC

PODIATRISTS

◆

FOOT & ANKLE SURGEONS

Michael J. Ryan, DPM
Board Certified, American Board of Podiatric Surgeons
Fellow, American College of Foot & Ankle Surgeons

David J. Garchar, DPM
Associate, American College of Foot & Ankle Surgeons

Jeffrey J. Glaser, DPM
Associate, American College of Foot & Ankle Surgeons

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ryanfootandankleclinic.com

110

June 25, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Dr. McClellan:

I have been in private practice in the Charlotte, North Carolina area since 1989. As a podiatrist, a significant portion of my practice is elderly or disabled and therefore participate in the Medicare program.

In the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), the Centers for Medicare & Medicaid Services (CMS) used the definition of physician that excludes podiatric physicians. I urge CMS to change the definition from 1861(r)(1) to 1861(r).

I prescribe and supply select DMEPOS items as part of patient care. I do not supply items to individuals who are not my patients and believe that requiring me to do so would harm Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

CMS will allow MD and DO suppliers to competitively bid to supply DMEPOS only to their patients and will permit them to execute a physician authorization. As a physician in the Medicare program, I should have those same rights. I use DMEPOS items as an integral part of patient care and believe that CMS should use the 1861(r) definition of physician in finalizing its regulations.

I became a supplier several years ago after seeing many of my patients improperly fitted for a prosthetic or not fitted in a timely fashion. This had a direct negative impact on the patient's outcome. If I see a patient who I diagnose with a fracture of the foot, I may decide that it is

medically necessary and appropriate to use a walking boot to treat my patient. I want to make sure the patient is not putting weight on the injured extremity and I need to make sure the walking boot fits properly for that patient. If I am not a supplier in the new program, I will not be able to do that and my patients will suffer.

I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.

Sincerely,

Michael J. Ryan, DPM, FACFAS

APTA
American Physical Therapy Association

1111 North Fairfax Street
Alexandria, VA 22314-1488
703 684 2782
703 684 7343 fax
www.apta.org

111

June 30, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201-1850

RE: Proposed Rule on Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues (71 FedReg. 25654, May 1, 2006)

Dear Administrator McClellan:

On behalf of our 66,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) appreciates the opportunity to comment regarding the proposed rule on competitive acquisition of certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

Physical therapists provide orthotics, ambulatory aids, and mobility assistance devices to the patients they serve to help them improve their function. These items become an integral part of the treatment plan for the patients who need them. Thus, physical therapists have a significant interest in this rule.

As the Center for Medicare and Medicaid Services (CMS) proceeds with implementation of competitive acquisition, APTA strongly urges you to ensure that this program does not obstruct or diminish beneficiary access to medically necessary items or disrupt the delivery of care to Medicare beneficiaries.

Background Information Regarding Provision of DMEPOS by Physical Therapists

Physical therapists practice in a wide variety of settings including acute care hospitals, inpatient rehabilitation facilities, skilled nursing facilities (SNFs), rehabilitation agencies, home health, physical therapist private practice offices, and comprehensive outpatient rehabilitation facilities (CORFs). Physical therapists in private practice (PTPPs) enroll in the Medicare program, obtain

individual provider numbers, and bill Medicare directly for the outpatient therapy services they furnish. Currently, if a physical therapist in private practice bills for DMEPOS items, the therapist must obtain a National Supplier Clearinghouse (NSC) supplier number in addition to their PTPP number. In contrast, physical therapists working in CORFs, rehab agencies, home health, and hospitals do not obtain their own Medicare provider numbers. Rather, their therapy services are billed through the facility. If the facility bills for DMEPOS, the facility must obtain the NSC number or obtain the DMEPOS items from a NSC supplier that bills the Medicare program for the item.

DMEPOS items are provided by physical therapists as an integral part of their physical therapy plan of care. The clinical judgment and expertise of the physical therapist is critical in selecting a particular DMEPOS item for the patient and is based on the therapist's evaluation of the individual patient. The physical therapist ensures that the item is appropriate to achieve the patient's functional goals, is properly sized and fitted for the patient, and that the patient and/or caregiver is educated in the proper use of the item. In many cases, it is essential that the patient have timely access to these items because the DMEPOS item may be necessary to immobilize and support an injured body part or to facilitate safe mobility or post-surgical recovery.

Providers and Practitioners Furnishing DMEPOS Integral to Their Plan of Care Should be Exempt or be Given Special Consideration

Under the proposed rule, providers (rehabilitation agencies, hospitals, CORFs, SNFs, physical therapists in private practice, and other practitioners who choose to bill for DMEPOS items) would be forced to competitively bid in order to continue to provide and bill Medicare for those items. CMS data shows that there are currently 40,000 practitioners and providers enrolled as NSC suppliers, including approximately 1,078 physical therapists in private practice that also have NSC supplier numbers.

APTA strongly urges CMS to exempt or give special consideration under the competitive bidding program to physical therapists in private practice, providers, and other practitioners enrolled in the Medicare program that provide DMEPOS integral to their plan of care. This exemption or special consideration should not apply if they are solely in the business of furnishing items, not providing patient care.

Special consideration should include: phasing in the program for providers and practitioners over at least 4 years; allowing them to provide items only to their patients rather than the entire competitive bidding area; exempting them from the requirement to provide all items identified in a product category; allowing them to participate even if they do not submit exactly the same type of bid required of much larger suppliers; and establishing a different standard for accreditation than that which would apply to a DMEPOS commercial supplier.

The private practice setting for physical therapists provides a clear example of why an exemption or special consideration is necessary. Physical therapists in private practice typically are small businesses providing DMEPOS only to their own patients as an integral part of their service. It does not make sense to apply the same standards to PTPPs as those applied to large commercial suppliers who are exclusively in the business of providing items.

Physical therapists in private practice typically provide services only to their own patients. Yet, under the proposed competitive bidding program, these therapists would be required to serve the entire competitive bidding area in which they practice and therefore provide items to beneficiaries who are not their patients. Physical therapists in private practice often specialize in treating certain conditions and provide a limited range of DMEPOS items for those particular conditions, such as specializing in lower extremity care or upper extremity care. It would be overly burdensome to require these physical therapists to provide all items in a product category when they do not treat patients with conditions that would require a particular type of item. Given the small size of physical therapy practices and the scope of services they furnish, most PTPPs will be unable to participate as contract suppliers under the competitive bidding program as currently proposed.

Medicare beneficiaries will be adversely impacted if physical therapists in private practice can no longer provide items to their patients in their offices. DMEPOS items such as prefabricated and custom orthotics and ambulatory assistance devices are commonly furnished by physical therapists in their office as part of an ongoing plan of care. Physical therapists must be integrally involved in providing DMEPOS items to their patients to ensure that the item is appropriate for the patient's condition or functional limitations, properly sized and fitted for the patient and the patient and or caregiver is instructed in the proper use of the item. In many instances, it is necessary for the physical therapist to provide the item before the patient leaves their practice. For example, physical therapists often provide patients with orthotics to immobilize a body part, such as fracture braces for humeral fractures, air casts for ankle sprains, or static wrist orthotics for carpal tunnel syndrome. When a physical therapist is treating a patient with a fracture or a sprain, it is necessary to immediately provide the patient with the orthotic to immobilize the injury. It would be unsafe and clinically inappropriate to delay the patient's access to items such as orthotics or ambulatory support devices.

Physical therapists also use orthotics to facilitate or augment a patient's movement. It is common for a patient who has had a stroke to develop weakness in his or her ankle dorsiflexors, resulting in a foot drop during the swing phase of gait. Physical therapists provide the patient with an ankle-foot orthosis (AFO) to facilitate movement at the ankle so the patient will not risk tripping or stumbling during ambulation. Patient falls frequently result in further injury and a cascade of other adverse events. By fitting the patient with the appropriate orthosis in the

office, the physical therapist can proceed with gait training to assess whether there are sensory or skin problems and determine whether the orthosis allows the patient to ambulate properly. In contrast, a vendor would provide the orthosis but would not instruct the patient or caregiver in functional activities or be able to determine whether the particular orthosis appropriately facilitates gait and allows the patient to safely perform functional activities.

DMEPOS products are frequently needed as part of an ongoing plan of care for patients with musculoskeletal, neurological and pulmonary related conditions. Ambulation aids including canes, walkers and crutches are required for patients with progressively deteriorating ambulation status to facilitate balance, unload painful joints and minimize unnecessary energy expenditure associated with ambulation. It would be unsafe for a physical therapist to send a patient out of his or her office without a walker, crutches, or cane if the patient needs such an ambulation aid.

One of the goals of the competitive acquisition program is to achieve cost-savings. If Medicare beneficiaries are not furnished with the appropriate item at the appropriate time, the result will ultimately be a higher cost to the Medicare program due to injury, skin breakdown, or delayed healing. Therefore, **CMS should either exempt providers and practitioners such as physical therapists in private practice from the competitive bidding program or give them special consideration.** Another option, described in more detail below, would be to exclude from competitive bidding DMEPOS products that are commonly dispensed from the offices of health care practitioners who also serve as suppliers.

Criteria for Item Selection

Under the program, CMS has authority to determine which items should be subject to competitive bidding. **We urge CMS to limit the items and product categories subject to competitive bidding as the program is largely untested.** By minimizing the number of items subject to competitive bidding, adverse impacts on beneficiaries may be avoided or reduced. **We urge CMS to provide a list of the items that they plan to include in the competitive bidding program prior to implementation and allow sufficient opportunity to provide public comment on that list to ensure that patient care is not negatively impacted.**

<u>CMS should amend the proposed definition of off-the-shelf orthotics</u>

Section 1847(a)(2)of the Social Security Act describes the items subject to competitive bidding as including off-the shelf (OTS) orthotics. It further defines OTS as orthotics which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual. CMS proposes that minimal self-adjustment would mean adjustments that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform without the assistance of a certified orthotist

(that is, an individual certified by either the American Board of Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification").

APTA strongly urges CMS to revise the definition of off-the-shelf orthotics to reflect the fact that physical therapists are qualified to make adjustments that require trimming bending, molding, assembling, or customizing to fit the individual. In other words, the definition of off-the-shelf orthotics should be modified to exclude products where trimming, bending, molding, assembling, or customizing to fit the individual requires the expert assistance of a physical therapist, occupational therapist or a certified orthotist. If CMS does not change the definition, many custom items would be included in the competitive bidding program, which was not the intent of Congress.

The Medicare statute clearly identifies physical therapists as qualified practitioners who furnish custom fabricated orthotics. Section 1834(h)(1)(F) of the Social Security Act, which was added by section 427 of the Medicare, Medicaid, and SCHIP Benefits Improvement Act of 2000 (BIPA) provides, in part, that no payment shall be made for prosthetics and certain custom-fabricated orthotics unless such items are furnished by a "qualified practitioner." Section 1834(h)(1)(F)(iii), in turn, defines "qualified practitioner" to include "a qualified physical therapist or a qualified occupational therapist." CMS has a well-established long-standing and consistent definition of "qualified physical therapist" within the Medicare program, which is included in the Medicare regulations at 42 CFR section 484.4 and the Medicare Manuals (Medicare Benefit Policy Manual, Chapter 15 Covered Medical and Other Services, Section 230.1B). **The statutory language clearly distinguishes physical therapists from orthotists and prosthetists and does not require that a physical therapist (who is licensed in all states) be ABC or BOC certified.**

<u>CMS should exempt items commonly furnished in physician and physical therapist private practices</u>

In the rule, CMS references section 1847(a)(1)(B)(ii) of the Social Security Act, which gives CMS the authority to phase in competitive bidding "first among the highest cost and highest volume items or those items that the Secretary determines have the largest savings potential." In addition, section 1847(a)(3)(B) of the Act grants CMS the authority to exempt items for which application of competitive bidding is not likely to result in significant savings.

We urge CMS to use this exemption authority to exclude from the competitive bidding program the types of items that are provided the offices of physicians, physical therapists or other practitioners that are integral to the provision of their services or necessary for the patient to safely depart from the physical therapist's or physician's office. These should include, but not be limited to: wrist, ankle, and finger orthotics; ankle foot orthotics; air casts; orthotic inserts' spine stabilization braces; cervical collars;

canes; crutches; and walkers. These items are commonly furnished by physical therapists in their office as part of an ongoing plan of care. Physical therapists must be integrally involved in providing DMEPOS to select the appropriate item for the patient to achieve his or her functional goals and to make sure it is properly sized and fitted for the patient to ensure maximum benefit from the item and also prevent skin breakdown or increased risk of falling. If the patient is not initially given the proper item in a timely manner, the Medicare program will incur greater costs. Thus, these items should be excluded from the competitive bidding program because they will not result in significant savings, but rather could result in increased expenditures.

CMS has indicated there is a high likelihood that wheelchairs will be included in the competitive bidding program. **If a product category is established for wheelchairs, we strongly urge CMS to use its exemption authority to exclude the K5 ultralightweight wheelchairs, which are highly customized and unlikely to result in cost-savings.** The defining characteristic of a K5 ultralightweight wheelchair is an adjustable axle plate which allows the physical therapist to determine the patient's proper center of gravity during both static and dynamic activities to promote maximum balance in the wheelchair while still allowing for the necessary seat to floor height for transfers. The axle also adjusts up, down, forward, backward, which is important in the proper positioning of the upper extremities in relation to the pushrim. This feature assists with the prevention of repetitive stress injuries, which is particularly important for people who have weakened shoulders or hands. Because these wheelchairs are highly customized, the competitive bidding process would not result in significant savings to the program.

Quality Standards and Accreditation

APTA is very concerned that CMS has yet to finalize the proposed quality and accreditation standards for DMEPOS suppliers. The standards as previously proposed may be appropriate for large national DMEPOS suppliers, but they would be extremely burdensome for clinicians such as physical therapists and physicians. Compliance with the standards could prevent clinicians and providers from participation in the bidding process and therefore the program. CMS should consider a less burdensome process that would apply to physical therapists in private practice, physicians, and other practitioners and providers. **We recommend that physical therapists in private practice that are licensed by their state board to practice should be "deemed" as qualified to provide patients with DMEPOS.**

Without knowing the true cost of compliance with the quality and accreditation standards, suppliers will not be able to calculate accurate bids that produce the pricing that the Medicare program is hoping for and that will also ensure they can continue to stay in business. A lack of understanding of the true costs associated with compliance could eventually have a negative impact on the timely supply of DMEPOS to beneficiaries including driving some suppliers out of

business. **We strongly urge CMS to delay the release of the final rule for the competitive acquisition of DMEPOS until after the quality and accreditation standards have been finalized. In addition, we urge CMS to give suppliers an adequate period of time to learn about and understand the implications of the quality standards, the associated accreditation process, and the various elements of the final rule before they are required to submit any kind of bid or other expression of interest in participating in the competitive acquisition program.**

Physician Authorization/Treating Practitioner
Under the current proposal, physicians can request a specific brand of DMEPOS for patients if the physician or treating practitioner determines that use of the particular item would avoid an adverse medical outcome for that patient. If the physician or treating practitioner requests a specific item, brand, or mode of delivery, contract suppliers would be required to furnish that item or assist the beneficiary in finding another contract supplier to provide that item. We believe that this provision is extremely important as we are deeply concerned that under the new competitive bidding program, suppliers will have strong incentives to offer lower quality brands and less selection due to cost pressures.

We strongly urge CMS to add language to the rule acknowledging that physical therapists play a key role in specifying the need for a particular brand item and the adverse outcome that will occur if the patient does not receive that item. In most cases a physical therapist assesses a patient and makes recommendations to the patient's physician concerning the best item for that particular patient's condition. The physician ultimately orders the item based on the therapist's recommendation. It is important to ensure that the patient is assessed by the appropriate practitioner in order to ensure that the appropriate brand item is selected.

Within each HCPCS code there are a number of different brands or products. Not all the brands described by the HCPCS code will address the patient's needs. For example, although wheelchair cushions may share the same code they do not share the same characteristics. Some wheelchair cushions use air to offer pressure relief but may not be as good for positioning the patient correctly in their wheelchair. Cushions that are filled with gel can provide good positioning but may not protect skin integrity adequately for patients who are very thin. Many factors are taken into consideration in making these recommendations for patients, and selection of the correct wheelchair cushion is critical in preventing skin breakdown and pressure ulcers. The proper wheelchair cushion can also assist patients with activities of daily living such as transfers. Physical therapists that specialize in seating and mobility are familiar with the products currently available and are experts in selecting the proper item for a given patient, taking all of these factors into account.

Although CMS is proposing that specific brands may be requested to avoid an adverse medical outcome, APTA remains concerned that there will be significant delays in receiving these items. When a request is made for a specific brand item that is not in the contract supplier's regular inventory, the contract supplier will need to go elsewhere to obtain the item. This could result in significant delays in access to these items, thereby limiting the ability of the therapist to proceed with the therapy plan of care and progress the patient to recovery. If they cannot proceed, the patient may lose functional gains they have previously made or remain in costly settings instead of being discharged to their home. The potential delays could have disastrous results to patients and could ultimately be more costly to the Medicare program.

We urge CMS to aggressively monitor contract suppliers to ensure that they are not providing a different item than that prescribed by the physician or treating practitioner, pressuring the physician to revise their order, or delaying delivery of the item. Such actions could result in delays in patient care and subject to the patient to risk of injury.

Submission of Bids

In the proposed rule, physicians and skilled nursing facilities are exempt from the requirement to furnish items to an entire competitive bidding area and can choose to furnish DMEPOS items to only those patients that they serve. **APTA strongly urges CMS to extend this exemption to other clinicians in private practice, such as physical therapists.** Given that clinicians are primarily focused on treating patients and provide DMEPOS items only to their own patients, physical therapists in private practice would be unduly burdened by having to furnish DMEPOS to an entire competitive bidding area. If they are required to provide services to the entire area, it is unlikely that many would reorganize their business to do so. Consequently, they will be unable to provide items to patients that are integral to their patient's plan of care. This is likely to disrupt the delivery of services and adversely affect the quality of care.

Payment Basis: Obligation to Furnish DMEPOS Items at Same Cost of Patient's Resident MSA

In the proposed rule, patients who live in competitively bid metropolitan statistical areas (MSAs) must be provided items of DMEPOS at the price of their resident MSA, and not where the DMEPOS is being furnished to them. Due to geographic differences in the pricing of items, it could be that a supplier may not wish to furnish items of DMEPOS at a lower cost than they would receive from an entity with their own MSA. This could result in potential access problems for individuals who travel to warmer climates during the winter months. In addition, non-contract suppliers may not be willing to furnish items to Medicare beneficiaries at a lower cost, which could result in the same difficulty accessing items. It will also be difficult for suppliers to find out what the competitively bid price is at a beneficiary's resident MSA, or at the minimum, add another administrative step in order to find this information.

We urge CMS to consider allowing Medicare beneficiaries to receive DMEPOS at the Medicare fee schedule amount in effect where they are physically located at the time the item is furnished to them, and not their resident MSA. At the very least, such a policy must be adopted in cases where the beneficiary maintains a permanent residence in one of the competitive bidding areas. It would be unfair to hold suppliers in areas being visited by a beneficiary to the contract price obtained by selected suppliers under a competitive bidding process (through which winning suppliers presumably obtain some advantages such as increases in market share) and where local costs may be far different.

Opportunity for Participation by Small Suppliers

Section 1847(b)(6)(D) of the Social Security Act requires CMS to take steps to ensure that small suppliers of items have an opportunity to be considered for participation in the competitive bidding program. Although CMS includes a reference to steps it has taken to allow small suppliers to participate, these steps are not sufficient to enable a small provider such as a physical therapist in private practice to participate in the program. This may be due to the fact that CMS is proposing to use a definition of "small supplier" that would include nearly all suppliers, rather than one recognizing the great diversity of such "small suppliers" in terms of size, number of products offered, the size of market currently being served, the integral nature of DMEPOS products to other professional services provided to Medicare beneficiaries, and other important factors. Clearly, the suppliers with the largest product offering that can obtain economies of scale benefit from the proposed competitive bidding program.

CMS mentions that it considered allowing suppliers with fewer than 10 full-time equivalent employees to designate a service area that is smaller than the entire competitive bidding area. We believe such a policy would be helpful to small suppliers. **To allow small suppliers a greater opportunity for participation, CMS should also allow any qualified supplier to provide DMEPOS if the provider is willing to accept the single payment amount determined under the competitive bidding process.** We believe this could be deemed to satisfy the requirement that a bid include "a particular price" at least for certain categories of small suppliers, such as physical therapists or other health care practitioners who provide DMEPOS products as an integral part of other professional services they provide to their own patients. **Additionally, these small suppliers should be allowed to submit a level of bid-related information more in keeping with the amount of DMEPOS products they typically provide to Medicare beneficiaries.** In other words, they should not be expected to go through the costly and time-consuming bidding process of preparing the same type of bid that CMS would require from large DMEPOS suppliers who provide millions of dollars of DMEPOS products and serve an entire community.

In order to allow small suppliers to participate, CMS proposes that suppliers form networks for DMEPOS bidding consisting of several companies joined together through a legal contractual relationship to submit bids. APTA believes this is not a realistic option for most small suppliers. Setting up a network would involve considerable legal resources to ensure that the network is not violating the antitrust laws, as well as significant administrative resources.

We are deeply concerned that if small suppliers are unable to participate, there will be a significant negative impact on patients. Often, small suppliers specialize in providing items for a specific condition, such as wound care products, orthotics, or a specific type of wheelchair. These suppliers offer considerable expertise in evaluating both the patient and the item in order to provide the patient with the best possible outcome. Many suppliers also use their expertise to provide adjustments and repairs of the items over an extended time frame.

Rebate Program

CMS proposes to allow contract suppliers that submitted bids below the single payment amount to provide the beneficiary with a rebate. We recommend CMS not proceed with implementation of such a program as offering such rebates would most likely be considered a violation of the federal anti-kickback statutes. The Department of Health and Human Services Office of Inspector General has issued numerous fraud alerts, bulletins, and advisory opinions in which it emphasizes that providing things of value to beneficiaries violates the anti-kickback laws. If one contract supplier offers a rebate to a Medicare beneficiary and another does not, the beneficiary clearly has an incentive to select the supplier that offers the rebate. The purpose of the anti-kickback laws is to prohibit financial incentives from driving the delivery of care.

Conclusion

In conclusion, among its key recommendations, the APTA urges CMS to take the following actions:

- Exempt or give special consideration under the competitive bidding program to physical therapists in private practice, providers, and other practitioners enrolled in the Medicare program who provide DMEPOS as integral to their plan of care. Special consideration should include: phasing in the program for providers and practitioners; allowing them to provide items only to their patients rather than the entire competitive bidding area; exempting them from the requirement to provide all items identified in a product category; allowing them to participate even if they do not submit exactly the same type of bid required of much larger suppliers.

- If CMS chooses not to exempt practitioners, the Agency should use its authority to exclude from the competitive bidding program the types of items that are commonly provided in a physician, physical therapist or

other practitioner's office that are integral to the provision of their service or necessary for a patient to depart from the physical therapist's or physician's office.

- Revise the proposed definition of off-the-shelf orthotics to reflect the fact that physical therapists also make adjustments that require expertise in trimming bending, molding, assembling, or customizing to fit the individual.

- Delay the release of the final rule for the competitive acquisition of DMEPOS until after the quality and accreditation standards have been finalized.

- Add language to the rule acknowledging that physical therapists play a key role in specifying the need for a particular brand item and the adverse outcome that will occur if the patient does not receive that item.

Thank you for your consideration of these comments. We look forward to working with CMS as you proceed with implementation of these rules. If you have any questions regarding the issues raised, please contact Gayle Lee at 703-706-8549 or Karen Stavenjord at 703-706-8508.

Sincerely,

G. David Mason
Vice President, Government Affairs

AOTA The American Occupational Therapy Association, Inc.

Occupational Therapy: Skills for the Job of Living

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June 30, 2006

Mark B. McClellan, M.D., Ph.D
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, Maryland 21244

Re: Proposed Rule on Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues

Dear Dr. McClellan:

On behalf of more than 35,000 occupational therapy professionals, the American Occupational Therapy Association (AOTA) submits the comments below in response to the proposed rule on the Competitive Acquisition for Certain DMEPOS and Other Issues (CMS-1270-P), published in the Federal Register on May 1, 2006 (71 FR 25654). AOTA appreciates the time and thoroughness the Centers for Medicare and Medicaid Services (CMS) provided in meeting with our organization on June 12, 2006 to discuss how the competitive acquisition proposed rule affects therapists.

Occupational therapy is a health, wellness, and rehabilitation profession working with people experiencing stroke, spinal cord injuries, brain injury, congenital conditions, developmental delay, joint replacements and surgeries, mental illness, and other conditions. Occupational therapists help people regain, develop, and build skills that are essential for independent functioning, health, and well-being in the home and community. Occupational therapy professionals have unique expertise in evaluating participation and enabling engagement in meaningful occupations (e.g., activities of daily living). Specifically, occupational therapy evaluation and treatment often is used pre- or post- orthopedic surgery or injury as well as to manage the negative effects of chronic conditions. It includes a multifaceted evaluation of a patient's range of motion, functional abilities, limitations (sensory, motor function, judgment, etc.), home and community needs, and other elements.

AOTA wants to assure that CMS is clear regarding the manner in which occupational therapists are involved in the evaluation for, selection and fitting of, design and fabrication of, training for use of, and provision of DMEPOS items. The major examples of occupational therapists' roles include (1) the role of occupational therapists with patients requiring off-the-shelf (OTS) orthotics, (2) the role of occupational therapists with custom fabricated orthotics, and (3) the role of occupational therapists with patients requiring wheelchairs, scooters and related mobility devices. We raise the issue of the role of occupational therapists with custom fabricated orthotics only with respect to the proposed rule's definition of OTS orthotics; we comment below on custom-fabricating only in this context since we know that custom-fabricated orthotics are not included in the competitive acquisition program.

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Orthotics and Occupational Therapy

Often a patient's occupational therapy plan of care includes the use of orthotics to help perform activities of daily living, or as a preparatory tool to enable a patient to regain functional abilities and range of motion. Medicare-covered occupational therapy services include the design, fabrication, fitting, provision of, and training in the use of orthotics as part of a Medicare patient's occupational therapy plan of care. In addition, Medicare pays for the device itself as DMEPOS. Currently, occupational therapists who work in private practice settings and who supply orthotics to Medicare beneficiaries are permitted to supply orthotics by obtaining a supplier number from the National Supplier Clearinghouse in order to submit claims for OTS orthotics that are billed using HCPCS Level II codes. Specifically, the DMEPOS item is billed using a HCPCS code and the separate occupational therapy services are billed using CPT codes. In this scenario, the occupational therapist is involved in: (1) evaluating the patient's need for the orthotic (2) selecting and providing the orthotic to the patient, which may involve fitting and training for the orthotic, and (3) providing continuing occupational therapy under a written plan of care as it concerns the orthotic and any additional appropriate occupational therapy services.

Wheeled Mobility and Occupational Therapy

In addition, occupational therapists working in a variety of settings evaluate Medicare beneficiaries' seating and position needs for wheelchairs, mobility devices, and assistive technology. The mobility-related equipment may be provided to the beneficiary in one of two ways: (1) an outside mobility device supplier provides the device directly to the beneficiary and bills the Medicare program or (2) the occupational therapist is a device supplier by virtue of having obtained his or her own supplier number and bills Medicare directly. While an occupational therapist in theory could be a commercial supplier of wheelchairs, an occupational therapist in practice rarely obtains a billing number for the sole purpose of supplying and billing for mobility-related equipment and rarely supplies this equipment directly to the beneficiary. Rather, the occupational therapist typically performs seating and positioning evaluations and assesses the home environment for potential modifications related to the mobility-related equipment. In this practice scenario, the beneficiary obtains the mobility-related equipment from a commercial supplier, and the occupational therapist provides ongoing treatment, evaluating functional needs and enabling engagement in activities of daily living. The occupational therapy evaluation and treatment is directly concerned with the appropriateness of the device for the individual as well as with the individual's other occupational needs and goals.

We hope that this background information is helpful in reviewing and considering our comments on the following sections of the proposed rule:

I. Criteria for Item Selection: Definition of Off-the-Shelf (OTS) Orthotics

AOTA has two main concerns with CMS' definition of OTS orthotics, specifically related to the meaning attributed to the phrase "minimal self-adjustment for appropriate use." First, CMS states that minimal self-adjustments "mean adjustments that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform without the assistance of a certified orthotist" and goes on to state that CMS would consider adjustments that can "only" be made by a certified orthotist as adjustments that require expertise to trim, bend, mold, assemble, and customize the orthotic to fit the patient. AOTA asserts that

occupational therapists, physical therapists, and physicians are also licensed and trained to trim, bend, mold, assemble, and customize the orthotic to fit the patient.

Second, by stating that adjustments which can "only" be made by a certified orthotist do not constitute self-adjustments, CMS has inadvertently implied that customized orthotics are those orthotics that only certified orthotists may customize and provide. AOTA strongly opposes this assertion and urges CMS to revise the definition of OTS orthotics. Under the Social Security Act, occupational and physical therapists are recognized as Medicare practitioners who furnish orthotics to Medicare patients pursuant to a written plan of care, while the Act recognizes orthotists as only suppliers of DMEPOS items, unconnected to a written plan of care. Thus, the definition of the term OTS orthotics in the proposed rule would be accurate only if CMS also recognized licensed physicians and therapists as professionals who possess the expertise to customize orthotics. We suggest the following revised language:

> "Minimal self-adjustment" means adjustments that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform without the assistance of a *physician, physical therapist, occupational therapist, orthotist, or other professional designated by the Secretary.*

In addition, with regard to exempting certain items from competitive acquisition, AOTA urges CMS to comply with the Congressional mandate of Section 1847(b)(7) of the Social Security Act and truly "consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals." CMS must invoke the authority conveyed by Congress and consider excluding from competitive bidding those DMEPOS items that are typically furnished to Medicare patients only in the course of clinical treatment under a plan of care by occupational therapists and others, such as physicians. Therefore, AOTA requests that CMS exclude from competitive acquisition certain OTS orthotics typically provided by occupational therapists that do not result in significant cost savings to the Medicare program.

In Appendix A, we are providing a list of custom fabricated orthotics, a list of prefabricated orthotics, and other orthotics that are typically provided by occupational therapists and other professionals. We realize that customized orthotics are not subject to the competitive acquisition program. However, we are nevertheless providing a list of custom fabricated orthotics that CMS should exclude because the demonstration projects in San Antonio and Polk County had included some customized orthotics. We want to prevent this confusing overlap from occurring again in the actual program. In contrast, we are also providing a list of prefabricated and other orthotics that we understand CMS may consider as OTS orthotics and, hence, subject to competitive bidding. Again, as stated above, we urge CMS to exclude from competitive acquisition certain OTS orthotics typically provided by occupational therapists that do not result in significant cost savings.

II. Submission of Bids under the Competitive Bidding Program: Providers and Physician Treatment

Occupational therapists generally work for Medicare providers (e.g., hospitals, SNFs, home health agencies, rehab agencies, CORFs) or in private practice (similar to physicians working in their offices or

clinics) with their own Medicare provider numbers. Occupation therapists are not "commercial suppliers." Like physicians, occupational therapists furnish DMEPOS items only to their patients, are regulated in every State, and furnish the full range of Medicare-covered services and items pursuant to the State scope of practice laws. In contrast, the Social Security Act permits orthotists to only supply DMEPOS items just like other "commercial suppliers." Therefore, there is no statutory, regulatory, or policy rationale for treating occupational therapists and physicians differently under the competitive acquisition program. Applying the same logic and facts employed by CMS to exempt physicians from the requirement to serve all Medicare beneficiaries in the competitive bidding area, CMS must also exempt from that requirement occupational therapists that serve only their patients and do not operate as commercial suppliers. When the Social Security Act restricts practice, it does so specifically and intentionally (e.g., orthotists can only supply DMEPOS). Treatment similar to the way physicians are treated in the proposed rule is our minimal expectation.

AOTA's preferred approach would be to exempt physicians, occupational therapists and others practitioners altogether. Simply put, the competitive acquisition program should be limited to "commercial suppliers." It should not be applied to physicians and non-physician practitioners who furnish DMEPOS items as an integral component of a written plan of care specifically established to treat a particular beneficiary.

In addition, CMS must define product categories narrowly. Because of the specialized training and education required to treat particular parts of the human anatomy, some physicians and therapists treat only certain parts of the body (e.g., only hands, wrists, and elbows or only knees and ankles). Therefore, if CMS designated all OTS orthotics as one product category, many physicians and therapists would not be able to participate in the competitive acquisition program because their practice is only in one area. It would be unethical for those professionals to be required to supply products outside their expertise or scope of practice. AOTA recommends that CMS designate OTS orthotics based on body region (i.e., upper extremity orthotics vs. lower extremity orthotics) because this is reflective of physician and therapist scope of practice and expertise.

III Conditions for Awarding Contracts

AOTA has attached the comments it submitted to CMS on the "Draft Quality Standards" (Attachment) and incorporates those comments as comments to the proposed rule on the competitive acquisition program. AOTA maintains that CMS must deem occupational therapists as being accredited based solely on the licensure and educational requirements they already fulfill and because their role as supplier is inextricably linked to their professional services.

IV. Opportunity for Participation by Small Suppliers

CMS must remember that Section 1847(b)(6)(D) is entitled "protection" of small suppliers and not the mere identification of small suppliers. AOTA urges CMS to again utilize its authority granted by Congress to indeed treat small suppliers differently. Occupational therapists are not "commercial suppliers" with warehouse-like facilities that ship volumes of DMEPOS items. Occupational therapists are health care professionals treating patients using various clinical techniques, including the use of DMEPOS items. In order to comply with this statutory provision, CMS must develop and implement steps that would proactively assist small suppliers, including occupational therapists, so that they may

participate in the competitive acquisition program. For each component of the competitive acquisition program (e.g., designation of each product category), CMS must carefully and fully consider the role of and impact on small suppliers.

V. Physician Authorization/Treating Practitioner

AOTA respectfully requests that CMS acknowledge the vital role of occupational therapists and physical therapists in determining whether a particular patient requires a particular brand of a DMEPOS item, especially in the area of wheelchairs and other mobility-related equipment. The proposed rule restricts this role to physicians. The occupational therapist must evaluate the patient's impairments and functional status to identify which equipment would meet the patient's clinical needs. Such an assessment involves, among other things, measurements of height, weight, obesity, cardiac and respiratory status, muscle strength, and physical environment.

The consequence of providing a beneficiary with inappropriate equipment or delayed delivery of the appropriate equipment would indeed constitute an adverse medical outcome. AOTA is concerned that a beneficiary may be furnished a brand of a wheelchair cushion, for example, by a commercial supplier that may not be appropriate for the patient merely because that commercial supplier "won" the bid for that competitive bidding area but does not stock the particular brand that is appropriate for the beneficiary. Requiring the patient, who may have developed skin ulcers as a result, to visit her treating physician or therapist to be fitted with the correct wheelchair cushion would hinder timely patient care and recovery. Such a scenario would also lead to significant increased costs to the Medicare program due to the necessity for multiple health care practitioner visits as well as additional cost of care to address unexpected problems that were unnecessarily caused by the improper equipment. CMS has already acknowledged the appropriate role of physicians in this process. Accordingly, AOTA requests that CMS both identify and incorporate the role of occupational therapists in the brand- or mode-specific authorization process by treating physicians and other practitioners equally.

VI. Quality Standards and Accreditation

Again, AOTA has attached the comments it submitted to CMS on the "Draft Quality Standards" (Attachment) and incorporates those comments as comments to the proposed rule on the competitive acquisition program. AOTA maintains that CMS must deem occupational therapists as accredited based solely on the licensure and educational requirements they already fulfill and because their role as supplier is inextricably linked to their professional services.

VII. Low Vision Aid Exclusion (Proposed § 414.15)

AOTA is concerned with CMS' global re-interpretation of the definition of eyeglasses found in § 1862(a)(7) of the Social Security Act. Medical technology is progressing on a daily basis, especially in connection with low vision rehabilitation. AOTA asserts that CMS' arbitrary redefining of technologically advanced low vision aides is outside the scope of this competitive acquisition rule. Such a large-scale ruling is better addressed through a separate regulatory process subject to notice and comment, and after meaningful discussions with all relevant stakeholders. AOTA urges CMS not to implement the low vision aid definition until further discussion and stakeholder feedback has been obtained and the appropriate regulatory process has been followed.

VIII. Conclusion

AOTA appreciates the opportunity to submit these comments on CMS' proposed rule on the competitive acquisition program. AOTA urges CMS to consider the impact of the competitive acquisition program on occupational therapists as well as physicians, physical therapists, and other Medicare practitioners who supply DMEPOS items to their Medicare patients, but do not operate as commercial suppliers. AOTA strongly recommends that CMS specifically treat occupational therapists in the same manner CMS has proposed to treat physicians, nurse practitioners, physician assistants, and clinical nurse specialists.

AOTA requests that due consideration be given to these comments. Thank you, again, for the opportunity to comment on the proposed rule. We look forward to a continuing dialogue with CMS on these issues.

Sincerely,

Christina A. Metzler
Chief Public Affairs Officer

Attachment: AOTA's comments to Proposed Recommendations on Quality Standards of Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Items and Services submitted to CMS on November 28, 2005 (with attachment).

cc: Herb Kuhn (via e-mail)
Carol Blackford (via e-mail)
Linda Smith (via e-mail)
Martha Kuespert (via e-mail)
Walt Rutemueller (via e-mail)
Joel Kaiser (via e-mail)
Sandra Bastinelli (via e-mail)
Stacy Coggeshall (via e-mail)
Pam West (via e-mail)

APPENDIX A

Custom Fabricated Orthotics

CODE	DESCRIPTION
L3671	SO, shoulder cap. Custom
L3672	SO, abduction, airplane, without joint,custom
L3673	SO, abduction, airplane, nontorsion, custom
L3702	EO, rigid, without joint, custom
L3763	EWHO, without joints, custom
L3764	EWHO, rigid, nontorsion, custom
L3765	EWHFO,rigid, without joints, custom
L3766	EWHFO,rigid, nontorsion, custom
L3800	WHFO short opponen no attach
L3805	WHFO long opponens no attach
L3900	Hinge extension/flex wrist/f
L3901	Hinge ext/flex wrist finger
L3904	WHFO electric custom fitted
L3906	WHO w/o joints CF
L3907	WHFO wrst gauntlt thmb spica
L3905	WHO, turnbuckle, custom
L3913	HFO, without joints, custom
L3919	HO, without joints, custom
L3921	HFO, turnbuckle, custom
L3933	FO, without joints, custom
L3935	FO, nontorsion joint, custom
L3961	SEWFO, shoulder cap, without joints, custom
L3967	SEWHO, abduction, airplane, without joints, custom
L3971	SEWHO, should cap, nontorsion, custom
L3973	SEWHO, abduction, airplane, nontorsion, custom
L3975	SEWHFO, Shoulder cap, without joints, custom
L3976	SEWHFO, abduction, airplane, without joints, custom
L3977	SEWHFO, shoulder cap, nontorsion, custom
L3978	SEWFO,abduction, airplane, nontorsion, custom
L3985	UE fx Forearm, hand with wrist hinge, custom
L3986	UE fx Humeral, rad/ulna, wrist, custom

Prefabricated Orthotics

L3650 SO, shlder fig 8 abduct restrain, prefab
L3651 SO, single shoulder, elastic, prefab
L3652 SO, double shoulder. Elastic, prefab
L3660 SO, figure 8, abduct restrainer canvas&web, prefab
L3670 SO, acromio/clavicular canvas&web, prefab
L3675 SO, canvas vest, prefab
L3700 EO, elastic w stays, prefab
L3701 EO, elastic, prefab
L3710 EO, elastic with metal joint, prefab
L3720 EO, forearm/arm cuffs free motion, preafab
L3730 EO, forearm/arm cuffs ext/flex assist, prefab
L3740 EO, forearm/arm cuffs adj lock w/ active control, prefab
L3760 EO, adjust locking position, prefabricated
L3762 EO, rigid, w/o joints, prefab
L3807 WHFO,no joint, prefabricated
L3908 Wrist cock-up non-molded
L3909 WO, elastic, prefab
L3910 WHFO swanson design, prefab
L3911 WHFO, elastic,prefab
L3912 HFO, flex glove w/elastic finger, prefab
L3914 WHO, wrist extension cock-up, prefab
L3916 WHFO, wrist extens w/ outrigg, prefab
L3917 HO, metacarpl fx orthosis, prefab
L3918 HFO, knuckle bender, prefab
L3920 HFO, knuckle bender with outrigg, prefab
L3922 HFO, knuckle bend 2 seg to flex joints, prefab
L3923 HFO w/o joints, prefab
L3924 WHFO, Oppenheimer, prefab
L3926 WHFO, Thomas suspension, prefab
L3928 HFO, extension w/ clock spring, prefab
L3930 WHFO, finger extension with wrist support, prefab
L3932 FO, safety pin, spring wire, prefab
L3934 FO, safety pin modified, prefab
L3936 WHFO, palmer, prefab
L3938 WHFO, dorsal wrist, prefab
L3940 WHFO, dorsal wrist w/ outrigger, prefab
L3942 HFO, reverse knuckle bender, prefab
L3944 HFO, reverse knuckle bend w/ outrigg, prefab
L3946 HFO, composite elastic, prefab
L3948 FO, finger knuckle bender, prefab
L3950 WHFO, combination Oppenheimer w/ knuckle bend, prefab

L3952 WHFO, combination Oppenheimer w/ rev knuckle 2 attachments, prefab
L3954 HFO, Spreading hand, prefab
L3956 Add joint upper ext orthosis
L3960 SEWHO, abduction, airplane, prefab
L3962 SEWHO, abduction, erbs palsey design, prefab
L3969 SEO, mobile arm support, monosuspension arm/hand supp, prefab
L3970 SEO, addition to mobile arm support, elevating proximal arm
L3980 UE fx orthosis humeral, prefab
L3982 UE fx orthosis rad/ul, prefab
L3984 UE fx orthosis wrist, prefab

Additional Orthotics

L3810 WHFO, thumb abduction bar, C bar
L3815 WHFO, second MP abduction assist
L3820 WHFO, IP ext assist w MP ext stop
L3825 WHFO, MP extension stop
L3830 WHFO, MP extension assist
L3835 WHFO, MP spring extension assist
L3840 WHFO, spring swivel thumb
L3845 WHFO, thumb IP ext assist w/ MP stop
L3850 WHFO, action wrist w/ dorsiflex assist
L3855 WHFO, adj MP flexion control
L3860 WHFO,adj MP flex control IP
L3890 Additon, UE joint, wrist or elbow concentric torsion

AOTA The American Occupational Therapy Association, Inc.

Occupational Therapy: Skills for the Job of Living

Via email to DMEPOS Quality Standards Public Comments@cms.hhs.gov
Via first class mail

November 28, 2005

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Mail Stop C5-11-24
Baltimore, Maryland 21244-1850

RE: Proposed Recommendations on Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Items and Services

Dear Doctor McClellan:

The American Occupational Therapy Association (AOTA) appreciates the opportunity to submit the comments below in response to the proposed "Quality Standards of Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and other items and services" ("Draft Quality Standards"), prepared by Abt Associates Inc. for the Centers for Medicare and Medicaid Services (CMS) and posted to the CMS website on September 26, 2005.

The AOTA represents more than 35,000 occupational therapy professionals, many of whom provide services to Medicare beneficiaries. Occupational therapy is a health, wellness, and rehabilitation profession working with people experiencing stroke, spinal cord injuries, brain injury, congenital conditions, developmental delay, joint replacements and surgeries, mental illness, and other conditions. Occupational therapists help people regain, develop, and build skills that are essential for independent functioning, health, and well-being in the home and community. Occupational therapy professionals have unique expertise in evaluating participation and enabling engagement in meaningful occupations (e.g., activities of daily living). Specifically, occupational therapy evaluation and treatment often is used pre or post orthopedic surgery or injury. It includes a multifaceted evaluation of a patient's range of motion, functional abilities, limitations (sensory, motor function, judgment, etc.), home and community needs, and other elements. Often a patient's occupational therapy plan of care includes the use of orthotics to help perform activities of daily living or as a preparatory tool to enable a patient to regain functional abilities and range of motion. Medicare-covered occupational therapy services include the design, fabrication, fitting, provision of, and training in the use of orthotics as part of a Medicare beneficiary's plan of care. Accordingly, occupational therapists are impacted by the draft standards developed by Abt Associates.

AOTA's comments will address several issues. First, the application of the Draft Quality Standards and accreditation requirements to occupational therapists; Second, the unnecessary duplication of safeguards for occupational therapists created by the Draft Quality Standards, Third, issues specifically related to the particular Draft Quality Standards relating to Supplier Product Specific Service Requirements for Customized Orthotics and Prosthetics ("O&P Standards") and Fourth, consistency with

CMS' proposal for fabrication and furnishing of custom orthotics and prosthetics offered during the negotiated rule making under §427 of the Benefits Improvement and Protection Act of 2000 ("BIPA") regarding Special Payment Provisions for Prosthetics and Certain Custom Fabricated Orthotics.

I. Application of the Draft Quality Standards and Accreditation Requirements to Occupational Therapists

Section 302(a) of the Medicare Modernization Act of 2003 (Pub. Law 108-173) ("MMA") establishes quality standards and accreditation requirements for the provision of DMEPOS. Section 302(a)(B) states that the Secretary of the Department of Health and Human Services may develop quality standards after consultation with representatives of relevant parties. The AOTA has reviewed the list of individuals and organizations that were consulted with respect to the Draft Quality Standards.[1] Specifically, AOTA notes that out of twenty experts consulted for all of the various supplier specific requirements, ten were representing orthotists and prosthetists according to the Draft Quality Standards. The AOTA respectfully submits that occupational therapists and other practitioners, such as physicians and physical therapists, were not consulted by Abt Associates as experts with respect to the O&P Standards, nor were adequately represented on the Program Advisory Oversight Committee (PAOC), which Abt consulted. Without the adequate consultation of occupational therapists and other practitioners, CMS has not met the statutory mandate of the MMA to develop quality standards "after consultation with representatives of relevant parties" if the Draft Quality Standards are to apply to such practitioners. ***Accordingly, the lack of consultation with occupational therapists or their representatives suggests that CMS has assumed that the quality standards do not apply to occupational therapists. AOTA proposes that CMS clarify that it does not intend the quality standards to apply to occupational therapists.***

II. Quality and Accreditation Standards For Occupational Therapists Providing DMEPOS Is Unnecessary and Duplicative

AOTA supports CMS in its efforts to implement the law to develop quality standards for providers of DMEPOS to ensure that Medicare beneficiaries receive high quality items. AOTA understands that due to the lack of state licensure for DME suppliers, as well as for orthotists and prosthetists (except in nine states)[2], that unregulated DME suppliers with little or no relevant education or training may provide ill-fitting orthotics to Medicare beneficiaries. AOTA agrees that only licensed or appropriately trained professionals should be providing such supplies to Medicare beneficiaries.

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[1] In addition to consulting with experts, Abt Associates requested advice from the Program Advisory Oversight Committee (PAOC) in completing its Draft Quality Standards. The PAOC was formed according to statute to provide advice on the development and implementation of the Competitive Acquisition Program. AOTA notes that the Quality Enhancement and Fraud Reduction provisions of Section 302(a) are separate and apart from the Provisions establishing Competitive Acquisition Programs, which are found in Section 302(b). In addition to Abt Associates failing to consult with any occupational therapy experts, neither highly qualified AOTA nominated representative was selected as a member of the PAOC.

[2] Those states that have granted licensure to orthotists and prosthetists have not precluded occupational therapists from designing, fabricating, fitting, furnishing, and training in orthotics and prosthetics.

A. Enrollment Status as Qualified Occupational Therapists

When considering to whom the quality standards for suppliers should apply, AOTA recommends that CMS first consider the enrollment status of the supplier. Although the terminology that is used to enroll Medicare Part B practitioners is to call them "suppliers," this term of art has a different meaning outside of the DMEPOS environment. Occupational therapists and their employers (e.g., hospitals and skilled nursing facilities (SNF)) are more appropriately viewed as providers.

An occupational therapist in private practice is required to have enrolled in Medicare and receive a provider number, separate and apart from a DME supplier number, prior to furnishing occupational therapy services to Medicare beneficiaries.[3] This requirement applies equally to other practitioners, such as physicians and physical therapists.

In order for an occupational therapist to enroll in Medicare or provide services through any other provider (e.g., hospital or SNF), they must first meet the definition of "Qualified Occupational Therapists." See Social Security Act §§1861(g), 1861(p)(2). The regulations defining "Qualified Occupational Therapists" require graduation from an accredited program. Specifically, the regulations define a "Qualified Occupational Therapist" as: a person who:

> (a) is a graduate of an occupational therapy curriculum **accredited** jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or
> (b) is eligible for the National Registration examination of the American Occupational Therapy Association; or
> (c) has two years of appropriate experiences as an occupational therapist, and has achieved a satisfactory grade on a proficiency exam conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a state or seeking initial qualifications as an occupational therapist after December 31, 1977.

42 C.F.R. § 484.4 (emphasis added).

In addition, occupational therapists are professional practitioners who are licensed or otherwise regulated in every state. According to state regulations and the AOTA Code of Ethics, occupational therapists must have or obtain competency for any service they provide, whether it is specific patient treatment or the fabrication and fitting of DMEPOS. By contrast, most states do not require DME suppliers or orthotists/prosthetists to meet any requirements.

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[3] In the alternative, occupational therapy services may be provided by enrolled providers (i.e.., skilled nursing facilities, hospitals, comprehensive outpatient rehabilitation facilities) who either employ or contract with qualified occupational therapy practitioners who meet the regulatory definition of qualified occupational therapists and qualified occupational therapy assistants.

CMS plans to update the definition of "Qualified Occupational Therapist" to conform to state law and occupational therapy certification references. AOTA's understanding is that the updated definition under review is:

> A qualified occupational therapist is a person who is licensed or who is otherwise regulated as an occupational therapist by the state in which he or she is practicing. In addition, the occupational therapist has graduated from an occupational therapy program **accredited** by the American Occupational Therapy Association's accreditation counsel for occupational therapy education (ACOTE) and is eligible for a national entry-level certification examination recognized by the American Occupational Therapy Association. (emphasis added).

Accordingly, prior to becoming a Medicare provider of occupational therapy services, an occupational therapist must demonstrate that she has met certain quality standards as determined by each State, as well as national accreditation bodies. There are no similar requirements for DME suppliers or orthotists or prosthetists in every State.

Thus, by virtue of becoming a "Qualified Occupational Therapist" under current and proposed Medicare regulations, occupational therapists must have successfully completed an accredited educational program. ***AOTA urges CMS to consider state licensure and completion of an education at an accredited educational program of occupational therapy – the same standards that CMS already relies upon as proof of qualification for providing occupational therapy services to Medicare beneficiaries - as meeting the accreditation standards under MMA section 302(a).***

B. The Breadth of Services and Supplies Furnished are Reflected in Both CPT and HCPCS

When an occupational therapist provides DMEPOS it is integral to the occupational therapy treatment plan for the patient. In fact, the design, fabrication, fitting and provision of orthotic devices are specific Medicare covered occupational therapy services. [4] The occupational therapy services, as well as the purpose and type of orthotics provided therein, are always documented in the patient's plan of care. When occupational therapists bill Medicare Part B for these services, they use the Current Procedural Terminology ("CPT") codes for the services they provide. The payment that is associated with each CPT code is established based upon a variety of factors, including practice expenses such as supplies and equipment. The payment is established through an elaborate process of the American Medical Association (AMA) Relative Value Update Committee (RUC), in which CMS is an active participant. The RUC, with CMS' input, determines that the relative value for a particular CPT code will or will not include the cost of certain supplies in the practice expense. In those situations where the supply costs are not included, such as with the serial casting CPT codes (25XXX), the physicians and practitioners are directed to report their services using both the appropriate CPT code as well as the Healthcare Common

[4] Medicare covers occupational therapy as a covered category. As an aside, there is no subset of covered Medicare services, such as hand therapy and, in fact, hand therapy, is not recognized by Medicare as a separately reimbursable service.

Procedure Coding System (HCPCS) code that encompasses the supply that has been excluded from the practice expense. Consequently, there is a vast range of HCPCS codes that physicians and occupational therapists report in conjunction with the CPT codes. If one only considers the HCPCS codes that physicians, therapists and other enrolled practitioners report, then the full range of services that they provide to Medicare beneficiaries cannot be appreciated.

To make a determination of whether an individual or entity should be required to meet the supplier standards based solely on the HCPCS codes that they report fails to consider the totality of their role in the Medicare program. Therefore, we recommend that CMS first consider all of the ways that the individual or entity participates in the Medicare program. This would include whether they are independently enrolled in Medicare Part B or whether their services are provided through enrolled providers (e.g., SNF, hospitals, etc.) and the entire scope of how they interact with beneficiaries, including whether they provide services reported through CPT. Those individuals and entities who also are enrolled as independent providers or bill their services through enrolled providers should be treated differently than those who merely provide beneficiaries with a product.

Simply because a Durable Medical Equipment Regional Carrier (DMERC) must be billed because a HCPCS number is utilized, which in turn requires a separate DMERC supplier number, should not change the fact that practitioners are otherwise separately enrolled in Medicare and interact with Medicare beneficiaries in a completely different way than pure DMEPOS suppliers. In fact, CMS has created specialty code 67[5] for use by an occupational therapist currently enrolled in Medicare when filing a DMERC supplier application, thus acknowledging that the DMEPOS items and supplies provided will be integral to the occupational therapy services and otherwise part of the occupational therapist's plan of care for the Medicare beneficiary. ***AOTA submits that CMS, through the National Supplier Clearinghouse, has the data it needs to distinguish physicians, occupational therapists, physical therapists, and other enrolled practitioners from those who solely bill a DMERC for supplies. AOTA suggests that the use of HCPCS codes to determine who should be subject to the quality standards is inappropriate and inadequate.***

C. Relevant Precedent Exists to Treat Occupational Therapists Distinctly from DMEPOS Suppliers

In an analogous situation, CMS has taken the position that physicians providing diagnostic testing to their own patients could bill for such diagnostic services under their group practice number and would not need to also enroll as an independent diagnostic testing facility ("IDTF"). See 42 C.F.R. § 410.33; CMS Program Integrity Manual Pub. 108 § 5.1. This Manual provision provides that a physician group will not need to enroll as an IDTF if it meets certain criteria demonstrating that the diagnostics tests it performs are part and parcel of the other medical services it is providing to the patients its routinely treats. To avoid IDTF enrollment, a physician group must show the following:

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[5] The enrollment of an occupational therapist using specialty code 67 as a DMEPOS supplier is not intended to permit the occupational therapist to hold him or herself out to the general public as a DME supplier for items or services unrelated to an occupational therapy plan of care.

1) The entity providing the test is a physician practice that is owned, directly or indirectly, by one or more physicians or by a hospital;
2) The entity primarily bills for physician services (e.g., evaluation and management (E &M) codes) and not for diagnostic tests;
3) The entity furnishes diagnostic tests primarily to patients whose medical conditions are being treated or managed on an ongoing basis by one or more physicians in the practice; and
4) The diagnostic tests are performed and interpreted at the same location where the practice physicians also treat patients for their medical conditions.

Similarly, occupational therapists providing orthotics may do so as independent practitioners through practices they own or through another provider, such as a hospital or skilled nursing facility. An independent occupational therapy practice (otherwise referred to as an occupational therapist in private practice OTPP or OTPP group) overwhelmingly bills for occupational therapy services, and not for DMEPOS. As explained above, the occupational therapist furnishes the orthotics or other DMEPOS such as canes and walkers to patients whose medical conditions are being managed by the occupational therapist through an occupational therapy plan of care . The orthotics or other DMEPOS will be furnished at the same location where the occupational therapy services are provided and are an integral part of these occupational therapy services. ***Based on the above, the precedence exists for CMS to treat occupational therapists that provide DMEPOS tangential to occupational therapy services differently than other DMEPOS suppliers and to not require occupational therapists to meet the same requirements as DMEPOS suppliers.***

D. Sufficient Safeguards Exist

Finally, AOTA urges CMS to consider that the educational and state regulatory requirements for Medicare enrolled occupational therapists provides more than adequate safeguards to protect Medicare beneficiaries from receiving substandard orthotics from occupational therapists. Accordingly, separate DMEPOS qualifications standards are not necessary, would be duplicative and could be contradictory and unnecessarily costly. In addition, CMS has not designated which accreditation bodies it will designate or what separate requirements they will place on DMEPOS suppliers. It is possible that an accreditation body could place requirements on occupational therapists that are contradictory to those regulatory requirements already required by CMS. ***Consequently, AOTA urges CMS to deem occupational therapists as already meeting the supplier quality standards by virtue of their regulatory requirements as qualified occupational therapy practitioners.***

III. The Particular Draft Quality Standards Relating to Supplier Product-Specific Service Requirements for Customized Orthotics and Prosthetics Are Not Necessary to be Applied to Occupational Therapists and Other Medicare-Recognized Practitioners

A. The Standards are Duplicative for Occupational Therapy Practitioners

As stated above, AOTA recognizes that the Draft Quality Standards may be meaningful for orthotists and prosthetists and other non-licensed DME suppliers that provide orthotics and prosthetics to Medicare beneficiaries in order to ensure quality. Establishing such standards will prevent unlicensed and unscrupulous DME providers who have no licensure or relevant education and training from providing substandard items or services to Medicare beneficiaries. Since only nine states regulate orthotists and prosthetists, AOTA agrees with the recommendation contained in the O&P Standards that CMS should require individuals in states where licensure is not required to be certified by ABC or BOC.

However, the O&P Standards within the Draft Quality Standards were clearly developed by the orthotists and prosthetists and reflect their large presence as expert consultants to Abt Associates. As stated above, the Draft Quality Standards, and particularly, these O&P Standards are not necessary for occupational therapists. Similarly, they are not necessary for physicians or other practitioners. Two statements in the general description of the O&P Standards particularly highlight the duplicative nature of the O&P Standards for occupational therapists.

Specifically, the O&P Standards state that the provision of orthotics and prosthetics "involves knowledge and understanding of human anatomy and beneficiary factors such as height, weight, level of physical activity, overall health, comorbidities and the specific diagnosis to make each fitting unique to that beneficiary." See Draft Quality Standards pg. 76. In addition, the O&P Standards state that the "suppliers should be trained in a broad range of treatment options to ensure that the item prescribed is optimal for the beneficiary's condition."

Occupational therapists, by virtue of their education and training through an accredited educational program and their overall treatment of the patient already are in the best position to understand human anatomy, beneficiary factors, and specific patient diagnoses and are able to uniquely fit each patient with the orthotic necessary for the continuation of the patient's care. Because occupational therapists provide not just an orthotic, but develop an entire occupational therapy plan of care specific to a particular patient and their condition(s), that plan of care requires the knowledge and understanding of human anatomy, beneficiary factors, specific diagnosis, and the ability to make each fitting unique to that beneficiary. Furthermore, since the occupational therapist is intimately involved in the beneficiary's plan of care, the occupational therapist is in the best position to know the patient's broad range of treatment options and to ensure that the item prescribed is optimal for the beneficiary's condition.

Occupational therapists providing care to Medicare patients also are already required to perform the services required in the Inspection and Preparation provision, including the requirements for Intake and Service Plan; the Training/Instructions to Beneficiary and Caregiver(s); and Follow-Up, by virtue of creating an occupational therapy treatment plan unique to each Medicare beneficiary for whom the occupational therapist provides occupational therapy, including the furnishing of DMEPOS. The patient's treatment plan is documented in the patient's plan of care, including progress notes, as required by Medicare. By urging CMS to not apply the Draft Quality Standards to occupational therapists and other practitioners, AOTA is not suggesting that occupational therapists would therefore have the ability to provide less than outstanding care to Medicare beneficiaries. ***AOTA requests that CMS articulate that occupational therapists already meet rigorous standards by virtue of the standards they meet to provide covered services as Medicare enrolled Qualified Occupational Therapists. Requiring compliance with***

these separate Draft Quality Standards, including the specific draft O&P Standards, would be duplicative and unnecessary.

B. Occupational Therapists Are Qualified to Furnish Custom Fabricated Orthotics

AOTA is particularly troubled by the statement in the opening section of the O&P Standards that states that customized orthotics and prosthetics "require the qualification and expertise of certified or licensed orthotists and prosthetists, and/or staff certified by the American Board for Certification and orthotists and prosthetics (ABC) or the Board for Orthotists/Prosthetists certification (BOC)." Id.

AOTA strongly disagrees with this statement. Occupational therapists are qualified to design, fit and fabricate customized orthotics. In fact, CMS has specifically acknowledged that occupational therapists and other practitioners are qualified to provide custom-fabricated orthotics and prosthetics and has specifically devised a methodology to allow occupational therapists and other practitioners to be recognized as provides of customized orthotics in the nine states where there is licensure for orthotists and prosthetists. See CMS Change Request 3959 "Full Replacement of Change Request 3607 Payment Edits in Applicable States for DMEPOS Suppliers of Prosthetics and Certain Custom-Fabricated Orthotics." (August 19, 2005) (In those nine states that have indicated that provision of prosthetics and orthotics must be made by licensed/certified orthotist or prosthetist, Medicare payment may only be made for prosthetics and certain custom-fabricated orthotics when furnished by physicians, pedorthists, physical therapists, **occupational therapists**, orthotics personnel and prosthetics personnel) (emphasis added).

In addition, during the negotiated rulemaking under Section 427 of BIPA, CMS agreed to specifically include in the text of the notice of proposed rulemaking that occupational therapists are qualified to furnish custom fabricated orthotics. CMS also stated its intent that qualified occupational therapists who fabricate definitive prostheses will have additional education and training. See CMS Statement of Intent and Final Compromise Document (attached). It is imperative that all of the Draft Quality Standards, including the O&P Standards, be consistent with current Medicare policy. ***Consequently, AOTA respectfully urges CMS to remove from the final standards that any language implying that only orthotists or prosthetists are qualified to fabricate, fit and furnish orthotics and prosthetics.***

IV. Any New Quality Standards Must Be Consistent with CMS' Proposal for Fabrication and Furnishing of Custom Orthotics and Prosthetics Offered During the Negotiated Rulemaking Under Section 427 of the Benefits Improvement and Protection Act of 2000 ("BIPA")

The impetus for Section 427 of BIPA is the same as the quality and accreditation standards requirement found in section 302(a) of the MMA; Congress' goal has been to prevent unscrupulous individuals having no relevant education or training and no licensure requirements from providing DMEPOS to Medicare beneficiaries. Under Section 427 of BIPA, occupational therapists were defined as "qualified practitioners" for purposes of furnishing and fabricating orthotics. During the negotiation, CMS agreed that occupational therapists are separate and apart from qualified suppliers, as reflected in the statutory language defining them as "qualified occupational therapists." CMS applied the term "qualified suppliers" to DMEPOS suppliers and other entities which fabricated or furnished certain custom orthotics

or prosthetics, but who were not otherwise qualified practitioners (e.g., orthotists, prosthetists and manufacturers). In order for these others to be a "qualified supplier" BOC or ABC certification was required. During the Negotiated Rulemaking, CMS acknowledged that occupational therapists only use their DMEPOS supplier number in conjunction with their occupational therapy practice. ***Accordingly, requiring the O&P Standards to apply to qualified practitioners such as occupational therapists would be inconsistent with Section 427 of BIPA.***

Finally, in the O&P Standards, Abt defined terms such as custom-fabricated in its recommendations. These terms are required to be defined by regulation pursuant to Section 427 of BIPA. In the absence of such final regulations, the definitions of the term custom-fabricated should be the definition that CMS offered in its compromise document at the conclusion of the negotiated rulemaking. ***CMS Should Not Adopt the Definitions contained in the O&P Standards, including "Custom Fabricated," "Custom Fitted High," and "Custom Fitted Low" since they are inconsistent with either CMS' compromise document or current policies.***

V. Conclusion

AOTA appreciates the opportunity to submit these comments on CMS' proposed quality standards for suppliers of DMEPOS. AOTA urges CMS to consider the impact of the Draft Quality Standards and accreditation requirements on occupational therapists as well as physicians, physical therapists, and other enrolled practitioners. AOTA strongly recommends that CMS specifically deem occupational therapists as already meeting the supplier quality standards by virtue of meeting the rigorous regulatory requirements required of qualified occupational therapy practitioners.

AOTA requests that due consideration be given to these comments. Thank you, again, for the opportunity to comment on the Draft Quality Standards. We look forward to a continuing dialogue with CMS on these issues.

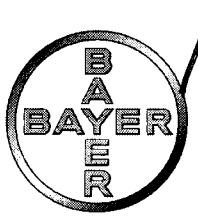
Sincerely yours,

Leslie Stein Lloyd, Esq.
Director
Reimbursement and Regulatory Policy Department

Attachment: CMS Statement of Intent and Final Compromise Document, Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom Fabricated Orthotics, Dated July 14, 2003

cc: Herb Kuhn
Carol Blackford
Linda Smith
Pam West

Bayer HealthCare



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June 29, 2006

By Hand Delivery

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Re: CMS-1270-P: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Medicare Prescription Drug Benefit

Dear Administrator McClellan:

Bayer HealthCare ("Bayer") submits these comments to the Proposed Rule titled "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (CMS-1270-P). We appreciate the Centers for Medicare and Medicaid Services' ("CMS") careful consideration of these comments and other suggestions from the supplier, physician, and patient communities. We commend CMS for its thoughtful implementation of the competitive bidding program and look forward to working together to develop an effective program that reduces costs for the Medicare program without compromising access to the quality diabetes care management products currently available to beneficiaries.

We are impressed by CMS' energetic efforts to plan the implementation of the competitive bidding program as Congress intended. We appreciate CMS requesting comments on these proposals and we would like to take the opportunity to offer specific suggestions with respect to the provision of durable medical equipment ("DME") products and supplies to beneficiaries with diabetes and more general comments to facilitate the overall implementation of the competitive bidding program. Due to the unique issues that are associated with the clinical

management of diabetes, we believe that it is critical that CMS incorporate the following thoughts and suggestions into the final rule.

Summary of Bayer Recommendations:

- CMS should exclude blood glucose monitors and other diabetes-related supplies in the initial phase of the competitive bidding program to ensure a smooth transition of these products into the new supply system since uninterrupted access to supplies is critical for management of diabetes and the prevention of complications associated with the disease.
- CMS should recognize the longstanding policy of the United States government to give small businesses an opportunity to compete for government contracts by declining to waive provisions of the Federal Acquisition Regulation that protect the interests of small businesses. In addition CMS must establish a means of providing assistance and information to beneficiaries and evaluating their satisfaction during and after the implementation process in order to maintain access to and quality of DME items supplied through competitive bidding.
- CMS should further ensure the participation of smaller suppliers by strengthening its networking provisions to give small businesses a meaningful opportunity to participate in the bidding process, which will benefit the process as a whole by expanding the pool of available bidders.
- CMS should continue to respect the clinical expertise of physicians and the individual needs of beneficiaries by ensuring that successful bid suppliers provide the brand and model of equipment and supplies that have been prescribed by the treating physician just as CMS required of its Medicare Part D plan providers.
- CMS should abandon the provision of rebates to beneficiaries by suppliers who bid below the single payment price due to the unfair advantage that these suppliers will have over other suppliers who are unable to provide such rebates and the serious fraud and abuse risks that would result from the implementation of this provision.
- CMS should not import bid prices into non-bid areas because of the lack of an economically sound method for transferring prices to a fundamentally different economic system.
- CMS should reconsider its requirement that non-competitive bidding suppliers receive the payment amount set by the beneficiaries' home competitive bidding area ("CBA") when the suppliers are providing supplies to beneficiaries who are traveling to other CBAs or to non-bid areas, in order to minimize the risk of refusal of local suppliers to provide products at rates that are lower than what they would normally receive for an item.

- CMS should more explicitly articulate the fundamental technical aspects of the bidding process and discuss how it will evaluate the sustainability of bids. CMS should seriously consider basing the pivotal bid of each competitive bid area on 125 percent of projected demand to avoid shortfall in supplies.
- CMS should reconsider use of a pivotal bid to establish the payment amount for an item because this methodology carries an inherent risk of failing to secure contracts with an adequate number of suppliers.
- CMS should reconsider its desire to force all beneficiaries to participate in a nationwide mail order system given the important role of local retail pharmacists in disease management and both the preference of, and convenience for, many beneficiaries who would chose to continue obtaining their diabetes-related supplies, which are widely available at the local retail level, from their neighborhood pharmacy. We recommend that CMS adopt the same geographic access provisions as CMS applied under the Medicare Part D program.
- CMS should use the CPI-health index to make inflation increase calculations more accurate, and CMS should explain how this provision operates for items that are currently under a price freeze in the fee schedule.
- CMS should modify the change in ownership provision by removing the sixty-day prior notification requirement and allowing successor entities to continue supplying beneficiaries in a CBA as the winning contract supplier as long as they meet the general requirements for contract suppliers.
- CMS should quickly establish thorough quality standards to assist suppliers in submitting the most accurate bid possible and CMS should set a separate comment period on its quality standards to more fully examine the impact and interplay of the quality standards with the competitive bidding program.
- CMS should exclude new DMEPOS items from the competitive bidding process to allow for the integration and acceptance of the new technology into the medical community before adding it to the list of bid items and applying the proposed gap-filling methodology. CMS should hold a second comment period to address the complexities related to the gap-filling process.
- CMS must establish an emergency provision that will allow beneficiaries to obtain needed DMEPOS from their old suppliers during the transition to the new supply system to avoid short term access issues.

I. Serious Health Consequences of Diabetes and Need to Provide Quality Diabetes-Related Supplies and Services

Bayer is a major manufacturer of blood glucose monitoring equipment and supplies that has been providing high quality diabetes-related products to generations of beneficiaries. Bayer's commitment to supplying patients with diabetes with the necessary blood glucose monitoring equipment and supplies has played a role in fighting the growing epidemic of diabetes. This is because, unlike most durable medical equipment, blood glucose monitors are diagnostic as well as therapeutic. Blood glucose monitors enable beneficiaries with diabetes to accurately self-diagnose their blood glucose levels, which in turn allows them to achieve desired therapeutic results by altering their diet or medication dosages. Medicare beneficiaries depend on wide access to high quality diabetes-related supplies and services to ensure their long-term welfare.

Diabetes, both Type 1 and Type 2, is characterized by elevated levels of sugar in the blood. Type 1 diabetes, a malfunction of the immune system, affects approximately a million people in the United States.[1] In Type 1, the immune system destroys the cells in the pancreas that make insulin.[2] In Type 2, the body's cells are not sufficiently receptive to insulin, or the pancreas makes too little of it, or both.[3] Approximately 95 percent of all cases are Type 2 diabetes.[4] This is of concern because Type 2 diabetes afflicts roughly 20 million Americans and is the nation's fastest growing health problem.[5]

Educators and public health experts are alarmed by the explosive growth of diabetes as it continues to be the only major disease with a death rate that is still rising.[6] The deadly disease now contributes to the deaths of 225,000 Americans each year.[7] The American Public Health Association has stated that diabetes "is clearly one of the most important threats facing us."[8] The American Diabetes Association has noted that the disease could actually lower the average life expectancy of Americans for the first time in more than a century.[9]

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[1] *See* Richard Perez-Pena, *Beyond 'I'm a Diabetic,' Little Common Ground*, N.Y. TIMES, May 17, 2006.
[2] *See* N.R. Kleinfield, *Diabetes and Its Awful Toll Quietly Emerge as a Crisis*, N.Y. TIMES, Jan. 9, 2006.
[3] *See id.*
[4] *See id.*
[5] *See* Perez-Pena, *Beyond 'I'm a Diabetic,' Little Common Ground.*
[6] *See* Ian Urbina, *Rising Diabetes Threat Meets a Falling Budget*, N.Y. TIMES, May 16, 2006.
[7] *See id.*
[8] *See* Urbina, *Rising Diabetes.*
[9] *See* N.R. Kleinfield, *Diabetes and Its Awful Toll Quietly Emerge as a Crisis*, N.Y. TIMES, Jan. 9, 2006.

Diabetes is the leading cause of kidney failure, blindness and non-traumatic amputation.[10] Just in the city of New York alone, there are roughly 2,000 largely avoidable diabetes-related amputations every year.[11] Patients with diabetes are two to four times more likely than others to develop heart disease or have a stroke, and three times more likely to die of complications from flu or pneumonia, according to the Centers for Disease Control ("CDC").[12] According to the CDC, during a twenty-four hour period, 4,100 people are diagnosed with diabetes; 230 amputations occur in people with diabetes; 120 people enter end-stage kidney disease programs; and 55 people go blind.[13]

Diabetes is destructive not only to an individual's body but also poses serious economic and social consequences. The American Diabetes Association estimates that the disease costs the U.S. economy about $132 billion per year for treatment and lost productivity at work.[14] Health officials fear that within a generation or so, a huge wave of new cases could overwhelm the public health system and engulf growing numbers of the population where cities will be crippled by the disease's damage.[15]

Although diabetes is a chronic disease, careful and consistent blood glucose monitoring can reduce negative health outcomes. Increased blood glucose levels affect every major organ in the body, and failure to adequately control blood glucose levels can lead to kidney failure, blindness, heart attacks, strokes, loss of feeling in the hands and feet, and decreased blood flow in the legs.[16] Loss of sensation and decreased blood flow in the legs can lead to ulcers, gangrene, and ultimately amputation of the lower extremities. These serious complications of diabetes can be minimized or at least delayed when the disease is controlled. In fact, diabetes is recognized as one chronic disease for which quality improvement efforts can make great strides.[17]

The most vital part of controlling diabetes is accurate and consistent daily self-monitoring of blood glucose levels. Blood glucose monitors allow beneficiaries with diabetes to check their blood glucose level to ensure that it is neither too high or too low. This daily diagnostic testing is the only way that

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[10] *See id.*
[11] *See* Ian Urbina, *In the Treatment of Diabetes, Success Often Does Not Pay*, N.Y. TIMES, Jan. 11, 2006.
[12] *See* Kleinfield, *Diabetes and Its Awful Toll Quietly Emerge as a Crisis.*
[13] *See id.*
[14] *See* Urbina, *supra* note 11.
[15] *See* Kleinfield, *supra* note 12.
[16] *See* CDC, *Prevent and Control Diabetes*, at 4, *available at* http://www.cdc.gov/diabetes/pubs/prevent.htm (last visited Jun. 15, 2006).
[17] *See* HHS, Agency for Healthcare Research and Quality (AHRQ), *Diabetes Care Quality Improvement: A Resource Guide for State Action*, No. 04-0072, at 18 (Sept. 2004), *available at* http://www.ahrq.gov/qual/diabqguide.pdf (last visited Jun. 14, 2006).

beneficiaries have to maintain their blood glucose level as close as possible to the normal range, which is the key to controlling their disease and minimizing the risk of complications. The first step for every beneficiary with diabetes in managing their disease and avoiding these potential complications is to obtain the correct glucose monitor. Selecting the right monitor is a critical and personal decision that a patient and doctor must make together based on the patient's individual needs. Not all monitors are the same. For example, some have features that allow older patients with arthritis to maneuver and handle the monitor more easily. Some monitors have larger screens that can be read by patients with visual impairments.

Tailoring the blood glucose monitor to the needs of patients so that patients can consistently and accurately monitor their diabetes is essential. Once a beneficiary is using a device that is suited to his or her needs, it is important that the beneficiary continues to have access to the strips and other supplies that are unique to the monitoring system that he or she is using. If the blood glucose monitoring system does not match the beneficiary's needs, the beneficiary may not be motivated to continue self-testing. We urge CMS to remember, when determining how best to implement the competitive bidding process for durable medical equipment, the unique issues associated with beneficiaries with diabetes and the high risk of harm that may result if these beneficiaries do not have access to appropriate, high-quality diabetes monitoring supplies to help keep in check what is one of the most significant public health concerns.

II. Competitive Bidding Areas (Proposed § 414.410)

Given the lack of statutory mandate to include diabetes care items in the 2007 competitive bidding program and the lack of inclusion of diabetes care items through the demonstration projects, exclusion of the diabetes-related supplies in the 2007 phase of the competitive bidding program is warranted. We encourage CMS to implement competitive bidding for diabetes-related supplies in a controlled manner within a limited area.

If CMS decides to include diabetes-related supplies in the competitive bidding program, we request that CMS exercise its discretion to exclude diabetes-related supplies from the competitive bidding program in this initial phase of the implementation. The Medicare Modernization Act ("MMA") clearly does not require CMS to include diabetes care supplies within the ten Metropolitan Statistical Areas ("MSAs") selected for competitive bidding in 2007. Since CMS has not yet identified the specific products that will be included in the 2007 phase, it can easily and should reserve the diabetes-related items for a later phase, consistent with the discretionary authority granted by the MMA.

Since the San Antonio and Polk County demonstration projects did not include diabetes care items, CMS simply has insufficient history to proceed with

these products in the ten largest MSAs in 2007. Without the experience afforded by a demonstration project, the potential for beneficiary harm exists due to potential barriers to access and increased risk of beneficiary non-compliance. The competitive bidding report issued by the Government Accountability Office ("GAO") noted CMS' decision not to include glucose monitors and supplies in the San Antonio and Polk County locations "because beneficiaries must frequently use brand-name supplies with their monitors."[18] CMS was rightly concerned that there are complicated operational issues for implementing competitive bidding for diabetes-related supplies due to certain beneficiaries' need for specific brands of glucose test strips.[19] Unfortunately, CMS still does not have any information on how access to diabetes-related supplies will be affected by the competitive bidding program. Furthermore, CMS has limited knowledge of how the quality standards will affect the availability of a wide pool of suppliers who are able to provide diabetes-related supplies or their willingness to participate in the program itself. The additional information available after a demonstration project for diabetes-related supplies or a limited implementation phase can be invaluable in anticipating unforeseen problems with beneficiary access and assisting CMS in maximizing its cost savings.

Despite CMS' extraordinary effort and careful consideration in establishing the Medicare Part D program, there were unexpected operational issues that arose during the course of implementation. That experience should impart CMS with a sense of caution about proceeding with sweeping programmatic changes without significant data on the impact of those changes.

If and when CMS decides to include diabetes-related supplies in the competitive bidding program, Bayer recommends that CMS implement competitive bidding for blood glucose monitoring items in a controlled manner initially within a limited area to test access, quality and cost savings. A thoughtfully designed, limited implementation plan is entirely consistent with the MMA. Careful control and analysis of the data derived from such an approach will support CMS in implementing a successful competitive bidding program for diabetes care management supplies. More importantly, controlled implementation will also provide greater protection to beneficiaries who depend on access to quality diabetes care management products. The long-term health and wellness of beneficiaries with diabetes cannot be placed in jeopardy by an inadequate program design or flawed implementation.

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[18] *See* GAO, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies*, Sep. 2004, at 10.
[19] *See id.*

III. Implementation Contractor (Proposed § 414.406) - Federal Acquisition Regulation Waiver and Beneficiary Satisfaction

CMS intends to use one or more Competitive Bidding Implementation Contractors ("CBICs") to help with design, oversight, access and quality management, bid evaluation, and beneficiary outreach and education for the competitive bidding program. We have two concerns regarding the Proposed Rule's description of CMS' use of CBICs. We believe that waiver of all requirements of the Federal Acquisition Regulation ("FAR")[20] will decrease the opportunity for small businesses to compete with larger firms to become a contract supplier. We believe that CMS must provide, through the CBICs, easily accessible help for beneficiaries who may experience difficulties integrating into the new system. In addition, CMS must provide a means for beneficiaries to rate their experience with suppliers in order to maintain high quality service.

A. Federal Acquisition Regulation Waiver

Bayer opposes the waiver of the FAR to the extent that small business interests are not adequately protected by such waiver. Such a waiver would both undermine the Small Business Act and the effectiveness of competitive bidding by decreasing the pool of suppliers and, ultimately, reducing the potential for cost savings.

It is the policy of the United States to give small businesses the opportunity to participate in federal procurements, both as prime contractors and as subcontractors, pursuant to the Small Business Act, Pub. L. 85-536, enacted in 1958, as well as the FAR. In addition, it is the policy of the federal government to encourage the participation of socially and economically disadvantaged businesses in federal procurements.

The Small Business Act best explains the basis for a longstanding policy favoring significant participation of small businesses in federal procurements. In relevant part, it states:

> The essence of the American economic system of private enterprise is free competition. Only through full and free competition can free markets, free entry into business, and opportunities for the expression and growth of personal initiative and individual judgment be assured. The preservation and expansion of such competition is basic not only to the economic well-being but to the security of this nation. Such security and well-being cannot be realized unless the actual and potential capacity of small business is encouraged and developed. It is

[20] *See* 48 C.F.R. ch. 1.

> the declared policy of the Congress that the Government should aid, counsel, assist, and protect, insofar as is possible, the interests of small-business concerns in order to preserve free competitive enterprise, to insure that a fair proportion of the total purchases and contracts or subcontracts for property and services for the Government (including but not limited to contracts or subcontracts for maintenance, repair, and construction) be placed with small-business enterprises, to insure that a fair proportion of the total sales of Government property be made to such enterprises, and to maintain and strengthen the overall economy of the Nation.[21]

This national policy, which reflects the intent and will of the Congress, is implemented through various provisions in the FAR regulations. For example, FAR § 19.201(a) states: "It is the policy of the Government to provide maximum practicable opportunities in its acquisitions to small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns. Such concerns [small, disadvantaged, or women-owned businesses] shall also have the maximum practicable opportunity to participate as subcontractors in the contracts awarded by any executive agency, consistent with efficient contract performance."[22]

Consistent with this policy, government contracting officers are required to include clauses entitled "Utilization of Small Business Concerns"[23] and "Small Business Subcontracting Plan"[24] in various solicitations and contracts. Undoubtedly, the policy to favor small business concerns and the interests of socially and economically disadvantaged businesses must be considered "to the fullest extent consistent with contract performance."[25] Under the subcontracting clause, a bidder must propose a subcontracting plan that includes, among other things, goals for subcontracting dollars to be spent related to small and small disadvantaged businesses and a description of the bidder's efforts to ensure that such businesses will have an equitable opportunity to compete for subcontracts.

In sum, the policy of the federal government, as reflected in both the Small Business Act and the FAR, is to provide small and small disadvantaged businesses with a fair opportunity to participate in federal procurements of all types. Such participation is essential to the continued growth of the national economy and, as stated in the Small Business Act, to the security of the United States. Any

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[21] *See* 15 U.S.C. § 631(a).
[22] *See also* FAR § 19.202-1 ("Small business concerns shall be afforded an equitable opportunity to compete for all contracts that they can perform to the extent consistent with the Government's interest.").
[23] *See* FAR § 52.219-8.
[24] *See* FAR § 52.219-9.
[25] *See* FAR § 52.219 8(b).

proposal that would eliminate or minimize such opportunities, such as a proposal that would waive, on a blanket basis, the FAR provisions discussed above and other FAR provisions requiring the participation of such small businesses, would be contrary to, and undermine, this longstanding and important national policy. It also would reduce competition, limit the number of bidders, and thereby operate to undermine the effectiveness of competitive bidding.

B. Monitoring Beneficiary Satisfaction With CBICs

Bayer encourages CMS to specify clearly in the final rule or require CBICs to identify the necessary telephone and internet resources that beneficiaries may use to raise questions and concerns related to the competitive bidding program. It is extremely important that beneficiaries have readily available access to information during their transition from their former suppliers to their new contract suppliers. Beneficiaries must be able to report the myriad of difficulties that they may face as the DMEPOS competitive bidding program is implemented for the first time, including problems with locating a new supplier or service quality concerns. We believe that the risk of negative press reports, even despite CMS' excellent efforts to launch this program, concerning the competitive bidding program will be significantly reduced if such contact information is readily available and apparent to the beneficiary population.

In addition, we strongly recommend that CMS establish a survey mechanism so that beneficiaries will be able to rate their satisfaction with the suppliers that they have chosen, as recommended by the September 2004 GAO report. While the Proposed Rule states that CMS may make available information on products for which suppliers will give rebates, it fails to provide a method to obtain feedback from beneficiaries regarding their satisfaction level with their contract supplier and disseminating this valuable information to other beneficiaries. Providing this information regarding the quality of service will assist beneficiaries in making an informed choice when deciding who they would like to fill their DMEPOS needs. The GAO report on competitive bidding recommended CMS' adoption of a survey program and stated that "routine monitoring of beneficiaries' concerns, complaints, and satisfaction can be used as a tool to help ensure that beneficiaries continue to have access to quality items."[26] We agree that such an evaluation system is essential to maintaining high quality of care long-term. Without such feedback, CBICs will be ill-equipped to judge, and thus monitor, either the quality of products that suppliers are providing or the accessibility of needed supplies to beneficiaries.

[26] *See* GAO, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies*, Sep. 2004, at 17.

IV. Opportunity for Networks (Proposed § 414.418)

The Proposed Rule allows suppliers to form networks in order to submit a single bid for certain product categories. We commend CMS for proposing various opportunities to encourage the participation of smaller suppliers in the competitive bidding program. We are encouraged by CMS' willingness to consider suggestions regarding various aspects of forming potential networks, including the types of legal entities that should be allowed to submit single bids for a product category under the competitive bidding process. We appreciate CMS' concerns regarding anti-competitive issues and value its efforts to ensure that networks will be formed in an appropriate, efficient fashion that serves the needs of beneficiaries. However, significant changes to the proposed networking rules are necessary to make them viable and effective.

A. Support for Conditions That Networks Must Satisfy

1. *Independent Eligibility to Bid*

We generally support CMS' articulated conditions for potential networks that are considering the submission of a single bid. In particular, we support the requirements that each member independently must be able to comply with all necessary accreditation and quality standards. We believe this rule is important to retain in the final rule.

2. *Financial Standards*

We believe that, consistent with the antitrust guidance regarding financially integrated joint ventures, CMS should permit networks, whether through appropriate insurance or otherwise, to meet the applicable financial standards on a network basis. This will permit smaller suppliers a meaningful opportunity to participate. By increasing the number of potential bidders, this modification will further ensure cost savings.

3. *Need for Further Safeguards to Ensure Quality Service and Items*

We believe CMS should implement further safeguards to prevent networks from being formed that do not provide beneficiaries with quality service and items. We urge CMS to closely analyze bids submitted by networks to verify that the information collected and provided accurately reflects the services available across the bidder's geographic area of operation.

B. Reservation of Network Provisions for Smaller Suppliers and Problems with the Twenty Percent Limitation

As written, the network provisions are not adequately reserved as a mechanism for smaller supplier bidding. Small suppliers should be the focus of the network provisions because such a focus would increase the pool of bidders, help to reduce program costs, and reflect the intent of Congress. We seek CMS' clarification on whether the network provisions apply to big suppliers or chains, given the ambiguity on the face of the Proposed Rule.

The Proposed Rule and the twenty percent limitation ignore the dynamic nature of these markets and appear to be designed to punish the suppliers who are most successful at meeting the needs of consumers. For example, if Network A is created in the first year of competitive bidding from suppliers who collectively have nineteen percent of the market, and Network A outperforms all of its competitors such that thirty percent of consumers choose to buy from it, it would appear that the "reward" for excellent service would be to require the break up of Network A in the second year of the competitive bidding program so that Network A's Medicare market share does not exceed the twenty percent ceiling.

The notion of an across-the-board twenty percent ceiling for networks is itself inconsistent with antitrust doctrine. Although antitrust review is highly dependent upon the facts found in specific markets, federal antitrust agencies have often acknowledged that, in various situations, market shares much higher than twenty percent pose no serious risk of anticompetitive conduct or consequences. CMS should set forth a sliding scale that exceeds twenty percent dependent upon various factors (such as the size of the independent entities in the market with which the network must compete) or permit networks to participate above twenty percent on an assumption of the antitrust risk basis.

C. Allowing Network Members to Bid Individually

Possible network members should not be forbidden from also bidding individually. This limitation on allowing network members to bid individually, in effect, discourages smaller suppliers from using the network option. This proposal, furthermore, poses a risk of threatening the ability of competitive bidding from being implemented in any area that does have network bids, as failure of the network bid could lead to the exclusion of so many suppliers as to deny CMS the necessary number of suppliers to serve the area adequately.

D. Providing Appropriate Time to Allow Small Suppliers to Create Networks and More Antitrust Guidance

Exploring the idea of establishing networks and coordinating such efforts will be an extremely time-consuming process. It is vital that CMS provide

adequate time for implementation of the networking provision. Small suppliers must not only locate appropriate networking partners but they must also select an entity that will coordinate the price information in a manner consistent with antitrust laws.

The current antitrust rules appear to require small suppliers to employ a "messenger model" in which a third-party will serve as the data collector that would not release the prices offered by other members of the network. We seek further clarification from CMS regarding the need to use a messenger model. We request that CMS work with antitrust authorities to provide additional guidance that would allow unimpeded financial and clinical integration of networks.

V. Physician Authorization/Treating Practitioner (Proposed § 414.420)

The Proposed Rule authorizes the Secretary to establish a process for certain items under which a physician may prescribe a particular brand or mode of delivery of an item within a particular HCPCS code if that physician or treating practitioner determines that use of that particular item would avoid an adverse medical outcome for the patient. When a specific item or mode of delivery is requested, contract suppliers would be required to furnish that item or mode of delivery, assist the beneficiary in locating another contract supplier within the competitive bidding area ("CBA") that can provide the particular item, or consult with the physician or treating practitioner to find a suitable alternative product or mode of delivery. The Proposed Rule requires the physician or treating practitioner who is willing to revise the order to memorialize it in a revised written prescription.

Bayer is supportive of a mechanism to allow physicians or treating practitioners to tailor medical treatment to specific patient needs by recommending specific products or modes of delivery. Indeed, we believe that this element of the proposal is absolutely essential to the appropriate implementation of competitive bidding and, particularly, the implementation of the program in a fashion that ensures a minimally acceptable level of quality. This mechanism is required to ensure that quality DMEPOS products become available to beneficiaries with variable medical needs.

The differences in glucose monitors, for example, can be critically important for many Medicare beneficiaries. Health care professionals consider many factors when selecting a diabetes care management system for a beneficiary with diabetes. These factors include the amount of blood required to perform a test if the beneficiary has difficulty obtaining a blood sample, the test strip size if the beneficiary has dexterity problems, the blood hematocrit range of the test if the beneficiary has a medical condition causing a low blood hematocrit, the size of the system display if the beneficiary has visual acuity problems, and data management features if the beneficiary has difficulty manually recording results. Unless the health care professional is able to choose the product that the health care professional

believes best serves the needs of the beneficiary with diabetes, the ability of the beneficiary to comply with the diabetes care treatment plan set forth by the health care professional is at risk. Given the limitation on multiple purchases of monitors in a given period under current DMEPOS policy, this would effectively result in many beneficiaries not having their needs met.

Thus, this type of consequence, the hindrance or failure of the patient's ability to comply with a diabetes care regimen, clearly constitutes an adverse medical outcome for patients with diabetes. We are concerned that contract suppliers will not appreciate or ignore the significant health impact that a particular type of blood glucose monitor will make on a certain beneficiary, particularly those with manual dexterity or visual impairments. CMS has the obligation to explain to the contract suppliers what constitutes an "adverse medical outcome" as part of its overarching mandate to protect beneficiary welfare and their access to essential medical products. This is consistent with CMS' actions in the Medicare Part D context where CMS was careful to explain to Part D contractors what CMS' expectations were in relation to appropriate beneficiary care such that Part D contractors could implement only limited cost control measures so as not to jeopardize the quality of services and access to necessary products. We request that CMS explicitly state in the final rule that the differences in diabetes care products may help avoid adverse medical outcomes for certain beneficiaries with diabetes under appropriate physician supervision and judgment.

In order for the protection afforded to beneficiaries by this provision to work appropriately and as intended, CMS must ensure that physicians or treating practitioners will be able to request an item through a simple process that is not burdensome to the physicians or treating practitioners. If the process used to implement this safeguard is burdensome, the process will discourage use of the safeguard and, thereby, result in the very problems that the safeguard was intended to prevent in the first instance.

VI. Rebate Program (Proposed § 414.416(c))

CMS proposes that contract suppliers that submitted bids for an individual item below the single payment amount should be permitted to provide beneficiaries with a rebate. The rebate may be equal to the difference between their actual bid amount and the single payment amount. The proposal does not contain provisions that condition the receipt of rebates on the financial need of beneficiaries, so there are no restrictions on which beneficiaries might receive the rebates. In addition, the proposal does not limit the amount of the rebate, other than stipulating that it not exceed the difference between a supplier's bid price and the single payment amount for that item. Thus, there is no correlation between the amount of the rebate and the beneficiary's co-payment or deductible. No proposition is in place to ensure that the rebate does not exceed the beneficiary's expenses.

While we appreciate CMS' laudable goal of trying to minimize beneficiary expenses, we think that the proposal should not be adopted. We have serious concerns about the implementation of Section 414.416(c). We believe that this proposal should be abandoned because it presents unacceptable fraud and abuse risks and will undermine the ability of successful bidders to compete on an equal basis.

The provision lacks any mechanism for ensuring that these rebates do not constitute an inducement for beneficiaries to use services unnecessarily or to favor certain providers over others in violation of both the Anti-Kickback Statute and the Anti-Beneficiary Inducement/Civil Monetary Penalty Provision. The proposed provision is simply and flatly inconsistent with the policies articulated by Congress, CMS, and OIG as expressed repeatedly in statutes, regulations, advisory opinions, and fraud alerts.

We believe that providing beneficiaries with monetary rebates will lead to increased utilization and spending, depriving the Medicare program of the very savings competitive bidding is designed to achieve. The use of rebates is fundamentally inconsistent with the cost-saving rationale that led Congress to pass the competitive bidding provision.

A. Good Faith Financial Need for a Waiver of a Co-Payment to Avoid Civil or Criminal Penalty

The provision of rebates or other remuneration to beneficiaries by healthcare suppliers or providers may violate civil and criminal statutes if it has the effect of influencing a beneficiary's choice of supplier or provider. Under the Anti-Kickback Statute, remuneration of any kind is prohibited if it is intended to reward or induce any order of any item payable under a federally funded health care program, including the Medicare program.[27] Allowing contract suppliers that bid below the single item payment amount to give cash rebates to beneficiaries will inevitably violate this basic criminal law. Although the OIG has permitted the waiver of patient obligations in situations where there is good faith financial need on the part of the beneficiary, the rebate provision is not in any way focused on such circumstances.

Similarly, the Anti-Beneficiary Inducement Prohibition imposes civil penalties on anyone who "offers to or transfers remuneration to any individual eligible for benefits... that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service."[28] Clearly the proposed rebates would affect the choice of supplier. Although the Civil Monetary Penalty provision, like the Anti-Kickback

[27] *See* 42 U.S.C. § 1320a-7b.
[28] *See* 42 U.S.C. § 1320a-7a(a)(5).

Statute, does not apply to good faith financial need waivers, that exception simply cannot justify the CMS proposal.

B. CMS' Position on Beneficiary Remuneration

In a wide variety of contexts, CMS has consistently stated that the offer of remuneration to beneficiaries is inappropriate. CMS' proposed policy permitting rebates to beneficiaries in the absence of any bona fide financial need is particularly surprising, given the dearth of utilization controls at the disposal of the government in the DME context. CMS' competitive bidding proposal is flatly inconsistent with CMS' own recent rejection of need-based patient assistance offered by individual manufacturers in the Part D context, notwithstanding the presence of broad, alternative utilization controls in Part D.

Furthermore, the Proposed Rule allows rebates to be realized by beneficiaries as direct monetary payments. In other contexts, the provision of money or cash equivalents has been rigorously avoided and considered particularly problematic. For example, Medicare Part C's Medicare Advantage rebates do not constitute any direct transfers of funds to beneficiaries and are only applied to supplemental health programs.[29]

A hospital outpatient rebate, allowed under 42 U.S.C. § 1396r–8, is distinguishable from the current proposed competitive bidding rebate because its purpose is to lower co-payments closer to the standard percentage for co-payments for the same services when provided at other sites of service. CMS' current competitive bidding proposal, however, would eliminate all co-payments in some cases and would take the co-payment below the amount that would otherwise typically apply in every case. By eliminating or substantially lowering the financial contribution of beneficiaries, CMS will unintentionally but inevitably increase utilization and overall costs.

C. OIG's Position on Rebates Outside of a Good Faith Financial Need Context

The OIG has consistently advised that waivers of co-payments and deductibles in circumstances analogous to the proposal implicate the fraud and

[29]Section 1854(b)(1)(C)(ii) of the Social Security Act specifies that "A rebate required under this subparagraph shall be provided through the application of the amount of the rebate toward one or more of the following: (I) PROVISION OF SUPPLEMENTAL HEALTH CARE BENEFITS AND PAYMENT FOR PREMIUM FOR SUPPLEMENTAL BENEFITS. . . (II) PAYMENT FOR PREMIUM FOR PRESCRIPTION DRUG COVERAGE. . . (III) PAYMENT TOWARD PART B PREMIUM." The Corresponding regulation, 42 C.F.R. § 422.266, mirrors the language of the statute. It states that "[t]he rebate required under this paragraph must be provided by crediting the rebate amount to one or more of the following: (1) Supplemental health care benefits. . .(2) Payment of premium for prescription drug coverage. . .(3) Payment toward Part B premium." 42 C.F.R. § 422.266(b).

abuse laws.[30] One fraud alert, targeted toward beneficiaries, warned Part B participants to "be wary of 'no out-of-pocket expense' offers," and specifically stated it was aimed at providers who "routinely waive Medicare deductible and co-payment charges."[31] OIG has also issued several advisory opinions regarding waiver of co-payments that consistently state that such waivers implicate the fraud and abuse laws.[32] Yet, this practice the OIG has identified to be problematic is exactly what the Proposed Rule would allow some suppliers to do if they happened to bid below the single payment amount.

In summary, the proposed rebate provision is inconsistent with current policy as it is expressed in the applicable statutes, regulations, and enforcement guidance. It should be rejected because it will lead to increased utilization that will decrease the savings competitive bidding may otherwise generate for the Medicare program.

VII. Authority to Adjust Payments in Other Areas (Proposed § 414.408(e))

CMS proposes to use the payment information determined under the competitive bidding program to adjust the payment amounts for the same DMEPOS in areas not included in the competitive bidding program for covered items furnished in 2009.[33] The proposed rule also states the possible general criteria CMS will use when deciding whether to exercise its authority under Section 1834(a)(1)(F)(ii) of the Social Security Act, which allows CMS to determine if such a course of action would be prudent. The criteria CMS will utilize to determine if it will use competitive DMEPOS prices to adjust prices outside of the bid areas are: (1) the savings needed for particular covered items and (2) the basis for adjustment including both the starting point for any such adjusted price and the method for adjustment. The Proposed Rule does not contain the specific methodology that would be used to adjust payments in other areas.

A. Summary of Bayer's Suggestions

We do not believe that CMS should attempt to use prices from within competitive bidding areas in areas that have not been bid competitively. While use of competitive bid prices outside of bid areas appears to be a plausible way of

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[30] The OIG issued a special fraud alert that unequivocally stated that providers who routinely waive Medicare co-payments may be held liable under the Anti-Kickback Statute. *See* 59 Fed. Reg. 242 (1994). This statement was reaffirmed in a later OIG Advisory Opinion, No. 97-4 (Sept. 1997).

[31] *See* HHS OIG Special Fraud Alert: Routine Waiver of Copayments and Deductibles Under Medicare Part B (May 1991).

[32] *See, e.g.,* OIG, Advisory Opinion No. 97-4 (Sept. 1997) (stating that the failure of a company to attempt to collect co-payments from beneficiaries, where an employer insurer refused to pay them, would be a violation of the Anti-Kickback Statute and Beneficiary Inducement Statute).

[33] *See* 71 Fed. Reg. 25654, 25664 (May 1, 2006).

securing additional savings in theory, in fact it would be very difficult to actually translate bid prices into economically sound prices for use outside of the competitive bid areas. This is because there is no principled way to account for the economic and other differences between competitively bid and non-competitively bid areas.

Even geographically contiguous competitive bid areas that are demographically similar will serve as a poor bases for determining reimbursement for non-competitively bid areas, as the absence of competitive bidding is itself too great and too fundamental a difference. Failure to account for all of these economic factors by attempting to impose bid prices in areas that have not undergone competitive bidding will undoubtedly lead to the unintended result of inadequate access and poor quality of care. CMS also should consider how the lack of CBIC oversight and other educational or administrative resources, which are an inherent part of the activities in competitive bidding areas, will affect the ability of the suppliers to provide quality access for the deflated reimbursement rates. It is a dangerous policy to implement competitive bid prices without a competitive bid process that will bring the necessary safeguards to bear.

B. Competitive Bid Areas Will Have Fundamentally Different Economic Environments Than Areas That Have Not Been Through the Bidding Process

The payment amounts derived from the competitive bidding program are a result of calculations that suppliers will make in anticipation of a greater market share as a consequence of the reduction in the total number of competitors. During the bidding process proposed by CMS, a set number of suppliers is awarded the right to furnish the item to beneficiaries. Suppliers assume that they will experience an increased volume in sales by winning a competitively bid contract. Taking that assumption into account, suppliers will set prices with the understanding that the increased volume can help cover overhead and other fixed costs.

Conversely, the suppliers in areas that have not been through the competitive bidding process cannot be assured that the imposition of a lower price will result in an increased share of Medicare business. There is no way for CMS to eliminate competitors in these areas to compensate suppliers for the lower prices, without going through the bidding process. In fact, there is no way for CMS to know, without undergoing the competitive bidding process, if the suppliers in any given area can meet a higher demand even if some of their competitors chose to leave the market due to the lower prices. Nor is there any way for CMS to predict which suppliers will be able to meet demand at lower prices and still maintain a profitable business. These facts are critical to ensuring that quality products are accessible to all beneficiaries.

Another complicating factor is the high potential for the competitive bidding process to favor large national suppliers as winners in any given bid area

because they are most likely to have the resources to service the increased volume, even at the lower single payment amount. Unless CMS targets only non-bid areas that are also serviced by large national suppliers, it would run the risk of adjusting prices in local areas serviced by small, regional outlets based on bid prices submitted by a different supplier mix. This would be grossly unfair.

All of these differences must be accounted for when setting the price in non-competitive bid areas, even where prices in bid areas locally, regionally, or nationally are or appear to be similar. Due to the fundamentally different assumptions that were the basis of the payment amounts from the competitive bidding program, as discussed above, it is inappropriate to apply them to contexts where the underlying factors are absent. CMS should not rely upon a process and a group of safeguards in some areas where competitive bidding prices apply and then fail to adopt that same process and those same safeguards in other areas where CMS proposes to use those same prices.

Non-bidding areas are fundamentally different than those subject to competitive bidding. Suppliers in areas that have not been through the bidding process should not have the lower bid prices imposed upon them without the attendant increase in volume accomplished through the elimination of competitors, a process that ensures that requisite quality safeguards are in place, and a means to ensure that adequate numbers of suppliers will continue to serve the market, notwithstanding the lower prices.

C. The Mechanisms Suggested in the Proposed Rule Appear to Be Inadequate

The Proposed Rule suggests a percentage adjustment of actual bid prices to account for the differing economic circumstances. The Proposed Rule fails to set out the extent of the proposed adjustment or the nature of the criteria that would be applied in making the adjustment. The lack of basic clarity in the proposal prevents the submission of truly meaningful and substantive comments regarding this issue. However, we believe that a percentage adjustment in any form underestimates the complexity of imposing artificially determined prices onto a free market system.

There is no standard methodology for imposing such artificial prices on a previously supply and demand driven system. Though the prices in a non-bid area are stipulated by the fee schedule, the suppliers in any given area competing for DMEPOS business are those that are able to provide product at the bid price. CMS has no relevant precedence to draw from in applying this kind of adjustment. Certainly a flat percentage adjustment to a bid price will not adequately account for differences in the ability of suppliers in non-bid areas to provide products at prices that suppliers in competitive bid areas have selected.

In summary, the best way to realize needed savings for a given item in areas that have not been through the competitive bidding process is to implement the same competitive bidding process. Failure to do so will undoubtedly lead to quality of care and access issues that stem from artificially imposing prices from a foreign economic system onto a local system that operates in a fundamentally different way. There is no feasible way to account for the differences in economics that will lead to a stable and efficient market for the item whose price is transferred. CMS should not take a risk with such an important benefit by blindly proceeding to apply bid prices in non-bid areas despite the obvious economic and market barriers to carrying out this policy. Such a course of action would be contrary to CMS' mission to "protect and improve beneficiary health" and to "foster high quality care."[34] The only equitable way of applying these payment amounts to non-competitive bidding areas, for both suppliers and beneficiaries, would be for CMS to conduct competitive bidding in that area. Failure to proceed in this fashion runs an unacceptably high risk of leading to quality of care and access issues.

VIII. Requirement to Obtain Competitively Bid Items from a Contract Supplier (Proposed § 414.408(f))

CMS proposes that a beneficiary who is traveling from a CBA to another CBA will be required to obtain supplies from a contract supplier. If the beneficiary travels from a CBA to a region that is not covered by the competitive bidding program, the beneficiary will be required to obtain supplies from a supplier that has a valid Medicare supplier number. The payment to the supplier in either case would be based on the single payment amount for the item in the CBA where the beneficiary maintains a permanent residence.

Bayer is concerned that suppliers across the nation will be affected adversely by this provision. The payment that a supplier may receive for a beneficiary that maintains a permanent residence in a CBA will be most likely lower than what they normally receive in reimbursement. In other words, Medicare suppliers that are providing services outside of the CBA will be forced to accept pricing that is lower than normal for servicing that beneficiary. Such non-competitive bidding suppliers will not have the increased volume to offset the lower pricing, as contract suppliers will within a CBA.

In an effort to minimize unfairness to the non-competitive bidding suppliers, CMS should compensate the supplier that is supplying a beneficiary who has traveled from a CBA to the supplier's region that is not covered by the competitive bidding program the fee schedule amount or, if applicable, the Federal Employee Health Benefit Program schedule amount. If CMS decides to proceed with applying the single payment amount, CMS should make every effort to educate

[34] *See* http://www.cms.hhs.gov/MissionVisionGoals/ (last visited Jun. 13, 2006).

non-competitive bidding suppliers regarding what to expect for payments in such situations. The education on non-competitive bidding suppliers will facilitate the ability of beneficiaries to access the equipment that they need and minimize the risk that non-competitive bidding suppliers will decline to provide services at those same rates in non-competitively bid areas.

IX. Evaluation of Bids (Proposed § 414.414(e)) – Need for Appropriate Technical Bidding Requirements

We recommend that CMS carefully review the capacity of suppliers and establish measures to examine the sustainability of bids.

A. Market Demand and Supplier Capacity (Proposed § 414.414(e))

The Proposed Rule is based upon the speculative proposition that it can accurately predict demand and supply conditions for numerous products in highly fluid and complex markets. Significantly, CMS and other federal agencies have not been able to make these predictions accurately in the past. For example, in the implementation of the Part D program, beneficiaries skewed the estimated demand and supply conditions by overstocking drugs out of concern that there would be unavailability of necessary drugs during the transition period. CMS has not provided any meaningful opportunity in this Proposed Rule to comment on this important question because CMS has not explained how it proposes to address these critically important issues of demand and supply.

A critical aspect of striking the appropriate balance between demand and supply is the capacity of individual contract suppliers to meet the variable needs of an increasing Medicare population. CMS should carefully determine the minimum capacity threshold that contract suppliers must be prepared to meet and consider incorporating an extra margin of 25 percent. This rate is reasonable because this cushion will avoid disruption of services if unanticipated circumstances, such as natural disasters, arise within a specific CBA. Without this additional cushion, it is possible that suppliers may be awarded bids without the ability to appropriately meet beneficiary demand over the course of the contract. Other, more qualified suppliers may be excluded from the program as a result.

Similarly, CMS should consider offering contracts to suppliers beyond the capacity threshold, whatever number that is, and identify supplies so that 125 percent capacity is served.

Once CMS has calculated a reasonable capacity threshold, we urge CMS to scrutinize individual bids to ensure that suppliers can meet the appropriate capacity standards. It should also examine the geographic distribution of contract suppliers within a CBA and secure an adequate number of suppliers to realistically service the entire bidding area. Beneficiaries' needs will not be adequately met if the

number of suppliers necessary to achieve capacity is evaluated by CMS in a manner that unduly restricts available distribution channels. In other words, CMS should consider not only if the supplier can serve the area but also how easily it will be for the beneficiary to actually reach the supplier.

To implement this review in a fair manner, we also request that CMS clarify the expectations related to evaluating "capacity." It is unclear to us whether CMS will be analyzing a supplier's capacity for each item in a product category or the highest volume item in a product category. Will CMS select a supplier who can meet the highest volume capacity in one item, but has significantly reduced capacity for another item in the same category? Given the uncertainty surrounding this important issue, we respectfully ask CMS to provide more information in its final rule.

B. Composite Bids (Proposed § 414.414(e))

The composite bid process creates incentives for a supplier to manipulate the system by submitting low bids on certain items and high bids on others to reach a favorable composite score. We urge CMS to carefully structure the composite bid process to minimize such opportunities for suppliers to present information that will yield a composite score not truly reflective of the costs or the type of services and items that will be provided. Otherwise, CMS may inadvertently exclude qualified suppliers.

We seek further clarification on these issues of demand, supply and sustainability in the final rule promulgated by CMS.

X. Determination of Competitive Bidding Payment Amounts (Proposed § 414.416(b)) – Single Payment Amount

The Proposed Rule contemplates a pivotal bid that would reflect the point at which an adequate number of potential contractors necessary to serve an area had been identified. Under the Proposed Rule, that number of bidders is then offered a contract that each bidder may either accept or reject. This presents the chance, even a likelihood, that the adequate number of suppliers determined by CMS will not, in fact, be available in a given competitive bidding area.

We are concerned that the median determination methodology proposed by CMS contains certain deficiencies that will result in disadvantaging suppliers who have submitted valid and appropriately supported bids. These suppliers will not receive adequate reimbursement to cover their operations in the competitive bidding program. The proposed methodology results in roughly half of the winning suppliers receiving less than they bid for a particular item. This, unfortunately, may translate into a payment level that is below what an excellent supplier offering the greatest capacity may be able to accept.

This methodology is inconsistent with the methodology utilized in the demonstration projects and we are unclear why CMS is rejecting that tested approach. In the demonstration project, each winning supplier received at least as much as the supplier bid. This approach is the least likely to unfairly disadvantage suppliers who submit fair and honest bids, and the most likely to encourage successful bidders to participate in the program. Consistent with the methodology applied in the demonstration projects, we recommend that CMS require that the winning supplier must receive, at a minimum, the payment level that the supplier has bid.

We are also concerned that the Proposed Rule does not provide a mechanism for CMS to examine the sustainability of bids. By this we mean an assessment of whether the bid amount reflects a legitimate estimate of the reimbursement necessary for a supplier to cover its cost during the entire contract period while meeting the relevant quality, delivery, service, scope and similar requirements of the program. A thoughtful review may reveal that the majority of supplier capacity is above the pivotal bid and that the single payment amount is not sustainable or reasonable. In order to address this issue, we recommend that CMS either: (1) perform an analysis that tests the sustainability of the bids before the unsustainable bids pollute the bid pool or (2) re-calculate the single payment amount based on bidders that qualify for and can perform fully under CBA contracts, even if a disqualified bidder was used to determine a pivotal bid.

XI. Nationwide or Regional Mail Order Competitive Bidding Program (Proposed § 414.410(d)(2))

CMS is currently considering the establishment of a nationwide or regional competitive bidding program for certain items such as diabetes-related testing supplies after January 1, 2010. CMS envisions the submission of competitive bids by mail order suppliers in 2010. The proposed implementation of a nationwide or regional mail order competitive bidding program for diabetes-related testing supplies raises patient benefit concerns and small supplier concerns, particularly in light of the lack of the required experience and expertise necessary to implement this proposal with any reasonable confidence. We are concerned that mandatory mail order service for diabetes testing supplies would severely limit patient choice and deny many beneficiaries functional access to these supplies. We also urge CMS to examine closely how a mail order competitive bidding program will affect small businesses.

A. Limited CMS Experience with Diabetes-Related Care Items in Competitive Bidding Program

Given that a number of the components of competitive bidding have not been included in the San Antonio and Polk County demonstration projects, including diabetes care management items, CMS simply has insufficient experience

to proceed with such an ambitious proposal. Significantly, even with respect to those items included in the prior demonstration projects, there is not any mail order channel experience for diabetes-related care items in the competitive bidding program. In light of the significant doubts that exist about CMS' ability to implement competitive bidding successfully, even in its essential, mandated elements, CMS should not unnecessarily complicate the implementation challenge it faces by adding a mail order component to that effort in a premature fashion without the benefit of needed experience and testing of that concept.

B. Impact on Beneficiaries

Broad, mandatory mail order programs for supplying diabetes testing supplies would not be convenient for *all* Medicare beneficiaries, and CMS should make every effort to retain patient choice in treatment options and furnishing of critically necessary supplies in the face of a diabetes epidemic. Contrary to the underlying assumption that mail-order delivery is a "convenience for beneficiaries" in the GAO report,[35] mail-order delivery is just one of multiple channels of distribution that beneficiaries choose to obtain their blood glucose monitoring supplies. The majority of patients obtain many of their diabetes care management supplies at retail pharmacies. We urge CMS to preserve the choices that beneficiaries currently have in the method through which they receive their vital medical supplies for the monitoring and treatment of their diabetes.

Mandatory replacement of all supplies such as test strips and lancets for Medicare beneficiaries through mail order suppliers effectively limits access to these critical items to the poorest and most vulnerable segment of the beneficiary population. As noted above in section I, patients with diabetes already encounter significant hurdles in obtaining adequate test strips and diabetes monitoring supplies and suffer avoidable health consequences.[36] Some Medicare beneficiaries do not have a regular place of residence with secured methods of receiving mail supplies. Other beneficiaries cannot successfully maneuver various phone numbers to seek assistance from mail order suppliers. Medicare beneficiaries greatly benefit from the personal counseling and disease therapy management provided by their retail pharmacists.

Bayer has significant concerns that the premature development of a mail order option will raise issues about the adequacy of patient education and counseling services, such that patient compliance and persistency may be undermined. We request CMS to conduct further studies to ascertain that implementation of such a program will not result in unintended consequences. If

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[35] *See* GAO, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies*, Sep. 2004, at 14.

[36] Ian Urbina, *In the Treatment of Diabetes, Success Often Does Not Pay*, N.Y. TIMES, January 11, 2006.

CMS decides to proceed with the implementation of a mail order competitive bidding program for diabetes-related items, Bayer urges CMS to preserve options for beneficiaries for whom mail order would be difficult and to implement it on a voluntary basis only.

C. Impact on Small Suppliers

Furthermore, a nationwide mail order competitive bidding program will severely limit the participation of small suppliers who specialize in particular regions and lack the capacity to service patients across the nation. This will decrease the parties available to bid, which, in turn, will undermine the ability of competitive biding to secure cost savings.

There is also a concern that fruitful relationships between individual beneficiaries and their suppliers, such as local pharmacies, will be unjustifiably disrupted. Beneficiaries often rely on expertise provided by pharmacists who observe and point out any potential drug interactions and provide invaluable information beyond the dispensing of supplies or medication.

In sum, Bayer challenges the notion that mail order delivery is convenient for all beneficiaries and urges CMS to review carefully the impact that implementation of a nationwide mail order competitive bidding program will have on beneficiaries and small suppliers. Implementation of a broad, mandatory mail order competitive bidding program may jeopardize beneficiaries' access to diabetes-related testing supplies and, ultimately, raise the cost of the federal health care program as beneficiaries with diabetes suffer the ravaging effects of the disease without proper monitoring and access to testing supplies.

XII. Payment Adjustment to Account for Inflation (Proposed § 414.408(b))

CMS proposes to apply an annual inflation update to the single payment amounts established for a competitive bidding program. Beginning with the second year of a competitive bidding contract, CMS will update the single payment amounts by the percentage increase in the CPI-U for the 12-month period ending with June of the preceding calendar year. This is consistent with the method that the DME fee schedule is updated. CMS believes that this proposal will obviate the need for a supplier to consider inflation in the cost of business when submitting its bids for furnishing competitively bid items under a multi-year contract.

While we appreciate CMS' efforts to address the inflation issue, we are concerned that application of an annual inflation rate to the single payment amounts will not adequately take into consideration other factors that may merit an increase in the single payment amounts. The use of the CPI index and not the more relevant CPI-health index will understate the relevant inflation. CMS has used specific

inflation rates in other contexts, as in the inflation factor with end-stage renal disease drugs as implemented in 2004, and should follow that precedent here.

We are also concerned how this inflation factor will apply to items that are currently under a freeze for fiscal years 2007 and 2008.[37] It is our understanding that diabetic testing supply costs are ineligible for inflation factor application since they are class II devices subject to the freeze imposed by statute.[38] We urge CMS to clarify whether the inflation factor would apply notwithstanding the prior restriction. We point out that the inflation freeze in the fee schedule context is distinct from the application of the inflation factor in the competitive bidding program. CMS needs to consider this in its entirety.

XIII. Change in Ownership (Proposed § 414.422(d))

Consolidation in the industry is inevitable as the competitive bidding program is implemented. Thus, the competitive bidding program needs to address this reality and allow for greater adaptability and flexibility in allowing suppliers to change ownership status. The current proposed Section 414.422(d) requires modification so as to avoid onerous restraints on changes of ownership involving contract suppliers.

The Proposed Rule, as it stands, fails to take into consideration the short time period in which acquisitions or mergers often occur in the marketplace. While we appreciate CMS' concern for an appropriate analysis of the change in ownership, we ask that CMS modify the current sixty-day prior notice requirement. Suppliers should have the flexibility to provide notice as the transaction closes or

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[37] *See* 42 U.S.C. § 1395m(a)(14)(H) for 2007— (i) subject to clause (ii), in the case of class III medical devices described in section 360c (a)(1)(C) of title 21, the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and (ii) in the case of covered items not described in clause (i), 0 percentage points; and
42 U.S.C. § 1395m(a)(14)(I) for 2008— (i) subject to clause (ii), in the case of class III medical devices described in section 360c (a)(1)(C) of title 21, the percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and (ii) in the case of covered items not described in clause (i), 0 percentage points; and
42 U.S.C. § 1395m(a)(14)(J) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year.

[38] *See* 21 C.F.R. § 862.1345 "Glucose test system. (a) *Identification.* A glucose test system is a device intended to measure glucose quantitatively in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma. (b) *Classification.* Class II."

when the parties sign a letter of intent if the transaction is due to close in less than a sixty (60) day period.

A successor entity should be allowed to continue supplying beneficiaries in a CBA as the winning contract supplier as long as it meets the general requirements for contract suppliers. While we appreciate CMS' concerns and desire to retain discretion to terminate a successor entity's contract with CMS for failure to comply with the general requirements, we do not think such broad discretion is warranted or consistent with ensuring appropriate access. The removal of any supplier determined to have been necessary to ensure adequate access at the time that contracts are entered into runs the inevitable risk that there will be insufficient suppliers to meet the necessary demand. This risk is unacceptable and unfair where a successor entity is willing to comply with the requirements of the applicable competitive bidding contract.

XIV. Quality Standards and Accreditation (Proposed § 414.414(c))

CMS notes in the Proposed Rule the statutory mandates limiting the award of a contract to entities that fully comply with the quality standards specified by the Secretary. CMS plans to further clarify quality standards at a later time. Bayer fully supports CMS' efforts to award contracts only to suppliers that fully comply with all accreditation requirements and quality standards but encourages CMS to implement the competitive bidding program only after the application of the relevant standards. Quality standards are an important part of CMS' effort to reduce fraud and abuse within the DMEPOS industry and ensure that beneficiaries are receiving high quality items and services.

Bayer, however, does urge CMS to provide further clarification regarding the quality standards that will be relevant to competitive bidders. Stakeholders have had to respond to the Proposed Rule regarding competitive bidding without having had the benefit of knowing the final quality standards. In order for suppliers to submit accurate bids under competitive bidding, suppliers need to be able to identify all fixed and variables costs in order to accurately determine a bid price for competitive bidding. It is unreasonable to expect a supplier to be able to quantify the additional costs incurred by compliance with the new quality standards without having adequate knowledge and experience with the financial reporting, quality standards, and accreditation requirements. CMS should not implement competitive bidding until the quality standards have been fully established and applied.

To allow greater and more substantive dialogue within the industry and medical community, CMS should set a second comment period to allow suppliers to evaluate how the newly issued quality standards will work in conjunction with the competitive bidding program.

XV. Establishing Payment Amounts for New DMEPOS Items (Gap-Filling) (Proposed § 414.210(g))

Bayer is concerned about the broad implications of the changes to the gap-filling process under the Proposed Rule and urges CMS to have a separate comment period to address the complex issues surrounding the gap-filling methodology. Bayer also requests that new technology be excluded from the competitive bidding cycle in which the product is introduced.

CMS has no formal process for establishing reimbursement amounts for new DMEPOS items. Currently, when a new DMEPOS item is introduced, CMS uses an informal and somewhat crude "gap-filling" process to determine the fee schedule rate. Since the product typically has no available historical pricing data, this crude process estimates what the average reasonable charges would have been for the item if Medicare had provided reimbursement during the fee schedule base period. The gap-filled base fees are updated by the covered item updates and are subject to regional fees, and ceiling and floor limitations. In certain circumstances, CMS may calculate the current payment amount by deflating the price of the product and then essentially re-inflating it.

CMS is proposing to establish a formal gap-filling process in the Proposed Rule. This proposal is a significant change to the existing, informal practice. Among other things, CMS plans to discontinue the practice of deflating supplier prices and manufacturer suggested retail prices to the fee schedule base period. CMS also plans to use a functional technology assessment process.

While we support CMS's desire to formalize this process, we strongly encourage CMS to undertake a separate notice and comment period to allow suppliers and other stakeholders to fully address the complicated issues related to this proposal. The changes CMS is proposing and the impact they have on the Medicare DMEPOS fee schedule and the competitive bidding program are significant. The Proposed Rule is not the appropriate place for this discussion.

In addition to our general concern about the timing of this topic, we also believe it is inappropriate for CMS to include new technology and new items, even if subject to a reasonable gap-filling process, in the competitive bidding program. Suppliers did not consider the availability or costs of these items when calculating their bids. It is unfair and unreasonable to assume that these new items will have no material impact on direct and indirect supplier costs. Instead, we recommend that CMS exclude the new technology from the competitive bidding cycle in which the product is introduced or for a defined period of two years after the product is brought to market.

This approach is consistent to what CMS has done in other contexts. When new technology is introduced into the market, there is an inevitable passage

of time before the medical and patient communities accept and integrate the new technology, and the operational costs and benefits are fully realized. To reflect the ordinary course of market acceptance, CMS should not arrive at a gap-filled price immediately after an item is introduced into the market, nor should the item be inserted into the list of products subject to competitive bidding. This slight deferral of inclusion of the new technology is analogous to the management of new technology in the hospital inpatient and outpatient payment systems. In this context, CMS has created temporary APC pass through payments based on acquisition costs to reflect the higher cost of the new technology. These rates are used until such time as that technology can be assessed and the payment rate created under the standard methodology.

For ease of administration, we urge CMS to exclude this new technology from the competitive bidding cycle in which the item is introduced or two years, whichever is longer. We suggest CMS similarly delay calculating the new payment rate for the item under the Medicare fee schedule.

XVI. Payment Basis (Proposed § 414.408)

The Proposed Rule does not appear to contemplate an emergency exception in which beneficiaries may obtain supplies from their original suppliers for a short duration of time under limited circumstances. Bayer is concerned that a grandfathered supplier or a non-contract supplier will refuse to assist the beneficiary who lives within a CBA. The proposed grandfathering provision does not apply to patients with new medical needs and the proposed payment basis provisions do not address situations in which a beneficiary is in dire need of an item or service and is not able to be immediately assisted by the new contract supplier. Thus, we recommend that CMS establish an emergency exception that allows beneficiaries to receive supplies from their current supplier even after the commencement of the competitive bidding program for a short period to ensure that beneficiaries do not have a disruption in their services or supplies.

XVII. Conclusion

We thank CMS for its tremendous efforts in implementing the competitive bidding program in a fair and effective manner. We appreciate this opportunity to share our thoughts and concerns with you. We are happy to discuss any of these issues and welcome any questions that you may have.

Sincerely,

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Mary Robinson

From: Goldberg, Ralph (CMS/CMM) [Ralph.Goldberg@cms.hhs.gov]
Sent: Friday, June 30, 2006 7:02 AM
To: Beverly Dennis; Mary Robinson; Vivian Braxton
Subject: FW: competitive bidding

The Brace Shop was having trouble getting to the website to list their comments on the reg. I asked them to send me their comments and I am forwarding them to you to log into the E-mail comments.

thank you

From: Brace Shop [mailto:braceshop@yahoo.com]
Sent: Thursday, June 29, 2006 3:06 PM
To: Goldberg, Ralph (CMS/CMM)
Subject: competitive bidding

Hi!
Some of the concerns we have about being a small business owner in this competitive bidding period are as follows: We are a little nervous about the bigger companies being able to order at a discount with larger supplies orders and not giving the smaller companies a fair shake. (A Wal-Mart situation). We do alot of custom work and to my knowledge this will not be effect our service to medicare patients. The larger companies already are a step up front because they are able to stock more off the shelf items and have multiple locations. Our firm is small but most of our Certified Orthotist have been with us for 25 to 40 years. We have alot of experience within our offices. We hope that this expertise does not get lost or compromised with a few discounted dollars. How do we compete and it be fair? How will Medicare promise to be fair to all companies. We hope that Medicare views everyone with a professional eye looking for experience and good old fashion patient care and not just a dollar discount. What steps do we take as a small business to stay a float? Thank you for your help and understanding with this issue.
Sincerely,

The Brace Shop, Inc.

DRUCKER DRUGS L.L.C.
DRUCKER HOME MEDICAL EQUIPMENT
DRUCKER HOME I.V. MEDICINES
110 East Main Street
Kingstree, SC 29556
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115-0
(40)

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sir/Madam:

I am writing to submit comments regarding CMS-1270-P.

Payment Basis

It is unfair to expect a contract supplier to assume responsibility for a Medicare beneficiary that has been renting oxygen equipment or other rental equipment from a non-contract supplier that is not willing to continue provision of equipment under the grandfathering clause. It is likely that this patient may only have 3-6 months left under their rental period and the contract supplier would receive few rental payments before this equipment would convert to purchase. It is not possible to factor a cost for this into our bid price. Providers do not have enough information to know how often this may happen, where the beneficiaries would be in their rental cycle, etc. If this is going to be expected of contract suppliers, then CMS needs to establish guidelines for when patients can transfer and agree to a minimum number of rental months for which the contract supplier would be paid.

Competitive Bidding Areas

It is recommended that CMS should stagger the bidding in MSAs in 2007 instead of implementing all 10 areas at once. This would allow CMS to identify problems and correct them before these problems are widespread in all 10 MSAs. It is imperative that the first 10 MSAs and the product categories are identified in the final rule to begin to give providers ample time to prepare for the competitive bidding process. Under the timelines that CMS has established, it is going to be impossible for small providers in these large MSAs to identify other providers for potential networks and to work through the legal processes to form these networks. These tight time constraints are going to significantly hinder the participation of small businesses in this process, thus putting at great risk the ongoing viability of these providers.

It is also recommended that New York, Los Angeles and Chicago be top priorities in the 2009 phase of implementation due to the potential for significant cost savings to the Medicare program. Even though these are large areas, the experience gained during

implementation of the first 10 MSAs should prepare CMS for these areas and they should be implemented first during the second phase due to the large cost savings that should be realized according to CMS projections.

Criteria for Item Selection

All products and HCPCs codes that are going to be competitively bid in each MSA should be published in the final rule. A competitive bidding product category may include products and HCPCS codes from multiple medical policies. The intent of the law is to exclude products where bidding would affect access or quality, but this protection is lost if medical policies are combined. There are many providers that may specialize in only one HCPCS code in a product category and they should not be kept from bidding. By combining medical policies, the only providers that are eligible to bid are those that carry the broadest product offerings, and sometimes, these aren't the providers with the strongest expertise in a specific product or HCPCS code.

It is also important that in both selection of MSAs and product selection, when CMS is projecting the potential savings, that full costs of implementation and overhead are factored into this process. The costs to implement and administer this project are going to be significant, and these costs cannot and should not be ignored when calculating the savings to be achieved through competitive bidding.

Submission of Bids under the Competitive Bidding Program

It is important to require the suppliers that are winning providers be physically located within a competitive bidding area. This would eliminate a tremendous amount of fraud and abuse in the Medicare program (with the exception of mail order supplies). On a frequent basis, I am faced with beneficiaries who have ordered from a company on television or the internet and this company drop-ships power wheelchairs, concentrators, etc. to Medicare patients with no training, etc. These patients call our office not knowing how to use the equipment, and many times not being able to get the power wheelchair through the front door. If these companies were required to have a physical location in the competitive bidding area, this would eliminate a significant portion of the fraud and abuse that is currently taking place in our industry. With the way the proposed rule is currently written, CMS is perpetuating the problem, not helping to solve it!

Conditions for Awarding Contracts

Only accredited providers should be eligible to submit bids. CMS should not proceed with competitive bidding until it is sure that this is possible. CMS needs to identify the criteria it will use to identify the accrediting bodies now and publish that criteria. CMS should grandfather all providers accredited by organizations that meet the criteria that CMS identifies. CMS should allow additional time for providers to analyze the quality standards in conjunction with the NPRM. The quality standards will have a significant impact on the cost of servicing our beneficiaries. Until these quality standards have been released and providers can implement them, as well as see the costs of becoming

accredited (both internal costs and the actual cost of the accreditation process), then it is impossible to prepare bid pricing. Companies that have not gone through the accreditation process can submit unrealistic bid prices due to the fact that they have not completed the process nor obtained accreditation. These low bids can significantly impact final pricing. And if these companies choose not to get accredited and drop out of the contract supplier group, they have lowered pricing for these products.

CMS should require accreditation of all locations of a company. It is not appropriate to think that if one branch of a business such as Wal-Mart is accredited, that all branches of the business provide the same level of service. This would also give the national companies an unfair advantage over the single location companies, because they could accredit one branch and spread that accreditation cost over many locations, while the single location small provider will have to absorb the large cost of accreditation and factor that into their bid price.

It is also important to note that the timelines that CMS are considering for implementation of competitive bidding are unrealistic based on accreditation requirements. For the majority of companies in this industry, they have not prepared for nor gone through the accreditation process. This is a time-consuming process and one that many companies do not want to prepare for until they have all the answers. Providers want to see final quality standards and then a list of the accrediting bodies recognized by CMS before they begin the lengthy, expensive process of accreditation. It requires a minimum of 6 months to prepare for your initial survey plus the majority of accreditation bodies require that companies be in compliance with quality standards for a minimum of 4 months prior to survey. So, realistically, providers going through accreditation for the first time will need 10-12 months to complete that process. Add on to that timeframe another 4-8 weeks after the survey before the accreditation body notifies the provider of the "official" results of their survey. So, it is important to realize that on average, CMS should expect it to take a minimum of one year to complete the accreditation process and become officially accredited. This doesn't even take into consideration the tremendous backlog that all accrediting bodies are going to face once quality standards are finalized and accreditation organizations are selected. It is unrealistic to think that this won't add additional time to the already lengthy process.

The final rule needs to contain more detailed information regarding financial standards that are going to be utilized during the bid process and how they are going to be utilized. CMS needs to define what financial ratios that they will be requiring, what the ratios should be, etc. so that providers know going in if they are considered viable candidates before submitting their bids. CMS also needs to decide how they are going to define a small business. Is it the business as a whole or is it each individual branch location? CMS should look at the business as a whole, not by supplier number.

CMS should not artificially limit bids by disqualifying bids above the current fee schedule. Otherwise, the competition is not truly competitive based on market prices.

There is no incentive in the proposed rule to exclude lowball bids, as bidders will assume they will be paid an amount higher than their bid. Bid evaluation and selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS should identify processes through which they will be able to determine that the bids are both rational and sustainable.

The NPRM describes a methodology of creating a composite score to compare suppliers bids in a category using weighting factors to reflect the relative market importance of each item. CMS should make clear that it will provide suppliers with the weighting factors that CMS will use to evaluate the bids in each MSA so that suppliers are able to determine how best to bid each HCPCS within a product category using the same criteria as CMS.

CMS' process to determine the number of suppliers to meet projected demand in an MSA and its methodology to estimate supplier capacity are stacked in favor of large, high volume regional suppliers despite CMS' assertion that the NPRM provides opportunity for small suppliers to participate. Moreover, there are no guarantees that any of the winning bidders will be small businesses or a network of small businesses.

Determining Single Payment Amount for Individual Items

The NPRM describes a rebate program that allows contracted suppliers to rebate the difference between their bid and the established payment amount to the beneficiaries. Providing rebates is contrary to laws applicable to the Medicare program such as the Anti-Kickback statute and the Beneficiary Inducement Statute. This rebate program could take fraud and abuse to a whole new level in our industry and would be almost impossible for CMS to oversee and regulate. This entire provision needs to be eliminated from the final rule.

Terms of Contracts

It is unrealistic to state that contract suppliers cannot refuse to repair or replace patient-owned equipment subject to competitive bidding. Many providers only provide one or two types of concentrators, for example, and based on the above statement, CMS would now expect contract suppliers to be able to service, repair and replace every type of concentrator made today. This is yet another example of how CMS is asking providers to continue to increase their costs, yet we are asked to significantly decrease our reimbursement. Not only does it increase a provider's costs to stock parts for every type of concentrator, but you must also train staff to be able to repair and service every type of concentrator.

The proposal to restrict the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. While it is appropriate for CMS to consider the buyer's quality and financial stability, CMS should not make approval of the acquisition contingent on the need to preserve capacity within the MSA.

Opportunity for Participation by Small Suppliers

CMS needs to define the definition of small business as it relates to the competitive bidding project. Is the $6 million in annual sales total sales for the company or Medicare sales only? Is this tracked by supplier number or by the company? These decisions impact many things as they relate to the proposed rule including requirements for reviewed financial statements versus audited financial statements.

Opportunity for Networks

Requirements for sub-contractors need to be clearly defined. If a contract supplier chooses to use sub-contractors, do they need to meet the same requirements as a contract supplier in terms of accreditation, financial standards, etc.? If so, how will CMS ensure that this happens?

For networks to be formed and to be anti-competitive, CMS will have to provide some type of data for providers to use to ensure that networks aren't formed that exceed the 20% of market share. Providers aren't going to want to go to the time nor expense to form a network and then find out when the application is submitted, that the network isn't eligible. This is another reason that financial standards need to be clearly defined up front by CMS in terms of their requirements regarding financial stability, financial ratios and what they should be, etc. Providers need detailed information so they can use this data to determine suitable partners for networks.

Clearly defined contract requirements also need to be outlined in the final rule so that providers ensure they meet CMS guidelines.

10 days is probably not a reasonable timeframe to resubmit an application if one of the members of the network is determined to be ineligible. The network will have to search for a replacement provider, determine that they can meet CMS guidelines and then have another legal contract drawn up for the revised network. This timeframe should be extended.

Thank you for your consideration of these comments. I appreciate the opportunity to submit these comments.

Sincerely,

Ruth Anne Hill
Drucker Drugs, LLC
110 East Main Street
Kingstree, SC 29556

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CARE
MEDICAL & REHABILITATION EQUIPMENT

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June 29, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1270-P – Notice of Proposed Rulemaking, Medicare Program (NPRM); Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Care Medical Equipment, Inc. is pleased to submit comments on CMS' Notice of Proposed Rulemaking for Competitive Acquisition for Certain DMEPOS and Other Issues. Established in 1970, Care Medical Equipment, Inc. an independent, family-owned company. has grown to include nine branch locations throughout Oregon and Washington states. Care Medical specializes in home medical equipment services, rehabilitation equipment services including custom seating and positioning, bariatric equipment and respiratory equipment services including home medical oxygen, ventilators, and sleep apnea product and has been serving the needs of the Pacific Northwest for over 35 years.

Care Medical Equipment submits the following comments on CMS' Notice of Proposed Rulemaking published May 1, 2006 in the *Federal Register* (71 *Federal Register* 25654), Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment,

Prosthetics, Orthotics, and Supplier (DMEPOS) and Other Issues. As CMS requested, our comments are divided into sections with "headers" that correspond to the particular subject in the proposed rule.

The information in the NPRM is inadequate to serve as a basis for public comments, especially with respect to the impact that the implementation of the Deficit Reduction Act of 2005 (DRA) will have on competitive bidding. Prior to implementing competitive bidding, CMS should issue an interim final rule to allow additional stakeholder comments. Further, because the NPRM raises more questions than it answers, does not identify the markets, or the products, and the final quality standards have not been published, CMS should also allow adequate time to schedule a meeting of the Professional Advisory Oversight Committee (PAOC) after it publishes an interim final rule. This will permit CMS to obtain industry input one more time before publishing a final rule and initiating program implementation.

Due to the accelerated changes CMS is presently undertaking with the development of new HCPC coding for wheelchairs, parts, cushions, adaptive seating, etc, the Interm Final Rule (IFR), National Coverage Determination (NCD), FEHBP reductions and the fee schedule relating to the new codes, CMS and suppliers must establish data to determine what products could potentially be part of the bidding process. CMS needs to factor what savings, if any, could actually be achieved. By waiting until the final rule is published, CMS is making it extremely difficult for providers to begin gathering the necessary data to submit realistic bids. This is the third time within the past two years that mobility codes have been re-worked by CMS. CMS is currently 18 months behind its original timeline. To implement competitive bidding in a rational and logical way that minimizes the inconvenience to the Medicare beneficiary is to implement competitive bidding in a reasonable timeframe.

Rushing implementation also negatively affects manufacturers by requiring that independent labs perform testing of manufacturer's equipment after the manufacturer has already invested in extensively testing the apparatus. Continuing to conduct internal testing for non-Medicare purposes will only add unnecessary costs to the manufacturer and the supplier. CMS states that manufacturers will have at least one year to re-test devices in an independent testing facility

using the SADMERC's new testing criteria. This requirement is unrealistic and the cost would be exorbitant for manufacturers, and in turn suppliers, which will result in higher bid amounts. If CMS continues to require that independent labs are used, manufacturers need time to add these additional costs into the products they are selling suppliers. How can a supplier know what to bid for a product or if they can afford to buy a product for bidding purposes if the product cost increases from the manufacturer after the bidding process has begun?

CMS must allow stakeholders an opportunity to comment on the quality standards before they are finalized. We understand that CMS has already received comments from 5600 organizations and individuals on the draft supplier standards, and the final standards will likely differ significantly from the draft. If so, under principles of administrative law, CMS must give stakeholders another comment period. Furthermore, an additional comment period is appropriate inasmuch as CMS has chosen to by-pass the procedural protections of the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget that would otherwise be part of the rulemaking process applicable to the quality standards.

CMS needs to realize that competitive bidding eliminates incentives for suppliers whether the supplier "wins" the bid or not for any product category. Presently, beneficiaries' have numerous choices regarding equipment selection because of our free-market enterprise system that allows patients to choose their provider and type of equipment. Competitive bidding will force suppliers into providing lesser quality products and supplies in order to maintain sound business practices. Suppliers will be unable to provide equipment in as efficient a manner under competitive bidding regulations. Services to patients that include delivery, setup, maintenance, education, quality control, product availability, and patient access will decline as a direct result of this incentive elimination.

"General"-Grandfathering Medicare Advantage. The NPRM does not address the impact of competitive bidding on Medicare Advantage patients who leave their plan to reenter traditional Medicare. These patients may have a provider who is part of the MA plan network, but that may not be a contract supplier. What rules will apply to this patient population under competitive bidding? Will these patients have the opportunity to continue to use their existing supplier when

they reenter the traditional Medicare program? We recommend that patients moving from an MA plan to traditional Medicare be given the option of remaining with their existing provider under the grandfathering provisions proposed in the NPRM. As CMS chooses the implementation structure and timelines for competitive bidding, it needs to realize that confusion already exists for suppliers and beneficiaries. Multiple significant changes have already occurred recently, including Part D and the resulting increase of beneficiaries transferring to Medicare Advantage plans.

"General" – Medicare As Secondary Insurance. CMS should exclude those Medicare beneficiaries where Medicare is a secondary payor from the competitive bidding process. These beneficiaries' claims should be paid under the standard fee schedule rate.

"General"- Getting It Right Is More Important Than Rushing Implementation. CMS should push back the implementation date of October 1, 2007 to a more reasonable timeframe. In addition, CMS should stagger the bidding in MSAs over a twelve-month period to allow for an orderly roll out of the program. This will also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread. Under the timeline CMS is proposing, providers will not have time to create networks, which eliminates them as a practical option for small providers that want to participate.

"General"-CMS Must Publish An Updated Implementation Timeline. CMS must publish an implementation timeline that at a minimum identifies the following steps and expected completion dates: a.) Publication of Supplier Standards; b.) Approval of accrediting organizations; c.) Issuance of final regulation; d.) Publication of final 10 MSAs and product categories; e.) Commencement of bid solicitations; f.) Conclusion of bid solicitations; g.) Announcement of winning bidders; h.) Education of beneficiaries and medical community; and i.) Implementation within each MSA. These projected completion dates should be realistic and not overlap one another. It is expected that the publication of such a timeline will highlight the significant problems that lie ahead based on an overly aggressive implementation plan.

"General"- The Program Advisory And Oversight Committee (PAOC) Must Be Included By CMS In The Review Of Public Comments And The Development Of The Final Rule. CMS must include the Program Advisory and Oversight Committee in the review of the public comments received during the 5/1/06 through 6/30/06 comment period and the development of the Final Rule. To not do so excludes the important counsel and advice of key stakeholders in a critical process and goes against the very intent of establishing the PAOC.

"General Comments" – Complex Rehab. Care Medical acknowledges that CMS and its contractors have given extensive consideration to the many proposals within this NPRM. However, Care Medical remains concerned that the only reason identified for products to be excluded from the competitive bidding program are purely based on potential savings. Care Medical believes that Congress intended for consideration to be given to clinical outcome for Medicare beneficiaries. Care Medical recommends that CMS accept the recommendations of PAOC committee members and presenters during the February 2006 PAOC meeting to exempt complex rehab and assistive technology devices from competitive bidding. We do not believe that products which are evaluated, fitted, configured, adjusted or programmed to meet the specific and unique needs of an individual with a primary diagnosis resulting from injury or trauma or which is neuromuscular in nature are appropriate for competitive bidding. While Care Medical will provide comments to many components in the NPRM for competitive bidding, our strongest recommendation is to exempt rehab and assistive technology devices and we want to be very clear that any recommendations regarding the NPRM are not in the least intended to offer alternatives to an exemption.

"Payment Basis"- Special Rules For Certain Rented Items Of DME & Oxygen. (proposed §414.408(k)) It is unclear from the NPRM how CMS intends to apply the DRA provisions on oxygen to grandfathered suppliers and beneficiaries. Will the "grandfathered" relationship terminate at the conclusion of 36 months? If Congress mandates a decrease in the number of months of capped rental, will the supplier still be required to convert ownership of the equipment? A supplier cannot predict this type of financial change when formulating a bid, so how can the supplier be expected to do so? The implementation of the DRA forced ownership provisions on oxygen and capped rental equipment has important ramifications for competitive

bidding. Stakeholders cannot provide meaningful comments on many issues in the NPRM without understanding how CMS will administer the DRA requirements. Consequently, it is important that CMS publish an interim final rule before it publishes the final rule on competitive bidding.

"Payment Basis"-Authority To Adjust Payment In Other Areas. The NPRM states that CMS has the authority, with respect to items included in a competitive bidding program, to use the payment information obtained through competitive bidding to adjust the payment amounts for those items in areas outside the competitive bidding area. With respect to DME, the authority is based on §1834a(1)(F)(ii). CMS states that the authority under §1834(h)(1)(H)(ii) is the basis for using the information obtained through competitive bidding to adjust the payment amounts for "prosthetic devices and orthotics."

CMS should note that the authority under §1834h(1)(H)(ii) applies only to orthotics as defined under §1847a. Specifically, the authority to adjust payment amounts in other areas applies only to "off-the-shelf" orthotics and not also to prosthetic devices as CMS contends. As we explain more fully below, Congress excluded prosthetic devices from the list of DMEPOS items subject to competitive bidding. Consequently, the authority to use information derived from a competitive bidding program to adjust payment in other areas does not apply to prosthetic devices or to supplies reimbursed under the prosthetic device benefit.

In implementing its authority under §1834a(1)(F)(ii), CMS should adhere to the inherent reasonableness (IR) methodology authorized by Congress under the Benefits Improvement and Patient Protection Act (BIPA). The IR methodology includes procedural steps to protect stakeholders and requires an analysis of the factors that influence a determination to make a payment adjustment. In using information derived from competitive bidding to adjust payment amounts in other areas, at least one of these factors is the comparability of the CBA to the areas where CMS intends to make a payment adjustment. Our ability to comment further on this issue is limited because CMS has not advanced a proposal that we can consider. CMS asks only for suggestions on how to implement its authority under §1834a(1)(F)(ii). We recommend that CMS initiate a separate notice and comment rulemaking to solicit comments on a specific proposal before implementing this authority in a final rule.

"Use of Terms" – Purposes & Definitions. (proposed §414.400) CMS needs to provide additional explanation of what the definition of "cumulative capacity" is and how cumulative capacity is calculated into the bidding program.

"Implementation Contractor" - The proposed rule states that CMS will contract with a new entity, the Competitive Bidding Implementation Contractor (CBIC), whose primary functions will be to provide oversight and decision making, operation design functions, bidding and evaluation, access and quality monitoring. There is no further information regarding how CMS plans to choose the CBIC; but Care Medical recommends that CMS ensure that any CBIC entity avoids any potential conflict of interest. For example, a conflict of interest would exist if a CBIC were also a private payor that negotiates directly with DME/HME providers in a managed care context.

"Payment Basis" Requirement To Obtain Competitively Bid Items From A Contract Supplier. Under the CMS proposal, in a state with 12 MSAs there could be 13 rates for the same item – one in each MSA and a non-contracted rate. CMS proposes that the supplier would be paid based upon a single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. For suppliers billing Medicare pricing confusion would be unfathomable. The time and expenses in billing will increase the cost of the product substantially. Requiring suppliers to accept payment based on another MSA bid amount where the beneficiary maintains permanent residency is unreasonable.

"Payment Basis" Inflation Update. (proposed §414.408(b)) CMS states that providers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U. Providers have no assurance that Congress will not override the update through subsequent legislation in any given year. CMS needs to address how it plans to assure providers that the inflation update to the competitive bid price will not be subject to subsequent freezes in the CPI-U. The durable medical equipment industry already has a history of being hit with CPI-U freezes. In 1990, 1998, 2000, 2002, and 2004, a freeze was placed on all equipment. In 2001, 2003, 2004, and 2005, a freeze was placed on a portion of products. In other words, the

DMEPOS industry has not received the CPI-U increase referenced in nearly a decade. If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids. Care Medical supports CMS' proposal to apply an annual inflation update to the single payment amounts established for a competitive bidding program, and recommends that CMS do this even if Congress were to not allow a CPI increase (or a portion thereof) for items not subject to competitive bidding.

"Payment Basis"- Allow Traveling Beneficiaries From Competitive Bidding Areas to Be Serviced At Standard Medicare Allowables. (proposed §414.408(f)) The NPRM states that if a beneficiary is visiting a non-competitive bidding area and requires service, the supplier would be paid at the single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. This proposed plan will make it difficult for beneficiaries to obtain products and services in some areas. Although it is current Medicare policy, the maximum payment difference from one State to another is currently only 15%, while the difference between a single payment price under competitive bidding and the fee schedule amount in a non-bid area could be substantially more than that. If a beneficiary receives service in a non-bid area, CMS should pay the traditional Medicare allowable amount that corresponds with the beneficiary's permanent residence for up to five months.

"Payment Basis" – Authority To Adjust Payments In Other Areas. (proposed §414.408(e)) Effective for items furnished on or after January 1, 2009, CMS has the authority to use payment information from the competitive bidding program to adjust payment amounts to items in an area not in a CBA. CMS is proposing to use this authority, but has not proposed any specific methodology for doing so. Instead, CMS invites comments and recommendations regarding a methodology CMS should use to implement this authority. Care Medical recommends that CMS issue a separate NPRM addressing this issue to allow for substantive comments on specific proposals.

"Payment Basis" – Rehab & Assistive Technology (proposed § 414.408) (a) In this section, CMS proposes that a beneficiary could chose, at any time, to transition to a contract supplier and the contract supplier would be required to accept the beneficiary as a customer. Care Medical finds

this requirement to be especially problematic. At this point in time, rehab and assistive technologies are primarily classified as inexpensive or routinely purchased and in the case of power wheelchairs, have a day-one purchase option. However, there was consideration given by Congress as recent as last year to remove the day-one purchase option for power wheelchairs. Under a capped rental scenario, accepting a new beneficiary transfer after several months of rental would be unrealistic. Care Medical believes that the costs associated with the initial set-up of highly configured and individually prescribed products are too high for a supplier to accept any amount below a full (13 months) rental period. In addition, the supplier would incur significant costs in acquiring medical necessity documentation to facilitate billing of power wheelchairs. Care Medical recommends that CMS must start the rental period over if beneficiaries are transferring to a contract supplier and payment is under capped rental. Care Medical believes it would be impossible for suppliers to accurately estimate their financial loss in these situations. Therefore, suppliers cannot accurately account for this loss in a bid amount.

"Payment Basis" Limitation on Beneficiary Liability. We understand that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. Under current Medicare rules, a supplier may furnish the beneficiary with an ABN notifying him that Medicare will not pay for an item. Other portions of the NPRM specifically state that ABNs will be permitted under a competitive bidding program, and the MMA requires that CMS continue to allow suppliers to use ABNs. CMS should clarify what it means when it states that a beneficiary will have no financial liability to a non-contract supplier for competitively bid items furnished by that supplier. CMS should allow a comment period and PAOC review of this clarification.

"Payment Basis"- Provide Details On How Pricing Will Be Used After January 1, 2009. CMS has the authority to use payment information for covered items furnished on or after January 1, 2009 that are included in a competitive bidding program, to use the payment information determined under that competitive bidding programs to adjust payments amount for the same DMEPOS in areas not included in the competitive bidding program. CMS needs to issue a separate NPRM addressing this issue to allow for substantive comments on specific proposals.

"Competitive Bidding Areas" – Establishing Competitive Bidding Areas. Care Medical recommends that CMS identify the initial ten MSAs in an interim regulation implementing competitive bidding. The geographic location of the initial ten MSAs is the most critical information that must be made public as soon as possible, to allow suppliers as much time as possible to become accredited and be able to prepare to submit bids.

"Competitive Bidding Areas" – Rates/Areas. CMS should first undergo an analysis of whether a bid rate is actually appropriate to apply in a non-bid geographic area. Factors such as distance needed to travel to beneficiaries being far greater will significantly impact suppliers' "total delivered costs" in, for example, a rural area, making application of bid amount from a densely populated metropolitan area wholly unreasonable in a rural area. CMS identified this criterion in its final rule in inherent reasonableness, acknowledging that amounts for a category of items or services in a particular locality may be higher or lower than payment amounts in other localities due to the relative costs of furnishing the category of items or services in the different localities.

Second, CMS should undertake an impact analysis before applying bid rates from a competitive bid area to items in a non-competitive bid area. That analysis should focus on the ability of suppliers to provide the item at that bid rate and the impact on beneficiaries and their ability to access quality items at that bid rate.

CMS should stagger the implementation of competitive bidding in the initial ten MSAs to allow for a more orderly roll out of the program. This would also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread or occur in all ten initial MSAs at once.

"Competitive Bidding Areas" - Do Not Extend Competitive Bidding Beyond Defined MSA Boundaries. (proposed §414.410(b)): CMS is proposing to establish competitive bidding areas (CBAs) in ten of the largest MSAs in 2007, and 80 MSAs in 2009. However, CMS does not believe it is confined to areas within an MSA, and proposes specific criteria for when to include areas outside an MSA. The statute appears crystal clear that CMS does not in fact have the authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established ***"in"*** an MSA. Therefore,

we strongly oppose any criteria CMS proposes to use to annex areas next to an MSA, and we urge CMS to reject its proposal to have the discretion to define a CBA to be larger than an MSA. The proposed rule refers to the possibility of extending the implementation of competitive bidding to areas adjacent to selected MSAs. This is not provided for in the legislation and should not be done. Dependent upon location, this could encompass rural areas where the cost of providing services are obviously higher. CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established in an MSA. CMS must identify the MSAs in which it will commence competitive bidding in 2007 in an interim final rule. CMS should also schedule a meeting of the PAOC after it identifies the MSAs.

Nationwide or Regional Mail Order (proposed §414.410(d)(2)) CMS is proposing to establish a nationwide or regional competitive bidding program, effective January 1, 2010, for the purposes of awarding contracts to suppliers to furnish these items across the nation or a region to beneficiaries who elect to obtain them through the mail order outlet. It is unclear why CMS anticipates having a separate CB program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in CB in MSAs during 2007 and 2009, a separate program for them in 2010 would be unnecessary. In addition, many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes. A cleaner definition of "mail order supplies" needs to be established.

There are many complicating factors such as changes in a beneficiary's level of supply needs that may inhibit the supplier's ability to get reorder supplies to a beneficiary within the required time frame. With glucose monitors, the type/brand that a beneficiary is initially prescribed may change based on the beneficiary's medical status and required changes in the brand of test strips supplied. For example, a beneficiary may develop arthritis and be unable to open the packages of test strips requiring that they be switched to a different brand in order to comply with the prescribed testing.

While mail order is an appropriate and cost effective vehicle for delivery of some replacement supplies such as test strips and lancets, it may not meet the needs of all beneficiaries who require

such supplies. Mail order, while efficient, is subject to the ability to get the supplies to the beneficiary by commercial carrier. Whether or not a beneficiary receiving such supplies lives in a competitive bidding MSA, they should have the option of being able to obtain these supplies locally. The Medicare program must allow multiple distribution channels to meet beneficiary needs.

These mail order situations should also be addressed in the supplier standards and the accreditation process. Glucose test strips are one thing, but drop shipping items which require adjustment, fitting or education should be excluded. An adjustable cushion for example, if not properly inflated or utilized could create a costly pressure sore and injury to the patient.

Finally, we note that this proposal represents another example of CMS' failure to provide the level of detail necessary for notice and comment rulemaking. CMS should publish an interim final rule to solicit additional public comment before implementing a national or regional competitive bidding program.

"Criteria for Item Selection"- Product Selection Must Be Conducted With Beneficiary Welfare In Mind. (proposed §414.412) (Criteria for Item Selection) How will "savings" be calculated; exempt items and services unless savings of at least 10 percent can be demonstrated as compared to the fee schedule in effect January 1, 2006; recognize problems with beneficiaries having to deal with multiple suppliers; recognition of items that are custom and service oriented that should not be competitively bid.

"Criteria for Item Selection"- Items Included In Competitive Bidding. CMS identifies three categories of items that are subjective to competitive bidding consistent with the requirements of §1847(a)(2): "Covered items" as defined under §1834a(13) for which payment would otherwise be made under §1834(a) and "supplies used in conjunction with durable medical equipment;" enteral nutrition, equipment, and supplies, and off-the-shelf orthotics (OTS). Prosthetics and prosthetic devices and supplies were not included in competitive bidding by Congress. Under §1834(a)(13), a "covered item" means "durable medical equipment" as defined under §1861(n). Ostomy products and supplies are not "durable medical equipment" and consequently do not

meet the definition of "covered items" as defined under §1834(a)(13). CMS should confirm that ostomy products and supplies are not included in competitive bidding under §1847(a)(2).

Regarding CMS' proposed criteria for selecting items to including in competitive bidding, Care Medical recommends that CMS add a critical step as it determines which products will be included in competitive bidding. Specifically, CMS should first identify the savings it believes may be attained by including the particular product category, and should compare those costs with the administrative costs related to implementing competitive bidding for that product category. We find it difficult to fathom that the costs associated with implementing the program would, in many product category cases, make the approach cost effective. Specifically, CMS estimates that its aggregate savings in 2008 will be $110 million. Using CMS' tables for the top ten eligible DME policy group allowed charges, with the allowed charges of $7.4 billion, savings of $110 million indicates a savings of 1.4% in 2008. That seems to be a waste of time and resources, including the creation of a new bureaucracy with new Medicare contractors, and other obvious related financial costs. We understand CMS is under a Congressional mandate, however, it would be far more logical for CMS to focus on product categories that will ensure savings that more than balance the associated administrative costs. Therefore, Care Medical recommends that CMS first identify the savings it believes may be attained by including the particular product category, and should compare those costs with the total administrative costs related to implementing competitive bidding for that product category.

Care Medical recommends that CMS exclude power mobility device and accessory codes from the 2007 round of competitive bidding. This is because all of these products are subject to a new coding system (64 codes replacing the four prior codes), new coverage, and most importantly, new fee schedules. Both CMS and the industry need time to implement and adjust to the new PMD coding and payment system; CMS needs to gain accurate utilization data under the new codes and assess how the coding changes impact cost before attempting to determine which if any of these products would produce adequate savings while ensuring Medicare beneficiaries achieve their desired clinical outcome. While we recognize that power wheelchairs are high in utilization and cost, CMS will already have realized significant savings as a result of the vast changes in coding, coverage and payment that has occurred in this product category over the last

year and the additional coding, coverage and payment changes that are imminent. There must be ample time to analyze the true impact of the changes before determining if any of these products are appropriate for competitive bidding. Again, once the new fee schedules for the new 64 codes are implemented, scheduled for October 1, 2006, we anticipate there will be no opportunity for any real savings associated with these new power wheelchair codes.

"Criteria for Item Selection"- Potential for Savings. CMS should explain and clarify what specific measures will be used to decide an item's potential savings as a result of CB. Specifically, CMS should address the following:

- Annual Medicare DMEPOS allowed charges: Is there a threshold expenditure level that will trigger CB for a product category?
- Annual growth in expenditures: Is there a threshold growth percentage and does it vary by the dollar size of the category?
- Number of suppliers: How will CMS determine the appropriate number of suppliers for a product category in each MSA? What supplier capacity thresholds will be used to determine this and how will those thresholds be determined?
- Savings in DMEPOS demonstrations: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects?
- Reports & studies: Which ones and types will be considered? Who will review the studies and determine their validity and applicability for modeling Medicare program savings?

"Criteria for Item Selection"- Additional Criteria for Item Selection. Under the proposal in the NPRM, item selection is driven by costs and utilization only. There is a risk that by focusing exclusively on cost and utilization criteria, CMS will allow competitive bidding to become a substitute for appropriate coverage policies as a way of controlling expenditures. In deciding to include a product under a competitive bidding program, CMS should also consider clinical and service factors specific to the product. Some products will be inappropriate for competitive bidding because of the clinical condition of the beneficiaries who use them. For example, invasive ventilators patients have clinical conditions that require clinical monitoring and oversight, making invasive ventilators inappropriate for competitive bidding. CMS should

publish the items it will include in the initial competitive bidding program in an interim final rule. CMS should also schedule a meeting of the PAOC to solicit additional public comment after it announces the product selections.

"Criteria for Item Selection"- Consider The Impact On The Patient. CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy.

"Criteria For Item Selection" - Coding Issues and Item Selection. The methodology that CMS proposes for item selection relies on historical data and does not take into account recent changes in a benefit that will affect utilization. For power wheelchairs, recent changes in the HCPCS codes, a new LCD, and new fee schedules will significantly change utilization for these items. Specifically, CMS would lack the cost and volume data required under the formula in the NPRM to select an item. CMS would be unable to determine which codes within this product category are the highest cost and highest volume for Medicare using current data. We recommend that CMS not include power wheelchairs in the initial rounds of competitive bidding because it would lack recent data from which to determine the HCPCS codes that represent the highest costs and highest volume for CMS. Moreover, assuming that the coding, pricing and coverage changes result in accurate utilization for these products, in future years there may not be a rationale for including power wheelchairs in competitive bidding under the formula CMS has proposed.

"Criteria For Item Selection" - Submission of Bids Under the Competitive Bidding Program (proposed §414.412) Under the proposed rule, each product category would also include all of the ancillary related supplies. Suppliers would be required to submit bids to reflect all items within the product category. We support this approach as it should allow Medicare beneficiaries a "one stop shopping" opportunity to receive the needed products and accessories in a product category from one contract supplier. Likewise, we support the proposal that would permit a supplier to bid for only the products and accessories they are seeking to furnish under competitive bidding as it permits suppliers to specialize if they so choose.

CMS needs to be more specific about the information it will give bidders so that they can determine an appropriate bid in light of the requirement that they must accept any beneficiary in the MSA regardless of the number of rental months remaining on capped rental or oxygen equipment.

CMS must supply data suppliers will need to determine "worst case" scenario – how many beneficiaries using oxygen and capped rental items – that winners may be forced to take on.

"Criteria For Item Selection" – Rehab & Assistive Technology (proposed §414.412) Care Medical believes that CMS should establish a savings threshold including on-going administrative costs to assess the appropriateness of competitive bidding for each product category. Care Medical further recommends that CMS use a consistent threshold of 10% net savings after adjusting to include administrative costs associated with the on-going support of the competitive bidding program to determine whether a product group should be competitively bid.

In addition to believing that there are no cost savings available for complex rehab and assistive technology items, Care Medical believes that to attempt to competitively bid these devices would result in a negative impact on the clinical outcome for the beneficiary. CMS, then HCFA, included K0004 high strength lightweight manual wheelchairs in the competitive bidding demonstration in San Antonio, TX. CMS had proposed including K0005 Ultra-lightweight Manual Wheelchairs also, but after receiving comments from the industry, CMS decided to exclude this category of products. Therefore, K0004 coded products are the closest CMS has come to demonstrating the impact of competitively bidding items that are uniquely prescribed for an individual. While K0004 coded products are not all equally configurable, we did glean some important information about the clinical impact for beneficiaries based on the San Antonio demonstration project.

In the November 2003 Final Evaluation Report, Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS, page 181, section 4.5 Wheelchairs and Accessories evaluates the impact of competitively bidding this class of wheelchairs. The report states that "referral agents raised a number of issues about wheelchairs". Further, the reports states," Referral agents also

found that the prescriptions needed to be very detailed to ensure that beneficiaries got the required product" and "prior to the demonstration, referral agents used suppliers who would provide wheelchairs with removable arms and adjustable leg rests as standard equipment. After the demonstration, they found that some suppliers stopped providing this equipment in every case, opting to do so only if these features were specifically ordered". The report also indicated a change in the service/delivery model for these wheelchairs. Some referrals noted that, prior to the demonstration, suppliers usually either had a physical therapist on staff or the wheelchair would be delivered by someone who was familiar with the product and how to measure its fit. When the wheelchair was delivered, the supplier delivering the chair would have the beneficiary sit in the chair and check the fit. However, during the demonstration, referrals reported examples of wheelchairs being delivered and left folded with no attempt to check fit, delivery staff being unknowledgeable about the products being provided or how to adjust or check for proper fit, and even that one supplier's policy was to deliver a 18" wheelchair to all patients and then replace it if a different size was required. Care Medical does not believe that the same degree of measuring, fitting and adjustments are needed for all manual wheelchairs. In fact, standard products are only available in limited sizes and with little to no adjustability. However, as one considers the products moving up the spectrum of manual wheelchairs, those that are available in more sizes, configurations and are adjustable to meet the functional needs of the patient require a more labor intensive evaluation on the part of the supplier and in collaboration with a clinician/physician to ensure that product solutions meet the current and anticipated medical needs of the beneficiary. The rehab company must employ trained and knowledgeable staff to perform the technology evaluations, fittings, adjustments as well as technicians to repair and service complex technologies. We recognize that many of the issues identified could be mollified by developing specific supplier standards for complex rehab and assistive technology. We believe CMS needs to create specific standards for complex rehab and assistive technology, this will ensure that all Medicare beneficiaries will be better served. Actually, CMS may find that the Medicare program will experience savings by using only suppliers that are qualified to provide this level of technology. This savings would result from the beneficiary receiving a comprehensive evaluation of their technology needs which would facilitate appropriate product selection up front as opposed to beneficiaries finding that the products they have been provided

do not meet their functional needs or the progressive nature of their disease was not taken into consideration in the initial evaluation.

In addition to exempting rehab and assistive technology devices from competitive bidding, Care Medical recommends that CMS exclude all manual and power wheelchair and accessory codes from the 2007 round of competitive bidding. This would allow time for CMS to implement new HCPCS codes for power and manual wheelchairs, gain accurate utilization data and assess how the coding changes impact cost before attempting to determine which if any of these products would produce adequate savings while ensuring Medicare beneficiaries achieve their desired clinical outcome. Care Medical recognizes that power wheelchairs are high in utilization and cost. However, we also believe that significant savings will result from the vast changes in coverage and conditions for payment that has occurred in this product category over the last year and the additional coding, coverage and payment changes that are imminent. There must be ample time to analyze the true impact of the changes before determining if any of these products are appropriate for competitive bidding.

Care Medical also recommends that CMS exclude wheelchair cushions, adaptive seating and positioning products and speech generating devices. Clients in need of complex rehab or assistive technology typically require a complete system to meet their functional and medical needs. A complete system means various pieces of equipment, each meeting a specific medical or functional need, have been determined to be compatible technologies.

"Submission of Bids Under the Competitive Bidding Program"- Only Companies Currently Delivering Service To Medicare Beneficiaries In An MSA Should Be Allowed To Submit A Bid For That MSA. Any company that submits a bid should have a track record of serving the targeted geography to validate its capabilities and service record.

"Submission of Bids Under The Competitive Bidding Program" – Inexpensive & Routinely Purchased DME Items. (proposed §414.412) Requiring a supplier to offer the option of renting routinely purchased DME items that are of minimal cost would create a financial hardship on the supplier and CMS and is unrealistic. An example would be a single-point cane at $2.00 per

month based on a purchase allowable of $21.00 or a walker at $12.00 per month based upon a $128.00 purchase allowable. Imagine CMS processing multiple rental claims for these amounts. The time and costs involved in processing these claims is significant for CMS and the supplier.

"Submission of Bids Under The Competitive Bidding Program" – Product Categories For Bidding Purposes. (proposed §414.412) Beneficiaries having to potentially deal with four companies for the same treatment: If a beneficiary needs a hospital bed, wheelchair, cushion and a concentrator, they would have to deal with four different suppliers to orchestrate their care. If a patient needs items for discharge from a hospital and the multiple suppliers cannot meet the needed delivery time for discharge, the patient will remain in the hospital potentially costing Medicare thousands of dollars. We have great concern that products will be grouped-based on product categories. This approach doesn't address the individual medical policy groupings that do not always follow product groupings. Even in the best grouping situations, patients and providers, along with inpatient and outpatient referring entities, could feasibly be placed at a significant disadvantage, since they would have to deal with multiple providers of different products for the same patient. Multiple providers of DMEPOS in a home is not only dangerous from a patient safety perspective, but extremely inefficient for the provider and physician who are supervising and coordinating the patient's overall care. Using product categories for determining the bidding process is confusing and cumbersome for a beneficiary who is experiencing physical and possibly mental difficulties as well as the referral sources coordinating their care. This could also lead to lost equipment for suppliers when another supplier inadvertently picks up another supplier's items when equipment need ends.

"Product Categories for Bidding Purposes" - General Issues. Clear definition of the product categories must be outlined for bidding suppliers. All HCPCS codes and their typical quantities should be identified for each product category that the supplier bids. For example, glucose monitors and supplies should include glucose monitors, test strips, lancets, lancing device, and replacement batteries. Glucose monitors for visually impaired (i.e.: E2100) should be identified and bid separately as the cost is drastically different. If the bid pricing is related to the product category and not each HCPCS code that makes up the category, then it may be cost prohibitive to

service visually impaired beneficiaries with the monitors resulting in service issues for beneficiaries.

"Product Categories for Bidding Purposes" - Requirements to Bid on all Products in a Category. Suppliers may choose to bid on one, some, or all of the product categories, but if a provider bids on a category, that provider must bid on each item included in the category. CMS must define products categories narrowly, to make sure that they are consistent and representative of the products that a supplier might actually furnish. Including a broad category for wheelchairs or power wheelchairs could be very problematic. Suppliers who do not specialize in rehab may not carry power wheelchairs under certain codes. Similarly, suppliers who do specialize in providing equipment to patients with complex needs may not carry all of the power wheelchairs designated by that product category.

Power wheelchair codes are in the process of being revised. A high probability exists for compromise of patient care due to the breadth of the category combined with the complexity of needs for the high-end rehab patient. Complex Rehab wheelchairs are predominantly custom-configured, and they utilize a minimal amount of standard in-stock components. Due to the high probability of inappropriate equipment being provided to the complex Rehab patient in the first level of review as well as subsequent provision of appropriate equipment, it is highly probable that a categorical bidding process will be more costly in the long run for complex Rehab and Assistive Technology.

Manual wheelchairs HCPCS codes will be subjected to a similar re-coding process beginning in 2007. Due to its greater breadth as a category, manual wheelchairs will probably cost more to bid categorically for similar reasons. Complex Rehab Technology patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the proposal in the NPRM, a provider who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. In many cases complex Rehab manual wheelchairs require multiple components from multiple manufacturers to achieve appropriate fit and function for the individual.

Those providers who are awarded a winning bid in a category for "Wheelchairs" could end up not being a winning bidder for the associated seating. In effect, many patients may need to deal with two or more providers for a single rehab wheelchair. This situation could lead to access issues in areas of the country where a winning provider is not equipped to provide the complexity of multiple seating and positioning services required in that area. Current HCPCS codes are too broad, encompassing items that represent vastly different technologies. CMS should develop narrow product categories so that providers may submit proposals for more standard bases with general purpose seating and positioning products compared to high end complex rehab technology services. It is dangerous to the end user for non-qualified providers to be submitting bids for services that they do not provide.

"Product Categories" – Submission Of Bids Under The Competitive Bidding Program" (proposed §414.412) Care Medical strongly believes that complex rehab products should not be competitively bid. The accessory codes are the same for accessories whether they are provided on a standard wheelchair or a complex mobility system. While Care Medical believes this is an inadequacy in the HCPCS code set, there is not time to address this issue. Care Medical believes any contract supplier for competitive bidding would be able to provide accessories even if they were not competitively bid. If necessary, CMS could require suppliers that provide the base wheelchair to also provide all needed accessories. This would meet the stated goal of minimizing disruption for the beneficiary while allowing non-contract suppliers to bill for the accessories needed for non-bid items.

"Bidding Requirements" – Capped Rental Items. (proposed §414.408) CMS proposes that the lump sum purchase option in §441.229(d) for power wheelchairs be retained under the Medicare DMEPOS Competitive Bidding Program. Care Medical agrees with this proposal, but again recommends that power wheelchairs not be included in the 2007 round of bidding and that utilization and price data be analyzed to determine which if any should be included in 2009. Complex rehab and assistive technology should be exempt.

"Conditions for Awarding Contracts" - Quality Standards and Accreditation (proposed §414.414) CMS is proposing to phase-in the accreditation requirement. Care Medical strongly

recommends that CMS explicitly require all suppliers submitting bids to demonstrate, as part of the bid submission, that they have already received accreditation status through an accreditation organization that has received "deemed status" from CMS. A "phase-in" approach is inappropriate because it leaves open the possibility that bids from suppliers who may not be successful in receiving accreditation status will be included in the single payment amount calculation, and would therefore taint the bid calculation and contract supplier selection processes.

Therefore, Care Medical disagrees with CMS's proposal in the NPRM where CMS states that it will allow a "grace period" during which unaccredited providers can participate in the bidding process. Care Medical strongly recommends that CMS not allow unaccredited providers to complete accreditation during any grace period. If CMS allows unaccredited suppliers to submit bids, then bid information from bidders who do not become accredited during the grace period will be woven into the various calculations – including supplier capacity, pivotal bids and single payment amount calculations, fundamentally tainting the validity of those calculations. CMS cannot eliminate this deficiency by simply later eliminating those bidders who do not become accredited. Instead of going through the administratively burdensome process of recalculating supplier capacity, pivotal bids, and single payment amounts, it will be far more efficient to allow a defined time period (consult accreditation organizations for what would be the appropriate period of time) to allow suppliers interested in submitting bids to go through the accreditation process.

CMS should not include any price in calculating the single price unless they are currently accredited. Suppliers that have actually been through the accreditation process will inherently have a better understanding of the costs associated with accreditation. It is critical that the final single bid amount be reflective of precise and informed bids.
Finally, CMS should grandfather all providers accredited by organizations that meet the criteria CMS identifies.

"Conditions for Awarding Contracts" - Eligibility (proposed §414.414) Care Medical recommends that the proposed eligibility rules be expanded to require that each bidder must

provide documentation in its bid submission that it has been accredited by an organization that has received "deemed status" with CMS.

"Conditions for Awarding Contracts"- Provisions Must Be Developed To Guard Against Unrealistic Bid Amounts. (proposed §414.414(e)) Suppliers could bid an extremely low price and indicate extremely low capacity to ensure inclusion. If too many use this strategy, it could profoundly affect the single bid price.

"Conditions for Awarding Contracts"- Financial Standards Must Be Clearly Defined And Evaluated Prior To Consideration Of Any Bid. (proposed §414.414(d)) Specific steps need to be established to allow a consistent evaluation of all companies and audited financial statements should not be required. The length of time a supplier has been supplying a specific product category should also be considered in determining a supplier's capacity to provide equipment to a beneficiary.

"Conditions for Awarding Contracts"- A Bidding Company Should Be Required To Submit Specific Financial Information To Verify Financial Capability Review. This information should consist of: (a.) Two-year comparative financial statements prepared in accordance with Generally Accepted Accounting Principles (GAAP). The financial statements must be accompanied by a "review" from an independent Certified Public Accountant. Audited financial statements should not be required as they place an undue expense on the bidding supplier. An audited financial statement for our organization would cost anywhere between $35,000 - $40,000. CMS did not specify "audited" financial reports as a requirement to bid in the CM-1270-P proposal; however, according to the draft form CMS-10169A (Medicare DMEPOS Competitive Bidding Program) application, the financial information required to bid lists "Audited Financial Reports". Audited financial reports are unnecessary when reviewed financial reports, credit rating and score reports, bank statements, insurance documentation, adequate business capacity, and a line of credit are already required, creating sufficient considerations for evaluating financial stability. Audited financial statements review a companies' accounting system practices whereas a reviewed financial statement, which would cost our organization approximately $14,000, analyzes the relationship of procedures and analytical approaches to

accounting practices in an organization. Care Medical has been in business for over 36 years and has never been required to have an audited financial statement performed. Generally, audited financial statements are only required for publicly held companies. CMS states that according to 2003 Bureau of Labor Statistics (BLS) data, the average hourly rate for an accountant and auditor was $24.35. This is not a realistic amount for the hiring of an outside (non-employee) accountant. In Oregon, the hourly rate for an accountant is between $150.00 and $350.00 per hour. We strongly oppose the requirement of having an audited financial statement regardless of the size of the organization submitting the bid. (b.) Certificate of Insurance verifying a minimum of $1,000,000 in general liability coverage and listing other appropriate insurance policies in force. (c.) Letter from primary institutional lender verifying current lending relationship. (d.) Letters from three primary product suppliers outlining purchasing volume over the last two years and its credit and payment history. (e.) Credit report from recognized credit rating organization. Once received, CMS should (a.) review all submitted documentation for completeness and appropriateness; and (b.) calculate basic business ratios to verify company's financial stability to consist of "Debt to Equity Ratio" and "Current Assets to Current Liabilities".

"Conditions for Awarding Contracts"- Use A Factor Of 130% In Calculating Supplier Capacity Needed In An MSA. (proposed §414.414(e)) In determining the number of suppliers needed, CMS should apply a factor of 130% to the identified Market Demand. This would promote more competition in the market, ensure more suppliers remain in the market to serve non-Medicare payors, and ensure better competition for any future bidding rounds. In addition, this minimizes the need to recruit more suppliers (that bid above the pivotal bid) if one of the contracted suppliers is terminated or elects to drop out of the competitive bidding program.

"Conditions for Awarding Contracts"- Safeguards Must Be Put In Place To Ensure Realistic "Capacity" Amounts Are Assigned To Bidding Companies. (proposed §414.414(e)) Significant problems will result if companies are allowed to claim unrealistic capacity. A company should not be permitted to claim a capacity greater than 25% over the number of units provided to Medicare beneficiaries the previous year.

"Conditions for Awarding Contracts"- A Company Should Be Able To Bid For Only A Portion Of An MSA. The draft rule requires that a bidding company service the entire MSA. This presents significant hardship to small businesses and may result in poor service in certain areas. A better solution is to allow a bidding company to indicate by zip code what areas of the MSA they will cover.

"Conditions for Awarding Contracts"- Do Not Restrict Submitted Bid Amounts. (proposed §414.414(f)) CMS proposes not to accept any bid for an item that is higher than the current fee schedule. This would require that the bid amount be equal to or less than the current fee schedule. It is acknowledged that CMS cannot contract for an amount higher than the fee schedule. However, requiring that the bid be equal to or less than the fee schedule as a requirement artificially restricts bidding. CMS should allow suppliers to bid based on the true costs associated with each bid item; otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS can then use this information to determine whether the savings is adequate to justify awarding contracts for these items. Concerns stated in the NPRM about a shift in utilization to higher priced items could be eliminated through appropriate coverage policies. This strategy makes competitive bidding competitive and sustainable and better ensures that Medicare beneficiaries have access to the most appropriate device to meet their medical needs.

"Conditions For Awarding Contracts" – (proposed § 414.414). CMS intending to include information from unqualified bidders in calculating a payment amount means that a supplier who is incapable of meeting the financial and qualifying standards to be a provider under the competitive acquisition program can submit a "low ball bid" that will fundamentally taint the calculation of the final amount. CMS should require all suppliers who submit a bid be accredited before they are allowed to submit their bid. CMS needs to recognize the cost to become accredited is only part of the financial impact on an organization that becomes accredited. Maintaining quality standards adds significant costs to DMEPOS. Additional staff, supplies and equipment are necessary to meet accreditation standards. CMS stated that it would phase in mandatory accreditation and ask approved accreditors to give preference to providers in those

areas. These accrediting bodies are businesses and CMS cannot tell them who they must accredit first.

"Conditions For Awarding Contracts" – Market Demand & Supplier Capacity. (proposed § 414.414). CMS states that to calculate demand for an item in a competitive bidding area CMS proposes to examine claims data to determine the number of units of each item supplied to Medicare beneficiaries during the past 2 years and then determine the number of new beneficiaries that have entered the market during the last 2 years. Two years worth of data is sufficient to identify trend analysis and utilization measurements; however, with the changes in cushion, wheelchair, and respiratory coding, allowables and supplier documentation requirements, there is not currently two years of applicable data to determine beneficiary demand for all product codes.

The NPRM states that CMS will evaluate market capacity and supplier capacity to determine the number of suppliers necessary to service beneficiaries in an MSA. We agree that CMS must carefully evaluate capacity issues to ensure adequate access to DMEPOS items in a competitive bidding area. Under the methodology proposed in the NPRM, CMS would array the composite bids from lowest to highest and count up from the bottom until it identifies the point where the bidders' cumulative capacity is sufficient to service the MSA. This will be the winning, or "pivotal" bid. This methodology does not include any mechanism to "rationalize" the bids to ensure that there are no unreasonably low bids. Although competitive bidding is premised on the theory that suppliers will submit their "best bid," in fact there will be suppliers with small individual capacity who may submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity.

We recommend that the bid solicitation and evaluation process include safeguards against this type of bidding strategy. We suggest one option below under the discussion on the single payment amount. At the very least, CMS should eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. If these safeguards are not part of the process, CMS can have no assurance that the competitive bidding payment amounts are sustainable over time.

The NPRM also states that if at least two suppliers are at or below the pivotal bid amount, CMS would designate the two suppliers as winning bidders. We urge caution in adopting this minimalist approach. CMS should select more suppliers than necessary to meet minimum capacity requirements in the competitive bidding area. Any number of circumstances, such as a natural disaster, could create unanticipated access problems for beneficiaries in the MSA. It is unlikely that CMS could address these types of access problems quickly enough to avoid serious disruption to patient care. Additionally, CMS should at least consider other variables beyond capacity that may affect the selection of winning bidders. For example, beneficiary convenience and proximity to contract suppliers would greatly diminish under a scenario where CMS selects only two or three contract suppliers.

"Conditions For Awarding Contracts" – Composite Bidding. (proposed § 414.414). Determining the bid amount for any product or product category under the CMS proposal of "item weight" or "weighed bid" is confusing and cumbersome. A bid process for determining bid rates should not need an outside agency to help formulate a bid. A straight forward bidding process is needed for suppliers. The proposal to composite bid using item weight and weighed bid would require outside assistance in many cases in order to make an educated bid.

"Conditions For Awarding Contracts" - Assurance of Savings (proposed §414.414(f)) CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Care Medical strongly opposes the proposal that suppliers cannot submit a bid that is above the current allowable. Section 1847(b)(2)(A)(iii) of the Act prohibits awarding contracts to any entity for furnishing items unless the total amounts to be paid to contractors in a competitive bidding areas are expected to be less than the total amounts that would otherwise be paid. To meet this requirement, CMS proposes not to accept any bid for an item that is higher than the current fee schedule. This would require that the bid amount be equal to or less than the current fee schedule. Care Medical strongly disagrees with this proposal because it places artificial constraints on a process that is trying to be designed to harness market forces. If CMS is truly using competitive bidding as a way to understand the price the market will bear, then CMS must allow suppliers to submit their lowest possible bid. Given the many new requirements associated

with providing the items and related services under the bid program, bids may rationally and realistically be greater than the current fee schedule amount for the particular item. Given the fact that the majority of suppliers will be incurring new costs of accreditation (compliance with quality standards), and the fact that in the last few years reimbursement has been cut for many of the major product categories (*e.g.*, FEHBP-based reductions), and some products have increased suppliers' documentation costs (e.g., power mobility device documentation requirements), it is highly likely that bids for certain product categories may realistically be at a rate that is higher than the current allowable.

CMS can still meet the "assurance of savings" requirement through alternative means. If bids received are higher than the current allowable, CMS should choose not to include that particular item or product category in the competitive bid program, because that is a strong indicator that savings are unlikely. Requiring that the bid be equal to or less than the fee schedule as a requirement of the RFB artificially restricts bidding. Instead, CMS should allow suppliers to bid based on the true costs associated with each bid item. CMS can then use this information to determine whether the savings is adequate to justify awarding contracts for these items. The "assurance of savings" requirement would be met when CMS only included items for which the winning bid amount were less than the current allowable.

"Conditions For Awarding Contracts" – Selection Of New Suppliers After Bidding. (proposed § 414.422) CMS needs to establish how a supplier will be chosen if there is not a supplier located in a MSA or none willing to supply products and services under competitive bidding. CMS should not assume that unwilling or unavailable providers will not be an issue.

"Conditions for Awarding Contracts" - Evaluation of Bids (proposed §414.414(e)): Overall, the bid evaluation and the selection of winning bidders processes should be designed to result in pricing that is rationale and sustainable. CMS has not identified any process in its proposed evaluation of bids procedures that will enable CMS to determine that the submitted bids are rational. Once it receives bids, after CMS arrays suppliers' composite bids from low to high, CMS must conduct an analysis of the composite bids and discard any that are unreasonably low.

"Conditions for Awarding Contracts"- An Appropriate Screening Process Must Be Developed To Determine Which Submitted Bids Will Qualify For Consideration. (proposed §414.414) CMS should clearly identify a screening process that will be used to determine whether a submitted bid will be given any consideration. This process should include, at a minimum, three steps that a bid must go through before it is entered into the bidding pool. First, is the company accredited? If not, the bid is rejected. Second, does the company meet the financial standards? If not, the bid is rejected. Third, is the claimed "capacity" realistic? If not, the capacity is lowered to an appropriate number. Only after the satisfactory completion of these three steps should a company's bid be processed for further review and consideration as to pricing.

"Conditions for Awarding Contracts"- Competitive Bidding Must Be Competitive And Sustainable. CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS has not identified any process through which it will seek to determine that the bids are either. Beneficiaries are already receiving limited access to some DMEPOS items based on current allowables. The proposed cap on bid amounts could potentially eliminate CMS even receiving bids on some items.

"Conditions for Awarding Contracts"- Do Not Make It Harder For Providers To Sell Their Businesses. (proposed §414.414(e)) The proposal to restrict the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. CMS should not make approval of the acquisition contingent on the need to preserve capacity within the MSA. If the sale of a contracted supplier does not weaken the company's ability to deliver service per their competitive bidding agreement and post-sale that company continues to meet the contract requirement, that contracted supplier and its new ownership should retain its contract.

"Determining Single Payment Amounts for Individual Items"- Provide More Details On The "Composite Bid" Calculation. The NPRM describes a methodology of creating a "composite" score to compare suppliers' bids in a category using weighting factors to reflect the relative

market importance of each item. CMS should provide suppliers with the weighting factors it will use to evaluate the bids in each MSA so that suppliers are able to determine how best to bid each HCPCS item within a category.

CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the "winning suppliers" that are at or below the pivotal bid for each individual item within each product category. This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects. More importantly, we believe Congress did not have this methodology in mind when it authorized competitive bidding under the MMA. Care Medical believes that no supplier should be paid less than their bid amount. It is also important that CMS analyze deviations in bid amounts to determine whether these deviations may indicate extremely high or extremely low bid prices. It is critical to ensure that the price ultimately established in a CBA for each item is adequate to ensure that beneficiaries receive quality products and services and to provide market stability in that CBA.

CMS should set the payment amount at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This method was used in the two demonstration projects. An alternative, which would also provide an assurance that the submitted bids are "rational" and not unreasonably low, is to pay contract suppliers an amount equal to their individual bids. Although we understand that the MMA requires CMS to pay a "single payment amount" and that CMS intends to comply with this requirement, the statutory payment basis is the fee schedule amount or the actual charge, whichever is less. Consistent with the requirement, CMS could calculate a single payment amount equal to the pivotal bid and require winning bidders to submit claims in the amount of their bid - the actual charge - not the single payment amount. This approach also achieves price "transparency" for CMS and beneficiaries.

"Determining Single Payment Amounts for Individual Items"- Setting Single Payment Amounts For Individual Amounts. (proposed §414.416(b)) CMS has requested comments on setting methodologies for single payment amounts. The current fee schedule determines what kinds of products are available as much as the available products determine the fee schedule. The current system is not very flexible. As technology changes, fee schedules have been extremely slow to adapt adding a complex bid structure won't improve that situation and could well create a feedback loop that leads to technological stagnation in the provision of DME permitting neither cost savings not advancement in care. This locks suppliers and manufacturers into only considering the lowest priced item. Innovation in product will be non-existent; therefore, quality patient care will suffer.

"Determining Single Payment Amounts for Individual Items"- Rebate Provisions Must Be Eliminated. (proposed §414.416(c)) The NPRM describes a rebate program that allows contracted suppliers to rebate the difference between their bid and the established payment amount to the beneficiary. There is no legal basis under the law for permitting rebates. Providing rebates is contrary to other laws applicable to the Medicare program, namely the Anti-Kickback Statute and the Beneficiary Inducement Statute. Providing rebates also is contrary to the statutory requirement that beneficiaries incur a 20% co-pay. The OIG has stated in several Fraud Alerts and Advisory Opinions that any waiver of co-pays likely violates both the Anti-Kickback Statute and the Beneficiary Inducement Statute.

The NPRM describes a rebate program that allows contract suppliers to give the beneficiary a rebate in an amount equal to the difference between their bid and the single payment amount. CMS proposes to make the rebate program voluntary and would not allow suppliers to advertise the rebate to beneficiaries. Instead, CMS would distribute program materials in the competitive bidding area that would identify contract suppliers that offer rebates. We have grave concerns about the program integrity ramifications surrounding this proposal and do not understand how CMS can reconcile a rebate program of this type with the statutory prohibition on beneficiary inducements under §1128A(a)(5) of the Act.

Specifically, §1128A(a)(5) prohibits the offering or transfer of remuneration when an individual or entity knows or should know that it is likely to influence the beneficiary's selection of a provider or supplier. Remuneration includes anything of value and would apply to the rebate proposed by CMS. While the statute contains exceptions to the definition of the term "remuneration," the rebate program proposed in the NPRM does not fit any of the statutory exceptions. For example, "remuneration" does not include unadvertised waivers of coinsurance or deductible amounts for individuals who have been determined to be in financial need. The rebate offered by contract suppliers under the CMS program would not fit into this exception. We are also unaware of any guidance from the Office of Inspector General (OIG) of the Department of Health and Human Services that would authorize the program CMS proposes. In light of the statutory prohibitions of §1128A(a)(5), CMS lacks the authority to implement a rebate program. Consequently, CMS should withdraw the proposal.

The OIG has published guidance in the form of advisory opinions, fraud alerts and special advisory bulletins to assist providers and suppliers in understanding their obligations to comply with the statutory prohibition on beneficiary inducements. OIG guidance has consistently held that inducements distort beneficiary decision making, increase costs to the Medicare program, and undermine competition among providers. In a Special Advisory Bulletin, Offering Gifts and Inducements to Beneficiaries, published in August 2002 (Bulletin), the OIG took an uncompromising stance against the practice of offering any inducements, other than items of nominal value, to Medicare beneficiaries. The OIG provided the following rationale for its position:

Offering gifts to beneficiaries to influence their choice of a Medicare or Medicaid provider raises quality and cost concerns. Providers may have an economic incentive to offset the additional costs attributable to the giveaway by providing unnecessary services or by substituting cheaper or lower quality services. The use of giveaways to attract business also favors large providers with greater financial resources for such activities, disadvantaging smaller providers and businesses.

CMS proposes two ways to ameliorate the fraud and abuse issues inherent in the rebate program. First, CMS would require any contract supplier that offers rebates to offer the rebate to all Medicare beneficiaries in the competitive bidding area. The supplier could not pick and choose which beneficiaries would get a rebate as a way of enticing desirable patient populations. For example, the supplier could not offer the rebate only to patients with a specific chronic diagnosis requiring long-term rental equipment. Second, the supplier could not advertise the fact that it offers a rebate.

Once an inducement is in the public domain, its harmful effects cannot be contained, even with the safeguards CMS intends to implement. The fact that a provider does not "actively" promote an inducement does not change the illegal nature of the activity or the disruptive repercussions it has on competition and quality of care. The OIG would be unlikely to approve of a rebate program like the one CMS proposes even if the supplier did not advertise the rebate: The "inducement" element of the offense is met by any offer of valuable . . . goods and services as part of a marketing or promotional activity, regardless of whether the marketing or promotional activity is active or passive. For example, even if a provider does not directly advertise or promote the availability of a benefit to beneficiaries, there may be indirect marketing or promotional efforts or informal channels of information dissemination, such as "word of mouth" promotion by practitioners or patient support groups.

CMS' proposal to allow contract suppliers to offer rebates fundamentally conflicts with the longstanding rationale underlying the prohibitions on inducements and kickbacks in federal health care programs. This type of activity distorts patient decision making and undermines true competition among health care providers. Importantly, the rebate program would promote exactly what Congress chose to prohibit when it enacted prohibitions on beneficiary inducements under §1128A(a)(5) - competing for business by offering Medicare beneficiaries remuneration. Consequently CMS should withdraw the proposal.

Currently, the standard cost to a supplier to refund a Medicare claim is approximately $30.00. The amount of paperwork and labor time required to process a rebate would burden the supplier. Beyond the financial burden to the supplier, a rebate program has the potential to harm the

providers' business and would ultimately confuse the beneficiary. For example, suppose two companies in the same MSA that are geographically located close to one another and service the same neighborhoods win a bid. Dealer One bids $100, which is the payment established by CMS, and Dealer Two bids $90.00 and then offers a rebate. Then a patient serviced by Dealer One and a patient serviced by Dealer Two go to a senior activity center and talk about their equipment. The patient serviced by Dealer Two talks about the $10.00 he/she got back. Dealer One's patient wonders where their $10.00 is, and when they call, are told they don't get it. Both dealers have complied with the law, but now patients are complaining about how they were ripped off by Dealer One. Also, the administrative costs associated with managing this rebate program will far exceed the savings CMS will achieve. The possibility of a "rebate" only serves to complicate an already challenging bidding process and implementation plan. Finally, allowing an illegal practice in the context of the competitive bidding program will only perpetuate the industry's cloud of fraud and abuse; CMS should not be fostering that perception through inappropriate means.

"Terms of Contract"- Modify Requirement That Only Winning Suppliers May Repair Patient-Owned Equipment. (proposed §414.422(c)) Any willing Medicare provider should be allowed to repair or do modifications and supply warranty services to all Medicare beneficiaries; however, we do agree it is appropriate for winning suppliers to be required to service any equipment they provide. However, this requirement should not be placed on equipment that is supplied by others. The current reimbursement rates for service and repair are inadequate and it is impossible for a bidding supplier to factor these unknown costs into their bids.

"Terms of Contract" – Length of Contracts (proposed §414.422) CMS states that the length of the contracts may be different for different product categories. Care Medical strongly urges CMS to have the same length contract for all products in a particular competitive bid area to minimize confusion among beneficiaries, referring physicians and suppliers. As it is, there are numerous variables that these stakeholders will have to understand (which products are part of the competitive bid; the boundaries of the competitive bid, etc.), it will simply add significantly more confusion if there are different lengths of contracts for different product categories in the same geographic area.

"Terms of Contract"- Repairs & Replacements Of Patient-Owned Items Subject To Competitive Bidding. (proposed §414.422) CMS does not realize that repair centers for DMEPOS are not profit centers for a supplier. DMEPOS that currently provide repair services to beneficiaries do so to enhance the supplier's scope of services for the patient. Repair centers are an invaluable resource for beneficiaries of POV/PMDs. There are a limited number of providers who have repair facilities or vehicles for outside repair of equipment. Patients should not be required to receive repair services from only winning suppliers. This limitation restricts patient access and will harm the beneficiary whose wheelchair is their sole means of mobility. Limiting suppliers in this fashion is another means of monopolization. If there are only two DMEPOS that can repair equipment in an MSA, then a beneficiary may have to wait an extended period of time before their wheelchair can be repaired. This "waiting time" can cause serious injury and harm to the patient. When competition is limited in an area, there is no incentive to provide good after market service to a beneficiary. If a supplier does not have a repair facility, the supplier should not be able to bid on an item that requires routine maintenance, repairs or replacement. Manufacturers should also be required to certify DMEPOS repair facilities. In addition, contract suppliers may not have access to the parts necessary to repair equipment sold by another supplier. Suppliers do not all carry the same brand of equipment. Also, some manufacturers desire to limit access to their products to those suppliers with sufficient knowledge to properly service, repair and otherwise support their products. To require that contract suppliers be able to service all patient owned equipment would require manufacturers to open accounts with suppliers that they may feel do not meet their requirements.

"Terms of Contract"- Termination of Contract. CMS must include procedural safeguards for contract suppliers prior to terminating their contract. Minimum requirements for the process are notice that CMS believes the supplier is in breach, an opportunity for the supplier to cure the breach, and a review or appeal mechanism if the supplier is terminated.

"Terms of Contract"- Judicial and Administrative Remedies. CMS should include a procedure for debriefing suppliers who did not win a bid and an opportunity for a review to determine at a

minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

"Terms of Contract"- Restrictions On What Products Can Be Supplied To Individuals Outside The Medicare Program Must Be Eliminated. (proposed §414.422) The terms and conditions section states "non-discrimination- meaning that beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier provides to other customers". This is unrealistic. In order for suppliers to bid lower prices they must either provide lower cost products or reduced services. Competitive bidding should be more like a contract with managed care where formularies are used. Medicare will be fully aware of what Medicare beneficiaries will receive, but it should not limit what customers outside of the competitive biding program receive.

"Terms Of Contract" – Furnishing Items To Beneficiaries Whose Permanent Residence Is Outside A CBA. The NPRM states that if the area that the beneficiary is visiting is not a competitive bidding area, or if the area is a competitive bidding area but the item needed by the beneficiary is not included in the competitive bidding program for that area, the supplier would be paid at the rate of the single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. This proposal will make it difficult for traveling beneficiaries to obtain products and services in some areas. While we recognize that this is the current Medicare policy, the maximum payment difference from one state to another is only 15%, while the difference between a single payment price under competitive bidding and the fee schedule amount in a non-bid area could be substantially more than that.

There are a significant number of beneficiaries who are "snowbirds," who spend a good portion of the year in a more southern area of the country. This proposed requirement will have a significant and undue impact on suppliers providing items and services to snowbird beneficiaries. It is simply not equitable to impose a bid rate on an item on a supplier in a different area of the country, without any analysis regarding the appropriateness of that new lower price. This proposal will have an undue negative impact on suppliers serving "snowbird" beneficiaries, and CMS should reject this proposal in the final rule. We recommend that CMS

modify its claims jurisdiction policy for these beneficiaries because these beneficiaries will likely find it difficult to obtain quality items and services when they are not at their permanent residence. This proposal needs to be changed to ensure that beneficiaries maintain appropriate access to medically necessary items.

Further, CMS states that it will monitor the programs to ensure that this type of "abuse or circumvention of the competitive bidding process and requirements to obtain items from a contract supplier does not occur." If this "avoidance of competitive bidding contract suppliers" activity does occur, CMS should understand that it is likely a strong indication that the competitive bid program is not meeting physician and beneficiary needs in that area. Beneficiaries would only seek out non-contract suppliers if they, and their referring physicians, are dissatisfied with the quality of items and services available from contract suppliers. This activity should therefore be monitored as a measure of whether contract suppliers are providing beneficiaries with a suitable level of quality and access; there would be nothing nefarious about this activity.

"Terms of Contract"- Do Not Require Wining Suppliers To Take On Beneficiaries That Are Currently Using Capped Rental Equipment From Another Supplier. (proposed §414.422(c))
CMS proposes that a contract supplier must agree to accept as a customer a beneficiary who began renting the item from a different supplier regardless of how many months the item has already been rented. The supplier is supposed to factor the cost of furnishing items to beneficiaries' whose supplier chooses not to continue to furnish the item in accordance with the grandfathering provisions. Suppliers are suppose to factor the cost of furnishing items into their bid submissions. How can a supplier possibly figure a bid amount with the amount of unknown variables such as:

- The number of beneficiaries in the MSA who are currently renting equipment
- The number of suppliers who chose not to participate in the "grandfathering" program and who do not win the bid for that item.
- The number of months left on a capped-rental for a particular item, for the number of beneficiaries who receive that item.

The grandfathering and transition policies are both unworkable and unfair. While losing suppliers may continue to service their oxygen patients at the new single payment amount, if they choose not to, "winning bidders" will have to serve these patients. A winning bidder could acquire an unknown number of patients who have been receiving home oxygen therapy for 20 or 30 months. The Deficit Reduction Act caps oxygen payments at 36 months when ownership of the equipment transfers to the beneficiary. How can a provider factor in these unknown costs?

Under a capped rental scenario, accepting a new beneficiary transfer after several months of rental with another supplier is unrealistic. It is impossible for a bidding supplier to factor in the cost of taking on beneficiaries that began service with another Medicare Supplier. If this requirement is to remain then a new rental period should start when the beneficiary begins to receive an item from a wining supplier.

"Opportunity for Networks"- Clarify Network Regulations. (proposed §414.418) What are structural requirements? Who can do billing and collection? Other operational issues?

"Opportunity for Networks" (proposed §414.418) CMS states that a provider cannot submit an independent bid and also bid as part of a network. Suppliers should be allowed to bid independently and as part of a network so every opportunity is afforded to the supplier to help ensure a successful bid.

"Opportunity for Networks"- Do Not Place Unreasonable Limitations On Formation Of Networks. (proposed §414.418) The 20% market share limitation should be removed. This is unnecessarily restrictive and does not apply to single entities that bid separately. Network members should be able to also bid through other means.

"Education & Outreach" – Beneficiary Education. The competitive bidding education must be provided by CMS to the supplier's referral sources, such as home health agencies, health insurance companies, HMOs (Health Managed Organizations), hospitals, physical and occupational therapists, and others. These agencies and the individuals they employ are an integral part of helping coordinate care of beneficiaries. CMS has a responsibility to provide education to them on the competitive bidding program and mandates under the program. Care

Medical believes that CMS must hold educational sessions for suppliers to ensure that there is some level of consistency in the way beneficiaries are educated and the information they are provided. In addition, Care Medical recommends CMS provide materials that can be used by suppliers to effectively educate beneficiaries regarding the Competitive Bidding Program. In addition, CMS should not depend solely on suppliers or the CMS website to educate Medicare beneficiaries. Care Medical recommends that CMS hold multiple town hall meetings in each CBA to ensure that beneficiaries and referral sources are knowledgeable about the competitive bidding program. Including the formal complaint system and how to lodge a complaint and what resources CMS is providing to remedy issues and problems.

"Monitoring & Complaint Services For the Competitive Bidding Program" CMS is proposing to establish a formal complaint monitoring system to address complaints in each competitive bidding area. CMS needs to establish protocols for addressing these complaints in a timely and effective manner. The proposal by CMS states an ombudsman will be established for each region. An independent evaluation committee made up of consumers, suppliers, manufacturers, industry leaders, and PAOC must be part of helping solve problems and resolve issues brought forth by industry stake holders. The formal complaint monitoring system needs to continually inform beneficiaries of the process for lodging a complaint with CMS. While creating these policies and regulations, it needs to be examined how a resolution can be determined. This complaint resolution is extremely subjective. Some consideration must also be given to the concept that on occasion a beneficiary may be at fault, not the supplier. Will there be exceptions to the requirement of servicing beneficiaries in extreme circumstances (i.e. on occasion suppliers have "discharged patients from service")?

"Physicians Authorization/Treating Practitioner" – Physician Authorization/Treating Practitioner & Consideration Of Clinical Efficiency & Value Of Items In Determining Categories For Bids. The supplier must have the ability to determine what brands to offer based upon an allowable. This decision will be based on medical necessity not solely at the discretion of the physician due to the cost of the item. The request must be based on need not want. If a supplier carries an item that meets medical need and is a product category that has been bid, is the supplier required to provide any item the manufacturer sells in that product category? For the physician to prescribe a

particular brand or mode of delivery of an item within a particular HCPC code is not compatible with competitive bidding by product category. How can a supplier determine a bid price if an outside entity has the ability to determine what brand of product is provided or the mode of delivery which the beneficiary will receive the item? If a supplier chooses one or two brands in a product category they have established that can make a reasonable or sustainable profit, an outside source cannot dictate an item of higher cost to the supplier. The cost of the item is an integral part in supplier's computing a sustainable bid.

We believe it is unnecessary for CMS to include this requirement as part of a competitive bidding program because a physician is always free to order a specific item he/she wants the beneficiary to have. Importantly, this requirement will promote a demand for premium or brand name items based on direct to consumer advertising, even though the "brand name" product has the same clinical benefit as other products. Physicians often are not well-informed about the features and benefits of new technologies; the homecare supplier is responsible for matching the patient's needs to the equipment or supplies. Further the proposal is contrary to how suppliers do business, not only under the Medicare program, but with all payers. Suppliers carry items and equipment that the FDA deems to be functionally equivalent to other products. Having to carry all possible items and equipment is extremely costly and burdensome and will increase suppliers' costs, reducing potential savings from competitive bidding. Inasmuch as CMS' authority to implement this requirement is discretionary under the MMA, we recommend that CMS not include this provision in the final rule.

"Quality Standards and Accreditation for Suppliers of DMEPOS"- Only Companies That Are Accredited Should Be Eligible To Bid. Only accredited providers should be eligible to submit bids. CMS should not proceed with competitive bidding until it is sure that this is possible. CMS needs to identify the criteria it will use to identify the accrediting bodies now. CMS should grandfather all providers accredited by organizations that meet the criteria CMS identifies. CMS should also allow additional time for providers to analyze the quality standards in conjunction with the NPRM rule. The quality standards will affect the cost of servicing beneficiaries and are an integral part of the bid process.

Finally, CMS needs to identify the criteria it will use to select accrediting bodies now. CMS should be encouraging accreditation rather than discouraging it and should grandfather all providers accredited by organizations that meet the criteria CMS identifies. We recommend that CMS "fast track" accreditation in the manner that was suggested during the PAOC meeting so that CMS can publish a notice soliciting public comments on the organizations that are seeking designation as an accrediting body. CMS' goal should be to promote an aggressive accreditation campaign to assure that providers in any MSA with a competitive bidding program are accredited before the bid solicitations are published.

At the very least, CMS should schedule a PAOC meeting after it publishes the quality standards. Care Medical Equipment strongly supports a requirement that all suppliers billing the Medicare program for DMEPOS must meet quality standards and be accredited. It is also critical that final supplier standards apply to any supplier desiring to submit a bid. Allowing an additional comment period is unlikely to significantly impact the overall implementation timeline. Even so, competitive bidding is a radical departure from traditional Medicare and this program is still mostly experimental; consequently, CMS should tolerate delays and not rush to implement the quality standards or any other aspect of competitive bidding.

It is important to note that the IR methodology established by Congress requires CMS to make a determination that using the "standard rules for calculating payment" results in a payment amount that is inherently reasonable. Congress directed the Secretary to identify the factors that it would use to determine that a payment amount is not "inherently reasonable" because it is either grossly excessive or grossly deficient. In determining whether a payment amount is inherently reasonable, and in establishing a new payment amount, CMS or its contractors must use "valid and reliable data" that meets specific criteria applicable to the data collection and analysis. 42 C. F. R. §405.502 (g). Importantly, the IR methodology contains specific procedural safeguards that apply to any determination to adjust a payment amount by more than 15%. For payment adjustments greater than 15%, on factor CMS must consider is the "potential impact of such a determination on quality, access, and beneficiary liability, including the likely effect on assignment rates and participation rates." §1842b (8) (C).

Care Medical recommends that CMS identify the factors it would consider in deciding to initiate a technology assessment. Care Medical further recommends that CMS allow participation in the technology assessment by interested stakeholders. Additionally, Care Medical recommends that CMS develop an appeals process in situations where the manufacturer disagrees with the recommendation of a contractor and has data to support their opinion.

This proposal has broad sweeping impact on the Medicare program, not only the competitive bidding program. The competitive bidding program proposals and the proposal regarding establishing payment for DME both inside and outside of the competitive bidding program should be two separate Rules. Sixty days does not provide enough time to develop substantive comments for both of these significant issues. As such, Care Medical recommends that CMS initiate a separate rulemaking proceeding to solely address changes to the pricing methodology for DME.

"Gap-filling"- Different Alternatives To Gap Filling Must Be Used. (proposed §414.210(g)) It is good to see the acknowledgement of the problems and inappropriateness of the gap filling pricing methodology. The provision for replacing the Gap Filling methodology for setting fees for new DMEPOS items is inappropriate for inclusion in the Competitive Acquisition NPRM. The three methodologies proposed to replace Gap Filling are not objective and not directly related to price/value assessment. In addition, none of the methodologies appear to involve the manufacturer and his/her health economic or other support data. Rather, the proposed rule calls for functional and medical benefit assessments to be conducted by CMS contractors who may or may not have expertise in the technology/therapeutic area. The proposal to use these methods to adjust prices that were established using Gap Filling at any time after January 1, 2007 makes it all the more important to include the manufacturer and other knowledgeable entities in the process.

"Gap-filling"- Develop More Equitable System To Price HCPCs Changes. CMS proposes that when revisions to HCPCS codes for items under a competitive bidding program occurs in the middle of a bidding cycle and a single HCPCS code for two or more similar items is divided into two or more separate codes, the payment amount applied to these codes will continue to be the

same payment amount applied to the single code until the next competitive bidding cycle. This is not an equitable solution and a more appropriate procedure must be developed.

CMS proposes not to require suppliers to provide every brand of products included in a HCPCS code. However, regardless of what brands the contract supplier furnishes, the single payment amount for the HCPCS code would apply. The current code set is inadequate and therefore only requiring suppliers to supply an item that meets the descriptor of the code will not adequately meet the needs of Medicare beneficiaries.

The current coding system, especially for complex rehab and assistive technology, groups items into very general codes. In many cases the items are designed for a similar use, but because of the anatomical anomalies, asymmetries, tone, functional limitations etc., beneficiaries must have access to a specific device within a code. Unfortunately due to differences in design, product cost and other factors, the costs associated with the devices are fundamentally different.

A basic example of problems within the current HCPCS code set is the current code for head rests- E0955. This code currently is used for all levels of headrests. However, an extremely broad range of technology falls within this code. The most basic item; a flat single pad with no adjustability and fixed, non-adjustable hardware would be the item most suppliers would base their bid on. However, this same code represents products with multiple pads, independently adjustable and contoured to allow intimate interface with the beneficiary's head, hardware that is adjustable in multiple directions that will also swing out of the way for transfers. The price differential between a basic headrest that merely supports the head when the beneficiary is tilted or reclined is significantly less than the headrest that controls the head, keeps it in proper alignment to prevent tonal reflexes and allows the beneficiary to drive a power wheelchair using an alternative input device controlled with precise head movements.

While focused and aggressive efforts are occurring that will hopefully develop an appropriate code set for rehab and assistive technology devices, the current HCPCS code set is grossly inadequate to support competitive bidding.

This proposal has broad sweeping impact on the Medicare program, not only the competitive bidding program. The competitive bidding program proposals and the proposal regarding establishing payment for DME both inside and outside of the competitive bidding program should be two separate Rules. Sixty days does not provide enough time to develop substantive comments for both of these significant issues. As such, Care Medical recommends that CMS initiate a separate rulemaking proceeding to solely address changes to the pricing methodology for DME.

"Gap Filling" - Adjustments To Competitively Bid Payment Amounts To Reflect Changes In The HCPCS Codes. (proposed §414.426) CMS proposes that when revisions to HCPCS codes for items under a competitive bidding program occurs in the middle of a bidding cycle and a single HCPCS code for two or more similar items is divided into two or more separate codes, the payment amount applied to these codes will continue to be the same payment amount applied to the single code until the next competitive bidding cycle. Care Medical strongly opposes this proposal. Allow manufacturers access to the contractor to be able to provide cost information related to engineering, product development and customer support, as well as costs associated with product support, service and delivery of the products in the field. In cases when a single HCPCS code for two or more similar items is divided into two or more separate codes, the single payment amount applied to these codes is the same single payment amount to the single codes, and contract suppliers must furnish the items in accordance with the new codes.

Care Medical disagrees with this proposal. The reasons that CMS would determine that new HCPCS are need is when there are differences in technology, clinical application and pricing. In these situations, it is inappropriate to expect suppliers to provide these products at the price of the single payment amount of the single code. Care Medical recommends, that in the event a single HCPCS code is divided into two or more separate codes during a bidding cycle, CMS should re-bid the codes in the new code set which are appropriate for competitive bidding.

"Regulatory Impact Analysis" - The Proposed Rule CMS predicts that, nationally, 37% of the total number of DME suppliers will be eliminated in each bidding round. A 37% decrease in the number of suppliers means an even higher increase in patient load for the remaining suppliers.

For example, say the current ratio of patients to DMEs is 10,000 patients per hundred DMEs, that's 100 patients per DME. What happens if we decrease the number of DMEs by 37%? The new ratio is 10,000 patients per 63 HMEs or 159 patients per DME. Clearly the patient load per DME has jumped from 100 to 159, a 59% increase! This remains true regardless of the number of patients or DMEs that are used in the calculation. In the actual CBAs the effect will be even greater, as 50% of bidding suppliers will be excluded from the program in their immediate geographic areas.

The problem with CMS' figures is that, going back to page 87 of the Proposed Rule, we are told that CMS had asked the PAOC for advice on dealer market capacity and were told at the Feb. 28, 2005 meeting that most suppliers would be able to increase their capacity by up to 20%, with a higher percentage for less labor intensive items like diabetic products. This was the only hard figure on potential capacity increase mentioned in the Proposed Rule. Increasing capacity for a DMEPOS is not really that easy. Because of accreditation, they must thoroughly train and test all new employees for competency (usually a yearly process). This is not just a simple matter of new inventory. Licensed professionals must be hired, additional facilities and vehicles purchased, new credit extended, billing issues resolved, etc. Clearly, if there are increases in patient load above 20% in life support services, there are real dangers both to the patient and accreditation standards. Yet the targeted 37% cut in available suppliers will forcibly raise the patient load for each contracted supplier by 59%. This is an intolerable workload increase for any health care company in a short span. Imagine a hospital suddenly raising its patient census by 59% before there has even been an opportunity to expand its qualified staff and facilities?

This proposed cut in participating suppliers is arbitrary and presents an unacceptable peril to the home health care system. Furthermore, it endangers accreditation standards, state licensing standards and the risk of malpractice lawsuits. Based on the initial advice of the PAOC, the patient load increase per supplier for all life support services should be no higher than 20%.

It is our view that the term "Competitive Bidding" is a misnomer for a flawed system which might more aptly be described as "Selective Acquisition." It is also our belief that the two pilot projects have demonstrated significant negative consequences for beneficiaries by effectively

eliminating the normal, healthy competition that currently exists between the DMEPOS provider community to provide beneficiaries with fast, efficient, and effective products and services.

Reasonable and significant cost-savings from providers can and should ultimately be achieved without eliminating normal competition in the marketplace and without eliminating virtually the entire, existing DMEPOS provider panel. We believe that creation of a "limited provider panel" through the proposed national competitive bidding (NCB) program is bad policy for beneficiaries and providers alike. While this NCB option may, in some instances, result in product price reduction, it will at the same time severely reduce overall patient access, choice and service, ultimately shifting increased care costs to other areas of the hospital system and health care continuum; e.g., increased length of stay in inpatient/acute settings and/or increased patient re-admission frequency or disease severity, etc. from moving to a "low price" model being encouraged by NCB.

The proposed rule appears to primarily utilize cost and volume for product selection. Unfortunately, the potential negative impacts in terms of overall patient access and inclusion and continuity with established care plans and protocols does not appear to be addressed. Consideration to overall medical appropriateness needs to be considered, as well as overall patient access to care and services.

Potential cost considerations that will affect many other areas of the overall health care continuum do not appear to be adequately considered or addressed. There appears to have been no examination of negative cost implications for physicians, home health nursing care providers, hospice, inpatient and outpatient hospitals, integrated healthcare delivery systems and owned-providers, as well as multiple and various other healthcare providers. It is obviously critical that protections and minimization of overall cost impacts throughout the health care service and cost continuum are clearly identified, discussed, and fairly addressed in the final rules. Pushing "costs" out of products alone will most certainly result in detrimental cost-shifting and even cost-increases in other areas of the continuum. Medicare will ultimately have to absorb these costs regardless of what "bucket" the money comes from.

"Summary" - Care Medical Equipment, Inc. has several strong concerns and objections regarding competitive bidding and the proposed rule. "Competitive Bidding" appears to be a poor choice of words for a horribly flawed system. While our responses to the individual items in the proposed rule have been outlined, we would like to emphasize the following points:

- We truly do not expect that Medicare will see any significant cost savings from this program. In the "Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration For Durable Medical Equipment, Prosthetics, Orthotics and Supplies", it is suggested that an additional 669 full time equivalent personnel at an approximate expenditure of $68.9 million will be required to manage competitive bidding. The proposed rule mentions a small staff at CMS being needed and perhaps an ombudsman in each region. These numbers grossly conflict with one another. There is also discussion within the NPRM of the need for an "implementation contractor". The projected costs associated with yet another entire contractor are not even mentioned. While we understand that perhaps some of these monies are pulled from different "buckets", we are not convinced that the administrative costs in managing competitive bidding truly will allow for the projected savings.

- The Medicare program as it stands has the lowest administrative cost of any other healthcare program in the country. Private insurance companies are competitive and we have to bid to be on the panel for every private payor we contract with and yet they all have higher administrative costs than Medicare, typically a five-fold higher administrative cost. Why would Medicare want to take a plan that is working to change it to emulate private plans whose administrative costs far exceed their own.

- The concept that the federal government is intentionally implementing policies, which will reduce the number of DMEPOS providers by over a third, is tantamount to the federal government intentionally creating monopolies. This system is only going to enhance the strength of national DMEPOS providers. These national providers are already decreasing the volume of staff involved in customer service and education. We firmly believe that decreasing the number of DMEPOS suppliers in this manner will not allow for increased

competition. We believe this system will encourage lower quality product and less customer service being supplied to beneficiaries. We also find it abhorrent that apparently no thought or consideration has been given to the emotional or economic impacts of the resulting displaced workers. This is a bigger picture issue than realized at first glance. These employees and their families are dependent upon their jobs for basic food, shelter and healthcare. The economic impact of 37% of the DME industry going on unemployment is unfathomable.

- As appears to be increasingly common with governmental regulations, we firmly believe the "cart has been put before the horse". This is made evident by several conflicting pieces of information. We agree that accreditation is appropriate for suppliers, so how then is it appropriate for non-accredited entities to submit a bid, "win" a bid and supply equipment to a beneficiary when CMS itself is stating that accreditation should be mandatory?

- We also firmly believe that product selection should be done extremely carefully. Rehab and custom equipment should be excluded including powerchairs and scooters. It has been demonstrated time and again that inappropriate equipment can cost significantly more in the long run. Creation of pressure sores, respiratory complications, contractures, etc. from inappropriate equipment only increase costs in other areas of healthcare, not to mention the pain and suffering of the beneficiary and family members, nor the economic impacts to all of us.

- Care Medical applauds CMS for its apparent intent to ensure that all suppliers providing items and services under the competitive acquisition programs meet defined Quality Standards. At the time of this writing, however, CMS has not issued the final DMEPOS Supplier Quality Standards. We believe that these Quality Standards must be analyzed in the context of this proposed regulation, and therefore ***recommend that CMS either extend the comment deadline for the NPRM to 60 days after CMS issues the final Quality Standards, or allow for a formal comment period on the Quality Standards, for a period of at least 60 days after CMS issues the final Quality Standards.*** In addition, ***CMS should respond to***

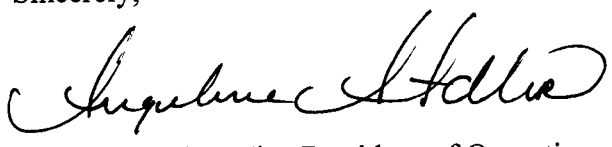
public comments on the Quality Standards as part of its response to comments it receives on this NPRM.

- Suppliers are being asked to make a bid that encompasses analyzing so many variables that are out of their control. Suppliers cannot control shipping costs; gas costs and manufacturer price increases, as well as increases in employee benefits such as health insurance. We propose that all suppliers be allowed to bid, regardless of the size of the organization. If suppliers agree to quality and financial standards set by CMS and they accept established payment amounts, suppliers should be allowed to service all Medicare beneficiaries in the areas they serve.

- CMS states that ""During the demonstration, evaluating quality and financial standards was time-consuming for the bid evaluation panel....". This statement implies that CMS may not plan to evaluate the quality and financial standards of all suppliers that submit bids at the outset of the bid evaluation process especially considering the implementation timeline CMS is holding supplier to. We are very disturbed by this implication. *(And CMS should not short-cut the procedures simply because it may be more administratively burdensome – such is the nature of this bidding process.)* Further, it is entirely unclear in the proposed regulation at what point CMS plans to evaluate whether bidders do in fact meet all the requirements, including quality standards (accreditation), financial standards, Medicare supplier standards, etc. It is imperative that CMS conduct this evaluation process at the outset before the bid evaluation process begins to ensure that bid information from a bidder that does not meet one or more of the requirements is not included in any part of the evaluation process. Otherwise, the entire bid calculation (including pivotal and single payment amount calculations) and contract supplier selection process will be fundamentally tainted with information from non-qualifying bidders.

Care Medical appreciates the time you have taken to read our comments on CMS-1270-P – Notice of Proposed Rulemaking, Medicare Program (NPRM); Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues. If you have any questions or need further clarification regarding our comments, please do not hesitate to contact me.

Sincerely,



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June 29, 2006

VIA ELECTRONIC MAIL and OVERNIGHT MAIL

Mark McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

File Code CMS-1270-P Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Dear Dr. McClellan,

Thank you for the opportunity to comment on the proposed regulations governing the competitive acquisition of certain durable medical equipment, prosthetics, orthotics and supplies as well as the implementation of the DMEPOS quality standards. I am writing on behalf of the American Board for Certification in Orthotics and Prosthetics, Inc. (ABC), the nation's oldest and largest standards setting organization for orthotic and prosthetic (O&P) patient care. ABC was established in 1948 and accredited its first O&P facility in 1949. Since that time, the standards contained in ABC's "Manual for O&P Patient Care" have been consistently revised and updated to reflect best practices and technological advances. ABC's mission is to establish and promote the highest standards of organizational and clinical performance in the delivery of orthotic and prosthetic patient care.

We are pleased that the Centers for Medicare and Medicaid Services (CMS) has endorsed the concepts of mandatory quality standards of care for all suppliers of O&P services including therapeutic shoes and post-mastectomy care and is proposing improved oversight over the delivery of those services. The coordinated efforts of the accrediting organizations, CMS and the National Supplier Clearinghouse will provide proper and cost effective beneficiary services through appropriate delivery of care to the Medicare beneficiary. The unique qualifications of the individuals employed by suppliers are critical to achieving quality patient care while maintaining patient access.

ABC welcomes the opportunity to offer the following comments and recommendations.

Quality Standards and Accreditation

§414.414(c) ABC recommends a six-month grace period for suppliers to obtain a valid accreditation following their application into the competitive bidding program.

§414.414(c)(2)(ii) states "A supplier satisfies paragraph (c)(2)(i) of this section if it was accredited by an organization that CMS designates as a CMS-approved accreditation organization under §424.58 of this chapter." This section is unclear whether a supplier's accreditation must be in good standing or if they simply have been accredited in the past. To clarify what we believe to be the intent of this section, we would recommend replacing "was" with "is." This change would eliminate any confusion regarding the point in time a supplier must be accredited.

Furthermore, we believe this part needs additional clarification to the effect that, in order to satisfy paragraph (c)(2)(i), the accredited supplier must have received an on-site survey by a qualified surveyor from the accrediting organization as a requirement of a valid accreditation. We believe an on-site survey, performed in-person by appropriately trained and qualified surveyors, best verifies the supplier's claims made in the application for accreditation and validates the accreditation process. This further serves to verify the legitimacy of the supplier and should help reduce the likelihood of fraud and abuse through false claims.

In order to accomplish the above two recommendations, we propose §414.414(c)(2)(ii) be modified as follows:

(ii) A supplier satisfies paragraph (c)(2)(i) of this section if it –

- Is accredited in good standing by an organization that CMS designates as a CMS-approved accreditation organization under §424.58 of this chapter, and
- Received an on-site survey conducted in-person by trained and qualified surveyors.

Accreditation

§424.58(b)(1) delineates the aspects of accreditation that an applying or reapplying accrediting organization must furnish to CMS. The process an accrediting organization employs to award accreditation must include more than a mere checklist of compliance with quality standards. That process should include reasonable mechanisms the accrediting organization must use to identify those suppliers which are not in compliance with minimum competency requirements. It also provides an opportunity to improve the beneficiary's experience by encouraging otherwise qualified suppliers to strive for a level of quality care that is beyond the reasonable expectation of mere compliance with minimum quality

standards. We encourage CMS to adopt the following recommendation that additional requirements be included under §424.58(b)(1).

- A description of the organization's method for determining the process surveyors utilize to assess compliance with each accreditation standard.
- A description of how the organization translates surveyor observations into scores for each accreditation standard.
- A description of how the individual standard scores aggregate into an overall score and how that score identifies competent suppliers.

§424.58(b)(1)(i) requires the applicant organization to provide "A list of the product-specific types of DMEPOS suppliers for which the organization is requesting approval." We believe that each accrediting organization should be compelled to demonstrate that it has the knowledge and experience necessary to properly classify suppliers and measure their organizational performance in the specific types of patient care for which approval is being requested. In providing the majority of O&P care/services, the interaction of disease progression and biomechanics requires special knowledge and skills to provide a beneficiary with appropriate care. Failure of an accrediting organization to appropriately recognize the various levels of orthotic and pedorthic patient care could result in misapplication of standards which would dramatically increase the potential for harm to patients.

§424.58(b)(1)(xi) ABC strongly recommends adding language under §424.58(b)(1)(xi) which would identify specialized categories of orthoses and therapeutic shoes to improve CMS' oversight of beneficiary care. The recognition of these very different categories will improve accessibility to the orthoses and therapeutic shoes which require lesser skills and involve lower patient risk. It will assure the beneficiary that suppliers have personnel who are qualified to provide services at the appropriate level of competency. It would further allow an accrediting organization to ensure that the site of care has the appropriate specialized equipment and facilities to provide patient care at the level required for the various categories.

The delivery models of low-level orthoses and therapeutic shoes have changed over time and are increasingly common in non-traditional supplier settings. It is not at all uncommon for some suppliers to limit orthoses to the lower-level/s because they do not have the qualifications or facilities to provide higher-level care. These settings are very different from traditional O&P sites of care and would not qualify for accreditation to provide the full range of O&P services.

By requiring O&P and pedorthic accrediting organizations to adopt certain definitions, suppliers providing high and/or low risk categories of patient care to beneficiaries must demonstrate competency in their respective scopes of practice. Limiting the accreditation of suppliers to their appropriate level, considering their qualifications and the amount of risk to the patient, will enhance the beneficiary's experience by ensuring that suppliers have qualified staff. If adopted, CMS can be confident that appropriate performance standards are enforced

and the care a beneficiary receives is appropriate for his/her condition and that coverage is provided only for the services a supplier is competent to provide. Beneficiary access to the various levels of care would be preserved.

Specifically, we recommend adding:

§424.58(b)(1)(xi) (•) Organizations seeking approval to accredit suppliers of orthoses must adopt the following category definitions.

- Custom-Fit Low Orthosis – A prefabricated orthosis described in section 1861(s)(9) of the Act which is sized/and or modified for use in accordance with a prescription that requires substantial clinical judgment (involving some patient assessment, formulation of a treatment plan and follow-up skills) and substantive alteration (involving low technical implementation skills) for appropriate use.

- Custom Fit-High Orthosis – A prefabricated orthosis described in section 1861(s)(9) of the Act which is sized/and or modified for use in accordance with a prescription that requires substantial clinical judgment (involving high patient assessment, formulation of a treatment plan and follow-up skills) and substantive alteration (involving medium technical implementation skills) for appropriate use.

- Custom Fabricated Orthosis – An orthosis described in section 1861(s)(9) of the Act which is fabricated to comprehensive measurements and/or a mold or patient model in accordance with a prescription that requires substantial clinical and technical judgment in its design, fabrication and fitting.

(The orthotic categories above refer to the particular procedure codes contained in the "Healthcare Common Procedure Coding System" and identified as such in the report Categorization of Orthotic HCPCS Codes by Provider Skill Level (revised August 8, 2005) submitted by the Orthotic and Prosthetic Alliance to the Centers for Medicare and Medicaid Services and enclosed as Exhibit 1.)

§424.58(b)(1)(xi) Organizations seeking approval to accredit suppliers of therapeutic shoes must adopt the following category definitions.

- Custom Therapeutic Shoes –A shoe that is custom fabricated from a mold of the patients foot in accordance with a prescription that requires substantial clinical and technical judgement in its design, fabrication and fitting.

- Non-custom Therapeutic Shoes –A shoe that is manufactured to accommodate multi-density inserts in accordance with a prescription that requires measurements to determine types of last, widths and proper construction to accommodate pathologies of the foot.

§424.58(c)(1) requires the approved accrediting organization to "Provide to CMS all of the following in written format and on a monthly basis ..." We request clarification of what constitutes "written format." Considering today's technology, electronic formats are recognized as industry standards and should be welcomed by CMS. Considering the volume and frequency of the information requested, electronic formats will facilitate both submission and subsequent interpretation and analysis. We encourage CMS to formally recognize formats other than "written."

§424.58(c)(1)(iii) requires "Notice of all complaints related to suppliers of DMEPOS and other items and services." We believe this requirement is overly broad and burdensome. It is redundant with §424.58(c)(1)(iv) and should be eliminated. Because §424.58(c)(1)(iv) requires information about suppliers who have had action taken, requiring separate notification of all complaints would unnecessarily burden both CMS and the accrediting organization with notifications of frivolous complaints.

§424.58(c)(1)(v) requires approved accrediting organizations to provide "Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accreditation organization." ABC has a dynamic accreditation program that is reviewed and revised on a periodic basis. We understand CMS' need to approve any proposed changes, but we respectfully request that CMS provide a reasonable timeframe in which to review the request for change. To be consistent with our recommendations of reasonable response guidelines that CMS expects from the approved organizations, we would recommend that CMS respond to any proposed change within 60 days of submission by the approved accrediting organization.

§424.58(c)(2) specifies that approved accrediting organizations must, "Within 30 days of a change in CMS requirements, submit to CMS:" We believe the 30 day requirement is not sufficient time to allow an accrediting organization to thoroughly review CMS' changes, assess the impact and develop an action plan to comply with the changes. We believe 90 days is a more reasonable time frame to submit the required information.

§424.58(c)(4) requires that approved accrediting organizations must, "Within 2 calendar days of identifying a deficiency of an accredited DMEPOS supplier that poses immediate jeopardy to a beneficiary or to the general public, provide CMS with written notice of the deficiency and any adverse action implemented by the accreditation organization." We believe the two calendar day requirement is an unreasonable request because it fails to recognize holidays and weekends as periods when complying with this requirement will be problematic. We believe it is more reasonable for CMS to require this critical notification via any format within five business days. We would further ask that CMS specifically identify those standards with which noncompliance would rise to the level of posing immediate jeopardy to a beneficiary or to the general public.

§424.58(c)(5) states that approved accrediting organizations must, "Within 10 days after CMS's notice to a CMS approved accreditation organization that CMS intends to withdraw approval of the accreditation organization, provide written notice of the withdrawal

to all the CMS approved accreditation organization's accredited suppliers." We believe the word "business" should be inserted between "10" and "days." Further, we believe this notice should be required only after CMS has issued a final determination that approval is to be withdrawn.

Thank you again for this opportunity to comment on CMS-1270-P, "Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues."

If you have any questions regarding our comments and recommendations, please contact our Director of Facility Accreditation, D. Scott Williamson, Jr., at (703) 836-7114 (ext 223).

Sincerely,

Jeffrey J. Yakovich, CO
President

Exhibit 1

Categorization of Orthotic HCPCS Codes by Practitioner Skill Level

(Submitted August 8, 2005)

Introduction and Update of Terms
June 29, 2006

Introduction

The American Board for Certification in Orthotics and Prosthetics, Inc. (ABC) has maintained a scope of practice for individuals in the profession of orthotics and prosthetics since 1948. The scope of practice is based on a psychometrically validated practice analysis study as well as the educational and experiential norms for the profession. The scope of practice recognizes the independent practice of certified orthotists and prosthetists, as well as certified orthotic fitters and certified mastectomy fitters. The certified orthotist's independent scope of practice includes the entire range of comprehensive orthotic care while certified fitters' have an independent scope of practice that includes "custom-fit low" and "off-the-shelf" orthoses.

Updated Term

Since the presentation of this report to CMS on August 8, 2005, ABC has changed the designation of orthotic and mastectomy fitters. Individuals holding the "fitter" credential were referred to throughout the report as "Registered Fitters." That designation has been retired and those individuals are now credentialed as "Certified Fitters."

Categorization of Orthotic HCPCS Codes by Practitioner Skill Level

(Revised August 8, 2005)

Executive Summary

The purpose of this report is to formalize a consensus reached by the primary orthotic and prosthetic groups in the profession regarding what type of provider is qualified to provide various types of comprehensive orthotic and prosthetic care. This document is meant to provide expert guidance on the content of the upcoming regulations to implement the Benefits Improvement and Protection Act, Section 427 and the Medicare Modernization Act, Section 302 to ensure a harmonized regulatory solution to assure quality patient care and program integrity. The groups supporting this report are:

- The American Board for Certification in Orthotics and Prosthetics, Inc. (ABC)
- The American Orthotic & Prosthetic Association, Inc. (AOPA)
- The American Academy of Orthotists and Prosthetists (AAOP)
- The National Association for the Advancement of Orthotics and Prosthetics (NAAOP)

In preparing this report, our work group used as our sources the *Orthotic and Prosthetic Scope of Practice (2003)* and the *Practice Analysis of the Disciplines of Orthotics and Prosthetics (2000),* both by the American Board for Certification in Orthotics and Prosthetics, Inc. as well as previous work done by the American Orthotic & Prosthetic Association Coding Committee.

During the process of resolution of our main question, what type of provider is qualified to provide certain orthotic and prosthetic care/services, it be came clear that we needed to resolve several sub-questions, as follows:

1) What knowledge and skills should each level of provider possess?
2) What knowledge and skills are needed to provide orthotic or prosthetic care?
3) How could we match skill levels and knowledge of providers with specific orthotic or prosthetic care/services?

It should be noted that our work covers only "base" codes within the HCPCS L code system and does not include "addition", "modification" or other miscellaneous codes. This is because any one addition or modification can be assigned to various base code categories.

Summary of Findings

The resolution of question one, "What education and skills should each level of provider possess?" can be seen in Table One and Appendices C and D. The table identifies the various domains of care that are involved in the provision of orthotic care: patient assessment, formulation of a treatment plan, implementation of that plan, follow up to that plan and overall practice management. (Definitions of these terms can be found in Appendix D.) It also identifies the degree of expertise in each of these domains that a certified practitioner, registered assistant, registered fitter and registered technician must have.

Appendix C then spells out the educational requirements for each type of provider, using as an example the ABC standard, and Appendix D identifies the knowledge and skill levels required.

Question Two, "What knowledge and skills are needed to provide each type of orthotic or prosthetic care?" is answered in Table Two. This contains the same information on provider skills as Table One, but then ties the types of provider back into categories of orthotic or prosthetic care. The device categories used are a.) custom fabricated, b.) custom fit high, c.) custom fit low, and d.) off the shelf. Each code is later assigned to one of these categories. (Definitions of these categories can be found in Appendix B.)

Finally Question Three, "How could we match skill levels and education of providers with specific orthotic or prosthetic care/services?" can be answered by using the data in Appendix F, which places each of the HCPCS L codes into one of the four categories of custom fabricated, custom fitted high, custom fitted low and off the shelf. By using this data in conjunction with Table Three, you can determine what qualifications a provider must have to provide specific devices.

It should be noted that in actual patient care, there will be times when the complexity of a specific patient's diagnosis or other underlying conditions will mean that a higher level of provider is required. For example, while for some patients it would be appropriate for an orthotic fitter to provide a simple type of ankle foot orthosis, if the patient had severe diabetes with significant vascular complications, the knowledge and expertise of a certified practitioner would be needed to safely provide that same orthosis and care for the patient. The work group stands ready to assist CMS with the development of criteria to determine when such situations arise.

Regarding the use of HCPCS codes, as opposed to specific device brand or type names, these codes are a nationally accepted mode of describing orthotic and prosthetic care and must be used to ensure that everyone is speaking the same "language", without any regional variations or misunderstandings. In addition, in general, each code represents a range of orthotic and prosthetic care/services that meets the code description, thus allowing classification of hundreds of devices, components and services in a more compact and manageable format. These codes can then be used to match care to patient needs, after an appropriate treatment plan is determined by an orthotic or prosthetic evaluation.

As noted earlier, the knowledge and skills necessary to provide orthotic and prosthetic care have been described using the ABC standard. ABC, as well as the Board for Orthotist /Prosthetist Certification (BOC) currently administers credentialing examinations granting orthotic and prosthetic certification to individuals in the profession for various levels of care. In this way, those who provide orthotic and prosthetic services are not restricted as long as they have passed these examinations and, thus, demonstrated their competency to provide orthotic services at the appropriate care level.

Competency assessment, through achievement of certification, is a long-standing and accepted method of identifying those medical and health care professionals who are qualified to care for patients. For example, acute care institutions, such as hospitals, typically require specialized education and training (as evidenced by certification) in order for independent practitioners to provide care under their sponsorship.

Regarding the issue of what other provider types are competent to perform specific orthotic services, the work group determined that it could make these determinations only for ABC certified practitioners. However, the skill level classification guidelines should assist CMS in classifying other provider types who may be allowed to perform orthotic services, as well as provide a reference to map other credentials to the ABC credential equivalents.

It is the Work Group's belief that by utilizing the skill level classification guidelines, a comprehensive plan can be established to ensure that all Medicare beneficiaries receive orthotic care from appropriately educated and qualified practitioners.

Comprehensive Report

Mission Statement

To develop guidelines for selecting qualified practitioners of orthotic and prosthetic services and devices, and to assist provider and payor organizations in reaching appropriate privileging decisions regarding clinical patient management.

Method

To maintain continuity with accepted orthotic and prosthetic practice standards, the group based its position on existing material whenever possible. These materials and standards included:

- ABC's *Practice Analysis of the Disciplines of Orthotics and Prosthetics* was selected to describe the tasks and domains, (specific activities) involved in the delivery of orthotic and prosthetic care.
- ABC's *Report Orthotics and Prosthetics Scope of Practice* was selected to define service categories of orthoses and prostheses (Appendix B).

The Work Group posed a series of questions to identify those competent to provide orthotic and prosthetic services:

1. What level of responsibility for performing tasks in the various domains do providers in each levels of care possess?
2. What level of competency in each of the domains is necessary to provide orthotic and prosthetic services in the various types of device categories?
3. Which types of devices/services should be provided by practitioners in the various levels of care?
4. To which type of skill level category would the various HCPCS codes be assigned?
5. When the qualifications of various practitioners are assessed, to which level of care should they be assigned?

Procedure

In order to answer these questions, the Work Group accepted the delineation of tasks and domains, as well as the definitions categorizing devices and services, from the American Board

for Certification in Orthotics and Prosthetics' (ABC) *Practice Analysis of the Disciplines of Orthotics and Prosthetics* and the *Orthotics and Prosthetics Scope of Practice*. These are as follows:

> **Domains:** global areas of responsibility performed by the credentialed O&P professional.
>
> **Tasks:** the activities performed within the domain in the course of practice.
>
> **Knowledge and skill statements:** the organized body of information and the physical or mental manipulation of information or things required to perform the tasks associated with each domain.

The Work Group relied on the existing orthotic and prosthetic service categories of "Custom Fabricated", "Custom Fitted" and "Off-the-shelf" and further divided the category "Custom Fitted" into "Custom Fitted, High" and "Custom Fitted, Low", to more accurately categorize individual orthotic service codes. The Work Group only classified base codes. It was presumed that all non-base codes would by default be categorized according to the base code with which they are associated.

From this basis, a series of tables was developed to speak to the previously noted questions. During this work, information describing the experiential and educational qualifications of a variety of providers was collected. The intent of this effort was to establish the basis for some measure of equivalency for providers in different professions and with differing qualifications.

Findings

What level of responsibility for performing tasks in the various domains do providers in each of the levels of care possess?"

Definitions:
High: the provider is independently and completely responsible for the aspects of the domain
Medium: the provider has some responsibility but frequently is not completely responsible for the aspects of the domain OR that the level of device complexity does not require a high level
Low: the provider has limited responsibility for the aspects of the domain

Table One: Level of Care Providers & Orthotic and Prosthetic Domains of Practice

Level of Care Providers: ABC Credential	Patient Assessment	Formulation of the Treatment Plan	Implementation of the Treatment Plan	Follow up Treatment Plan	Practice Management
Certified Practitioner	High	High	High	High	High
Registered Assistant *	None	None	Medium	Medium	None
Registered Fitter	Medium**	Medium**	Medium**	Medium**	Medium***
Registered Technician	None	None	High****	Low	None

*The Registered Assistant credential does not currently provide for independent patient care
**This measure of responsibility is assigned within the Registered Fitter's Scope of Practice of providing custom fit low devices.
***This Medium measure of responsibility is assigned only **if** the Registered Fitter is practicing **independently** and is responsible for the management of the facility.
****This High measure for the Registered Technician's responsibility is in relation to the **fabrication** portion of the domain.

In considering Table One it should be noted that the specific Levels of Care providers may share equal responsibility within the Domains, particularly Implementation of the Treatment Plan. This does not imply that they share equal skills, capabilities, or duties, but responsibility of execution. For instance, a Certified Practitioner may delegate certain specific components within the "Implementation of the Treatment Plan", such as fabrication of a custom device, to a Registered Technician.

What level of competency in each of the domains of practice is necessary to provide orthotic and prosthetic services in the various categories of devices?

Table Two: Competency Required In the Domains of Practice For The Various Types of Devices

		Orthotic and Prosthetic Domains of Practice			
Types of Devices	**Level of Care Providers:**	**Patient Assessment**	**Formulation of the Treatment Plan**	**Implementation of the Treatment Plan**	**Follow up Treatment Plan**
Custom Fabricated	Certified Practitioner	High	High	High	High
Custom Fitted High	Certified Practitioner	High	High	High	High
Custom Fitted Low*	Certified Practitioner	Medium	Medium	Medium	Medium
	Registered Fitter	Medium	Low	Medium	Low
Off the Shelf	No requirements				

*Diagnostic complexity will affect level of provider.

To further understand the definitions of the device types, please refer to Appendix B.

What types of devices/services should be provided by which professionals in the various levels of care?

Based upon the previous tables, the Work Group agreed upon the composition of the following competencies identified as *necessary* in Table Two, as well as the measures of responsibility in Table One.

Table Three: Level of Independent Care Providers by Device Type

Levels of Care: ABC Credential	Custom Fitted Low*	Custom Fitted High	Custom Fabricated
Certified Practitioner	X*	X	X
Registered Fitter	X*		

* Diagnostic complexity will affect level of provider.

To which type of device category would the various HCPCS codes be assigned?

The complete list of HCPCS codes referenced to practitioner skill classification is delineated in Appendix E.

In completing this list the Work Group applied a decision tree process when reviewing each code. This decision tree can be found in Appendix A. At its basis, the decision tree helps to classify each code as a "base code" versus an "addition code", then filters the code by fabrication type. The fabrication type determination was made by specific HCPCS code descriptor language. In the absence of specific fabrication type language, common and/or historical fabrication methods were applied.

When the qualifications of various providers are assessed, to which level of care should they be assigned?

A considerable body of information was collected depicting the qualifications of a variety of providers. The original intent was to analyze this data in light of the competencies required in the various domains delineated for providing orthotic and prosthetics care, then group the providers into one or another of the levels of care to establish equivalency. It was also thought that the group would specify which individual devices/services (as specified by the HCPCS codes) the various providers are competent to provide.

However, it was determined that the Work Group would not attempt to establish equivalency with ABC credentials. It was felt that the information immediately available was inadequate to perform the task. For example, individual schools determine the amount of information physical and occupational therapists receive about orthotics and prosthetics in order to familiarize them with the field. The Work Group professional organizations have no information available about the specifics of the various educational programs, specifically the amount of exposure to orthotics and prosthetics. The Work Group also did not render an opinion about the qualifications and equivalencies of the providers selected for consideration. It was felt that such decisions should be reached by other bodies (i.e., payer agencies) or through discussion among the concerned parties.

However, it is the Work Group's belief that by utilizing the skill level classification guidelines, a comprehensive plan can be established to ensure that all Medicare beneficiaries receive their care from appropriately educated and qualified practitioners. In order to consider another credential "equivalent" to the ABC credential, the Work Group recommends that the following minimum qualifications be required:

1. To ensure all providers are held to the same standards of care, the facility must be accredited in orthotics or prosthetics by an entity recognized by CMS;

2. Education at a collegiate level in basic sciences, including but not limited to biology, chemistry, physics, anatomy, physiology, and kinesiology;

3. Evidence of core orthotics and prosthetics education including the following:

    a) Biomechanics
    b) Materials science
    c) Orthotic and prosthetic componentry,
    d) Assessment of patient's functional outcome;

4. Appropriate training in measurement, impression taking, model rectification, fitting and alignment of orthoses and prostheses;

5. Documentation of experience in the form of an accredited residency; and

6. Undertaking and passing a practitioner or fitter credentialing examination offered by ABC or BOC.

Comments

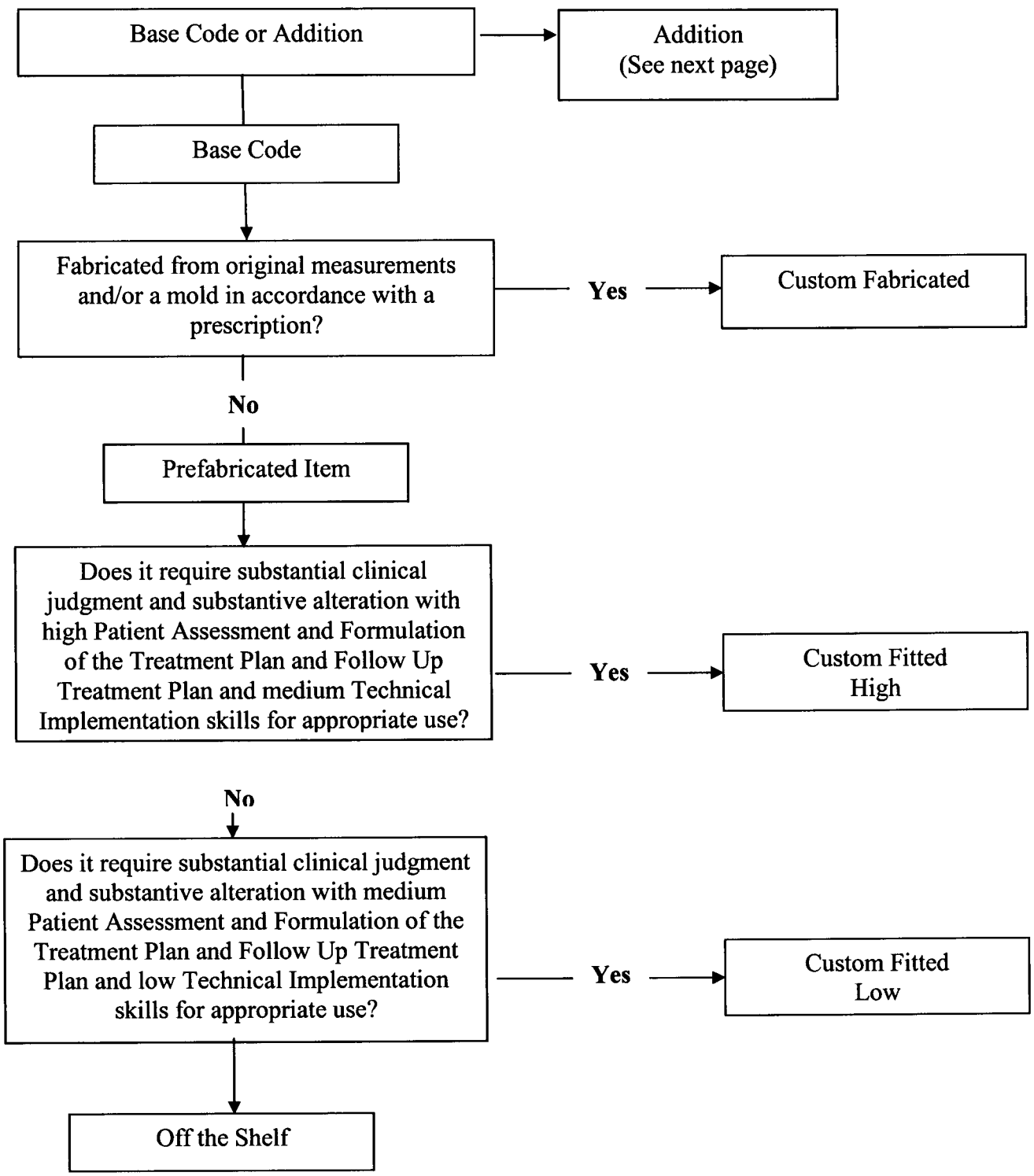
The group also agreed that three additional explanatory notes be included in this report, as follows:

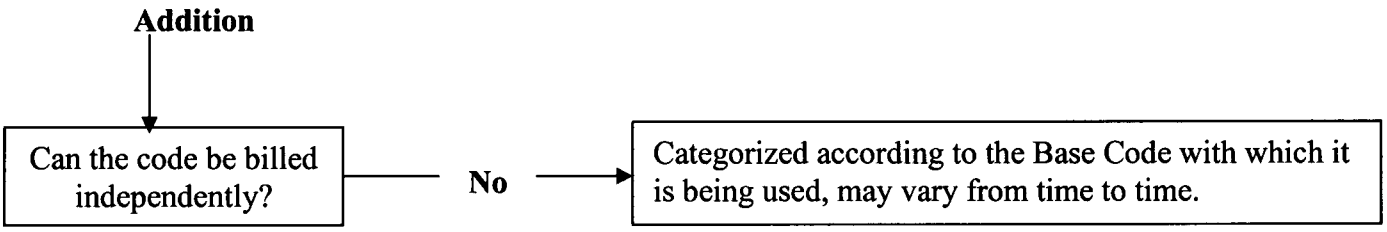
1. The devices/services referenced in this report are provided based upon a physician's written prescription.

2. Any reference to a provider's competencies should be understood to refer only to their ability to provide orthotic/prosthetic devices/services and in relation to their Scope of Practice (e.g. Certified Pedorthists: the foot; Hand Therapists: the upper extremity). No judgment is made or implied about the provider's competency in their "parent" discipline; in the instance when that discipline is not orthotic/prosthetic based.

3. This project deals primarily with orthotic base codes, under the assumption that any accompanying addition codes would fall within the same category as the base code with which they are billed. In addition, all prosthetic devices/services must be provided by a certified provider.

Appendix A
Decision Tree
(Formulated in reference to Table two)




Addition
Can the code be billed independently?
No
Categorized according to the Base Code with which it is being used, may vary from time to time.

Appendix B
Types of Devices

The following definitions were taken from ABC's, *Orthotics and Prosthetics Scope of Practice* Glossary of Terms.

Custom Fabricated Device
A device fabricated to comprehensive measurements and/or a mold or patient model for use by a patient in accordance with a prescription and which requires clinical and technical judgment in its design, fabrication and fitting.

Custom-Fitted Device
A prefabricated device made to patient measurements sized or modified for use by the patient in accordance with a prescription and which requires clinical judgment and substantive alteration in its design.

Off-the-Shelf
A prefabricated device sized and/or modified for interim, evaluative or short term use by the patient in accordance with a prescription and which does not require clinical judgment and substantive alteration for appropriate use.

It will be noted that Custom Fitted is intermediary between Custom Fabricated and Off-the-Shelf devices. Perhaps a greater sense of this relationship can be gained from the following table.

	Custom Fabricated	**Custom Fitted**	**Off-the-Shelf**
Prescription required?	Yes	Yes	Yes*
Fabrication mode	Custom	Prefabricated	Prefabricated
Clinical and technical judgment in design and fitting or substantive alteration required for appropriate use?	Yes	Yes	No

*Off the shelf items are often found in the retail market and are available without a prescription.

In its deliberations, the Work Group divided Custom Fitted into two groups, high and low; as it was felt that the original category was too broadly drawn when considered with respect to specific orthotic services described by the HCPCS codes. The distinction between the two sub-categories was made on the basis of the competency required to properly provide the devices/services in the two sub-categories. The Work Group's thoughts on this point are to be found in Table Two. For at least the purposes of this report, the definition of Custom Fitted Device would be modified as follows.

Custom-Fitted Device (High)
A prefabricated device sized and/or modified for use by the patient in accordance with a prescription and which requires substantial clinical judgment (involving high Patient Assessment and Formulation of the Treatment Plan and Follow Up Treatment Plan skills) and substantive alteration (involving medium Technical Implementation skills) for appropriate use.

Custom-Fitted Device (Low)
A prefabricated device sized and/or modified for use by the patient in accordance with a prescription and which requires substantial clinical judgment (involving medium Patient Assessment and Formulation of the Treatment Plan and Follow Up Treatment Plan skills) and substantive alteration (involving low Technical Implementation skills) for appropriate use.

Appendix C
ABC Scope of Practice for the ABC Credentials and Eligibility Criteria for ABC Credentialing:

A. ABC Certified Orthotist and/or Prosthetist

An ABC certified orthotist or prosthetist is an allied health professional who is specifically trained and educated to manage the provision of comprehensive orthotic and prosthetic care, based upon a clinical assessment and a physician's prescription, to restore physiological function and/or cosmesis.

The ABC certified practitioner independently provides or supervises the provision of comprehensive orthotic and prosthetic care. This includes patient assessment, formulation of a treatment plan, implementation of the treatment plan, follow-up and practice management.

Certified Practitioner Eligibility Pathways (leading to the three certification examinations: written, written simulation and clinical patient management)

1. Traditional Pathway
    - Baccalaureate degree in O&P-or
    - Baccalaureate degree in another field with an orthotic and/or prosthetic certificate from a CAAHEP accredited program

    And
    - A 12-month NCOPE accredited residency program

2. Unique Qualifications Pathway

    Extension of ABC Credential
    - Original practitioner certification in good standing
    - Minimum of 5 years of patient care in other discipline
    - Case Histories of specific devices (12 prosthetics, 22 orthotics)
    - 6 letters of attestation
    - Achievements (papers, lectures, awards, etc.)

    10 Year Pathway
    - HS/GED and a minimum of 15 semester credit hours in collegiate science courses (biology, chemistry, physics, anatomy and physiology) and 12 continuing education hours each of biomechanics and gait analysis/ pathomechanics
    - 10 Years of active patient care experience
    - Case Histories of specific devices (12 prosthetics, 22 orthotics)
    - 6 letters of attestation
    - Achievements (papers, lectures, awards, etc.)

B. ABC Registered Assistant

An ABC registered assistant is an individual trained and qualified to participate in the delivery of orthotic and prosthetic care while under the clinical supervision of an ABC certified practitioner.

The registered assistant supports the ABC certified practitioner by assisting in orthotic and prosthetic patient care. Under the guidance and supervision of the ABC certified practitioner, registered assistants may perform orthotic and prosthetic procedures and related tasks in the management of patients. The registered assistant also fabricates, repairs and maintains devices to provide maximum fit, function and cosmesis.

ABC registered assistants may not use their credentials as independent practitioners engaged in unsupervised patient care.

Registered Assistant Eligibility Pathway (no examination required at this time)

- 3 years of experience under an ABC certified practitioner
- Attestation of specific items
- Letters of recommendation from a referral source such as an MD, PT, OT located in the same community

C. ABC Registered Technician

An ABC registered technician is an individual who supports the ABC certified practitioner by providing the technical implementation tasks and services associated with the support of patient care. Under the supervision of and in consultation with the practitioner, the registered technician fabricates, repairs and maintains devices to provide maximum fit, function and cosmesis. The registered technician is expected to keep abreast of all new fabricating techniques, must be familiar with the properties of pertinent materials and must be skilled in the use of appropriate equipment.

ABC registered technicians may not use their credentials as independent practitioners engaged in direct patient care.

Registered Technician Eligibility Pathways (leading to the registration examination: a written and a practical)

1. Traditional Pathway
   - HS/GED and
   - Certificate from an NCOPE accredited technician program

   Or
   - HS/GED and
   - Two years of qualified experience under the supervision of an ABC certified practitioner (or in some cases an ABC registered technician)
2. Unique Qualifications Pathway
   - Case-by-case review of qualifications equivalent to the above

D. ABC Registered Fitter-Orthotics

An ABC registered fitter-orthotics is an individual trained and qualified to participate in the fitting and delivery of prefabricated orthotic devices and/or soft goods. An ABC registered fitter-orthotics is competent to practice orthotics within a scope of practice that is specific to fitting prefabricated and off-the-shelf orthoses as described below:

*Cervical orthoses not requiring more than minor modification
*Pressure gradient hose
*Trusses
*Prefabricated spinal orthoses, except those used in the treatment of scoliosis, rigid body jackets made of thermoformable materials and halo devices
*Prefabricated orthoses of upper and lower extremities, except those used in the treatment of bone fractures

Registered Fitter Eligibility Pathways

1. Two years of fitter experience (minimum of 3,800 hours) under the supervision of an ABC certified practitioner, or
2. One year of fitter experience (minimum of 1,900 hours) under the supervision of an ABC certified practitioner in an ABC accredited patient care facility, or
3. Successful completion of an ABC approved orthotic fitter education program (CAMP, DeRoyal, Truform/SAI, DonJoy Orthopedics) and 1,000 hours of orthotic fitter experience, or
4. Possession of an orthotic fitter license (not an orthotic fitter assistant license) issued by a state orthotic/prosthetic licensing board, or
5. Possession of an orthotic practitioner credential (not a fitter credential) awarded by ABC or another national orthotic/prosthetic credentialing body.

All ABC credentialed individuals provide orthoses and prostheses by a written prescription, are bound by the ABC Canons of Ethical Conduct, which are enforced by a Professional Discipline program and are obligated to support and conform to professional responsibilities that promote and assure the overall welfare of the patient and the integrity of the profession. The time-limited credentials are based on participation in the Mandatory Continuing Education program.

Appendix D
Domains of Practice, Tasks and Knowledge and Skill Statements

The ABC *Practice Analysis of the Disciplines of Orthotics and Prosthetics* (2000) defines six domains of practice and fifty-one tasks and sixty-eight knowledge and skill statements for the ABC credentialed individual.

Domains are global areas of responsibility. Tasks are the activities performed within a domain in the course of practice. Knowledge and skill statements describe the organized body of information and the physical or mental manipulation of information or things required to perform the tasks associated with each domain.

Domains and Related Tasks:

Patient Assessment: Perform a comprehensive assessment of the patient to obtain an understanding of patient's orthotic/prosthetic needs.

- Review patient's prescription/referral
- Take a comprehensive patient history, including demographic characteristics, family dynamics, previous use of an orthosis/prosthesis, diagnosis, work history, avocational activities, signs and symptoms, medical history (including allergies to materials), reimbursement status, patient expectations, results of diagnostic evaluations
- Assist in formulating the treatment plan by performing a diagnosis-specific functional clinical examination that includes manual muscle testing, gait analysis, and evaluation of sensory function, cognitive ability, range of motion, joint stability, skin integrity, and compliance
- Consult with other healthcare professionals and caregivers about patient's condition to assist in formulating a treatment plan
- Communicate to patient and/or caregiver about the recommended treatment plan and any optional plans, include disclosure of potential risks/benefits in order to involve them in orthotic or prosthetic care
- Verify patient care by documenting history, ongoing care, and follow-up, using established record-keeping techniques
- Refer patient, if appropriate, to other healthcare professionals (e.g., psychologist, therapist, physician) for intervention beyond orthotic/prosthetic scope of practice

Formulation of the Treatment Plan: Create a comprehensive orthotic/prosthetic treatment plan to meet the needs and goals of the patient.

- Evaluate the findings to determine an orthotic/prosthetic recommendation
- Formulate treatment goals and expected orthotic/prosthetic outcomes to reduce pain/increase comfort, enhance function and independence, provide stability, prevent deformity, address cosmesis, and/or promote healing
- Consult with physician/referral source to modify, if necessary, the original prescription and/or treatment plan
- Identify material, design, and components to support anticipated outcome
- Develop a plan for patient needs, including patient education and follow-up
- Document treatment plan using established record-keeping techniques to verify patient care
- Inform patient or responsible parties of their financial responsibilities as they pertain to proposed treatment plan

Implementation of the Treatment Plan: Perform the necessary procedures to deliver the appropriate orthotic/prosthetic services, including fabrication.

- Inform patient, family, and/or caregiver of the orthotic/prosthetic procedure, possible risks, and time involved in the procedure
- Select appropriate material/techniques in order to implement treatment plan
- Provide patient with preparatory care for orthotic/prosthetic treatment (e.g., diagnostic splint, stump shrinker)
- Prepare patient for procedure required to initiate treatment plan (e.g., take impression, digitize, delineate, scan)
- Implement procedure (e.g., take impression, digitize, delineate, scan)
- Select appropriate materials, components, and specifications for orthosis/prosthesis based on patient criteria to ensure optimum strength, durability, and function as required
- (e.g., choose ankle or knee joints, feet, knee units; choose material of components, lamination layups)

- Consult technical component/material resources as required

- Prepare delineation/impression/template for modification/fabrication (e.g., prepare impression/reverse delineation, seal and fill impression/pour cast, digitize, strip model, download shape to carver or modification software)

- Modify and prepare patient model for fabrication

- Fabricate/assemble prescribed device by assembling selected materials/components in order to prepare for fitting and/or delivery (e.g., laminate/vacuum-form, remove socket/orthosis from model, smooth and finish orthosis/prosthesis, contour side bars to model/delineation, smooth and finish side bars, bench align components to socket, strap orthosis/prosthesis as necessary, perform final assembly of orthosis/prosthesis for patient fitting/delivery)

- Assess device for structural safety and ensure that manufacturers' guidelines have been followed prior to patient fitting/delivery (e.g., torque values, patient weight limits)

- Assess/align orthosis/prosthesis for accuracy in sagittal, transverse, and coronal planes in order to provide maximum function/comfort

- Ensure that materials, design, and components are fit/delivered as prescribed

- Complete fabrication process after achieving optimal fit of orthosis/prosthesis (e.g., convert test socket to definitive orthosis/prosthesis)

- Educate/counsel patient and/or caregiver about the use and maintenance of the orthosis/prosthesis (e.g., wearing schedules, therapy, other instructions)

- Reassess orthosis/prosthesis for structural safety prior to patient delivery (e.g., screws tightened, cover attached)

- Document treatment using established record-keeping techniques to verify implementation of treatment plan

Follow-up Treatment Plan: Provide continuing patient care and periodic evaluation to assure/maintain/document optimal fit and function of the orthosis/prosthesis.

- Solicit subjective feedback from patient and/or caregiver to determine status (e.g., wear schedule/tolerance, comfort, perceived benefits, perceived detriments, ability to don and doff, proper usage and function, overall patient satisfaction)

- Assess patient's functional level
- Assess patient's skin condition (e.g., integrity, color, temperature, and volume)
- Assess patient's general health, height, and weight, and note any changes
- Assess patient's psychosocial status, and note any changes (in family status, job, or caregiver)
- To determine need for changes relative to initial treatment goals, assess fit of orthosis/prosthesis with regard to strategic contact (e.g., 3-point force systems, total contact)
- To determine need for changes relative to initial treatment goals, assess fit of orthosis/prosthesis with regard to anatomical relationships to orthosis/prosthesis (e.g., trimlines, static/dynamic alignment)
- Formulate plan to modify orthosis/prosthesis based on findings and inform patient and/or caregiver of plan to modify orthosis/prosthesis
- Make or delegate modifications to orthosis/prosthesis (e.g., relieve pressure, change range of motion, change alignment, change components, add pressure-sensitive pad)
- Assess modified device for structural safety and ensure that manufacturers' guidelines (e.g., torque values, patient weight limits) have been followed
- Evaluate modifications to orthosis/prosthesis, including static and dynamic assessment, in order to confirm that goals and objectives of modifications have been met
- Reassess patient knowledge and understanding of goals and objectives to ensure proper use of orthosis/prosthesis relative to modifications
- Document all findings and actions and communicate with appropriate healthcare professionals (e.g., referral sources, colleagues, supervisor) to ensure patient status is updated
- Develop long-term follow-up plan relative to diagnosis/prognosis

Practice Management: Develop, implement, and/or monitor policies and procedures regarding human resource management, physical environment management, business/financial management, and organizational management.

- Plan, implement, evaluate, and document policies and procedures in compliance with all applicable federal and state laws and regulations and professional and ethical guidelines (e.g., FDA, ADA, OSHA, MSDS, ABC Canon of Ethics)

- Develop and implement personnel policies and procedures (e.g., benefits, training, incentives, staff recognition, regular performance appraisals)

- Establish procedures for patient care that comply with accepted medical/legal requirements by maintaining current education in those areas

- Demonstrate proper documentation of patient history and financial records by using established record-taking techniques in order to verify patient care and other pertinent information

- Communicate roles and expectations of employer or employees by providing documentation in order to create a professional, cooperative working environment and improve patient care

Promotion of Competency and Enhancement of Professional Practice: Participate in personal and professional development through continuing education, training, research, and organizational affiliations.

- Participate in continuing education and/or provide such education for other healthcare professionals, orthotic and prosthetic practitioners, associates, technicians, and office staff (e.g., publications, seminars, case studies)

- Participate in education for residents, students, and trainees

- Conduct or participate in product development research, clinical trials, and outcome evaluation studies

- Participate in the development, implementation, and monitoring of public policy regarding orthotics/prosthetics (e.g., provide testimony/information to legislative/ regulatory bodies, serve on professional committees and regulatory agencies)

- Participate in/with consumer organizations and nongovernmental organizations in order to promote competency and enhancement of orthotic/prosthetic profession

Knowledge and Skill Statements

Knowledge of musculoskeletal anatomy, including upper limb, lower limb, spinal

Knowledge of neuroanatomy

Knowledge of anatomical landmarks

Knowledge of kinesiology, including upper limb, lower limb, spinal

Knowledge of normal human locomotion

Knowledge of normal and pathological gait

Knowledge of tissue characteristics/management

Knowledge of volumetric control

Knowledge of planes of motion

Knowledge of biomechanics

Knowledge of pathologies (e.g., neurologic, muscular, orthopedic)

Knowledge of medical terminology

Knowledge of referral documents

Knowledge of procedures to record data

Knowledge of policies and procedures regarding privileged information

Knowledge of roles and responsibilities associated with other professions

Knowledge of reimbursement protocols (e.g., DMERC, HCFA)

Knowledge of material safety procedures and standards (e.g., OSHA, MSDS)

Knowledge of universal precautions, including sterile techniques and infection control

Knowledge of ethical standards regarding proper patient management

Knowledge of scope of practice related to orthotic/prosthetic credentials

Knowledge of when to refer the patient to other healthcare providers/caregivers

Knowledge of orthotic/prosthetic design

Knowledge of orthotic/prosthetic fitting criteria

Knowledge of trimlines

Knowledge of examination techniques, including range of motion (ROM) and manual muscle tests

Knowledge of impression-taking techniques, materials, devices, and equipment

Knowledge of rectification/modification procedures as they relate to specific orthotic/prosthetic designs

Knowledge of measurement tools and techniques

Knowledge of orthotic/prosthetic forms (e.g., assessment, orthometry, measurement, evaluation, outcomes)

Knowledge of materials science

Knowledge of componentry

Knowledge of alignment devices and techniques

Knowledge of hand and power tools

Knowledge of mechanics (e.g., levers and force systems)

Knowledge of care and maintenance of orthoses/prostheses

Knowledge of computer-aided design and manufacturing (CAD/CAM)

Knowledge of item warranty and warranty limitations

Knowledge of loss control (e.g., risk management, inventory control)

Knowledge of research methodology and literature

Knowledge of human development and aging, ranging from pediatric to geriatric, as they relate to orthotic and prosthetic treatment

Knowledge of available educational materials (e.g., videotapes)

Knowledge of federal and state rules, regulations, and guidelines (e.g., FDA, ADA)

Skill in interpreting referral documents (including X-rays)

Skill in interviewing patients and referral sources

Skill in taking histories and performing physical examinations

Skill in gross surface anatomy (e.g., identification of anatomical landmarks)

Skill in patient examination techniques (e.g., measuring range of motion [ROM], measuring muscle strength, positioning body segments)

Skill in interpretation of physical findings (e.g., recognizing skin pressures, dermatological conditions)

Skill in normal and pathological gait/motion analysis

Skill in orthotic/prosthetic gait/motion analysis

Skill in managing patients relative to their condition

Skill in impression-taking/measuring for orthoses/prostheses, including upper limb, lower limb, spinal

Skill in using mechanical measuring devices

Skill in using electrical measuring devices

Skill in using computer-based measuring devices

Skill in patient delineation rectification and/or patient model modification

Skill in orthotic/prosthetic fabrication

Skill in use of safety equipment

Skill in using hand and power tools

Skill in use of materials and components

Skill in use of alignment devices

Skill in cosmetic finishing

Skill in evaluating fit and function of an orthosis/prosthesis

Skill in maintaining and repairing components

Skill in restoring optimal fit and function of orthoses/prostheses

Skill in solving patient's problems related to ADLs (e.g., dressing, driving)

Skill in documentation

Appendix E
Categorization of Orthotic & Prosthetic HCPCS Payment Codes by Practitioner Skill Level

HCPCS Code	CMS Description	Device Rating
A5500	For Diabetics Only, Fitting (Including Follow-Up), Custom Preparation And Supply Of Off-The-Shelf Depth-Inlay Shoe Manufactured To Accommodate Multi-Density Insert(S) Per Shoe	Custom Fitted, High
A5501	For Diabetics Only, Fitting (Including Follow-Up), Custom Preparation And Supply Of Shoe Molded From Cast(S) Of Patients Foot (Custom Molded Shoe), Per Shoe	Custom Fabricated
A5508	For Diabetics Only, Deluxe Feature Of Off-The-Shelf Depth-Inlay Shoe Or Custom Molded Shoe, Per Shoe	Custom Fabricated
A5510	For Diabetics Only, Direct Formed, Compression Molded To Patient's Foot Without External Heat Source, Multiple Density Insert(S), Prefabricated, Per Shoe	Custom Fitted, High
K0628	For Diabetics Only, Multiple Density Insert, Direct Formed, Molded To Foot After External Heat Source Of 230 Degrees Fahrenheit Or Higher, Total Contact With Patient's Foot, Including Arch, Base Layer Minimum Of ¼ Inch Material Of Shore A 35 Durometer Of 3/16 Inch Material Of Shore A 40 Durometer (Or Higher), Prefabricated, Each	Custom Fitted, High
K0629	For Diabetics Only, Multiple Density Insert, Custom Molded From Model Of Patient's Foot, Total Contact With Patient's Foot, Including Arch, Base Layer Minimum Of 3/16 Inch Material Of Shore A 35 Durometer Or Higher, Includes Arch Filler And Other Shaping Material, Custom Fabricated, Each	Custom Fabricated
K0630	Sacroiliac Orthosis, Flexible, Provides Pelvic-Sacral Support, Reduces Motion About The Sacroiliac Joint, Includes Straps, Closures, May Include Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, low
K0631	Sacroiliac Orthosis, Flexible, Provides Pelvic-Sacral Support, Reduces Motion About The Sacroiliac Joint, Includes Straps, Closures, May Include Pendulous Abdomen Design, Custom Fabricated	Custom Fabricated
K0632	Sacroiliac Orthosis, Provides Pelvic-Sacral Support, With Rigid Or Semi-Rigid Panels Over The Sacrum And Abdomen, Reduces Motion About The Sacroiliac Joint, Includes Straps, Closures, May Include Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
K0633	Sacroiliac Orthosis, Provides Pelvic-Sacral Support, With Rigid Or Semi-Rigid Panels Placed Over The Sacrum And Abdomen, Reduces Motion About The Sacroiliac Joint, Includes Straps, Closures, May Include Pendulous Abdomen Design, Custom Fabricated	Custom Fabricated
K0634	Lumbar Orthosis, Flexible, Provides Lumbar Support, Posterior Extends From L-1 To Below L-5 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Pendulous Abdomen Design, Shoulder Straps, Stays, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, low
K0635	Lumbar Orthosis, Sagittal Control, With Rigid Posterior Panel(S), Posterior Extends From L-1 To Below L-5 Vertebrae, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Stays, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted High

HCPCS Code	CMS Description	Device Rating
K0636	Lumbar Orthosis, Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From L-1 To Below L-5 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
K0637	Lumbar-Sacral Orthosis, Flexible, Provides Lumbo-Sacral Support, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Stays, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
K0638	Lumbar-Sacral Orthosis, Flexible, Provides Lumbo-Sacral Support, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Stays, Shoulder Straps, Pendulous Abdomen Design, Custom Fabricated	Custom Fabricated
K0639	Lumbar-Sacral Orthosis, Sagittal Control, With Rigid Posterior Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Stays, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
K0640	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Disks, Includes Straps, ...** .... Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment **Per SADMERC, Should Read "Sagittal Control", Not "Sagittal-Coronal Control" And Should Have The Phrase "Closures, May Include Padding, Shoulder Straps," Inserted At Asterisk.**	Custom Fitted, High
K0641	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Custom Fabricated **Per SADMERC, Should Read "Sagittal Control", Not "Sagittal-Coronal Control."**	Custom Fabricated
K0642	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Posterior Frame/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Stays, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
K0643	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Posterior Frame/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Stays, Shoulder Straps, Pendulous Abdomen Design, Custom Fabricated	Custom Fabricated

HCPCS Code	CMS Description	Device Rating
K0644	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Lumbar Flexion, Rigid Posterior Frame/Panels, Lateral Articulating Design To Flex The Lumbar Spine, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Anterior Panel, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
K0645	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Lumbar Flexion, Rigid Posterior Frame/Panels, Lateral Articulating Design To Flex The Lumbar Spine, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Anterior Panel, Pendulous Abdomen Design, Custom Fabricated	Custom Fabricated
K0646	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
K0647	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Custom Fabricated	Custom Fabricated
K0648	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Rigid Shell(S)/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xiphoid, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Overall Strength Is Provided By Overlapping Rigid Material And Stabilizing Closures, Includes Straps, Closures, May Include Soft Interface, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
K0649	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Rigid Shell(S)/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xiphoid, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Overall Strength Is Provided By Overlapping Rigid Material And Stabilizing Closures, Includes Straps, Closures, May Include Soft Interface, Pendulous Abdomen Design, Custom Fabricated	Custom Fabricated
L0100	Cranial Orthosis (Helmet), With Or Without Soft Interface, Molded To Patient Model	Custom Fabricated
L0110	Cranial Orthosis (Helmet), With Or Without Soft Interface, Non-Molded	Custom Fitted, High
L0112	Cranial Cervical Orthosis, Congenital Torticollis Type, With Or Without Soft Interface Material, Adjustable Range Of Motion Joint, Custom Fabricated	Custom Fabricated
L0120	Cervical, Flexible, Non-Adjustable (Foam Collar)	Off the Shelf

HCPCS Code	CMS Description	Device Rating
L0130	Cervical, Flexible, Thermoplastic Collar, Molded To Patient	Custom Fabricated
L0140	Cervical, Semi-Rigid, Adjustable (Plastic Collar)	Custom Fitted, Low
L0150	Cervical, Semi-Rigid, Adjustable Molded Chin Cup (Plastic Collar With Mandibular/Occipital Piece)	Custom Fitted, Low
L0160	Cervical, Semi-Rigid, Wire Frame Occipital/Mandibular Support	Custom Fitted, Low
L0170	Cervical, Collar, Molded To Patient Model	Custom Fabricated
L0172	Cervical, Collar, Semi-Rigid Thermoplastic Foam, Two Piece	Custom Fitted, Low
L0174	Cervical, Collar, Semi-Rigid, Thermoplastic Foam, Two Piece With Thoracic Extension	Custom Fitted, Low
L0180	Cervical, Multiple Post Collar, Occipital/Mandibular Supports, Adjustable	Custom Fitted, High
L0190	Cervical, Multiple Post Collar, Occipital/Mandibular Supports, Adjustable Cervical Bars (Somi, Guilford, Taylor Types)	Custom Fitted, High
L0200	Cervical, Multiple Post Collar, Occipital/Mandibular Supports, Adjustable Cervical Bars, And Thoracic Extension	Custom Fitted, High
L0210	Thoracic, Rib Belt	Custom Fitted, Low
L0220	Thoracic, Rib Belt, Custom Fabricated	Custom Fabricated
L0430	Spinal Orthosis, Anterior-Posterior-Lateral Control, With Interface Material, Custom Fitted (Dewall Posture Protector Only)	Custom Fitted, Low
L0450	TLSO, Flexible, Provides Trunk Support, Upper Thoracic Region, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Disks With Rigid Stays Or Panel(S), Includes Shoulder Straps And Closures, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L0452	TLSO, Flexible, Provides Trunk Support, Upper Thoracic Region, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Disks With Rigid Stays Or Panel(S), Includes Shoulder Straps And Closures, Custom Fabricated	Custom Fabricated
L0454	TLSO, Flexible, Provides Trunk Support, Extends From Sacrococcygeal Junction To Above T-9 Vertebra, Restricts Gross Trunk Motion In The Sagittal Plane, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Disks With Rigid Stays Or Panel(S), Includes Shoulder Straps And Closures, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, low
L0456	TLSO, Flexible, Provides Trunk Support, Thoracic Region, Rigid Posterior Panel And Soft Anterior Apron, Extends From The Sacrococcygeal Junction And Terminates Just Inferior To The Scapular Spine, Restricts Gross Trunk Motion In The Sagittal Plane, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Disks, Includes Straps And Closures, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0458	TLSO, Triplanar Control, Modular Segmented Spinal System, Two Rigid Plastic Shells, Posterior Extends From The Sacrococcygeal Junction And Terminates Just Inferior To The Scapular Spine, Anterior Extends From The Symphysis Pubis To The Xiphoid, Soft Liner, Restricts Gross Trunk Motion In The Sagittal, Coronal, And Transverse Planes, Lateral Strength Is Provided By Overlapping Plastic And Stabilizing Closures, Includes Straps And Closures, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High

HCPCS Code	CMS Description	Device Rating
L0460	TLSO, Triplanar Control, Modular Segmented Spinal System, Two Rigid Plastic Shells, Posterior Extends From The Sacrococcygeal Junction And Terminates Just Inferior To The Scapular Spine, Anterior Extends From The Symphysis Pubis To The Sternal Notch, Soft Liner, Restricts Gross Trunk Motion In The Sagittal, Coronal, And Transverse Planes, Lateral Strength Is Provided By Overlapping Plastic And Stabilizing Closures, Includes Straps And Closures, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0462	TLSO, Triplanar Control, Modular Segmented Spinal System, Three Rigid Plastic Shells, Posterior Extends From The Sacrococcygeal Junction And Terminates Just Inferior To The Scapular Spine, Anterior Extends From The Symphysis Pubis To The Sternal Notch, Soft Liner, Restricts Gross Trunk Motion In The Sagittal, Coronal, And Transverse Planes, Lateral Strength Is Provided By Overlapping Plastic And Stabilizing Closures, Includes Straps And Closures, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0464	TLSO, Triplanar Control, Modular Segmented Spinal System, Four Rigid Plastic Shells, Posterior Extends From Sacrococcygeal Junction And Terminates Just Inferior To Scapular Spine, Anterior Extends From Symphysis Pubis To The Sternal Notch, Soft Liner, Restricts Gross Trunk Motion In Sagittal, Coronal, And Transverse Planes, Lateral Strength Is Provided By Overlapping Plastic And Stabilizing Closures, Includes Straps And Closures, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0466	TLSO, Sagittal Control, Rigid Posterior Frame And Flexible Soft Anterior Apron With Straps, Closures And Padding, Restricts Gross Trunk Motion In Sagittal Plane, Produces Intracavitary Pressure To Reduce Load On Intervertebral Disks, Includes Fitting And Shaping The Frame, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0468	TLSO, Sagittal-Coronal Control, Rigid Posterior Frame And Flexible Soft Anterior Apron With Straps, Closures And Padding, Extends From Sacrococcygeal Junction Over Scapulae, Lateral Strength Provided By Pelvic, Thoracic, And Lateral Frame Pieces, Restricts Gross Trunk Motion In Sagittal, And Coronal Planes, Produces Intracavitary Pressure To Reduce Load On Intervertebral Disks, Includes Fitting And Shaping The Frame, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0470	TLSO, Triplanar Control, Rigid Posterior Frame And Flexible Soft Anterior Apron With Straps, Closures And Padding, Extends From Sacrococcygeal Junction To Scapula, Lateral Strength Provided By Pelvic, Thoracic, And Lateral Frame Pieces, Rotational Strength Provided By Subclavicular Extensions, Restricts Gross Trunk Motion In Sagittal, Coronal, And Transverse Planes, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Disks, Includes Fitting And Shaping The Frame, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0472	TLSO, Triplanar Control, Hyperextension, Rigid Anterior And Lateral Frame Extends From Symphysis Pubis To Sternal Notch With Two Anterior Components (One Pubic And One Sternal), Posterior And Lateral Pads With Straps And Closures, Limits Spinal Flexion, Restricts Gross Trunk Motion In Sagittal, Coronal, And Transverse Planes, Includes Fitting And Shaping The Frame, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High

HCPCS Code	CMS Description	Device Rating
L0480	TLSO, Triplanar Control, One Piece Rigid Plastic Shell Without Interface Liner, With Multiple Straps And Closures, Posterior Extends From Sacrococcygeal Junction And Terminates Just Inferior To Scapular Spine, Anterior Extends From Symphysis Pubis To Sternal Notch, Anterior Or Posterior Opening, Restricts Gross Trunk Motion In Sagittal, Coronal, And Transverse Planes, Includes A Carved Plaster Or Cad-Cam Model, Custom Fabricated	Custom Fabricated
L0482	TLSO, Triplanar Control, One Piece Rigid Plastic Shell With Interface Liner, Multiple Straps And Closures, Posterior Extends From Sacrococcygeal Junction And Terminates Just Inferior To Scapular Spine, Anterior Extends From Symphysis Pubis To Sternal Notch, Anterior Or Posterior Opening, Restricts Gross Trunk Motion In Sagittal, Coronal, And Transverse Planes, Includes A Carved Plaster Or Cad-Cam Model, Custom Fabricated	Custom Fabricated
L0484	TLSO, Triplanar Control, Two Piece Rigid Plastic Shell Without Interface Liner, With Multiple Straps And Closures, Posterior Extends From Sacrococcygeal Junction And Terminates Just Inferior To Scapular Spine, Anterior Extends From Symphysis Pubis To Sternal Notch, Lateral Strength Is Enhanced By Overlapping Plastic, Restricts Gross Trunk Motion In The Sagittal, Coronal, And Transverse Planes, Includes A Carved Plaster Or Cad-Cam Model, Custom Fabricated	Custom Fabricated
L0486	TLSO, Triplanar Control, Two Piece Rigid Plastic Shell With Interface Liner, Multiple Straps And Closures, Posterior Extends From Sacrococcygeal Junction And Terminates Just Inferior To Scapular Spine, Anterior Extends From Symphysis Pubis To Sternal Notch, Lateral Strength Is Enhanced By Overlapping Plastic, Restricts Gross Trunk Motion In The Sagittal, Coronal, And Transverse Planes, Includes A Carved Plaster Or Cad-Cam Model, Custom Fabricated	Custom Fabricated
L0488	TLSO, Triplanar Control, One Piece Rigid Plastic Shell With Interface Liner, Multiple Straps And Closures, Posterior Extends From Sacrococcygeal Junction And Terminates Just Inferior To Scapular Spine, Anterior Extends From Symphysis Pubis To Sternal Notch, Anterior Or Posterior Opening, Restricts Gross Trunk Motion In Sagittal, Coronal, And Transverse Planes, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0490	TLSO, Sagittal-Coronal Control, One Piece Rigid Plastic Shell, With Overlapping Reinforced Anterior, With Multiple Straps And Closures, Posterior Extends From Sacrococcygeal Junction And Terminates At Or Before The T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xiphoid, Anterior Opening, Restricts Gross Trunk Motion In Sagittal And Coronal Planes, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0700	Cervical-Thoracic-Lumbar-Sacral-Orthoses (CTLSO), Anterior-Posterior-Lateral Control, Molded To Patient Model, (Minerva Type)	Custom Fabricated
L0710	CTLSO, Anterior-Posterior-Lateral-Control, Molded To Patient Model, With Interface Material, (Minerva Type)	Custom Fabricated
L0810	Halo Procedure, Cervical Halo Incorporated Into Jacket Vest	Custom Fitted, High
L0820	Halo Procedure, Cervical Halo Incorporated Into Plaster Body Jacket	Custom Fabricated
L0830	Halo Procedure, Cervical Halo Incorporated Into Milwaukee Type Orthosis	Custom Fabricated

HCPCS Code	CMS Description	Device Rating
L1000	Cervical-Thoracic-Lumbar-Sacral Orthosis (CTLSO) (Milwaukee), Inclusive Of Furnishing Initial Orthosis, Including Model	Custom Fabricated
L1005	Tension Based Scoliosis Orthosis And Accessory Pads, Includes Fitting And Adjustment	Custom Fitted, High
L1200	Thoracic-Lumbar-Sacral-Orthosis (TLSO), Inclusive Of Furnishing Initial Orthosis Only	Custom Fabricated
L1300	Other Scoliosis Procedure, Body Jacket Molded To Patient Model	Custom Fabricated
L1310	Other Scoliosis Procedure, Post-Operative Body Jacket	Custom Fabricated
L1500	Thoracic-Hip-Knee-Ankle Orthosis (THKAO), Mobility Frame (Newington, Parapodium Types)	Custom Fitted, High
L1510	THKAO, Standing Frame, With Or Without Tray And Accessories	Custom Fitted, High
L1520	THKAO, Swivel Walker	Custom Fitted, High
L1600	Hip Orthosis, Abduction Control Of Hip Joints, Flexible, Frejka Type With Cover, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, low
L1620	Hip Orthosis, Abduction Control Of Hip Joints, Flexible, (Pavlik Harness), Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1630	Hip Orthosis, Abduction Control Of Hip Joints, Semi-Flexible (Von Rosen Type), Custom-Fabricated	Custom Fabricated
L1640	Hip Orthosis, Abduction Control Of Hip Joints, Static, Pelvic Band Or Spreader Bar, Thigh Cuffs, Custom-Fabricated	Custom Fabricated
L1650	Hip Orthosis, Abduction Control Of Hip Joints, Static, Adjustable, (Ilfled Type), Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1652	Hip Orthosis, Bilateral Thigh Cuffs With Adjustable Abductor Spreader Bar, Adult Size, Prefabricated, Includes Fitting And Adjustment, Any Type	Custom Fitted, High
L1660	Hip Orthosis, Abduction Control Of Hip Joints, Static, Plastic, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1680	Hip Orthosis, Abduction Control Of Hip Joints, Dynamic, Pelvic Control, Adjustable Hip Motion Control, Thigh Cuffs (Rancho Hip Action Type), Custom Fabricated	Custom Fabricated
L1685	Hip Orthosis, Abduction Control Of Hip Joint, Postoperative Hip Abduction Type, Custom Fabricated	Custom Fabricated
L1686	Hip Orthosis, Abduction Control Of Hip Joint, Postoperative Hip Abduction Type, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1690	Combination, Bilateral, Lumbo-Sacral, Hip, Femur Orthosis Providing Adduction And Internal Rotation Control, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1700	Legg Perthes Orthosis, (Toronto Type), Custom-Fabricated	Custom Fabricated
L1710	Legg Perthes Orthosis, (Newington Type), Custom Fabricated	Custom Fabricated
L1720	Legg Perthes Orthosis, Trilateral, (Tachdijan Type), Custom-Fabricated	Custom Fabricated
L1730	Legg Perthes Orthosis, (Scottish Rite Type), Custom-Fabricated	Custom Fabricated
L1750	Legg Perthes Orthosis, Legg Perthes Sling (Sam Brown Type), Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low

HCPCS Code	CMS Description	Device Rating
L1755	Legg Perthes Orthosis, (Patten Bottom Type), Custom-Fabricated	Custom Fabricated
L1800	Knee Orthosis, Elastic With Stays, Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L1810	Knee Orthosis, Elastic With Joints, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L1815	Knee Orthosis, Elastic Or Other Elastic Type Material With Condylar Pad(S), Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L1820	Knee Orthosis, Elastic With Condylar Pads And Joints, With Or Without Patellar Control, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L1825	Knee Orthosis, Elastic Knee Cap, Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L1830	Knee Orthosis, Immobilizer, Canvas Longitudinal, Prefabricated, Includes Fitting And Adjustment	Custom Fitted,Low
L1831	Knee Orthosis, Locking Knee Joint(S), Positional Orthosis, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L1832	Knee Orthosis, Adjustable Knee Joints, Positional Orthosis, Rigid Support, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L1834	Knee Orthosis, Without Knee Joint, Rigid, Custom-Fabricated	Custom Fabricated
L1836	Knee Orthosis, Rigid, Without Joint(S), Includes Soft Interface Material, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L1840	Knee Orthosis, Derotation, Medial-Lateral, Anterior Cruciate Ligament, Custom Fabricated	Custom Fabricated
L1843	Knee Orthosis, Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint, Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1844	Knee Orthosis, Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint, Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Custom Fabricated	Custom Fabricated
L1845	Knee Orthosis, Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint, Medial-Lateral And Rotation Control, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1846	Knee Orthosis, Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint, Medial-Lateral And Rotation Control, Custom Fabricated	Custom Fabricated
L1847	Knee Orthosis, Double Upright With Adjustable Joint, With Inflatable Air Support Chamber(S), Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1850	Knee Orthosis, Swedish Type, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L1855	Knee Orthosis, Molded Plastic, Thigh And Calf Sections, With Double Upright Knee Joints, Custom-Fabricated	Custom Fabricated
L1858	Knee Orthosis, Molded Plastic, Polycentric Knee Joints, Pneumatic Knee Pads (CTI), Custom-Fabricated	Custom Fabricated
L1860	Knee Orthosis, Modification Of Supracondylar Prosthetic Socket, Custom-Fabricated (Sk)	Custom Fabricated
L1870	Knee Orthosis, Double Upright, Thigh And Calf Lacers With Knee Joints, Custom-Fabricated	Custom Fabricated

HCPCS Code	CMS Description	Device Rating
L1880	Knee Orthosis, Double Upright, Non-Molded Thigh And Calf Cuffs/Lacers With Knee Joints, Custom-Fabricated	Custom Fabricated
L1900	Ankle Foot Orthosis, Spring Wire, Dorsiflexion Assist Calf Band, Custom-Fabricated	Custom Fabricated
L1901	Ankle Orthosis, Elastic, Prefabricated, Includes Fitting And Adjustment (E.G. Neoprene, Lycra)	Off the Shelf
L1902	Ankle Foot Orthosis, Ankle Gauntlet, Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L1904	Ankle Foot Orthosis, Molded Ankle Gauntlet, Custom-Fabricated	Custom Fabricated
L1906	Ankle Foot Orthosis, Multiligamentus Ankle Support, Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L1907	Ankle Foot Orthosis, Supramalleolar With Straps, With Or Without Interface/Pads, Custom Fabricated	Custom Fabricated
L1910	Ankle Foot Orthosis, Posterior, Single Bar, Clasp Attachment To Shoe Counter, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L1920	Ankle Foot Orthosis, Single Upright With Static Or Adjustable Stop (Phelps Or Perlstein Type), Custom-Fabricated	Custom Fabricated
L1930	Ankle Foot Orthosis, Plastic Or Other Material, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1932	Ankle Foot Orthosis, Rigid Anterior Tibial Section, Total Carbon Fiber Or Equal Material, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1940	Ankle Foot Orthosis, Plastic Or Other Material, Custom Fabricated	Custom Fabricated
L1945	Ankle Foot Orthosis, Plastic, Rigid Anterior Tibial Section (Floor Reaction), Custom-Fabricated	Custom Fabricated
L1950	Ankle Foot Orthosis, Spiral, (Institute Of Rehabilitative Medicine Type), Plastic, Custom-Fabricated	Custom Fabricated
L1951	Ankle Foot Orthosis, Spiral, (Institute Of Rehabilitative Medicine Type), Plastic Or Other Material, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1960	Ankle Foot Orthosis, Posterior Solid Ankle, Plastic, Custom-Fabricated	Custom Fabricated
L1970	Ankle Foot Orthosis, Plastic With Ankle Joint, Custom-Fabricated	Custom Fabricated
L1971	Ankle Foot Orthosis, Plastic Or Other Material With Ankle Joint, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1980	Ankle Foot Orthosis, Single Upright Free Plantar Dorsiflexion, Solid Stirrup, Calf Band/Cuff (Single Bar 'BK' Orthosis), Custom-Fabricated	Custom Fabricated
L1990	Ankle Foot Orthosis, Double Upright Free Plantar Dorsiflexion, Solid Stirrup, Calf Band/Cuff (Double Bar 'BK' Orthosis), Custom-Fabricated	Custom Fabricated
L2000	Knee Ankle Foot Orthosis, Single Upright, Free Knee, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs (Single Bar 'AK' Orthosis), Custom-Fabricated	Custom Fabricated
L2005	Knee Ankle Foot Orthosis, Any Material, Single Or Double Upright, Stance Control, Automatic Lock And Swing Phase Release, Mechanical Activation, Includes Ankle Joint, Any Type, Custom Fabricated	Custom Fabricated
L2010	Knee Ankle Foot Orthosis, Single Upright, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs (Single Bar 'AK' Orthosis), Without Knee Joint, Custom-Fabricated	Custom Fabricated

HCPCS Code	CMS Description	Device Rating
L2020	Knee Ankle Foot Orthosis, Double Upright, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs (Double Bar 'AK' Orthosis), Custom-Fabricated	Custom Fabricated
L2030	Knee Ankle Foot Orthosis, Double Upright, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs, (Double Bar 'AK' Orthosis), Without Knee Joint, Custom Fabricated	Custom Fabricated
L2035	Knee Ankle Foot Orthosis, Full Plastic, Static (Pediatric Size), Without Free Motion Ankle, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L2036	Knee Ankle Foot Orthosis, Full Plastic, Double Upright, Free Knee, With Or Without Free Motion Ankle, Custom-Fabricated	Custom Fabricated
L2037	Knee Ankle Foot Orthosis, Full Plastic, Single Upright, Free Knee, With Or Without Free Motion Ankle, Custom-Fabricated	Custom Fabricated
L2038	Knee Ankle Foot Orthosis, Full Plastic, Without Knee Joint, Multi-Axis Ankle, Custom-Fabricated	Custom Fabricated
L2039	Knee Ankle Foot Orthosis, Full Plastic, Single Upright, Poly-Axial Hinge, Medial Lateral Rotation Control, With Or Without Free Motion Ankle, Custom-Fabricated	Custom Fabricated
L2040	Hip Knee Ankle Foot Orthosis, Torsion Control, Bilateral Rotation Straps, Pelvic Band/Belt, Custom Fabricated	Custom Fabricated
L2050	Hip Knee Ankle Foot Orthosis, Torsion Control, Bilateral Torsion Cables, Hip Joint, Pelvic Band/Belt, Custom-Fabricated	Custom Fabricated
L2060	Hip Knee Ankle Foot Orthosis, Torsion Control, Bilateral Torsion Cables, Ball Bearing Hip Joint, Pelvic Band/ Belt, Custom-Fabricated	Custom Fabricated
L2070	Hip Knee Ankle Foot Orthosis, Torsion Control, Unilateral Rotation Straps, Pelvic Band/Belt, Custom Fabricated	Custom Fabricated
L2080	Hip Knee Ankle Foot Orthosis, Torsion Control, Unilateral Torsion Cable, Hip Joint, Pelvic Band/Belt, Custom-Fabricated	Custom Fabricated
L2090	Hip Knee Ankle Foot Orthosis, Torsion Control, Unilateral Torsion Cable, Ball Bearing Hip Joint, Pelvic Band/ Belt, Custom-Fabricated	Custom Fabricated
L2106	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Cast Orthosis, Thermoplastic Type Casting Material, Custom-Fabricated	Custom Fabricated
L2108	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Cast Orthosis, Custom-Fabricated	Custom Fabricated
L2112	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Orthosis, Soft, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L2114	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Orthosis, Semi-Rigid, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L2116	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Orthosis, Rigid, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L2126	Knee Ankle Foot Orthosis, Fracture Orthosis, Femoral Fracture Cast Orthosis, Thermoplastic Type Casting Material, Custom-Fabricated	Custom Fabricated
L2128	Knee Ankle Foot Orthosis, Fracture Orthosis, Femoral Fracture Cast Orthosis, Custom-Fabricated	Custom Fabricated
L2132	KAFO, Fracture Orthosis, Femoral Fracture Cast Orthosis, Soft, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L2134	KAFO, Fracture Orthosis, Femoral Fracture Cast Orthosis, Semi-Rigid, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L2136	KAFO, Fracture Orthosis, Femoral Fracture Cast Orthosis, Rigid, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High

HCPCS Code	CMS Description	Device Rating
L3000	Foot, Insert, Removable, Molded To Patient Model, "UCB" Type, Berkeley Shell, Each	Custom Fabricated
L3001	Foot, Insert, Removable, Molded To Patient Model, Spenco, Each	Custom Fabricated
L3002	Foot, Insert, Removable, Molded To Patient Model, Plastazote Or Equal, Each	Custom Fabricated
L3003	Foot, Insert, Removable, Molded To Patient Model, Silicone Gel, Each	Custom Fabricated
L3010	Foot, Insert, Removable, Molded To Patient Model, Longitudinal Arch Support, Each	Custom Fabricated
L3020	Foot, Insert, Removable, Molded To Patient Model, Longitudinal/ Metatarsal Support, Each	Custom Fabricated
L3030	Foot, Insert, Removable, Formed To Patient Foot, Each	Custom Fabricated
L3040	Foot, Arch Support, Removable, Premolded, Longitudinal, Each	Off the Shelf
L3050	Foot, Arch Support, Removable, Premolded, Metatarsal, Each	Off the Shelf
L3060	Foot, Arch Support, Removable, Premolded, Longitudinal/ Metatarsal, Each	Off the Shelf
L3070	Foot, Arch Support, Non-Removable Attached To Shoe, Longitudinal, Each	Custom Fitted, Low
L3080	Foot, Arch Support, Non-Removable Attached To Shoe, Metatarsal, Each	Custom Fitted, Low
L3090	Foot, Arch Support, Non-Removable Attached To Shoe, Longitudinal/Metatarsal, Each	Custom Fitted, Low
L3100	Hallus-Valgus Night Dynamic Splint	Off the Shelf
L3140	Foot, Abduction Rotation Bar, Including Shoes	Custom Fitted, High
L3150	Foot, Abduction Rotation Bar, Without Shoes	Custom Fitted, High
L3160	Foot, Adjustable Shoe-Styled Positioning Device	Custom Fitted, High
L3170	Foot, Plastic Heel Stabilizer	Off the Shelf
L3201	Orthopedic Shoe, Oxford With Supinator Or Pronator, Infant	Custom Fitted, Low
L3202	Orthopedic Shoe, Oxford With Supinator Or Pronator, Child	Custom Fitted, Low
L3203	Orthopedic Shoe, Oxford With Supinator Or Pronator, Junior	Custom Fitted, Low
L3204	Orthopedic Shoe, Hightop With Supinator Or Pronator, Infant	Custom Fitted, Low
L3206	Orthopedic Shoe, Hightop With Supinator Or Pronator, Child	Custom Fitted, Low
L3207	Orthopedic Shoe, Hightop With Supinator Or Pronator, Junior	Custom Fitted, Low
L3208	Surgical Boot, Each, Infant	Custom Fitted, Low
L3209	Surgical Boot, Each, Child	Custom Fitted, Low
L3211	Surgical Boot, Each, Junior	Custom Fitted, Low
L3212	Benesch Boot, Pair, Infant	Custom Fitted, Low
L3213	Benesch Boot, Pair, Child	Custom Fitted, Low
L3214	Benesch Boot, Pair, Junior	Custom Fitted, Low
L3215	Orthopedic Footwear, Ladies Shoes, Oxford	Custom Fitted, Low
L3216	Orthopedic Footwear, Ladies Shoes, Depth Inlay	Custom Fitted, Low
L3217	Orthopedic Footwear, Ladies Shoes, Hightop, Depth Inlay	Custom Fitted, Low
L3219	Orthopedic Footwear, Men's Shoes, Oxford	Custom Fitted, Low
L3221	Orthopedic Footwear, Men's Shoes, Depth Inlay	Custom Fitted, Low
L3222	Orthopedic Footwear, Men's Shoes, Hightop, Depth Inlay	Custom Fitted, Low
L3230	Orthopedic Footwear, Custom Shoes, Depth Inlay	Custom Fabricated

HCPCS Code	CMS Description	Device Rating
L3250	Orthopedic Footwear, Custom Molded Shoe, Removable Inner Mold, Prosthetic Shoe, Each	Custom Fabricated
L3251	Foot, Shoe Molded To Patient Model, Silicone Shoe, Each	Custom Fabricated
L3252	Foot, Shoe Molded To Patient Model, Plastazote (Or Similar), Custom Fabricated, Each	Custom Fabricated
L3253	Foot, Molded Shoe Plastazote (Or Similar) Custom Fitted, Each	Custom Fitted, High
L3260	Surgical Boot/Shoe, Each	Custom Fitted, Low
L3265	Plastazote Sandal, Each	Custom Fitted, High
L3485	Heel, Pad, Removable For Spur	Off the Shelf
L3650	Shoulder Orthosis, Figure Of Eight Design Abduction Restrainer, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3651	Shoulder Orthosis, Single Shoulder, Elastic, Prefabricated, Includes Fitting And Adjustment (E.G. Neoprene, Lycra)	Custom Fitted, Low
L3652	Shoulder Orthosis, Double Shoulder, Elastic, Prefabricated, Includes Fitting And Adjustment (E.G. Neoprene, Lycra)	Custom Fitted, Low
L3660	Shoulder Orthosis, Figure Of Eight Design Abduction Restrainer, Canvas And Webbing, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3670	Shoulder Orthosis, Acromio/Clavicular (Canvas And Webbing Type), Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3675	Shoulder Orthosis, Vest Type Abduction Restrainer, Canvas Webbing Type Or Equal, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3677	Shoulder Orthosis, Hard Plastic, Shoulder Stabilizer, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3700	Elbow Orthosis, Elastic With Stays, Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L3701	Elbow Orthosis, Elastic, Prefabricated, Includes Fitting And Adjustment (E.G. Neoprene, Lycra)	Off the Shelf
L3710	Elbow Orthosis, Elastic With Metal Joints, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3720	Elbow Orthosis, Double Upright With Forearm/Arm Cuffs, Free Motion, Custom-Fabricated	Custom Fabricated
L3730	Elbow Orthosis, Double Upright With Forearm/Arm Cuffs, Extension/ Flexion Assist, Custom-Fabricated	Custom Fabricated
L3740	Elbow Orthosis, Double Upright With Forearm/Arm Cuffs, Adjustable Position Lock With Active Control, Custom-Fabricated	Custom Fabricated
L3760	Elbow Orthosis, With Adjustable Position Locking Joint(S), Prefabricated, Includes Fitting And Adjustments, Any Type	Custom Fitted, High
L3762	Elbow Orthosis, Rigid, Without Joints, Includes Soft Interface Material, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3800	Wrist Hand Finger Orthosis, Short Opponens, No Attachments, Custom-Fabricated	Custom Fabricated
L3805	Wrist Hand Finger Orthosis, Long Opponens, No Attachment, Custom-Fabricated	Custom Fabricated
L3807	Wrist Hand Finger Orthosis, Without Joint(S), Prefabricated, Includes Fitting And Adjustments, Any Type	Custom Fitted, High

HCPCS Code	CMS Description	Device Rating
L3900	Wrist Hand Finger Orthosis, Dynamic Flexor Hinge, Reciprocal Wrist Extension/ Flexion, Finger Flexion/Extension, Wrist Or Finger Driven, Custom-Fabricated	Custom Fabricated
L3901	Wrist Hand Finger Orthosis, Dynamic Flexor Hinge, Reciprocal Wrist Extension/ Flexion, Finger Flexion/Extension, Cable Driven, Custom-Fabricated	Custom Fabricated
L3902	Wrist Hand Finger Orthosis, External Powered, Compressed Gas, Custom-Fabricated	Custom Fabricated
L3904	Wrist Hand Finger Orthosis, External Powered, Electric, Custom-Fabricated	Custom Fabricated
L3906	Wrist Hand Orthosis, Wrist Gauntlet, Custom-Fabricated	Custom Fabricated
L3907	Wrist Hand Finger Orthosis, Wrist Gauntlet With Thumb Spica, Custom-Fabricated	Custom Fabricated
L3908	Wrist Hand Orthosis, Wrist Extension Control Cock-Up, Non Molded, Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L3909	Wrist Orthosis, Elastic, Prefabricated, Includes Fitting And Adjustment (E.G. Neoprene, Lycra)	Off the Shelf
L3910	Wrist Hand Finger Orthosis, Swanson Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3911	Wrist Hand Finger Orthosis, Elastic, Prefabricated, Includes Fitting And Adjustment (E.G. Neoprene, Lycra)	Off the Shelf
L3912	Hand Finger Orthosis, Flexion Glove With Elastic Finger Control, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3914	Wrist Hand Orthosis, Wrist Extension Cock-Up, Prefabricated, Includes Fitting/Adjustment	Off the Shelf
L3916	Wrist Hand Finger Orthosis, Wrist Extension Cock-Up With Outrigger, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3917	Hand Orthosis, Metacarpal Fracture, Orthosis, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3918	Hand Finger Orthosis, Knuckle Bender, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3920	Hand Finger Orthosis, Knuckle Bender With Outrigger, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3922	Hand Finger Orthosis, Knuckle Bender, Two Segment To Flex Joints, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3923	Hand Finger Orthosis, Without Joint(S), Prefabricated, Includes Fitting And Adjustments, Any Type	Custom Fitted, High
L3924	Wrist Hand Finger Orthosis, Oppenheimer, Prefabricated, Includes Fitting And Adjustable	Custom Fitted, High
L3926	Wrist Hand Finger Orthosis, Thomas Suspension, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3928	Hand Finger Orthosis, Finger Extension, With Clock Spring, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3930	Wrist Hand Finger Orthosis, Finger Extension, With Wrist Support, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3932	Finger Orthosis, Safety Pin, Spring Wire, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low

HCPCS Code	CMS Description	Device Rating
L3934	Finger Orthosis, Safety Pin, Modified, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3936	Wrist Hand Finger Orthosis, Palmer, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3938	Wrist Hand Finger Orthosis, Dorsal Wrist, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3940	Wrist Hand Finger Orthosis, Dorsal Wrist, With Outrigger Attachment, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3942	Hand Finger Orthosis, Reverse Knuckle Bender, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3944	Hand Finger Orthosis, Reverse Knuckle Bender, With Outrigger, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3946	Hand Finger Orthosis, Composite Elastic, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3948	Finger Orthosis, Finger Knuckle Bender, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3950	Wrist Hand Finger Orthosis, Combination Oppenheimer, With Knuckle Bender And Two Attachments, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3952	Wrist Hand Finger Orthosis, Combination Oppenheimer, With Reverse Knuckle And Two Attachments, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3954	Hand Finger Orthosis, Spreading Hand, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3960	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning, Airplane Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3962	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning, Erbs Palsey Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3963	Shoulder Elbow Wrist Hand Orthosis, Molded Shoulder, Arm, Forearm And Wrist, With Articulating Elbow Joint, Custom-Fabricated	Custom Fabricated
L3980	Upper Extremity Fracture Orthosis, Humeral, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3982	Upper Extremity Fracture Orthosis, Radius/Ulnar, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3984	Upper Extremity Fracture Orthosis, Wrist, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3985	Upper Extremity Fracture Orthosis, Forearm, Hand With Wrist Hinge, Custom-Fabricated	Custom Fabricated
L3986	Upper Extremity Fracture Orthosis, Combination Of Humeral, Radius/Ulnar, Wrist, (Example--Colles' Fracture), Custom Fabricated	Custom Fabricated
L4350	Ankle Control Orthosis, Stirrup Style, Rigid, Any Type Interface (E.G. Pneumatic, Gel) Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L4360	Walking Boot, Pneumatic With Or Without Interface Material, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L4370	Pneumatic Full Leg Splint, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L4380	Pneumatic Knee Splint, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low

HCPCS Code	CMS Description	Device Rating
L4386	Walking Boot, Non-Pneumatic, With Or Without Joints, With Or Without Interface Material, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L4396	Static AFO, Including Soft Interface Material, Adjustable For Fit, For Positioning, Pressure Reduction, May Be Used For Minimal Ambulation, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L4398	Foot Drop Splint, Recumbent Positioning Device, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low

Note: All prosthetic devices are custom fabricated.
Orthotic repair codes L4000 through L4210 are considered custom fabricated.

ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

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June 28, 2006

2006 JUN 28 PM 3:38

Mark McClellan, MD, PhD
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Humphrey Building, Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Proposed Rules on Competitive Acquisition for Durable Medical Equipment (CMS-1270-P)

Dear Dr. McClellan:

These comments are submitted by the American Society of Clinical Oncology (ASCO) in response to the proposed rules on the competitive acquisition program for durable medical equipment (DME) published in the Federal Register on May 1, 2006. ASCO is the national organization representing physicians who specialize in the treatment of cancer.

As discussed below, ASCO has two concerns with the proposed rules related to the use of ambulatory infusion pumps, which oncologists use to administer certain types of chemotherapy to patients:

- Although physicians are permitted to submit bids to become vendors under the program, it seems likely that physicians will fail to qualify if there is a large vendor with substantial capacity that is also bidding. ASCO requests that physicians who furnish ambulatory infusion pumps only to their own patients should be permitted to do so if they are willing to accept the Medicare payment amount determined in the competition.

- The proposal appears to require vendors of ambulatory infusion pumps to supply the drugs involved as well as the pumps. This approach could be disruptive to appropriate cancer care, and ASCO requests that physicians should be permitted to continue furnishing the drugs even if the pump is obtained from a vendor.

Background

Under the proposed rules, CMS would phase in a competitive acquisition program for DME. In the case of items subject to the program that are furnished in the geographical areas covered by the program, Medicare would reimburse for an item only if it is obtained from one of the vendors selected in the competitive bidding process.

The proposed bidding process would require each bidder to specify the volume of items that it is capable of supplying. CMS would select as winning bidders the vendors with the lowest bids but only as many such bidders as is necessary to fulfill the estimated quantity required. The law requires that there be at least two vendors selected. If the lowest bidding vendors have a large capacity to provide items, it seems likely that only the minimum two would be approved.

The proposal specifies that bidders would have to furnish supplies used in connection with the DME, including drugs. Thus, in the case of ambulatory infusion pumps, the vendors would apparently be required to supply the drugs administered through the pumps.

Physicians who furnish DME to their patients would be required to bid successfully in order to continue doing so if the DME at issue is subject to the competitive acquisition program. Unlike other bidders, who must furnish DME to the general community, physicians who are successful bidders may furnish DME only to their own patients.

Ambulatory Infusion Pumps

Oncologists often furnish ambulatory infusion pumps to their patients. These pumps are used in certain chemotherapy regimens that call for continuous infusion by pump. The so-called Stark law, which generally prohibits physicians from furnishing DME to their patients, expressly allows physicians to furnish infusion pumps.

ASCO is concerned about how the proposed rules would affect the ability of oncologists to furnish ambulatory infusion pumps to their patients. First, under the proposal, if the lowest bidders are able to satisfy the volume of DME needed, no further bidders will be selected. If there is a bidder with a large capacity, this method seems likely, as a practical matter, to exclude physicians from the possibility of bidding successfully. ASCO suggests that physicians who intend to serve only their own patients should not subject to selection in the same manner as vendors who intend to serve the general community. The rules should permit physicians who are willing to provide ambulatory infusion pumps at the rate approved for successful bidders to continue to do so.

Second, we question the proposed requirement that vendors of ambulatory infusion pumps must supply the drugs involved. Currently, even if a pump is obtained from an outside vendor, the drugs involved are typically prepared in the oncologist's office. Under this approach, oncologists have confidence in the integrity of the drugs and the accuracy of the amount of drug

in the pump. The logistics of requiring the pump vendor to prepare the drugs for specific patients would also seem to present practical problems that could be disruptive to appropriate patient care. ASCO requests that, even if a pump is obtained from an outside vendor, physicians should be permitted to furnish the drugs involved.

Thank you for your consideration of these comments.

Sincerely,

Joseph S. Bailes

Joseph S. Bailes, MD
Interim Executive Vice President and CEO

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June 29, 2006

VIA HAND DELIVERY

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: **CMS-1270-P; Comments Regarding Covered Item Updates for Class III Durable Medical Equipment for CYs 2007 and 2008**

Dear Dr. McClellan:

Smith & Nephew, Inc. is pleased to submit comments on the Covered Item Updates for Class III Durable Medical Equipment (DME) for Calendar Years (CYs) 2007 and 2008 in the proposed rule issued by the Centers for Medicare and Medicaid Services (CMS).[1] Smith & Nephew develops and markets advanced medical devices that help healthcare professionals treat patients more effectively by specializing in innovative, cost-effective products that meet pressing healthcare needs. Our three global business units are comprised of orthopaedics, endoscopy and advanced wound management. With the help of our products, doctors, nurses and surgeons can provide treatment more quickly and economically – and with better results. Patients, likewise, enjoy improved mobility and/or flexibility, recover from surgery quicker, find their conditions easier to manage and see an improved quality of life.

As you know, Section 4062 of the Omnibus Budget Reconciliation Act of 1987[2] added section 1834 to the Social Security Act (SSA) and implemented a fee schedule payment methodology for most DME products, prosthetic devices, and orthotic devices furnished after January 1, 1989. The SSA also set forth separate and unique payment categories of DME and describes how the fee schedule for each category is established.[3] As the proposed rule notes, a fee schedule amount is calculated for each item or category of DME that is identified

[1] Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed rule with comment period, 71 Fed. Reg. 25654 (May 1, 2006).

[2] Pub. L. 100-203.

[3] SSA § 1834(a)(2) through (a)(5) and § 1834(a)(7), as well as § 414.200 through §414.232 (with the exception of §414.228) of the regulations.

by a code in the Healthcare Common Procedure Coding System (HCPCS) and this fee schedule is generally adjusted annually by the change in the CPI-U[4] for the 12-month period ending June 30 of the preceding year.

Section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandates that in making the appropriate fee schedule update percentage for CY 2007 for DME Class III medical devices[5], the Secretary shall take into account recommendations contained in a report from the Government Accounting Office (GAO) regarding the appropriate update percentages for these devices. The GAO report must be submitted to the Congress and transmitted to the Secretary of Health and Human Services by no later than March 1, 2006.[6] Indeed, the GAO submitted its report to Congress on March 1, 2006.[7] In conjunction with the GAO's recommendations, CMS is soliciting comments on how to determine the appropriate fee schedule percentage change for these devices for CY 2007 and 2008. Smith & Nephew is pleased to comment on the fee schedule update, particularly as it relates to the GAO's recommendations.

As the proposed rule states, Class III devices paid in accordance with the DME fee schedule payment methodology include osteogenesis or bone growth stimulators, among other items.[8] Smith & Nephew Orthopaedics makes a low-intensity pulsed ultrasound treatment for nonunion bone fractures. The device is called the Exogen™ Bone Healing System. In recognition of the important health benefits offered by this non-invasive technology, CMS recently expanded its coverage (by no longer requiring a failed surgical intervention prior to coverage).

Smith & Nephew respects the importance and necessity of implementing a sound, reasonable fee schedule for all medical devices. With healthcare budgets under continuous pressure, cost-effective treatment is paramount to payers, providers and patients. Indeed, we take pride in the fact that our products provide cost-effective, high quality treatment with clinically-proven results. In fact, our ability to continue to produce high-quality, cost-effective products relies greatly on the payment we receive from the Medicare program, and for the reasons described below, we urge CMS to continue with the CPI-U annual update for Class III medical devices.

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[4] Consumer Price Index for all urban consumers, as compiled by the Bureau of Labor Statistics.

[5] As described in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)) § 513(a)(1)(C), a Class III medical device intended for human use is subject to pre-market approval because (I) insufficient information exists to determine the assurance of the safety and effectiveness of the device, and because (II) the device is purported or represented to be for use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human life.

[6] MMA § 302(c)(1)(B).

[7] GAO-06-62 Medicare Durable Medical Equipment, Class III Devices Do Not Warrant a Distinct Annual Payment Update.

[8] 71 Fed. Reg. at 25660.

In its March 2006 report to Congress, the GAO recommends that the Secretary of Health and Human Services establish a uniform payment update to the DME fee schedule for 2007 for Class II and III devices. It also recommends that Congress should consider establishing a uniform payment update to the DME fee schedule for 2008 for Class II and III devices.[9] Smith & Nephew respects the diligent research that GAO researchers undertook in preparing their report. In fact, Smith & Nephew communicated with the GAO both orally and in writing to help with research efforts. Nevertheless, we were dismayed that the GAO concluded that Class III devices do not warrant a distinct annual payment update. We have several concerns regarding the conclusions reached by the GAO.

First, GAO only compared pre-marketing costs of certain Class II and Class III devices, and wrongly concluded that because these pre-marketing costs are similar and included in initial retail pricing, Class III devices do not warrant unique updates. However, pre-marketing costs for Class III devices are generally far higher than Class II devices. Pre-marketing costs, such as FDA user fees; research and development costs; maintenance and improvement; and the revenue "withhold" time incurred waiting for FDA application and approval processes, all generate significantly more expense to Class III devices when compared to Class II devices.[10] However, these differences are not apparent from the GAO's comparison of Class II and Class III devices, since the Class II devices GAO chose to analyze are not fair representatives of *all* Class II products. The GAO looked only at a small number of Class II products that are "similar" to Class III devices, without showing that these Class II products are representative of most Class II products, and then decided, based on this small comparison of products, to recommend that *all* Class III devices be held at the same payment update as *all* Class II counterparts.

Moreover, the GAO states that "because the initial payment rates for all classes of devices on the Medicare DME fee schedule are based on retail prices, or an equivalent measure, they account for the costs of Class III and similar Class II devices in a consistent manner." This is the crux of the GAO's decision to recommend no distinct updates for the two different classes of devices. However, as the GAO reveals in its report, "the payment rate of a device is generally lower than its retail price." Contrary to the GAO's recommendation, we at Smith & Nephew believe this statement actually warrants a payment update.

Second, in our opinion, the GAO report's conclusion is unclear. The report concludes that "Class III devices do not warrant a distinct annual payment update," and readers are left to assume that because Congress has specified a 0% update for Class II devices in 2007, that the same would be appropriate for Class III devices. However, the GAO report only supports its conclusion by comparing Class III with a limited number of "similar" Class II devices; therefore, it would be equally valid to conclude that, rather than receiving a 0% update, these similar Class II devices actually warrant an update equal to the annual percentage increase in

[9] GAO-06-62 at p. 10-11.

[10] Specifically, the GAO found that the user fee for Class III devices subject to review in 2005 was $239,237, while the fee for Class II devices in 2005 was $3,052.

the CPI-U, which would put them on par with previous DME fee schedule updates for Class III devices.

Third, post-marketing costs differ significantly for Class II and Class III devices, and the GAO report did not analyze these postmarketing costs. Significant modifications to and new indications for Class II devices generally require pre-market notification, which generally does not require the submission of clinical data and only requires payment of minimal user fees. However, expanding the indications of, or making improvements to Class III devices often requires pre-market approval (PMA), which often requires the submission of clinical data and significant user fees. Smith & Nephew has submitted over 10 PMA supplements for Exogen in the last six years. These costly efforts to improve Class III products and expand their indications improve patient care, but would not be possible without adequate reimbursement.

In addition, manufacturers of Class III devices are often required to perform post-marketing clinical studies as a condition of a PMA. These studies involve continuing the follow-up of a pivotal clinical trial or an entirely new study. According to FDA, between 1998 and 2000, 35.4% of all PMAs required condition of approval clinical studies. Costs for post-approval studies are similar to those for pivotal pre-approval trials. However, 510k clearances for Class II devices do not require condition of approval studies.

Finally, we believe that the GAO mischaracterizes DME manufacturers' responses to the report's conclusions. The GAO report states that "industry representatives who reviewed a draft of this report did not agree or disagree with our matter for congressional consideration or our recommendation for executive action." To the contrary, Smith & Nephew, along with other Class III device manufacturers, expressed our concerns to the GAO regarding its recommendation both orally and in writing.

After the GAO report's publication, the Orthopaedic and Rehabilitation Devices Panel within the FDA's Center for Devices and Radiological Health (CDRH) announced its decision to retain Class III status for non-invasive bone growth stimulators.[11] Specifically, the panel made a recommendation to the FDA on the RS Medical reclassification petition to reclassify the non-invasive bone growth stimulator from Class III into Class II.[12] The committee panel recommended that non-invasive bone growth stimulators indicated for the treatment of established nonunion fractures should *not* be reclassified to Class II and should, instead, remain in Class III. The decision emphasizes the uniqueness of bone growth stimulators from their Class II counterparts and, we believe, warrants their distinction from Class II devices from a payment update category, as well.

In a market-oriented economy, innovation is intricately linked to proper reimbursement, as determined by complete analyses of underlying data. As described above, the GAO's report,

[11] CDRH Orthopaedic and Rehabilitation Devices Panel meeting held on June 2, 2006.

[12] Docket 2005P-0121. Summary of panel meeting can be found at http://www.fda.gov/cdrh/meetings/060206-summary.html

although a good first step, is incomplete. It would be a disservice to public health if the creation, refinement, and clinical study of original, cost-effective, life-saving and/or life-enhancing devices were stifled because innovators could not reap reasonable benefits to offset the risk of new product development. In the MMA, Congress specified that an update percentage equal to CPI-U would be reasonable for Class III devices in 2004, 2005, and 2006.[13] Therefore, consistent with this Congressional determination, we respectfully suggest that CMS provide an update for Class III DME equal to CPI-U for 2007. For 2008, the MMA again explicitly specifies a payment update equal to the annual percentage increase in the CPI-U, and we look forward to CMS implementing this statutory provision.[14]

* * *

Smith & Nephew hopes that these comments will be useful to CMS in determining the appropriate fee schedule percentage updates for Class III devices. We look forward to further dialogue on this issue and encourage CMS to contact us promptly with any questions, comments, or requests for additional information.

Sincerely,

Barbara Rohan

Barbara Rohan
Vice President, Government Affairs

[13] P.L. 108-173 § 302.

[14] Id.

DONALD A. MANZULLO, ILLINOIS
CHAIRMAN

NYDIA M. VELÁZQUEZ, NEW YORK

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Congress of the United States

House of Representatives

109th Congress

Committee on Small Business

2361 Rayburn House Office Building

Washington, DC 20515-6315

June 30, 2006

Via Hand and E-Mail Delivery
The Honorable Mark McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; CMS-1270-P, 71 Fed. Reg. 25,654 (May 1, 2006)

Dear Administrator McClellan:

On May 1, 2006, the Centers for Medicare and Medicaid Services (CMS)[1] published a proposed rule to implement § 302 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) mandating competitive acquisition of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that are covered under Medicare Part B. Specifically, the proposed rule establishes a bidding mechanism to determine the price at which bidding suppliers will be entitled to provide DMEPOS to Medicare-covered beneficiaries. CMS correctly found that the proposed rule is significant under Executive Order 12,866 and prepared a regulatory impact analysis. The agency also accurately concluded that the proposed rule will have a significant economic impact on a substantial number of small entities pursuant to the Regulatory Flexibility Act, 5 U.S.C. §§ 601-12 (RFA) and prepared an initial regulatory flexibility analysis proffering a number of alternatives designed to limit the adverse economic consequences of the proposed rule.[2] 71 Fed. Reg. at 25,690-96. CMS should be commended for this effort. These comments focus on alternatives that CMS can adopt to reduce burdens on

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[1] Section 302 of the MMA, 42 U.S.C. § 1395w-3, delegates the responsibility for implementing a competitive acquisition program to the Secretary. However, the Secretary delegated rulemaking authority to CMS. For ease of reference, these comments will refer to CMS rather than the Secretary.

[2] CMS combined the regulatory impact analysis with the initial regulatory flexibility analysis. This is permitted by statute. 5 U.S.C. § 605(a); *see Associated Fisheries of Maine v. Daley*, 127 F.3d 104, 115 (1st Cir. 1997) (noting validity of combining environmental impact statement and final regulatory flexibility analysis).

small business without undermining the efforts to institute a market-based solution for the supply of DMEPOS.

I. Use of Competitive Bidding Implementation Contractors (CBICs) will Create Gaps in Accountability to Small Businesses

The Committee has extensive experience in oversight of CMS's regulation of small healthcare providers. In particular, the Committee tried to resolve the problems that small providers have when caught between the Scylla of Medicare contractors and the Charybdis of CMS. For example, the Committee worked for three years to address reimbursements provided to small business portable X-ray providers. The providers were faced with three bureaucracies: skilled nursing facilities (SNFs), Part B carriers, and CMS. In attempting to redress the complaints of small businesses, the Committee found that SNFs blamed portable X-ray providers for their own problems, portable X-ray providers blamed SNFs and CMS, and CMS, including testimony by then Administrator Scully, laid some of the blame on Part B carriers. Small business owners, who have enough difficulties maintaining their businesses, have neither the time nor the appropriate resources to challenge the frequently contradictory assertions of multiple bureaucracies. The Committee fears that CMS, unfortunately, is going down that same well-trodden path in implementing § 302 of the MMA.

CMS proposes to designate one or more CBICs to provide the following functions: "preparing the request for bids (RFB), performing bid evaluations, selecting qualified suppliers, and setting single payment amounts for all competitive bidding areas."[3] *Id.* at 25,661. In the typical federal procurement, these functions are performed by federal employees with specialized training known as contracting officers whose decisions may be subject to challenge in a variety of arenas including the Government Accountability Office and federal court. CMS's delegation, combined with the foreclosure of judicial review on the contracting decisions,[4] essentially eliminates any accountability within this system.

When a small business has a complaint about the bidding process, the Committee expects that CMS will tell the DMEPOS small business provider to contact the CBIC. In turn, the CBIC will respond that the supplier contact CMS because the CBIC has no power or discretion to

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[3] Section 302 of the MMA does not establish a conventional federal procurement program in which winning bidders are the only suppliers. Rather, the system uses a bidding process as the primary mechanism for determining the single price for each item of DMEPOS. Then any supplier who submitted a bid and is willing to accept that single price will be eligible to supply DMEPOS to Medicare-eligible beneficiaries.

[4] Congress forbade judicial review of the establishment of payment amounts, award of contracts, areas designated for competitive acquisition, phased-in implementation, selection of items and services for competitive acquisition, and bidding structure and number of contractors selected. 42 U.S.C. § 1395w-3(b)(10). Since the only protection against irrational and ad hoc rulemaking is judicial review, *see Morton v. Ruiz*, 415 U.S. 199, 232 (1974); *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967), the Congressional decision to foreclose judicial and administrative review of these decisions enables CMS and the CBICs to make completely irrational decisions.

respond to the complaint. The delegation of a purely governmental function to a private contractor (the operation of a federal procurement system) leaves the small business owner without any recourse to simple errors or irrational actions. The faulty decisionmaking process may cost the small business the opportunity to provide goods and services to existing and future customers – the most severe burden imaginable to a small business owner. At that point, the only recourse is a complaint to Congress. When Congress investigates, the already delineated absence of accountability will again re-emerge with the CBIC and CMS each denying responsibility. If CMS does not delegate the bid selection process to a CBIC, Congress knows who is ultimately responsible.[5] CMS should reject the CBIC option and make competitive acquisitions decisions through its own contracting officers.

The Committee's antipathy to the CBIC process should not be interpreted as a complete rejection of CMS seeking contracts to advise it in the implementation of a DMEPOS competitive acquisition regime. The Committee concurs that CMS certainly must obtain necessary assistance from contractors to help it design the contracts, establish an appropriate bidding mechanism, and even develop options that reduce burdens on small businesses. However, such advice is a far cry from delegating the ultimate decisonmaking process to a private enterprise. Determination of awards must be made by qualified CMS employees and not CBICs or some other private entity.

Should CMS decide to go forward with CBIC proposal, the agency must develop some type of accountability and oversight of CBIC decisionmaking. The accountability must include person or persons at CMS that have the authority to override a CBIC decision. The appeal process contemplated by the Committee does not violate the bar against administrative review in § 302 of the MMA. Nothing in that section prohibits CMS from instituting an internal appeals process of a private company's decision because CMS delegated that initial decision to a private entity. The Committee opines that this alternative will give small businesses an easily navigable process to voice complaints and enable Congress to hold government officials accountable for the decisions made in the DMEPOS competitive acquisition program.

II. Appropriate Allowance of Joint Networks will Reduce Potential Burdens on Small Business Providers of DMEPOS

The current system allows any qualified supplier to offer DMEPOS to a Medicare-eligible beneficiary upon that person's presentation of a valid certificare of necessity and the supplier's willingness to accept the fee schedule payment for the particular item or service. 71 Fed. Reg. at 25,656. Thus, the existing system contains few limits on the total number of DMEPOS suppliers.

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[5] The argument that the system is better because it eliminates the possibility of political pressure on CMS is unavailing. The normal federal government procurement system resists political pressure and has done so for many years. CMS taking responsibility for contracting decisions in the DMEPOS acquisition program should be no different.

All competitive acquisition schemes used by the federal government limit the number of potential suppliers. The program mandated by § 302 of the MMA and the proposed implementation by CMS is no different. The most obvious adverse economic consequence to existing small business suppliers of DMEPOS is the loss of customers if they are not awarded a contract. CMS correctly recognizes the potential loss of business even though the agency found it "difficult to estimate how much revenue a losing supplier will lose because of the DMEPOS competitive acquisition program." *Id.* at 25,694.

CMS suggests that one means of reducing possibility of lost revenue is to allow suppliers to form networks for the purpose of submitting bids. *See* Proposed 42 C.F.R. § 414.418. The current CMS proposal allows any suppliers of DMEPOS to form a network as long as the network does not control more than 20 percent of the market. While the Committee appreciates CMS's concern over potential market power of a network, the Committee thinks a slightly modified approach to the network proposal will have greater utility in protecting small businesses.

Current size standard regulations for purposes of federal government procurement permit a joint venture to have as many small businesses within the joint venture and still not be considered a large business as long as each member is small for the industrial classification corresponding to the contract. 13 C.F.R. § 121.103(h)(3).[6] The standard does not incorporate a market share limitation because the purpose of the joint venture size standard[7] is to increase participation by small businesses in the federal procurement process. If CMS wants to ensure increased participation by small business suppliers of DMEPOS, then it should strongly consider adapting the joint venture definition set forth in Title 13 of the Code of Federal Regulations to the competitive acquisition program for DMEPOS. The Committee suggests that CMS allow small businesses to form joint ventures or networks for the purpose of bidding in response to a DMEPOS request for bids, without regard to market share, as long as all of the members of the network or joint venture are small business suppliers of the particular item of DMEPOS. In

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[6] The Small Business Act grants the Administrator of the Small Business Administration final authority to determine what constitutes a small business for the purpose of the Small Business Act or any other statute unless another statute contains a specific definition of small business. 15 U.S.C. § 632(a)(2)(A). This authority is explicit with respect to federal government procurement. *See* 48 C.F.R. §§ 19.301-.308. Nothing in § 302 of the MMA establishes a separate definition of small business so the Administrator's authority remain plenary with respect to the size of a business that is considered small for the purposes of implementing the competitive acquisition program.

[7] There are additional restrictions applicable to the joint venture size standard rule. However, those exceptions further support the applicability of the regulation to the DMEPOS competitive acquisition program. The joint venture is considered small if all the businesses are small and the joint venture is bidding on a bundled contract. The proposal established by CMS for competitive acquisition of DMEPOS would be considered a bundled contract as that term is defined in § 3(o)(2) of the Small Business Act, 15 U.S.C. § 632(o)(2). Even if the contract is not bundled, a joint venture containing only small businesses still will be considered small if the size of the contract exceeds $10 million. It certainly is not beyond the realm of reason to assume that many contracts for particular DMEPOS items in a geographic area may exceed in $10 million.

addition to the benefit to small businesses, the proposal reduces burdens on CMS because the agency will not have to calculate the market share of networks or joint ventures that consist solely of small business suppliers.

As a corollary to the Committee's suggested modification of the network standard, CMS should strongly consider whether the size standards DMEPOS suppliers developed by Small Business Administration (SBA) are appropriate. To be sure, the administratively simple solution is to adopt the existing size standards established by the SBA. However, those standards were designed to operate within the context of normal federal government procurement. The competitive acquisition program established by § 302 of the MMA is certainly not a conventional federal acquisition program.[8] Therefore, CMS should examine whether the SBA size standards are appropriate or whether different size standards are needed and those size standards may vary depending upon the DMEPOS item to be acquired.[9] The Committee reminds CMS that should it adopt a different size standard, it will need to comply with the procedural requirements of § 3(a)(2)(C)(i) and § 3(a)(3).

The Committee recognizes that there are instances in which it may prove beneficial for small businesses to enter into joint ventures or networks with large business suppliers of DMEPOS. The recommendation to allow small business suppliers of DMEPOS to form networks irrespective of market share should not be interpreted to exclude small and large suppliers an option to form networks or joint ventures. If CMS allows that option, the Committee concurs with the agency's preliminary determination to impose a cap on network size based on market share.[10] However, if it does so, the burden of demonstrating that the venture is below the market share cap should rest on the large business or CMS and not on the small suppliers. That would represent an unnecessary and expensive market research burden that would deter many small businesses from entering into a joint venture or network.

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[8] No further proof is needed than the fact that Congress authorized CMS to waive the application of the Federal Acquisition Rules. 71 Fed. Reg. at 25,661, citing 42 U.S.C. § 1395w-3(a)(1)(C). In this program, the government itself never takes possession of any good or utilizes a service. Rather, the competitive DMEPOS program establishes a single price and the universe of suppliers of DMEPOS to Medicare-eligible beneficiaries.

[9] Such variation in size standards is not uncommon for other federal auction/competitive bidding situations. The most closely analogous procedure was the sale of electromagnetic spectrum pursuant to the authority set forth in § 332 of the Federal Communications Act in which the Commission developed different standards for small businesses based on the specific spectrum that was to be auctioned.

[10] The Committee is not convinced that 20 percent share evidences market power. It also is possible that 20 percent may be appropriate for certain DMEPOS items and not others. If antitrust law teaches one thing, there are no bright line tests for determining market power. *See* 2A P. AREEDA & H. HOVENKAMP, ANTITRUST LAW ¶¶ 423, 515 (2004). While administratively useful, the bright line suggested in the proposed rule may be overbroad and prohibit network formation that raises no problem with respect to market power even though the network's market share exceeds the proposed 20 percent. The Committee recommends that CMS obtain the advice of the Antitrust Division of the Department of Justice and the Federal Trade Commission.

III. CMS Must Consider Small Business Participation in Establishing the Competitive Bidding Areas

Section 302 of the MMA does not specify the size of the competitive bidding areas that CMS must establish. If the sole goal of the program is government efficiency, then CMS would be constrained to establish the largest bidding areas possible given the item of DMEPOS to be acquired. However, efficiency is not the sole criterion for the program. CMS recognizes other important aspects of competitive acquisition including the need to ensure small business participation and the delivery of quality services to Medicare-eligible beneficiaries.[11]

This Committee's perspective on CMS's proposal to establish competitive acquisition areas must be filtered through the Committee's experience with other federal agency procurement activities through the utilization of contract bundling. Contract bundling is defined as the consolidation of two or more procurement requirements (be they for goods or services or a combination of both) that are consolidated into one contract previously provided under separate smaller contracts. The consolidation only becomes problematic bundling if the terms of the contract make it unlikely to be suitable for award to small businesses because of size of the contract, the dollar value of the contract, the geographical dispersion for performance, or any combination of these factors. 15 U.S.C. § 632(o). The Committee on Small Business has more than a decade-long record in opposition to contract bundling because it drastically reduces opportunities for small businesses. Furthermore, the use of bundled contracts runs counter to the Congressional policy set forth in § 15 of the Small Business Act that requires small business be given their fair share of opportunity to supply good and services to the federal government. 15 U.S.C. § 644(a).

With this history and concern in mind, it is not surprising that the Committee has significant concerns about the competitive acquisition program proposed by CMS. The program has all the characteristics of a bundled contract. Medicare-eligible beneficiaries now can select any supplier and that supplier is reimbursed; this is not dissimilar to a federal government contract currently performed by a small business. The proposed rule would consolidate these "separate contracts" into one metropolitan statistical area-wide contract. This is the type of consolidation that may not be suitable to award to small business because of the geographic dispersion of the contract. In many cases, small business suppliers of DMEPOS will not have the logistical or financial resources to provide service to an entire metropolitan area.[12]

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[11] This is particularly true with respect to DMEPOS that contain a significant component of service assoicated with the provision of the item such as respiratory technician monitoring of oxygen tanks.

[12] To some extent, the networking procedures will vitiate this concern. However, formation of networks to bid constitutes a significant transaction cost that will dissuade many small business suppliers. Furthermore, these smaller suppliers may be chary of entering into business partnerships with entities that they normally view as competitors creating potential difficulties in competition outside of the Medicare arena.

The Federal Communications Commission (FCC) was faced with a problem analogous to that currently facing CMS. In 1993, Congress mandated that the FCC auction spectrum it had previously simply licensed on a first-come first-serve basis or on the basis of which applicant would best serve the public interest. Congress also dictated that the FCC ensure that small businesses have the opportunity to participate in these auctions. This prevented the FCC from simply auctioning licenses for personal communications services (PCS)[13] on a national basis because small businesses did not have the financial resources to compete in an auction against giant telecommunications companies. The FCC then adopted a bifurcated strategy of separate PCS auctions. One auction involved large companies bidding for spectrum to serve major trading areas which generally included an entire state or multiple states. A series of auctions then were held for smaller businesses to purchase spectrum to serve smaller regions called basic trading areas which were generally contiguous with metropolitan statistical areas. *See High Plains Wireless, L.P. v. FCC*, 276 F.3d 599, 603 (D.C. Cir. 2002). Small businesses did not participate and were not expected to participate in the auctions for major trading areas. However, they did participate, and, in certain instances, were the only participants in the auctions for spectrum allocated to basic trading areas.

CMS can adapt the strategies employed by the FCC in a number of ways. The most obvious one is to reduce the size the of the geographic regions from metropolitan statistical areas to some smaller division of those areas.[14] In the alternative, CMS can allow bids for an entire metropolitan statistical area; then set aside for small businesses to bid on smaller regions such as cities or counties within the metropolitan statistical area.[15] Finally, CMS can use metropolitan statistical area bidding to establish the single price and then allow small businesses to make offers using that bid price but allowing the small businesses to designate their service

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[13] PCS is type of mobile communication similar to cellular service but operating in the 1.9 GHz band.

[14] It is important to note a prime distinction between DMEPOS and electromagnetic spectrum for use in PCS. In providing telecommunication services, it is vital that entire economic regions be covered otherwise no one will purchase the service. Dividing the United States into areas smaller than basic trading areas would not permit the establishment of a commercially-viable telecommunications service. *See Amendment of the Commission's Rules to Establish Personal Communications Services*, 8 FCC Rcd 7700, 7732 (1993). Given the difference between logistics of supplying DMEPOS and the physics of electromagnetic spectrum, CMS cannot use the FCC's adoption of basic trading areas as proof that metropolitan statistical areas constitute the appropriate geographic size for participation by small business suppliers of DMEPOS.

[15] Should CMS wish, it might use the bids on the metropolitan statistical area to establish the single price and if bids on smaller areas exceed the single price, reject any or all bids above that single price. On the other hand, bids of small suppliers may be even lower than the metropolitan statistical area bids. CMS then has the opportunity to blend the two prices in order to obtain a single bid price applicable to larger and smaller competitive bidding regions. The United States Department of Agriculture uses a variation of this blending strategy in the implementation of milk marketing orders which establish the price of various classes of milk in those regions of the country subject to a milk marketing order. *See* 7 C.F.R. § 1000.50; 7 C.F.R. Parts 1001-1135 (pricing for specific market order regions).

territories.[16] The Committee strongly urges CMS to consider these and similar alternatives that do not force small suppliers to bid on serving an entire metropolitan statistical area.

IV. Mandatory Subcontracting Plans

CMS determined that the federal acquisition rules should not apply to the implementation of the DMEPOS competitive acquisition program. 71 Fed. Reg. at 25,661. The Committee recognizes that the federal acquisition rules are complex and may reduce agency discretion in procurement. Furthermore, as already noted in these comments, the competitive acquisition program is not a typical federal procurement program. Nevertheless, CMS should strongly consider adopting one aspect of the federal acquisition rules – the requirement for subcontracting plans.

Section 8(d) of the Small Business Act, 15 U.S.C. § 637(d), mandates that prime contractors give small businesses the maximum opportunity practicable to participate as subcontractors. *Accord* 48 C.F.R. § 19.702. The regulations implementing § 8(d) require that prime contractors, other than those that are small businesses, submit a subcontracting plan, *id.* at § 19.702(a)(1)-(2), that among other things, contains "a description of the principal types of supplies and services to be subcontracted." *Id.* at § 19.704(a)(3). Subcontracting plans, despite this Committee's ongoing concern about compliance,[17] do provide significant opportunities for small businesses to participate in the federal contracting arena.

The Committee recommends that CMS adapt the federal acquisition rule subcontracting regime to the competitive acquisition DMEPOS program. The Committee does not expect that CMS will impose an identical subcontracting plan requirement that is imposed on federal prime contractors.[18] However, CMS may require that large bidders submit subcontracting plans after

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[16] Under this regime, CMS must bar the small business from designating a service territory contiguous with the metropolitan statistical area. If the small supplier wants to serve an area contiguous with the entire metropolitan region than it must participate in the bidding process for the entire area. Any other result enables some small businesses to game the system in their favor and the Committee is requesting CMS examine methods to reduce burdens on small suppliers not provide them with an unfair advantage.

[17] *See* H.R. REP. NO. 108-325 at 180 (2003) (describing changes made by H.R. 2802 to improve prime contractor compliance with their subcontracting plans).

[18] Federal subcontracting plans are designed to achieve a variety of economic opportunity goals including the increased utilization of small businesses owned by women, minorities, veterans, service-disabled veterans, and those operating in historically underutilized business zones. The primary purpose of the competitive acquisition DMEPOS is to replace the current fee schedule arrangement for reimbursement of DMEPOS items while maintaining quality provision of services to Medicare-eligible beneficiaries. Given the significantly different underlying purposes of the two regimes, CMS should not be required to develop subcontracting plans that focus on particular subgroups within the small business community.

the winning bidders are determined[19] as a condition of their continued participation in the program. The plans should include the following items: 1) the type of goods and services that they will utilize small business subcontractors;[20] 2) the type of outreach that the they will perform to identify potential subcontractors; and the 3) the recordkeeping that will be done by the prime contractor to ensure that subcontractors comply with CMS quality standards in the delivery of services to Medicare-eligible beneficiaries. CMS also may condition the use of subcontractors on the basis that such utilization will not modify the single price reimbursement to the prime contractor. Adaptation of the subcontracting plan requirement from the federal acquisition rules will provide opportunities for small business suppliers of DMEPOS to obtain some revenue from the competitive acquisition program even if they decide not to bid on a particular item or are not awarded a contract.

V. Conclusion

CMS does not have an enviable task in the development of a competitive acquisition scheme for DMEPOS. The Committee commends CMS for recognizing at an early stage that implementation may have significant adverse consequences for small businesses. Adoption of the alternatives set out in these comments will ameliorate some of the adverse consequences to small business suppliers of DMEPOS. The Committee recommends that CMS work with the Office of Advocacy of the United States Small Business Administration, RTI (its contractor for developing the small business focus groups that the agency convened prior to the issuance of the proposed rule), and the small supplier community to develop other alternatives that will reduce the adverse economic consequences of the DMEPOS competitive acquisition program.[21] The

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[19] If CMS determines that a sufficient number of awards in a particular area have been made to small businesses, CMS may elect to waive the subcontracting plan requirement for that specific DMEPOS item in that geographic bidding area. Should CMS select this procedure, the Committee would expect that a sufficient number of small business awardees represent a not insubstantial amount of the market share in a given region for the DMEPOS.

[20] As an example, a large supplier of power wheelchairs, might utilize smaller, local businesses to provide delivery or maintenance of the wheelchairs.

[21] The courts recognize that an agency "may develop additional information in response to comments without starting anew [a new comment period]...." *Personal Watercraft Indus. Ass'n v. Department of Commerce*, 48 F.3d 540, 544 (D.C. Cir. 1995). This stems from two aspects of the Administrative Procedure Act. First, and unlike an adjudicatory proceeding, there is no concept of ex parte contacts or communications because there are no specific parties in an informal rulemaking. *Sierra Club v. Costle*, 657 F.2d 298, 400-02 (D.C. Cir. 1981). Second, as long as the rulemaking constitutes a logical outgrowth of the proposed rule, the use of additional information is neither inappropriate nor prejudicial. *E.g.*, *Texas Office of Pub. Util. Coun. v. FCC*, 265 F.3d 313, 327 (5th Cir. 2001); *Solite Corp. v. EPA*, 952 F.2d 473, 481 (D.C. Cir. 1991) whether produced by the agency or the agency's consultants. *Burke v. Board of Governors of the Federal Reserve System*, 940 F.2d 1360, 1367 (10th Cir. 1991), *cert. denied*, 504 U.S. 916 (1992); *United Steelworkers v. Marshall*, 647 F.2d 1189, 1220-22 (D.C. Cir. 1980), *cert. denied*, 453 U.S. 913 (1981). In this instance, all parties are on notice that CMS is considering the development of a competitive acquisition program that seeks participation by small suppliers and minimizes the potential of lost revenue. No person interested in the rulemaking then will be surprised if CMS adopts a competitive acquisition

(continued...)

Committee staff stands ready to assist CMS in the continued development of this competitive acquisition program. Should your staff have any comments about this letter, please contact the Committee's Chief Counsel, Barry Pineles at 202-225-5821.

Sincerely,

Donald A. Manzullo
Chairman

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[21](...continued)
program that utilizes techniques not set forth in the proposal that achieve its regulatory objective concerning small suppliers even though it might include alternatives not specifically raised in the notice. *See Association of Battery Recyclers v. EPA*, 208 F.3d 1047, 1058-59 (D.C. Cir. 2000).

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June 30, 2006

BY COURIER

Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201
Attention: CMS-1270-P

Re: Comments on Proposed Rule, CMS-1270-P, Competitive Acquisition for Certain DMEPOS and Other Items

Dear Madam or Sir:

The following comments are being submitted on behalf of the Diabetic Products Suppliers Coalition (the "Coalition"), an organization whose members are Medicare-participating, direct-to-consumer (mail order) suppliers of diabetic products and supplies. Overall, while the Coalition does not challenge the concept of competitive acquisition of durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS"), the Coalition and its members have serious concerns about many of the substantive proposals set forth by the Centers for Medicare and Medicaid Services ("CMS") in the May 12, 2006 proposed rule, CMS-1270-P, Competitive Acquisition for Certain DMEPOS and Other Items ("Proposed Rule" or "NPRM"), as well as areas where CMS failed to provide sufficient detail and the overall timing of implementation. We recognize the difficulties inherent in devising a completely new program, such as competitive acquisition, and applaud the agency's efforts to take on this challenge. We hope to be able to work with the agency, however, to deal with many of the issues raised in these comments, which we believe will pose significant challenges to the long-term success of competitive acquisition. In short, we intend for our comments to be constructive and not critical in light of the obvious challenges.

The Coalition recognizes that mail order is neither appropriate for all patients nor all products and supplies. Nonetheless, for many beneficiaries mail order is essential for them to receive timely the products and supplies that they require to maintain their health in accordance with their physician's order(s). Many beneficiaries have limited mobility and are unable to get to a storefront supplier on a regular basis to obtain their needed products and supplies. Other beneficiaries reside in areas where the products or brands of their preference may not be readily available or may require driving long distances. Still others rely on the toll-free numbers and

immediate access for their regular questions. Perhaps most importantly, the regular contact and services of specialists in diabetes care offered to beneficiaries (particularly those with chronic diseases like diabetes) by mail order businesses provide unparalleled benefits to beneficiaries that most other suppliers are unable to equal. There can be no doubt that the key features offered by mail order suppliers of no-cost delivery directly to the beneficiary's home, broad product selection and toll-free telephone access are essential to many beneficiaries and, therefore, the Medicare program generally.

Further, through our members extensive contacts with beneficiaries, the Coalition is worried that CMS may not yet have received a very representative understanding of how beneficiaries may be affected if the CBP would be implemented as proposed. We understand that the agency's primary contacts with beneficiaries regarding the CBP has been based on meetings with a focus group of 44 beneficiaries. We believe that beneficiaries needs are essential to any effective program, and that CMS has yet not received a very representative or accurate picture of beneficiary needs and concerns. Further, it is unlikely that there will be sufficient comment on this NPRM from beneficiaries and their representatives. Accordingly, at CMS' request, our members would be happy to provide the agency with additional feedback from some of the many thousands of beneficiaries serviced by our members.

For the ease of CMS, we have divided our comments into two main sections (1) our general comments, including issues that are not specifically defined by any section in the preamble or regulations of the Proposed Rule and (2) our comments on the specific text of the preamble and proposed regulations that track the order in which presented in the NPRM.

GENERAL COMMENTS

I. ACCESS TO BENEFICIARIES AND PRICING FOR SUPPLIERS

The Coalition is concerned about the potential effect of the Proposed Rule on the accessibility of diabetic testing supplies to be provided to Medicare beneficiaries under the competitive bidding program ("CBP").

Diabetes is a serious disease that afflicts, by conservative estimates, over 10 million seniors. Both Congress and CMS are well aware of the significant problems caused by diabetes, both from a medical perspective, as well as from a financial perspective. Since there is still no cure for diabetes, there is near universal agreement that education and prevention are the most effective ways to combat the all too common perils of this disease. Numerous clinical studies have demonstrated that diabetes education and compliance with a patient's physician-prescribed glucose testing regimen are keys to diabetes management. Through the Diabetes Caucus and various CMS efforts at promoting preventive care for diabetes, Congress and the agency have acknowledged the merit of these studies.

Unlike many of the other product categories that may be considered for inclusion in the competitive acquisition program in 2007, there is no historical information to guide us on how

beneficiaries, and their care for their diabetes, may be affected if diabetic testing supplies are included. The fact that there is no information, such as that which could have been derived through demonstration projects or other limited pilot programs, means that there can be no assurance that beneficiary access to their essential testing supplies will not be impeded.

There are a number of likely scenarios under the Proposed Rule that could unduly affect beneficiary access. First, in order to ensure that there will be sufficient beneficiary access to needed DMEPOS products, and particularly diabetic testing supplies, the competitively bid single price established for each product must be sufficient to allow all selected suppliers to agree to participate and to remain competitive. Thus, the single price for each product or supply should be set at a level no less than the highest bidding supplier selected by CMS to meet the anticipated demand within a competitively bid area ("CBA"). Setting the price at the median of the bids of the winning bidders for selected products will mean that up to one half or more of the selected suppliers may be paid less than their bids, even though they were selected. Many of those selected suppliers may be reluctant to accept lower prices, particularly in the initial round of bids in consideration of the great likelihood that there will be unforeseen costs and unexpected problems with claims that have not been factored into what was already their lowest bids. We expect many may be forced decline to accept that price, and accessibility will suffer. Moreover, we fear that many others will agree to contract with CMS, but will ultimately be forced to drop out because the single price will not be sustainable for their business. Ultimately, this will result in continuing displacement of beneficiaries (even during the bidding cycle) and continued reductions of suppliers that can conveniently furnish covered supplies to beneficiaries within a competitively bid area. The processes used in the two demonstration projects avoided these issues by allowing all contracted suppliers to furnish competitively bid items at or above their bid price.

Second, and particularly with diabetes testing supplies, not all supplies are alike. Even if many diabetes testing supplies purport to have the same clinical benefits, their features and functions vary significantly. In many cases, these differences may be insufficient to allow a prescribing physician to justify the need for one brand over another; however, from the beneficiary's standpoint, these differences may be the difference between testing as prescribed and not testing at all. Medicare beneficiaries are elderly, and many have difficulty adjusting to changes of products that they have used for years. The Proposed Rule does not adequately protect beneficiaries' access to a sufficiently wide array of products.

With diabetic testing supplies, many of the supplies (and all testing strips) are proprietary to the home blood glucose monitor. There is no assurance that selected suppliers of diabetic testing supplies (if these supplies were to be selected as a product category, against our recommendations as discussed below) would even offer the brand of reagent strips necessary to fit a beneficiary's current monitor. Even with such assurances (such as requirements that contracted suppliers furnish at least some array of brands), there is no guarantee that such selected supplier(s) would be convenient for the beneficiary. If beneficiaries cannot easily get the supplies that they need and are accustomed to, it is likely that their testing compliance will

decline to the harm of those beneficiaries and the Medicare program (which will ultimately absorb higher costs from increased Part A admissions).

Accordingly, with regard to beneficiary access to diabetic testing supplies, it is essential that (1) a fair single price be set that is no lower than the bid of all winning suppliers; (2) beneficiaries have access to multiple types and locations of suppliers, including retail storefront locations conveniently located throughout each CBA, mail order, physician offices and other settings; and (3) beneficiaries have reasonable and convenient access to each brand and type of product that is subject to bidding.

II. TREATMENT OF DIABETIC TESTING SUPPLIES AS A BID CATEGORY

Over 21 million Americans have diabetes, including a great number of elderly Medicare beneficiaries. The cost of hospitalizations and other care of diabetic patients is well over $132 billion per year. Medical authorities universally agree that testing and monitoring of blood glucose levels by people with diabetes is the most important action that can be taken to minimize the complications of this disease and the huge medical costs associated with the care of the most common complications. The American Diabetes Association recently reported on several studies that conclude that diabetics are not getting adequate treatment now. CMS Administrator Mark McClellan specifically recognized the benefits of prevention efforts such as testing and indicated that the Agency's focus will shift to encourage more use of prevention services. Given the consistent recognition among scholars, advocacy organizations, physicians and even CMS that diabetes is a disease that deserves more attention and greater efforts directed at prevention, nothing should be done to discourage, prevent or make it inconvenient for Medicare diabetic patients testing or having adequate access to testing supplies. Accordingly, we ask that diabetes testing supplies not be included as a competitive bidding category of products at least until further review and study (such as a demonstration project) can be conducted to ensure that the application of a competitive bidding process to this important category of supplies will not (1) unduly restrict access of beneficiaries to the supplies they currently use; (2) result in reduced compliance with prescribed testing regimens; and (3) lead to increased complications and Part A admissions at significant additional costs to the Medicare program that would more than offset any potential cost savings gained through this program.

III. DISPARATE TREATMENT OF "MAIL ORDER" SUPPLIERS

The Coalition is very concerned that the Proposed Rule could create a bias against direct-to-consumer suppliers who furnish products and supplies primarily through the mail. There appears to be a lack of understanding of the operations of, and benefits offered by, "mail order" suppliers generally. In this regard, we reiterate our offer to meet with CMS to provide any additional information that the agency may require to better understand this important segment of the DMEPOS industry.

As indicated above, "mail order" businesses provide a number of benefits for beneficiaries and the Medicare program generally. These benefits are particularly important with

regard to beneficiaries with diabetes. First of all, many "mail order" suppliers of diabetic testing products, including our Coalition members, specialize in these products and in the care of diabetes. This specialized care is able to be provided by consolidating operations in one or a few select locations and employing individuals knowledgeable about the disease and testing care. Second, mail order allows many beneficiaries to obtain supplies needed to manage their disease when other purchase options may not be available. Many beneficiaries have limited mobility and are unable to get to a storefront supplier on a regular basis to obtain their needed products and supplies. Other beneficiaries reside in areas where the products or brands of their preference may not be readily available or may require driving long distances. Still others rely on the toll-free numbers and immediate access for their regular questions. Perhaps most importantly, the regular contact and services of specialists in diabetes care offered to beneficiaries (particularly those with chronic diseases like diabetes) by mail order businesses provide unparalleled benefits to beneficiaries that most other suppliers are unable to equal. These benefits no only help beneficiaries, but help to keep costs down for the Medicare program as a whole.

With all of the benefits offered by the mail order model, mail order suppliers should not be held to any greater or different standards than other suppliers. In fact, mail order suppliers are generally indistinguishable in most important aspects from all other types of suppliers, so much so that CMS would be hard pressed to offer a reasonable definition of a "mail order supplier." This lack of distinction is evident from two key facts. First, the current 21 Medicare supplier standards (42 C.F.R. § 424.57) essentially require all suppliers to operate a walk-in storefront facility. Supplier standards (7) and (8) require all suppliers, including mail order suppliers, to maintain a physical facility on an appropriate site, which must be accessible during reasonable business hours to beneficiaries and to CMS, and must maintain a visible sign and posted hours of operation. Thus, all "mail order" suppliers are required to operate the same types of bricks-and-mortar storefront locations as other suppliers. Second, and equally as important, many (if not most) suppliers offer some items and supplies via mail or delivery. Accordingly, supplier standard (12) requires that all suppliers must be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery. Thus, no suppliers are exclusively mail order suppliers, and most suppliers furnish at least some items through the mail or similar delivery, making the term "mail order" virtually meaningless.

If CMS' attempt to single out some subsection of DMEPOS suppliers as "mail order" is an attempt to designate a subset of suppliers that are believed to have lower price structures than other "non-mail order suppliers," its methods are flawed. First, the cost structures of all suppliers, including each of the members of our Coalition, vary significantly. There is no data to support that certain suppliers who furnish DMEPOS more often through the mail have lower costs or would necessarily be able to furnish supplies to Medicare beneficiaries at a lesser price. Second, even were that the case, there are many other types of suppliers that likely would have similar or even lower cost structures. For example, Part A providers, such as skilled nursing facilities and home health agencies, that operate DMEPOS suppliers likely have little additional overhead for furnishing Part B covered supplies. A similar argument could be made with regard to items furnished directly by physicians. Many large retail pharmacy chains that purchase

supplies in large volumes have lower overall costs than typical mail order suppliers that may include significant mail order businesses. Thus, there is no logic in singling out "mail order" businesses. Finally, like Part A suppliers and physicians, "mail order" suppliers offer an array of benefits to Medicare beneficiaries that suppliers that do not offer products via the mail cannot provide. For many beneficiaries, mail order is essential for them to receive timely the products and supplies that they require to maintain their health in accordance with their physician's order(s). Many beneficiaries have limited mobility and are unable to get to a storefront supplier on a regular basis to obtain their needed products and supplies. Other beneficiaries reside in areas where the products or brands of their preference may not be readily available or may require driving long distances. Still others rely on the toll-free numbers and immediate access for their regular questions. There can be no doubt that the key features offered by "mail order" suppliers of no-cost delivery directly to the beneficiary's home, broad product selection and toll-free telephone access are essential to many beneficiaries and, therefore, the Medicare program generally; however, these benefits do not come without a cost. Yet, CMS seems to be completely ignoring these types of benefits, as well as those offered by Part A providers and physicians.

Accordingly, as discussed in additional detail below, we do not believe that any separate category of "mail order" suppliers should be used or considered in any facet of the final rule.

IV. TIMING OF IMPLEMENTATION

Along with the entire DMEPOS supplier industry, we have great concerns that there will be insufficient time to fairly and effectively implement the CBP in the time frame anticipated by CMS. We endorse the position of the American Association of Homecare and others that, where competitive bidding is concerned, it is more important to "get it done right" rather than getting it done quickly. We recognize the many challenges CMS will face in implementing a program of this complexity. Failure to address these challenges effectively can only lead to bad results such as: (1) complaints and dissatisfaction of beneficiaries (as CMS has seen with regard to the implementation of Part D); (2) decreased access and quality of care for beneficiaries; (3) increased administrative costs to CMS; (4) increases to the cost of care covered by the Medicare program; and (5) irreparable harm to the businesses of countless suppliers.

We are most concerned that the selection of products and product groups to be included in the initial evaluation will be made without adequate discussion or input from the supplier community and without adequate analysis of whether there is a likelihood of truly significant savings. We are also very concerned that suppliers may be forced to bid without sufficient time to assess the costs and issues that will surely be faced with the implementation of a new accreditation process under the forthcoming DMEPOS Quality Standards.

Accordingly, we recommend starting slowly, with only those products that have been shown to produce savings in the two demonstration products. CMS already has experience in bidding these products and has demonstrated cost savings. Likewise, suppliers have the experience of those in Polk County, Florida and San Antonio, Texas on which to draw in making

informed bids. Other products, which no such experience or information is available (including diabetic testing supplies), can be added after adequate study and discussions with the industry (such as additional demonstration projects or pilot programs). Finally, those products likely to be proposed for regional or nationwide bidding should be excluded from the initial bidding and reviewed further (such as through a demonstration project) prior to any implementation of regional or nationwide bidding in 2010.

SPECIFIC COMMENTS ON THE NPRM

Our comments below are set forth in the order presented in the Preamble of the Proposed Rule. Accordingly, the order of these comments does not necessarily represent the importance of each of the following subjects for diabetic product suppliers generally, or the Coalition specifically. In addition, note that the Coalition is commenting on a number of sections of the proposed regulations that, while possibly not having a direct effect on the provision of diabetic products and supplies, do effect generally Medicare beneficiaries, the DMEPOS industry and taxpayers generally. Thus, the Coalition feels bound to make additional comments in areas we fear may otherwise be overlooked by the commenters at large. Finally, the Coalition is also commenting on the other proposals included in the NPRM that do not directly relate to the CBP, including the revised method for calculating fee schedule amounts for new DMEPOS items known as "gap filling."

I. "PAYMENT BASIS"

A. Grandfathering Suppliers

The NPRM proposes to permit "grandfathering" of suppliers of oxygen, capped rental items and certain inexpensive routinely purchased items that require frequent servicing and repair. Under the NPRM, such suppliers could continue to furnish products that a beneficiary residing in a CBA had begun using prior to the implementation of the CBP for that product, provided both the beneficiary and the old supplier agree to a continuation of the service and the supplier agrees to accept the single price under the CBP.

We recognize the wisdom of grandfathering suppliers who have been furnishing items and supplies to beneficiaries within a CBA and do not become the contact supplier for that beneficiary upon implementation of the CBP. Medicare beneficiaries strongly rely on the continuity of their care in order to help to maintain their health. While we recognize that a change of more substantial items, such as capped rental items during a rental period, could be particularly traumatic on a beneficiary, we believe that the potential trauma and displacement may be similar in many other cases besides the three enumerated product groupings.

Thus, we believe that every beneficiary should have the right to maintain continuity with their DMEPOS supplier. Accordingly, we believe that every beneficiary should be offered the opportunity to continue to get their same products or supplies from their existing supplier at the single price under the CBP and that the supplier should not have the ability to decline unless they

do not remain in business. With regard to the three product groups identified by CMS in the NPRM under section 414.408(k), we suggest that a special rule be created which would require beneficiaries to continue to receive their products and services from their existing supplier throughout their use of that product, again, unless the supplier does not remain in business.

This recommendation is based on three points. First, the average beneficiary will not understand the implications of a choice between a grandfathered supplier and a winning supplier under the CBP, and it will be impossible for the contractor to adequately counsel each beneficiary regarding the choice. Second, allowing the grandfathered supplier the ability to decline continued provision of the products will permit "gaming" of the program. The old supplier, who is nearing the end of the rental period and has recovered its costs, will reject grandfathering, repossess its rented equipment, and require the CBP contract supplier to provide a new product to the beneficiary with little or no reimbursement and ongoing expenses for repair and maintenance. Finally, there is no way for bidding suppliers to reasonably estimate how many rentals will be "dumped" on them, and at what points in the rental period such dumping may occur, such that they will not be able to reasonably factor such losses into their bids.

With regard to products enumerated in section 414.408(k), the CBP should only apply to those products whose rental period begins after the CBP implementation date. Pre-existing rental arrangements should be required to be continued with the old supplier throughout the remaining use by the beneficiary. It should continue to be paid by the local DMERC, at the full fee schedule amounts, not the CBP. In other words, these items should not be subject to CBP. Similarly, contract suppliers that lose their contract status in a subsequent CBP, but during a current rental period, should be required to continue to provide those products to the beneficiaries throughout the period used, at the CBP rate initially contracted.

B. Inflation Factor

The NPRM provides that an inflation factor be applied annually during the term of the contract equal to the regulatory-established update which is tied to the consumer price index update ("CPI-U"). We agree with the proposal, but believe that the update provision must be specifically included in the written contract with the contract suppliers, such that it is not subject to any reduction or freeze imposed on inflation factors for non-CBP DMEPOS items by Congress. Bidders must be able to count on a stable inflation factor.

C. Obtaining Competitively Bid Items when Beneficiary Is in Travel Status

The NPRM allows for beneficiaries covered under a CBP program to secure covered items from a local supplier when in travel status. We agree that a beneficiary residing in a CBP area should be able to obtain new CBP items from a local supplier when in travel status. However, if the products are supplies for chronically ill beneficiaries being received through mail order under a CBP contract, the beneficiary would simply have to contact the contract supplier and have the products delivered to their travel location. Accordingly, if the contract supplier has a mail order capability, such items should be denied if provided by a local supplier.

D. Limitation on Supplier Liability

The NPRM provides that a non-contracting supplier in a CBP area who provides a covered item to a beneficiary will neither be reimbursed by Medicare for the item, nor be able to charge the beneficiary for the item. We disagree in part with this proposal. Beneficiaries should be informed of their options, and should never be prevented from paying for supplies on their own (if adequately informed) Accordingly, we suggest that non-contract suppliers in CBP areas who supply products to beneficiaries residing in the area should be required to provide written notice to beneficiaries that: (1) the products are not covered when furnished by the non-contract supplier; (2) the products would be covered if furnished by a contracted supplier; and (3) that there is a listing of contracted suppliers available on the CMS Web site and other locations. In addition, if a supplier can demonstrate that a beneficiary misrepresented their place of permanent residence, their Medicare status, or other factors that would lead the supplier to reasonably believe that the provision of the product would not be subject to the CBP, the supplier should be entitled to bill the beneficiary and collect payment.

II. "COMPETITIVE BIDDING AREAS"

We recognize that the Medicare Modernization Act (the "MMA") authorized CMS to exempt rural areas and areas with low population density within urban areas. We also recognize that CMS believes it can expand a selected metropolitan statistical area ("MSA") to add areas outside the MSA to the CBP (presumably as long as the additional areas outside of the MSA are not subject to the aforementioned exception).

We strongly oppose either of these options at this time. The addition or reduction of areas outside of, or within, the established MSAs will necessarily be based on somewhat arbitrary criteria, will be extremely difficult to establish, and will likely be subject to significant local backlash. At this point in the CBP maturation, it is not advisable to take on a task whose determination will cause considerable delay in the implementation. The CBP is already recognizably difficult to establish, and this fine-tuning is neither needed nor beneficial to anyone involved. CMS may want to consider this option in subsequent CBP cycles once more data is available.

In addition, we question the legality of expanding the MSAs selected in light of the specific statutory language. The Office of Management and Budget defines an MSA as "A Core Based Statistical Area associated with at least one urbanized area that has a population of at least 50,000. The Metropolitan Statistical Area comprises the central county or counties containing the core, plus adjacent outlying counties having a high degree of social and economic integration with the central county as measured through commuting." (65 Fed. Reg. 82238 (Dec. 27, 2000).) The OMB and Census Bureau apply this definition, adopted by the MMA, by specifically defining those counties and Zip Codes included within each enumerated MSA. Accordingly, we do not believe CMS should attempt to adopt such a questionable position in the initial implementation of the statute.

A. Nationwide or Regional Mail Order CBP

The NPRM provides for consideration of national or regional mail order CBPs beginning on or after January 1, 2010. The Coalition has concerns about this proposal, which has not been sufficiently developed in the NPRM and poses many potential problems and inequities if finalized without an additional round of proposals and comments, and discussion with the industry and beneficiaries.

If a national or regional CBP would be implemented, we respectfully suggest that CMS supplement its policy rationale by articulating why the core capabilities of "mail order suppliers" are necessary and beneficial to the Medicare program and beneficiaries. For example, "mail order suppliers" can furnish services equally in smaller urban areas and less populated areas, where storefront locations are often less available to beneficiaries. From a quality perspective, "mail order suppliers," and particularly those that focus on key product areas such as diabetes testing, communicate regularly with beneficiaries about their prescribed regimens, and provide invaluable assistance with supporting them in their efforts to remain compliant with their physician's plan of care. We hope that these reasons for the basis for identifying "mail order" as the single source of delivery in on a national or regional basis. We believe that, if this type of national or regional bidding is to take place, winning bidders should be the only source for covered products in any bid category. If this would be the case, then we would desire to work with CMS to help to effectuate such a proposal. By supplying a more detailed policy rationale in the final rule, CMS could address a number of these concerns.

Importantly, the lack of clarity provided in the NPRM, raises issues that this portion of the proposal may be intended to allow for a second mode of delivery and pricing, other than the single prices in the CBAs and the fee schedules in all other areas. If this is the case, and beneficiaries would still have the option of purchasing supplies from other suppliers not subject to the national/regional CBP, then our concerns over this proposal are even more serious. First, the proposal unfairly singles out an as yet undefined segment of the supplier industry that the Proposed Rule refers to as "mail order suppliers." Second, this proposal apparently would establish multiple tiers of pricing that neither appear warranted, supported by statute, or ultimately effective. Finally, there is insufficient data at this time for CMS or the supplier industry to truly evaluate the likely effects of such a proposal.

As discussed above in our general comments, we are steadfast that mail order suppliers should not be held to any greater or different standards than other suppliers. While we would certainly argue that our members are more than capable of meeting most beneficiary demands and providing high quality services (for both initial orders and refill orders), there are still many troubling aspects to this proposal if it would treat mail order suppliers differently.

In response to the comments requested on the ability of national mail order suppliers to easily, effectively and conveniently perform the services associated with the provision of home glucose testing supplies, let us assure you that not only are mail order diabetic product suppliers able to perform these services, they are unquestionably better at providing these services than

most general DMEPOS suppliers. That is true because these mail order diabetic product suppliers specialize in diabetic supplies and employ staff who devote their full-time efforts to working with patients who have diabetes. It is not surprising that the associated services provided by these specialty mail order suppliers are as up-to-date and professional as can reasonably be expected of a supplier of diabetic testing supplies.

Mail order suppliers are generally indistinguishable in most important aspects from all other types of suppliers, so much so that CMS would be hard pressed to offer a reasonable definition of a "mail order supplier." This is likely why there is no such definition contained in the Proposed Rule. This lack of distinction is evident from two key facts. First, the current Medicare supplier standards (42 C.F.R. § 424.57) essentially require all suppliers to operate a walk-in storefront facility. Supplier standards (7) and (8) require all suppliers, including mail order suppliers to maintain a physical facility on an appropriate site, which must be accessible during reasonable business hours to beneficiaries and to CMS, and must maintain a visible sign and posted hours of operation. Thus all "mail order" suppliers are required to operate the same types of bricks-and-mortar storefront locations as other suppliers. Second, and equally as important, many (if not most) suppliers offer some items and supplies via mail or delivery. Accordingly, supplier standard (12) requires that all suppliers must be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery. Thus, no suppliers are exclusively mail order suppliers, and most suppliers furnish at least some items through the mail or similar delivery, making the term "mail order" virtually meaningless.

The agency's attempts to single out a subsection of DMEPOS suppliers referred to as "mail order" is troubling, especially because it may be seen as a flawed attempt to leverage lower reimbursement on an important subset of suppliers that furnishes admittedly important services to Medicare beneficiaries. We challenge CMS to provide data that supports that this undefined supplier type of "mail order" suppliers has lower price structures than other "non-mail order suppliers." Even if true, this fact would seem to warrant attempts to work with these suppliers to provide greater care to beneficiaries, rather than place them at a competitive disadvantage with other suppliers of the same types of products. First, the cost structures of all suppliers, including each of the members of our Coalition, vary significantly. We are unaware of any data to support that certain suppliers who furnish DMEPOS more often through the mail have lower costs or would necessarily be able to furnish supplies to Medicare beneficiaries at a lesser price. If we did, we surely would have trumpeted such data to Congress in advance of the passage of the MMA. Second, even were it the case that "mail order" suppliers have lower costs, there are many other types of suppliers that likely would have similar or even lower cost structures. For example, although they may have higher costs in acquiring products on a wholesale basis due to having smaller volume purchases, Part A providers, such as skilled nursing facilities and home health agencies that operate DMEPOS suppliers, likely have little additional overhead for furnishing Part B covered supplies. No additional personnel or physical space may be necessary, and there are no delivery costs. A similar argument could be made with regard to items furnished directly by physicians. Many large retail pharmacy chains that purchase supplies in large volumes have lower overall costs than typical mail order suppliers that may include

significant mail order businesses. In fact, many retail pharmacies are also "mail order businesses." Thus, there is no logic in singling out "mail order" suppliers.

"Mail order" suppliers provide significant benefit to beneficiaries and the Medicare program alike. Like Part A suppliers and physicians, "mail order" suppliers offer an array of benefits to Medicare beneficiaries that suppliers that do not offer products via the mail cannot provide. For many beneficiaries, mail order is essential for them to receive timely the products and supplies that they require to maintain their health in accordance with their physician's order(s). Many beneficiaries have limited mobility and are unable to get to a storefront supplier on a regular basis to obtain their needed products and supplies. Other beneficiaries reside in areas where the products or brands of their preference may not be readily available or may require driving long distances. Still others rely on the toll-free numbers and immediate access for their regular questions. There can be no doubt that the key features offered by "mail order" suppliers of no-cost delivery directly to the beneficiary's home, broad product selection and toll-free telephone access are essential to many beneficiaries and, therefore, the Medicare program generally; however, these benefits do not come without a cost. Yet, CMS seems to be completely ignoring these types of benefits, as well as those offered by Part A providers and physicians.

In addition to the unfair and inappropriate treatment of "mail order" suppliers, the Coalition believes that a thorough analysis of the potential savings of selected products needs to be made prior to the determination as to whether a nationwide or regional mail order CBP would be justified. We are particularly concerned that the preamble of the Proposed Rule suggests that diabetic testing supplies would be an appropriate product for such program. First, only about forty percent (40%) of diabetic testing supplies are currently furnished via the mail, with the vast majority being furnished through retail pharmacy locations. Second, with the recent, significant reductions in fee schedule payments pursuant to the MMA, and the low margins that currently exist for diabetic product suppliers, we believe that diabetic testing supplies would not yield sufficient savings to justify a nationwide or regional mail order CBP for those supplies. Finally, we are concerned that the complete winnowing of diabetic testing suppliers, by potentially subjecting them to competitive bidding in both the top 100 MSAs and in separate regional or national bidding, would do harm to the long-term competition in this area and potential future savings for the Medicare program. If very few suppliers remain in business after the initial three-year contracts expire, pricing can go nowhere but up at that time.

Thus, we strongly object to any proposals for national or regional competitive bidding at this time, at least until further dialogue is established and data is available.

If, against our objections, the final rule incorporates some version of this as yet unsubstantiated plan for national or regional competitive bidding, it makes no sense to have the same products that CMS plans to subject to a regional or nationwide mail order CBP also to be included in the local CBA products set to begin in 2007. If the regional/nationwide mail order CBP price is lower than the local CBP price, then only that single process should be used. "Mail

order" suppliers should not be forced to compete against their own bids in the CBAs, which raises further questions about whether prices set under a regional/national CBP would be effective in CBAs. A second tier of pricing within the CBAs would go against the plain language of the MMA, which requires a single price.

Finally, we are concerned that providing a national or regional CBP for "mail order" products will unfairly disadvantage the "mail order" suppliers. For example, many larger retail suppliers, such as retail pharmacy chains, have mail order capacities as well as hundreds (or thousands) of retail outlets. Absent adequate definitions and much more developed rules, there is nothing to prevent such potential bidders from choosing to compete only as "non-mail order" suppliers under the CBP. As such, these suppliers could likely continue to access most of their traditional patient bases at the likely higher reimbursement rates offered outside of the national or regional CBP, while still offering mail order services without having to make such services available to the Medicare program. This is inherently inequitable and places undue burden on suppliers who focus primarily on the furnishing of DMEPOS via "mail order."

As an additional point, we want to respond to CMS' specific request for public comment on the feasibility of requiring all replenishment of diabetes testing supplies to be furnished through mail order suppliers. We believe that a "mail order" supplier is fully qualified to furnish diabetic testing supplies to all beneficiaries in all cases, including initial orders. There simply is no clinical reason that even initial supply orders cannot be furnished appropriately via the mail. The Coalition firmly believes that the service model followed by our members, which includes regular patient outreach and access to personnel dedicated to the furnishing of diabetes testing supplies, is one that could benefit all beneficiaries. We recognize that certain items of DMEPOS such as oxygen may require in person contact, but this should be item specific and not broadly required because it will only diminish the opportunity for savings otherwise available to the program. Therefore, we respectfully request that CMS clarify that nothing in the Proposed Rule would preclude any supplier from furnishing a beneficiary's initial supply of diabetes testing supplies. We also urge that any process be consistent for all suppliers, such that the same reimbursement opportunities are available to all suppliers bidding to furnish the same products or supplies to the same beneficiary.

We ask that CMS revisit both of these proposals with a new NPRM with significantly more detail after the initial ten MSAs are bid and more data becomes available.

III. "CRITERIA FOR ITEMS SELECTED"

The MMA requires that CMS select as items to be included in the CBP, "first among the highest cost and highest volume items or those items that the Secretary determines have the largest savings potential." (Emphasis added.) Further, the MMA grants CMS the authority to exclude from the CBP those products for which significant cost savings cannot be demonstrated. Neither the MMA nor the NPRM provide definitions of the terms "savings potential" or "significant cost savings." The Coalition is concerned by the lack of definitions of these terms, which appear to leave far too much discretion and uncertainty in an area that was of great

importance to Congress. We believe that in spite of the lack of definition in the MMA, Congress intended that there be certain boundaries for these terms. Accordingly, we believe that CMS should propose definitions that would allow for public comment on these important terms. We also would like to point out that while Congress set forth guidance as to how CMS should select specific items and categories for inclusion in, and exclusion from, the CBP, Congress did not mandate that any particular product or category, or any particular numbers of products or categories, be included in the CBP at any specific date. Unfortunately, nowhere in the NPRM does CMS suggest what products or categories would truly have the most significant savings potential. CMS' reliance on total costs is not indicative of likely savings, and CMS has produced very little data, which is limited only to the demonstration projects, to allow the industry to comment sufficiently on its theories or projections of cost savings. Accordingly, we ask that CMS use its granted authority under the MMA to implement the CBP at a slower rate than that proposed in the NPRM. Starting with few product categories, such as those where there is already considerable experience due to inclusion in demonstration projects, is both authorized and makes good sense.

With respect to definitions of cost savings, we ask that CMS remain consistent with existing regulation. CMS has been often criticized in the past for increasing the confusion and complexity of the Medicare program by adopting different definitions and standards in related areas of the program. Consistency is welcomed. The "Inherent Reasonableness" ("IR") regulations define "significant reductions" as 15% or more. We believe that same definition should be applied to the CBP with respect to product categories under consideration for inclusion in the CBP. Thus, if IR reductions would not be appropriate for a particular product, that should be sufficient for CMS to demonstrate that significant cost savings cannot be achieved by including the product in the CBP.

In addition, we believe that savings (both with regard to product selection and exclusion) must be measured not only in total potential dollar savings within a bid category, but equal weight should be given to the amount of reduction from current fee schedule pricing. While diabetic testing supplies clearly are among the highest volume DMEPOS products purchased by Medicare beneficiaries, these supplies are among the lowest per unit cost of any products available. Additionally, as noted previously, the MMA significantly reduced the fee schedule payments for certain products under consideration for inclusion in the CBP, including diabetic testing supplies. At least with respect to diabetic testing supplies, the MMA cuts have resulted in corresponding reductions to the already thin profit margins of suppliers of these products. CMS should refrain from targeting product categories where the savings is likely measured in only pennies per product.

As to the total potential dollar savings, the savings in Medicare outlays should be reduced by the share of the administrative costs attributable to operating the program that can reasonably be allocated to inclusion of the product in the CBP. We believe that CMS has drastically under-accounted for such costs. We do not believe that it is possible for CMS to have taken into account all of the likely costs to be incurred in implementing and administering the program.

Specifically, we understand that likely costs for beneficiary education and advertising regarding this important change and transition have not been included in fee estimates. Further, a number of private reports have cast doubt on the agency's projected staffing, even with the proposal to use third party contractors. One 2002 report from Don Muse & Assoc. titled "Regulatory Mandates Imposed Under the New Medicare Competitive Bidding Program" projected that CMS would require at least 1,626 additional full-time employees to effectively manage a competitive bidding program. If the total costs of the many implementation contractors, DMERCs/MACs and CMS itself (including reimbursement at the single price for covered items) results in only a net insignificant savings for a particular item or group of items, those items should not be included, regardless of their volume.

Further, if there is credible evidence presented to CMS that a product's inclusion in the CBP may result in reduced beneficiary access to, or use of, needed supplies, the total cost savings (or projected deficit) to the Medicare program over the term of the contract period must be considered. As we noted earlier, numerous studies show that the use of diabetic testing greatly reduces the extraordinary cost of caring for complications of uncontrolled diabetes. If added costs of non-compliance with prescribed testing regimens that many experts predict will occur if these products are included in the CBP are figured into the savings computation, any reduction in the accessibility of testing supplies will significantly increase total program expenditures. Treatment of diabetes related complications is already identified as one of the highest Part A costs incurred by the Medicare program. The failure to include the likely increases to these already onerous costs is a failure to adequately assess cost savings as Congress intended. Well aware of these costs, CMS has proposed several initiatives over the past six years to improve coverage for prevention of diabetes related complications. It would be in opposite to longstanding CMS policy to destroy those important efforts to improve prevention, by changing coverage for the most effective form of prevention that most diabetics have – testing their blood sugar levels frequently, as prescribed by their physician.

Finally, if significant consideration is being given to making diabetic testing supplies one of the nationwide mail order competitive bidding program after 2009, it makes no sense to include these products in local CBPs starting in 2007. The delay until 2009 will give CMS needed time to determine whether there can be savings for these products under a nationwide or regional mail order CBP. Until then, it is clear that under a local CBP there will be no significant savings for diabetic testing supplies, under a reasonable definition of "significant," and that the cost of caring for the complications of uncontrolled diabetes resulting from beneficiaries reducing their testing because the supplies are not easily accessible will greatly exceed any imaginable savings.

IV. "SUBMISSION OF BIDS UNDER THE CBP"

A. Providers

The Proposed Rule would require that a skilled nursing facility ("SNF") that provides covered products to only its inpatients would still have to apply and be selected to provide these

products under the CBP. The SNF's only relief is exemption from having to supply the products to those non-patients who request them—an unlikely scenario, and one not necessarily beneficial to the SNF.

We believe that SNFs that furnish Part B DMEPOS items only to their own residents ought to simply be exempt from the CBP. This would eliminate the need for thousands of SNFs to apply under this program. We believe that the statute can be liberally interpreted to provide for such exemption.

On the other hand, we do not believe an exemption should apply to products provided to SNF patients by entities that are joint ventures between the SNF and a local supplier, or one where the local supplier operates an SNF-owned supply business under a "turn-key" operation. In these cases, even though the SNF has some involvement, the actual supplier is the joint venture (which is distinguishable from the SNF), and the CBP process should apply to those DMEPOS items covered under the CBP.

We suggest, however, that the SNFs be required to enter into contracts with CMS just as any other winning supplier would be required to do. Although the SNFs could furnish supplies at the fee schedule prices, they would be subject to the same subcontracting limitations as any other supplier.

B. Physicians

The Proposed Rule requires physicians who provide covered items to their patients in their offices to qualify for and be selected to continue to provide the items under the CBP.

As noted in the Preamble, most physicians do not supply DMEPOS items for home use to their patients, in part, because of the prohibitions of the physician self-referral law, commonly known as the Stark Law (42 U.S.C. § 1395nn). However, we note that there are certain exceptions to the Stark Law prohibitions for DMEPOS items that are so integral to the physician's in-office service, particularly those that are necessary for beneficiaries to ambulate when leaving the office, such as canes, crutches, walkers and folding manual wheelchairs. See 42 C.F.R. § 411.355(b). The Stark Law exception was created out of the agency's recognition that it is often essential for beneficiaries to have these items just to get home from the physician's office. Both for purposes of consistency of CMS regulations (as we have also urged above) and for purposes of meeting the essential needs of beneficiaries, we believe doctors who meet the Stark Law exception should be permitted to continue to provide these items, without participating in the CBP.

Between permitting this exception and the Stark Law prohibitions, we doubt whether many physicians would need to submit bids and become a contract supplier under the CBP.

C. Product Categories for Bidding Purposes

The Coalition generally agrees with the proposition that products should be bundled together for beneficiary convenience, however, in addition to setting fair pricing for products including those categories, there are a number of potential pitfalls that could significantly jeopardize the effectiveness of the program when grouping items into product categories. Access to beneficiaries may be thwarted and bids could be compromised if the categories are not set appropriately. Unfortunately, the Proposed Rule does not set forth any proposed methodology for grouping items into product categories. It therefore is not possible for us to comment on this general proposition. Without even a proposed methodology, it is impossible to know what items would be included as diabetes testing supplies or to comment most effectively on the method of calculating the composite bid. Accordingly, we respectfully ask that CMS prepare a second NPRM to propose some reasonable methodology for grouping items into product categories and what those categories themselves may be. We believe that a formal notice and comment period is essential to effectively address this most important aspect of the Proposed Rule, as among other things this issue will certainly affect the public's ability to appropriately comment on the method for calculating the composite bid and other aspects of the Proposed Rule that may be impacted.

We reiterate our position that it is more than likely that there will be no significant savings for diabetic testing supplies for all the reasons indicated in these comments under the heading "Criteria for Items Selected," herein.

V. "CONDITIONS FOR AWARDING CONTRACTS"

A. Quality Standards and Accreditation

We strongly believe that only accredited providers should be eligible to submit bids. For the following reasons, we strongly urge CMS to delay implementation of the bidding process until all potential bidders have had sufficient time to secure accreditation. First, we have significant concerns about the ability of many suppliers to be able to secure timely accreditation. There are over 150,000 suppliers currently enrolled in the Medicare program. It will be nearly impossible for accrediting organizations (which have not even been selected yet) to accurately determine which suppliers will be submitting bids under the CBP, and which will not. The Proposed Rule quite correctly does not restrict suppliers from outside of a CBA from bidding within that CBA; however, this will make it very difficult for accrediting organizations to accurately assess which suppliers should be given the greatest priority, especially when many of these accrediting organizations will have little history in accrediting DMEPOS suppliers at all. Second, we believe that many of the currently enrolled suppliers will never be able to meet the rigorous demands, or likely expenses, of the accreditation process. These suppliers should never be allowed to submit bids in the first place. Their bids can only add to the confusion of administering the CBP and may inappropriately affect the selected single prices. Finally, suppliers need to have a better understanding of the costs that they are likely to incur to be accredited before they can submit informed bids. The failure to allow sufficient time for

suppliers to understand the true costs of accreditation can only lead to inappropriate bids. Such bids are likely to affect the long-term stability of winning suppliers and ultimately beneficiary access to the products they require.

So as not to unduly delay implementation of the CBP, CMS should "grandfather" for the first bidding cycle any supplier that has received accreditation by any organization that meets minimal accreditation standards, even if that organization is not ultimately selected as an accrediting organization, or if the standards used are not totally consistent with the standards required by CMS.

To be consistent with longstanding regulations regarding accreditation of other providers and suppliers in the Medicare program, securing accreditation from a CMS-approved accrediting organization should "deem" the supplier as acceptable for participation in the Medicare program and in the CBPs. It seems nonsensical to have tougher standards for DMEPOS supplier program participation than for hospitals where deeming of qualification for program participation by approved accrediting organizations has always been an accepted practice. In addition, it makes no sense to duplicate the approval process though the DMEPOS standards. The role of the Medicare National Suppliers' Clearinghouse ("NSC") should be limited to reviewing complaints regarding non-compliance, spot checks for compliance with the accreditation standards, and to issuing supplier numbers based on accreditation verification. The NSC would still approve those suppliers who wish to operate in non-CBP areas or to provide non-CBP products, and choose not to become accredited. The NSC also should be responsible for ensuring that contract terms are met, such as subcontracting provisions and ownership changes.

B. Eligibility

The Proposed Rule would require disclosure of any prior or current legal actions, debarments, or sanctions by any federal, state or local government program. We agree that bidding suppliers must disclose any debarments or exclusions by federal, state or local programs. The reporting of sanctions, however, should be limited to those sanctions which could effect the right to provide services. An overpayment on disputed claims, a fine for late filing of a license, or similar actions could be considered sanctions, and should not have to be reported. "Legal actions" is too broad a term, and no reporting should be required unless there is a final judgment against a supplier. To consider a supplier ineligible based on an allegation or legal action brought, where there is no verdict, is a violation of the legal principal that a party is deemed innocent until convicted.

C. Financial Standards

Proposed regulation section 414.414(d) requires bidders to provide bank references, credit history, insurance documentation, evidence of lines of credit and business capacity, and other information, but does not detail how those financial standards may be applied to suppliers. We believe that the lack of detail on this important section of the Proposed Rule makes it impossible to provide effective comments. The absence of any transparency with respect to the

financial standards is not at all appropriate in view of the centrality of the standards in the bid process, and leaves open the possibility that such standards could be used to unfairly discriminate against and eliminate many willing and respectable businesses from participation in the CBP. Nonetheless, we agree that satisfaction of some type of very definite and objective standards must be a precondition to bidding. If the standards are too restrictive, fewer suppliers will be able to participate in the bid process, diminishing beneficiary choice and potentially adversely affecting the single payment amount. If the standards are not restrictive enough, unsound suppliers may be awarded contracts. Accordingly, we believe that the financial standards are another issue that should be included in a new NPRM for public comment before any final rule or interim final rule is issued. Like the selection of product categories, this too is an essential element of the CBP, and public dialogue is important to ensure that the issue is addressed effectively for the Medicare program, beneficiaries and suppliers. We ask that this additional round of comments be completed before the proposed rule, in part, because the method of assessing the financial capability of suppliers planning to meet demand through expansion should be known so that suppliers can have a reasonable amount of time to address these standards when planning for expansion and making bids..

In addition, we urge that the proposed rule contain standards for rejecting bids that are unreasonable on their face, such as those that are clearly below a supplier's marginal cost. Such standards are essential to prevent one or more suppliers from bidding below cost in order to become one of the few contract suppliers in a CBA. These unfair bids would completely disrupt the integrity of the bidding process. Such bids may lead to suppliers being unable to meet their expected demands, or even dropping out of the CBP. Equally as important, after competing suppliers have been driven out of business within the CBA, these below-market bidders will be able to significantly raise their bid prices in subsequent bid cycles. This is far from a competitive environment.

D. Market Demand and Supplier Capacity

CMS is quite correct in its suggesting that suppliers that focus on certain types of products, particularly those that may be provided via the mail, will have a greater capacity to expand their existing services if they are chosen as a contract supplier than suppliers of other types of products that are limited to more localized delivery, such as oxygen and beds. For many of these suppliers, including suppliers focusing primarily on diabetic testing supplies, measuring past capacity is likely not the strongest indicator of supplier capacity. Instead, we ask that CMS include in a new NPRM with opportunity for public comment specific criteria that would be required in a business plan that would be reviewed and evaluated by CMS for each supplier. Again, this such is an essential aspect of the CBP that there must be further public comment and discussion before any final rule is published.

In addition, in determining market demand, CMS must carefully account for continued growth that is anticipated in key product areas, such as diabetes testing. Demand should also be judged based in consideration of the breadth of brands and types of products and supplies that are

currently available in each CBA, and which are used most often by beneficiaries. Demand cannot be met by providers offering a single brand of product. In this regard, demand and access are synonymous. Thus, the test for determining when capacity meets expected demand may have to be different for different types of products.

E. Composite Bids

The Proposed Rule seeks comments on the best method for weighing individual items within a product category to determine the composite bid. The method may have to differ depending on the products chosen and the product categories to which they are assigned. At this point, it is impossible to comment effectively until the products and product categories are determined and identified. This is another example of CMS rushing implementation without a chance to appropriately study the situation. We believe that "getting it right" is more important than rushing implementation before important issues like this one can be resolved. Accordingly, we request that CMS seek additional public comments following its proposal of product categories to be included in the CBP. Such request and comments should take place well before any bids are solicited for those product categories.

F. Determining the Pivotal Bid

Under the Proposed Rule, only those bidders at or below the pivotal bid will be given contracts. We believe that suppliers whose bids are very close, but slightly higher than the pivotal bid, should not be excluded, but instead invited to participate at the single price determined under the CBP. Alternatively, the pivotal bid could produce a range determined statistically as within a certain number of standard deviations from the pivotal bid, depending on the distribution of all bids. Anyone below the top of the range would be selected to participate. In many cases, bids over the pivotal bid will differ by only pennies. CMS should allow these higher bidding suppliers a fair opportunity to participate by agreeing to contract with CMS at the single price. This additional inclusion would only serve to enhance the CBP by helping to ensure additional access for beneficiaries, while not affecting the price or cost savings for the program.

We strongly believe that something must be done to prevent a supplier from bidding far less than a reasonable price to assure participation at the higher single payment rate. We are concerned that these suppliers will show a small capacity, so as not to effect the actual selected price, and then sell far in excess of its estimated capacity at the higher rates determined under the CBP. We recommend elimination of suppliers who submit bids that clearly are below the cost of the product or supply, and possibly submitted only to "game" the system. Such suppliers should not be rewarded by securing winning bids.

We also reiterate our above comments with regard to the fact that (1) the pivotal bid must accurately reflect the winning suppliers' abilities to meet beneficiary demand for the bid products and (2) only accredited suppliers should be considered in selecting the pivotal bid.

G. Assurance of Savings

Under the Proposed Rule, bids for items above the current fee schedule will disqualify the bid. We strongly oppose CMS not accepting bids for a product category if a bid for an item within that category is higher than the current fee schedule for that item. In a number of cases, fee schedule reimbursement is already low, and suppliers furnish items at a loss in order to be able to better serve their patients. These issues should not hamper a supplier from being able to bid effectively on a product category.

First, it is only by permitting such bids that CMS can determine whether it is unlikely for there to be substantial savings to the program and make the decision to eliminate those products from consideration under the CBP. It was clearly the intent of Congress for CMS to make such a determination.

Second, the key to a bid will be its composite bid price and not the price of individual items in the product category. A supplier may be saying, "I would be willing to take a loss on some products in the category, if I can keep up the profits on others." Thus, their composite bids may be determined by this higher and lower than fee schedule pricing proposals.

Finally, we think it is unfair not to accept the entire bid of a supplier, where one or two of the bid amounts for products in the product category do not meet the savings test.

As to the assurance of savings itself, as indicated earlier in these comments, we believe that CMS needs to define savings before products can be included in the CBP as "substantial" or "significant" savings both by dollar amount, and by percentage amount, and consider the administrative costs of operating the CBP in determining if there are substantial savings.

H. Assurance of Multiple Contractors

CMS seems to have taken the position that they have met the Congressional intent with regard to "small" suppliers by assuring their ability to apply, not by assuring their ability to participate. We think Congress wanted to assure that "small" suppliers would be participating in the program. The provisions of the NPRM do little if anything to ensure such participation.

I. Selection of New Suppliers after Bidding

CMS has indicated that selected suppliers may have their contracts suspended or terminated, and, thus, they will need to add suppliers. A equally likely scenario is that some selected suppliers will decline participation, especially if the single price is set below their actual bid (a result of using the median of winning bids or for other reasons).

We believe that if an insufficient number of suppliers accept contracts to reach the needs of the beneficiaries in the area, CMS should conclude that cost savings for the Medicare program are not achievable. Alternatively, a new round of bidding should be made. Offering the CBP

prices to suppliers whose bids were even higher than the pivotal bid makes little sense. For starters, many of these suppliers may be forced out of business if they are not awarded a contract under the CBP. If CMS truly anticipates the need to go back to suppliers above the pivotal bid at some point, CMS should be setting the pivotal bids at a high enough level such that the CBA will be able to sustain some level of natural losses of suppliers. We are further concerned that the process of seeking additional suppliers could all too easily become an open solicitation to "all willing" suppliers to furnish supplies at the single price. This defeats the purpose of the CBP.

VI. "DETERMINING THE SINGLE PAYMENT AMOUNTS FOR INDIVIDUAL ITEMS"

A. Setting Single Payment Amounts for Individual items

The Proposed Rule contemplates that the MMA mandated single payment amount for an individual item in a CBA will be based upon the median of the supplier bids which are at or below the pivotal bid for that item. The Coalition strongly opposes this proposal and believes that such an approach violates Congressional intent and basic economic theory. We further believe that the proposed methodology will result in suppliers being unable to uphold their CMS contracts, creating access problems for beneficiaries.

Congress' overarching purpose in enacting the competitive bidding portions of the MMA were to allow market forces to determine the price of DMEPOS rather than a somewhat artificial system based on allowables, fee schedules and gap-filling. Congress' view was that a robust competitive bidding process would enable the government to get the best available price while at the same time not compromising the quality of service received by Medicare beneficiaries. For example, Senator Kyl, during the debate on the MMA, stated "What is the solution? . . . . Simply allow competitive bidding. Let the markets decide what the right levels are." (Cong. Rec. S8544 (daily ed. June 25, 2003) (Statement of Sen. Kyl).) Similarly, CMS' own press release on competitive bidding stated that "Competitive bidding provides a way to harness market dynamics...." The method proposed in the CMS Release does not truly allow the market to set the price for a particular product and violates traditional economic theory on multiple bidder/multiple item purchasing. As a result, the Proposed Rule is likely to do economic harm to bidding suppliers, which harm will have significant harmful effects on both beneficiaries and the Medicare program itself.

We strongly recommend that the highest bid of a winning supplier for each item in a bid category should become the single payment amount in each CBA. Consistent with our comments with regard to market demand, CMS' contract awards under the Proposed Rule are contingent upon the notion that the services of all winning bidders are needed to meet the anticipated demands of beneficiaries in the CBA. If each of these suppliers is necessary to ensure sufficient access for beneficiaries, then each winning bidder must be able to furnish all items within a product category at a price that is sustainable for that supplier. Since the very purpose of the CBP is to induce suppliers to bid their lowest possible price to compete, reimbursement that is lower than that bid price is unsustainable by the winning supplier.

The median price proposal has the potential to create havoc within the CBP. First of all, it was unclear from the proposed regulations whether or not CMS intends to compel winning suppliers to provide items to all beneficiaries within the CBA, particularly if reimbursement within the CBA is substantially below the price at which the supplier bid. If CMS intends to force suppliers to supply DMEPOS at prices below their bids, a very significant question remains as to whether or not the suppliers will be willing or, for that matter, economically able to provide items on that basis. Unfortunately, the unwillingness or inability of contracted suppliers to supply DMEPOS at the single payment amount proposed by CMS will ultimately be to the detriment of Medicare beneficiaries who will be unable to access medical supplies which they require.

In addition, the process proposed by CMS could result in significant pricing anomalies. Consider the following hypothetical. In a particular CBA, there are thirteen contract suppliers who have successfully bid an item. Five of the suppliers have been in the DME business for a number of years and fully understand their cost structures and service requirements of the market. The five suppliers currently share 80% of the market in that MSA. The remaining eight suppliers are small suppliers with little experience in this market and share approximately 10% of the market. They each believe they can grow their businesses significantly. The use of the bid item requires a significant amount of service, patient training and clinical in service. The fee schedule amount for this item is $100. The first five suppliers bid between $87.50 and $85.00. The remaining eight suppliers bid between $52.00 and $64.00. Under CMS' proposed rule, the single payment amount would be $62.00 (the bid amount of supplier number 7), despite the fact that this bid (and the bids which were lower) represent less than 10% of the market. Although it is possible to debate the likelihood of this scenario occurring, it is absolutely true that there are thousands of small suppliers (and some less-sophisticated larger suppliers) who will seek to participate in competitive bidding (and in many cases whose very existence will depend upon being selected as a winning bidder) and likely distort the bidding process by submitting unrealistically low bids.

In this scenario, the price established under the CMS proposed regulations would have a number of unintended consequences. It is likely that the five major suppliers in the above scenario would be unwilling or, at best, unenthusiastic about serving the needs of Medicare beneficiaries in the CBA. In addition, it is unlikely that any of the smaller suppliers would be able to provide the service, training and in-service necessary in order to use the DMEPOS items safely and effectively, especially at an inappropriately low single price. Moreover, this problem will be exacerbated if the larger suppliers begin to withdraw from the market, and the smaller DMEs are forced to attempt to expand rapidly.

One significant reason that we are faced with the issues alluded to above is that the Proposed Rule is a dramatic departure from the pricing rules used in the two completed demonstration projects (Polk County, Florida and San Antonio, Texas). In the demonstration projects, individual bidders were awarded contracts based on the actual prices they had bid. We recognize that, because the MMA requires a single payment amount, this approach is no longer

viable. The concept of the demonstration projects, which ensured that no winning bidder would be required to furnish supplies at a price lower than their winning bid, must be sustained. The single price mandate is not a proper reason to distort the bidding process in the manner CMS has proposed.

As indicated above, the Coalition has grave concerns that, due to the likely significance attributed by many suppliers of winning a contract under the CBP (for many suppliers, this could be upwards of 70%-80% of their business), many suppliers are likely to bid unreasonably low, unsustainable prices in an attempt to make sure that they can maintain their principal source of revenue. In addition, many suppliers, particularly small businesses, do not fully understand their own cost structures. This situation is exacerbated by the fact that the supplier community will not be able to accurately assess the cost of complying with the proposed (but not yet final) quality standards or the cost of becoming accredited. As a result of these facts and the impact of the proposed methodology for calculating the single payment amount, it is likely that the single payment amount for many items will be extremely low and, in some cases, below the supplier's cost of providing the bid item.

Although the goal of competitive bidding is to reduce the price paid by CMS to suppliers for medical devices, the goal should never be to reduce the prices paid below the suppliers' true cost. Unrealistically low prices would have a number of negative consequences. First, it will cause a number of suppliers to fail, and, as a result, there will not be a sufficient number of suppliers to properly serve the beneficiaries in their CBA, and beneficiaries will experience reduced access and quality of service. Secondly, artificially low prices will cause suppliers to provide only the least expensive devices within a HCPCS code to patients - even in situations where a patient would benefit from a more expensive, sophisticated device. Because so many DMEPOS items, like diabetic testing supplies, are used for preventive care aimed at keeping beneficiaries functioning safely in their own homes, and out of the inpatient setting, ultimately, this could increase, rather than decrease, the total cost to Medicare of treating a particular beneficiary. Finally, unrealistically low prices may cause suppliers to fail to provide beneficial (but not required) services to beneficiaries.

Accordingly, we strongly encourage CMS to set the single price for each product at the highest price bid for that product by any winning bidder.

B. Rebate Program

Under this proposal, bidders who bid under the single payment amounts could offer beneficiaries rebates up to the difference, but could not directly or indirectly market the availability of the rebates. This proposal received universal public criticism at the recent Program Advisory and Oversight Committee ("PAOC") meeting in May 2006. The Coalition commends CMS on its attempts to help the beneficiary and give incentives to suppliers to bid their lowest price; however, this is simply a bad idea. Contractors would be prohibited from directly or indirectly marketing these rebates to beneficiaries or referral sources, but, of course, that would be what they would want to do in order to secure a larger share of the market. This

limitation would lead to covert actions to market the rebates and would become an open invitation to commit program fraud. These same types of incentives have been repeatedly turned down in other contexts by the Office of Inspector General and likely would not comply with numerous state laws against kickbacks. Furthermore, it is quite possible that rebates could lead to windfalls for beneficiaries by exceeding the amount of the beneficiary's co-payment. For example, consider a situation in which the three winning bids in a product category were $100, $85 and $75, with the single price being set at $100. In this case, the beneficiary would have a $20 co-payment (or 20 percent of $100); however, the supplier that bid $75 dollars could offer a beneficiary a $25 rebate. Thus, the beneficiary could essentially turn a profit merely by choosing a supplier. This goes against every principle by which the Medicare program generally and the co-payment concept specifically have abided. Instead, CMS should make clear that winning contract suppliers are not bound to bill at the contracted price, regardless of their bids. It should be clarified that they can bill "no more than" the contracted price. Consistent with current Medicare reimbursement methodologies, where Medicare pays the lower of the supplier's actual charge or the fee schedule, suppliers should retain the right to charge less then the single bid. By reducing their charge, suppliers can legally provide incentives to beneficiaries who will benefit from the lower charge by having a lower co-payment or deductible amount. As long as the supplier only charges Medicare its reduced price, that would prove acceptable to all parties and fulfill the purpose of the proposed Rebate Program. The regulations should be clarified accordingly.

VII. "TERMS OF THE CONTRACT"

A. Terms and Conditions

The Proposed Rule requires that all beneficiaries inside and outside of a CBA receive the same products that the contract supplier would provide to other customers. We believe that this non-discrimination provision needs to be revised significantly. Many suppliers have available and will supply to non-Medicare patients who will pay for the higher priced, premium brands of products, which they do not normally provide under Medicare. There is nothing improper about this, and it is a common practice. In most cases, wholesale prices for these premium brands or products are already well above Medicare fee schedule amounts. If CMS desires to have every level of product available to Medicare beneficiaries, bids will reflect that mandate and likely will not be lower than the current fee schedules.

We also believe it should be made clear that a winning supplier is not obligated to enter into a contract just because it was selected. As noted earlier, because of the implementation contractor's ability to manipulate the single payment pricing, those prices may be well below the winning supplier bid, even though the winning supplier's bid was at or below the pivotal price.

Similarly, CBP contracts must allow suppliers the ability to terminate the contracts if they cannot sustain their business due to unreasonably low single prices. Contracted suppliers must not be conscripted into providing services at a loss, especially when in most cases there is very little available data for suppliers to make bids with any level of assured sustainability given all of

the additional costs that the CBP will place on suppliers (including accreditation, quality standards and contract requirements).

B. Furnishing of Items

It should be clarified that a contract supplier can limit the number of items it provides under CBP in each category to its contracted capacity. A supplier may be unable to supply items to all beneficiaries who request them, and this caveat ought to be provided for in this provision.

C. Repairs and Replacement of Patient Owned Items

The Proposed Rule states that contract suppliers cannot refuse to repair or replace patient-owned items subject to competitive bidding. This requirement is particularly problematic where the contract supplier does not carry a particular brand of a product and has no relationship with that brand's manufacturer. In effect, suppliers will be required to supply parts for, and have technicians trained to repair, medical devices they have never stocked or supplied. We believe that there are a number of inherent problems with this proposal. First, it is dangerous to require contract suppliers to repair items which they do not normally stock. Their repair specialists would be required to repair items for which they have received little or no training and on which they do not regularly perform repair services. The results of such repairs could cause harm to Medicare beneficiaries and create unnecessary liability for suppliers. Most manufacturers have specialized training for the repair of their respective devices, and it would be virtually impossible for a small supplier to have technicians who were trained to repair eight or ten different brands of a particular item. Second, the costs of such an undertaking would be enormous, particularly for smaller suppliers. Finally, many types of DMEPOS cannot be repaired efficiently, and, as a result, they are more often replaced than repaired. For example, this would be the case with respect to glucose monitors. As a result, the Proposed Rule would have the effect of requiring contract suppliers to replace products which have been damaged, despite the fact that they were not the supplier that sold the item in the first place. The cost of undertaking this obligation would be enormous and would make it very difficult for a supplier to accurately assess its costs in submitting a bid.

Therefore, we recommend that where the beneficiary has purchased the product from a non-contracting supplier prior to CBP, that non-contracting supplier should be responsible for repairs and replacements and be paid accordingly.

D. Furnishing Items to Beneficiaries Whose Permanent Residence Is Within a CBP

Please note our earlier comments under "Payment Basis" regarding which supplier should be liable for the furnishing of rental and other products subject to grandfathering. Our comments and recommendations also are appropriate where the contract supplier does not carry the same brand or model that the beneficiary previously purchased, and the beneficiary does not want to change products.

Our recommendation is that the old supplier (whether contracted or not) be required to continue the rental and be paid in accordance with the fee schedule in place at the commencement of the rental period.

E. Furnishing Items to Traveling Beneficiaries Whose Permanent Residence Is Within a CBA

We generally agree with the proposal in the NPRM that beneficiaries whose permanent residence is within a CBA should be able to purchase items and supplies from non-contract suppliers when those beneficiaries are traveling outside of the CBA. However, if CMS is somehow going to determine a special class of suppliers referred to as "mail order suppliers," beneficiaries who are regular customers of such suppliers within a CBA should not be entitled to purchase their needed items or supplies from a non-contract supplier. A "mail order supplier" could easily furnish items to the beneficiary at the site of the beneficiary, even outside of the CBA. "Mail order suppliers" already routinely provide these services for "snowbirds" and other beneficiaries when traveling. We note that the Proposed Rule does not address supplies furnished to beneficiaries residing within a CBA who travel outside of the United States.

F. Information Collection from the Supplier

The Proposed Rule would require contracted suppliers to provide information as requested regarding the "integrity" of each product sold and billed under the CBP, as well as information on the integrity of the supplier's business as a whole. We do not believe that contract suppliers should be required to provide information on product integrity as long as there is a SADMERC coding verification that the product has been approved for billing under a particular CPT code. In addition, we do not believe that it is appropriate for suppliers to be required to provide information on the supplier's business integrity. Such assessments should be sufficiently covered in the supplier's certification process. It will add potentially significant and unnecessary costs for suppliers to substantially duplicate various reporting processes, especially if the potential reporting requirements and/or criteria are not identical. Accordingly, we ask that CMS consolidate such requests into a single process. We believe that the SADMERC's reviews and the proposed accreditation processes are the appropriate means to handle these types of issues.

G. Suspension or Termination of a Contract

The Proposed Rule permits suspension or termination of a supplier contract, not only for any breach of the contract, including failure to meet all requirements, but also simply for the "convenience" of the government. Since the criteria for suspension or termination are so arbitrary and can be easily abused, we believe the suspended or terminated supplier should be entitled to a "prompt" hearing and appeal of such suspension or termination. The provision of "No Administrative or Judicial Review" in the MMA does not apply to suspension or terminations of awarded contracts. Arbitrary suspensions and terminations without due process

may be considered to be an illegal taking under the Fifth Amendment to the United States Constitution.

VIII. "ADMINISTRATIVE OR JUDICIAL REVIEW"

We recognize that the MMA is generally clear with regard to there being no formal administrative or judicial review. However, because the review and award of CBP contracts will be labor intensive, it is likely that there will be many inadvertent human and computer errors and/or indisputably arbitrary decisions. Fairness requires there to be some avenue to bring these types of clear errors to the agency's attention. While the MMA grants CMS much discretion in making determinations under the CBP, Congress has not granted the authority to mute the authority of published regulations by using known improper or erroneous information to effect those regulations. We, therefore, recommend a "reconsideration process" with regard to the award of contracts only, and authority for the Provider Reimbursement Review Board or some similar body within CMS set up to hear such requests for reconsideration. We recognize that the agency's decisions could not be administratively or judicially appealed; however, at least there would be a process for correcting clear errors. Please also note that we ask CMS to also consider our above comments with regard to decisions to suspend or terminate contract awards.

IX. "OPPORTUNITY FOR PARTICIPATION BY SMALL SUPPLIERS"

We believe that Congress clearly intended that small suppliers should participate in the CBP, not merely that the ability to be in the bidding process should be assured. We also believe that the term "Organizational Conflicts of Interests" requires further definition. In addition, we believe that the term "Employee Information" should be defined in a manner that will not place onerous burdens on suppliers, since many larger suppliers may have hundreds of employees and the burden and cost of gathering the information may be significant. Additionally, we believe that bankruptcy proceedings of affiliated companies should be irrelevant to the selection process and should not be requested. Finally, we believe that program certification should assure compliance with several of these items, such as "Training and Qualifications" and "Customer Service Protocol."

Finally, we note that, at the May 2006 PAOC meeting, when it was discovered that many decisions were being made based on meetings with a focus group of 44 beneficiaries, there was considerable doubt that CMS had received a appropriately representative or accurate picture of beneficiary needs and concerns. At CMS' request, our members would be happy to provide the agency with additional feedback from some of the many thousands of beneficiaries serviced by our members. As indicated above, we believe that the agency has been very misinformed about the likely problems and complaints that beneficiaries are almost certain to have as a result of the proposed CBP. Similarly, we question how many small suppliers were actually in the focus groups on small suppliers and whether this number was sufficient to reach any conclusions or recommendations, especially in light of our belief that the overwhelming majority of the more than 150,000 suppliers currently enrolled in the Medicare program would qualify as small businesses under the Proposed Rule.

A. Change in Ownership

The Proposed Rule would impose significant limitations on contracted suppliers when selling their businesses or changing their ownership structures during the term of their CBP contract. We agree that a successor entity will need to meet all requirements applicable to a contract supplier and will need to agree to accept the obligations of the contract through a novation agreement; however, we strongly object to any requirement that the new contractor must be required to meet expected demand for capacity for the bid items or be subjected to any greater review than is currently accorded to changes of ownership for Part B suppliers under existing Medicare regulations. The selling contract supplier originally secured its contract on the basis that its participation, along with other contracted suppliers in the CBA, met the anticipated beneficiary demand for the bid products. There is no reason for CMS to doubt or challenge the buyer's ability to maintain at least the same level of service as the seller. This limitation would seriously jeopardize legitimate merger or acquisition plans of contract suppliers. Part of the market theory behind the CBP is to encourage suppliers to bid their best prices in order to win contracts, with the understanding that winning contracts will increase the value of their business. If this provision is adopted as proposed, the value of winning businesses would not be increased, as the barriers to sale would be far too great. At the very least, if the agency proceeds with this proposal, CMS must be willing to make expedited approvals (with rights for appeal or reconsideration) of potential successors prior to settlements of sales or mergers.

X. "EDUCATION AND OUTREACH"

Certainly, we favor the proposed efforts for education and outreach. We are concerned, however, that the proposal, in spite of its importance, will further delay the timetable for implementation. Under the concept of it is more important to "get it right" than to rush implementation, we favor delaying implementation of the CBP until such time as the education and outreach can be done effectively. This is especially true for educating beneficiaries, which is extremely important to the success of this program. We are very concerned that beneficiaries are going to be essentially blindsided by the changes that may be effected by the CPB, especially beneficiaries with chronic diseases, like diabetes, who have longstanding relationships with suppliers and longstanding preferences for certain brands of products.

XI. "PHYSICIAN AUTHORIZATION/TREATING PRACTITIONER"

Pursuant to the requirements of the MMA, the Proposed Rule provides that, where a physician who orders a particular brand of a product because use of another brand will have an effect on the medical outcome, the supplier may not provide a different brand than the physician ordered. Physicians often indicate their preference for a particular brand of a product as a result of their history of patients using that product or because of manufacturer hard marketing, even if there would be no effect on medical outcome using another product. Even if a physician certifies that for a particular patient, the physician believes the patient needs a specified product to avoid an adverse medical outcome, there is often simply no basis for a supplier (which is not a physician, and often has no face-to-face contact with the patient) to accept or reject this

certification. In a similar situation, suppliers are frequently denied reimbursement for items and services when, in spite of having a valid physician's order or certificate of medical necessity ("CMN") signed by the physician and indicating the beneficiary's need for the ordered items, the supplier is unable to produce medical record documentation substantiating the order. Suppliers are not physicians and have no ability or desire to second guess physician orders and certifications.

The Proposed Rule would create innumerable logistical issues for suppliers. How would the supplier determine whether the physician certification is accurate? Many physicians may falsely make the required certification merely to support the preferences of their patients. Would CMS hold the supplier accountable if the physician could not back up the certification? What type of supporting documentation would be necessary? Obtaining supporting documentation takes time and could prevent beneficiaries from receiving the items that they require in a timely manner. How long may a supplier take to locate and provide specified items that the supplier does not carry? In many cases, certain products are sold only through certain contracted suppliers. How could such products be obtained? In many cases, items may only be able to be acquired via retail purchases, which may be substantially in excess of the single price. For example, retail prices for most diabetic testing supplies are already in excess of the current Medicare fee schedules (another reason why we believe that CMS cannot achieve substantial cost savings in this product category). If suppliers must factor in all of these potential purchases when making their bids, the likelihood of substantial cost savings will significantly decrease.

Accordingly, suppliers should be given the option to decline to provide the brand specified in the order or CMN, but in such case must consult with the physician to see if the physician is willing to revise his or her order to allow for a substitute brand to be furnished or otherwise refer the patient and physician to the CMS listing of other contract suppliers in the CBA. If the supplier chooses, and the physician agrees, to substitute a different product, the supplier should be required to obtain a revised order or CMN. However, it should be made clear that the supplier does not need to (1) actually provide the brand ordered or (2) locate another supplier that will agree to furnish the particular brand of product. Each supplier must be able to decline to provide a specific product, even if no other supplier will furnish it (in which case CMS will have done a very poor job of ensuring beneficiary access by appropriately selecting winning suppliers who can meet market demands). In addition, DMACs should not have any authority to deny claims if the supplier is ultimately unable to obtain documentation to support the physician's order of a particular brand (other than the physician's order or CMN itself).

The best way to address the issue of brands is for CMS to ensure that in selecting the pivotal bid, the agency selects a sufficient number of suppliers to provide the array of brands currently provided to beneficiaries. For example, the Proposed Rule would not otherwise address the ability of beneficiaries to obtain branded items with which they are familiar or comfortable. In the context of diabetic testing supplies, this is very important.

Since most brands of glucose monitors have similar effectiveness, in most cases there would be very little clinical reason for a physician to be able to substantiate the need for one brand over another. However, CMS must not forget that the CBP affects real people. The people in question are senior citizens who often have trouble making changes and who may have difficulty adapting to the use of products that are different in any material way from those that they have used for years. Yet, these preferences, while not clinically demonstrable, will most certainly have clinical results if beneficiaries are unable to adapt. As discussed above, if beneficiaries fail to test their blood sugar levels at their prescribed frequencies, they run serious risks for incurring common complications. Nonetheless, CMS can make this a non-issue if it adequately ensures that an array of brands are available in sufficient quantities in all CBAs.

XII. "QUALITY STANDARDS AND ACCREDITATION OF SUPPLIERS OF DMEPOS"

The Coalition has previously submitted formal comments with regard to the agency's proposed Quality Standards. Again, we reiterate our concern that the accreditation process will be time consuming and potentially costly. Accordingly, we ask that CMS delay the timeline for implementation of the CBP until this process can be fully completed and understood by the supplier community. We also, again, must indicate that we believe that "deeming" by an approved accrediting organization should eliminate the need for that supplier to get further approval from the NSC.

XIII. "LOW VISION AID EXCLUSION"

This section has little or nothing to do with the CBP. The CBP proposal is so extensive and so detailed that adding non-related matters to it will delay implementation of all the provisions. We suggest that this proposal be "spun off," republished as a separate NPRM, and withdrawn from this proposal.

XIV. "GAP-FILLING"

This is a major proposal and should be considered separate and apart from the CBP proposed rule. Because so much effort is needed to respond to the CBP proposal, this provision will not get its full consideration. We strongly urge that this proposal be "spun off," republished as a separate NPRM, with a separate comment period, and withdrawn from this proposal.

As to the proposal itself, we favor discontinuing the practice of deflating supplier prices and manufacturer suggested retail prices to the fee schedule base period for new products as the proposal does. We agree that the fee schedule for a new product should be based on the prices in effect at the time when the product receives its new HCPCS codes.

We, however, oppose any ability on the part of CMS to reduce prices on new or old products based on studies of competing different products or on the prices for products with

different codes that may be secured under CBP. Reductions should be limited to already existing authority under the "inherent reasonableness" provisions, as Congress intended.

We agree with the proposed handling of a change in HCPCS coding during a CBP cycle. We believe, CMS should agree to handling the pricing of non-CBP products, where HCPCS coding changes at any time, in the same manner. We note that this was not done for blood glucose monitor batteries.

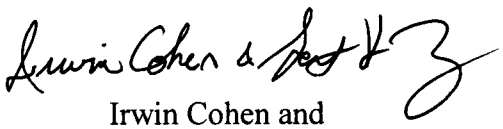
CONCLUDING REMARKS

The Diabetic Product Suppliers Coalition appreciates being afforded the opportunity to comment on this important proposal. While we commend CMS for the work that it has done to date in preparing this NPRM, we are very concerned that the proposal lacks necessary detail for sufficient public comment in many, many areas. Accordingly, while we ask that CMS treat these and other comments with great deference and careful consideration, we respectfully believe that the proposed timeframes cannot be achieved if a workable, sustainable and fair program is to be implemented. There is much work yet to be done, and the Coalition offers our assistance as a commenter, sounding board or participant in any discussions and considerations, particularly those pertaining to diabetes and to so-called "mail order" issues. Failure to adopt reasonable and workable regulations, that protect beneficiaries, provide cost savings for the Medicare program and do not unduly, adversely affect the supplier industry as a whole or disproportionately one or more sectors of the industry, would be a disservice to Medicare beneficiaries and the program as a whole, and could cause significant damage to the competitive abilities of certain sectors of the DMEPOS supplier industry over the long run. The final regulations must (1) be practical; (2) be clear, concise and easy to interpret and follow; (3) include requirements that are each in their own right fair, reasonable and intended to address a specific identified need for access, quality or fraud prevention; (4) not be unduly costly for suppliers; and (5) not disproportionately affect "mail order suppliers" or smaller suppliers. It is essential that the concerns of "mail order suppliers," like our Coalition's members, be heard and addressed as part of this process. Because these regulations are so essential to the future of the DMEPOS industry, they should neither be rushed or forced. CMS must allow adequate time and further industry comment to ensure that the final rule will meet their intended goals without causing undue hardship to suppliers, beneficiaries or the program as a whole. We urge CMS to consider adopting more reasonable timeframes for implementation.

Finally, because many of our comments address issues pertaining to diabetes and to so-called "mail order suppliers" – two important sectors that have been underrepresented throughout public discussions of the CPB (including no representation on the PAOC), we want to make the agency aware that we are willing and available at any time to provide additional information about these important sectors. We hope that CMS will consider seeking informal comment and information from us as this process moves forward. Any questions or requests for additional information may be directed to Seth Lundy (202-662-4711 or slundy@fulbright.com) or Irv

Cohen (202-662-4679 or icohen@fulbright.com). Your careful consideration is greatly appreciated.

Very truly yours,



Irwin Cohen and
Seth H. Lundy

IC/SHL/ams
cc: Diabetic Product Suppliers Coalition Members

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AMERICAN PODIATRIC MEDICAL ASSOCIATION, INC.

June 29, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1270-P: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues, 71 Fed. Reg. 25,654, May 1, 2006

Dear Dr. McClellan:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 of America's premier podiatric physicians and surgeons, is pleased to present comments on the Centers for Medicare & Medicaid Services (CMS) proposed rule, *Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*. The proposed rule would implement competitive bidding programs for certain covered items of DMEPOS. We believe that as proposed, the new program has the potential to interfere with patient care and will harm Medicare beneficiaries. We urge CMS to revise its proposals prior to implementation of a new competitive bidding program.

We would like to take this opportunity to express appreciation to your staff from the Chronic Care Policy Group and Division of Community Post Acute Care, who met with us on June 21 to discuss provisions of the proposed rule in greater detail. That meeting assisted us in clarifying specific issues of concern and we offer the following comments:

Submission of Bids under the Competitive Bidding Program

The proposed rule specifies that "physicians" that are also DMEPOS suppliers must submit bids and be awarded contracts in order to furnish items subject to competitive bidding in an area. It also notes that "physicians" that do not become contract suppliers must use a contract supplier to furnish competitively bid items to their Medicare patients. Further, the proposed rule states that "physicians" will not be required to furnish these items to beneficiaries who are not their patients if they choose not to function as commercial suppliers. In other words, such "physicians" would not be required to serve an entire competitive bidding area. Finally, the proposed rule has chosen to define the term "physician" by reference to 1861(r)(1) of the Social Security Act (which covers

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only doctors of medicine and doctors of osteopathy), rather than the more typical reference to 1861(r), which would also include doctors of podiatric medicine. Below we outline in considerable detail our concerns about these aspects of the proposed rule. We begin by describing how podiatric physicians use certain DMEPOS products as an integral part of the services they provide to their patients, and how the new competitive bidding program could interfere with the practice of podiatric medicine.

DMEPOS Use by Podiatric Physicians

As podiatric physicians and surgeons, our members prescribe and supply DMEPOS items as an integral part of patient care. Similar to medical doctors (MDs) and doctors of osteopathy (DOs), our members are required to obtain a valid supplier number and must adhere to the existing 21 supplier standards. Our members are licensed in the state in which they practice, are subject to the same Stark requirements that apply to MDs and DOs and must satisfy all other Federal and State regulatory requirements.

According to CMS, there are more than 7,300 podiatric physicians who are DMEPOS suppliers. Our members provide medically necessary and appropriate DMEPOS items in treating Medicare beneficiaries. Examples of how podiatric physicians utilize DMEPOS in patient care include:

A patient presents complaining of foot pain and swelling after tripping on a sidewalk. The podiatric physician diagnoses multiple fractures of the metatarsals and determines that a Cam walker is necessary for immobilization of the injured foot. If that podiatrist no longer functions as a supplier, the patient will be forced to travel to another location to obtain the brace, treatment will be delayed or perhaps never implemented, and the patient will risk further injury to the foot.

Or, the podiatric physician may treat a patient with an acute ankle injury and determine that an ankle brace is necessary to stabilize the ankle and that crutches are necessary to limit weight-bearing on the injured extremity. If that podiatric physician is not a DMEPOS supplier in the new competitive acquisition program because he or she was unsuccessful in competing to bid to supply to the entire Metropolitan Statistical Area (MSA) rather than just to his patients, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

Patients with conditions requiring acute care (e.g., fractures, foot or ankle injuries), must have immediate access to appropriate treatment, including DMEPOS items such as pneumatic walkers, non-pneumatic walkers, ankle braces, crutches, canes and walkers. These items need to be sized

and fitted by the doctor. The patient needs to be instructed on proper use of the item, including weight-bearing activities.

If the patient is unable to acquire the item from the treating physician and must instead obtain the item from another supplier due to the new competitive acquisition program, negative consequences could result. A delay in care could put the patient at risk for additional injury, which could result in increased costs to the Medicare program for the care of that patient.

For instance, if the patient with the foot fracture falls because she is unable to bear full weight on the injured extremity and breaks her hip as well, additional expenses will be incurred by the Medicare program. Or, a delay in receipt of necessary DMEPOS items could result in the deterioration of the patient's medical condition. A stable fracture could become unstable, thereby increasing the severity of the existing injury. A fracture that could initially be treated with a closed reduction could require an open reduction, which would increase costs to the Medicare program. At the very least, a delay in treatment could lead to increased, prolonged disability or less than desired results that may have a permanent impact on the activities of daily living (ADLs) of the patient.

For non-acute cases, the clinical judgment and expertise of the physician remain essential. The selection of a particular item, as well as its size and fit, should be based on the physician's evaluation of the patient. Instruction on the proper application or use of the item is important. The physician dispenses the item based on the pathology of the patient and can best explain why the item is necessary and how it must be used. The physician is able to check the fit of the item and can determine if the patient will be able to use it successfully. A different item may be needed than the one originally prescribed and the physician is the best person to make this determination.

If difficulty in using an item is not immediately identified by the physician and the patient receives it from a separate supplier and the fit is incorrect, the patient may ultimately not use the item or may use it improperly, all of which could contribute to the deterioration of the patient's condition and lead to increased costs to the Medicare program. Or, some patients may return to the physician's office with questions or for assistance, which would also increase costs due to the need for additional care or instruction.

Exclude All Physicians and Qualified Healthcare Practitioners From the DMEPOS Competitive Bidding Program

The APMA believes that all physicians, including podiatric physicians, as well as other qualified healthcare practitioners who utilize DMEPOS when caring for Medicare beneficiaries, should be exempted from the requirement to competitively bid to supply DMEPOS to their own patients. According to 2004 data on DMEPOS services, practitioners were responsible for 3.1% of DMEPOS allowed charges as a percent of all allowed charges while entities categorized as "suppliers" were responsible for 96.4% of those charges. Clearly, there is a vast difference in the amount of DMEPOS supplied by physicians and other practitioners compared to that supplied by traditional suppliers.

Most of our physicians supply limited quantities of DMEPOS items to Medicare beneficiaries. They do not maintain significant inventories and sometimes may have only one or two of a particular type of item available in the office. As an item is used, it is replenished. We seriously question the ability of our members or other physician or practitioner suppliers to compete against entities with the ability to purchase vast quantities of products in bulk. If individuals believe that competing against these larger entities is hopeless, many will not even try. If CMS expects physicians and other qualified practitioners to be able to successfully bid to supply items for the future, it needs to provide more details on the selection process; otherwise, individuals will be deterred from bidding before the program even starts.

Physicians and other practitioners who operate as small businesses and whose primary mission is to provide quality patient care that is medically necessary and appropriate and who use DMEPOS solely for purposes of enhancing that care will face significant administrative and financial burdens in trying to compete in this new program. To the detriment of patient care, many will decide against submitting a bid and will be excluded as suppliers. Rather than disrupt Medicare beneficiary access to care that is in their best interest and that occurs at a single point-of-service, we urge CMS to exclude all physicians recognized by Medicare, as well as other qualified healthcare practitioners from the requirement to competitively bid.

It is clear to the APMA that any financial gains made as a result of the proposed rule would be minimal whereas the potential risks to patient health would be huge. We fail to understand the logic of this proposal that would prevent doctors of podiatric medicine (DPMs) from being defined as physicians. We also are convinced that while the competitive bidding process may save the program some money in the initial phase, it will not only cost more to care for the complications of delayed and inappropriate care but will harm the patients we are committed to serve.

Exempt Items Integral to Patient Care

If CMS is uncertain whether the current statute would permit the agency to exclude physicians from competitive bidding altogether, as we recommend, we believe there is another alternative, at least during the early rounds of competitive bidding. CMS could exempt from competitive bidding items that are used as an integral part of patient care provided by physicians and other qualified healthcare practitioners. This would not only allow physicians to continue to serve their Medicare patients without undue interference, it would also provide time for CMS to consult with relevant Congressional Committees regarding the current statutory language and the possible need for amendments or clarifications.

In broad terms, we suggest that the following product categories be excluded from competitive bidding: diabetic shoes, diabetic inlays, prosthetics for the foot, and diabetic adjustments; fractures/sprain/injury related items, such as crutches, pneumatic walkers, other fracture ankle-foot orthoses (AFOs), items for ankle injuries, including braces and splints, and plantar fascia splints; AFOs, including non-pneumatic walkers; and select wound care products, including negative pressure wound therapy (NPWT). If CMS prefers a more detailed list of suggested products for exclusion, we will be happy to comply. We are prepared to suggest items by HCPCS code if necessary and request that CMS contact us if more specific recommendations are required.

As we understand it, CMS believes that Therapeutic Shoes for Individuals with Diabetes (TSD) items are not subject to competitive bidding, although this is not specifically mentioned in the proposed rule. APMA strongly supports such exclusion. These items are provided for patients identified as being at risk and ensuring proper fit of TSD items is essential. If items are not fitted and used properly, complications could occur that might result in loss of limb or life. Since specific existing regulations apply regarding the certification of need, prescription and dispensing of those items, we believe that including them in competitive bidding would be counter-productive to patient care.

Additionally, we note that the proposed rule mentions in passing (in the impact analysis) that surgical dressings are not eligible for competitive bidding, and we support such exclusion as well. Many of the surgical dressings are used in wound care and must be available to patients undergoing treatment for acute or chronic wounds.

Specifically in relationship to the treatment of wounds, we believe that physician choice when determining appropriate wound care products is of paramount importance. Our members treat a wide variety of wounds, including diabetic ulcers. Our members save life and limb and contribute to the improvement of the quality of life and duration of life for Medicare beneficiaries, especially

those with diabetes. There are a variety of challenges in providing wound care, not the least of which is that proper care can be costly, involve pain and suffering for patients, and interfere with the patient's activities of daily living and other normal activities.

We are concerned that physician choice and access to certain wound care products could be restricted as a result of the new competitive bidding process. An item of particular concern for our members is negative pressure wound therapy. In October 2000, a new HCPCS code, E2402, was established for NPWT and since 2003 more than 3,000 physicians have ordered NPWT more than 36,000 times.

In recent months, new products have been added to the E2402 code despite the fact that these new products are clinically different from the original NPWT product. Case studies involving the original NPWT product are attached for your review. As demonstrated, these products are used for wounds that are significant. In one of the case studies, the product is used post-amputation and after eight weeks of use, wound healing is evident. If this product were no longer available because only newer items described by HCPCS code E2402 are provided by contract suppliers, it is conceivable that wound healing could be compromised.

Since the category described by E2402 includes newer items that are not yet well understood or established and physician choice in selecting an item must be respected, we suggest that it is too risky to competitively bid that category at this time. Therefore, we recommend that NPWT products are not among those subject to the initial round of competitive bidding.

Finally, we note that, as mandated by the MMA, the proposed rule calls for subjecting only off-the-shelf orthotics (and not custom-made orthotics) to competitive bidding. APMA strongly supports the Congressional decision to exclude custom-made orthotics from the list of products eligible for competitive bidding.

Allow Physicians to Continue as Suppliers at the MSA Rate

Another option CMS could consider is to allow physicians and other qualified healthcare practitioners to continue to supply DMEPOS as they currently do provided they agree to supply the item at the single payment amount, the same rate that applies to the entire MSA. Since the proposed rule suggests establishing a single rate for each product subject to bidding in each MSA, the "bid" of the physician or other qualified healthcare practitioner would simply be a statement confirming their willingness to serve as a supplier and to supply items at the rate established by CMS. For physician-suppliers, we believe that such a bid could still be viewed as satisfying the statutory requirement that a bid specify "a particular price." In addition, since all or nearly all

physician-suppliers are likely to easily satisfy any definition of "small supplier," our recommended approach for handling bids from physician-suppliers would help CMS respond to the statutory requirement that the Secretary "take appropriate steps to ensure that small suppliers...have the opportunity to be considered for participation in the [DMEPOS competitive acquisition] program."

This option would ensure that Medicare beneficiaries' access to patient care and to medically necessary and appropriate items is not negatively impacted as a result of the new program. They could continue to receive items from their physician or other qualified healthcare professional while still allowing CMS to achieve cost savings since the item would be provided at the CMS rate.

Physician Definition Should be Changed to 1861(r)

Based upon our June 21 meeting with CMS representatives, we understand that it is the agency's position that the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)* requires CMS to establish a competitive bidding program for all suppliers of DMEPOS. While we continue to believe that physicians and other qualified practitioners should be exempted from the requirement to competitively bid, it appears that CMS will proceed with competitive bidding for all suppliers. There are provisions within the proposed rule that will negatively impact a podiatric physician's ability to supply medically necessary and appropriate DMEPOS to Medicare beneficiaries as an integral part of patient care.

The proposed definition of "physician" could lead some to conclude that podiatric physicians would not be allowed to participate in the new DMEPOS competitive bidding program. However, as we understand it, that was **not** CMS' intent. As noted earlier, more than 7,300 podiatric physicians currently have DMEPOS supplier numbers, and thus it seems rather doubtful that Congress would have intended to bar these individuals from continuing to serve as suppliers. In any case, the proposed definition of "physician" would appear to have other negative consequences for podiatric physicians and their patients. Since CMS did not recognize podiatrists as physicians for purposes of the proposed rule, podiatric physicians will not be able to bid to supply DMEPOS items to their patients only. Additionally, podiatric physicians will not have the ability to execute a physician authorization when they determine that a particular brand of item is necessary for the patient. We believe this decision will have serious consequences for our members and the Medicare beneficiaries they serve.

As noted earlier, in the proposed rule, CMS defined physician using the narrow 1861(r)(1) definition, which applies to MDs and DOs only. Since the prescribing, fabricating, fitting and dispensing of DMEPOS is within our scope of practice as defined by state law, this proposed action is in direct conflict with those laws as written.

We question why CMS selected this definition when our members provide DMEPOS items the same way that they are provided by MD and DO physicians. Our members perform a thorough evaluation of the patient prior to determining a course of treatment. As stated previously, our members prescribe and supply DMEPOS items as an integral part of patient care. They are required to obtain a valid supplier number and must adhere to the existing 21 supplier standards. They are licensed in the state in which they practice, are subject to the same Stark requirements that apply to MDs and DOs and must satisfy other Federal and State regulatory requirements. If a DMEPOS item is necessary, our members prescribe the item and if they have a valid supplier number, they may dispense that item in their office. Therefore, we urge CMS to revise the physician definition to 1861(r) so that all physicians recognized by Medicare are able to bid to supply items to their patients only and are able to execute a physician authorization. Additionally, we believe that other qualified healthcare practitioners should be able to supply DMEPOS that is used as an integral part of patient care.

We see nothing in the MMA that requires the proposed, narrow definition of "physician" for purposes of the DMEPOS competitive bidding program. We recognize that a separate provision, relating to the need for a face-to-face examination of a patient for coverage of certain DMEPOS, does limit the definition of physician to 1861(r)(1), but this provision is currently being applied only to power mobility devices and does not directly relate to the competitive bidding program.

In sum, we urge CMS to modify the definition used for physicians who may bid to supply DMEPOS to their patients only and who may execute a physician authorization from 1861(r)(1) to 1861(r).

Criteria for Item Selection

We realize that CMS has yet to identify the specific products or product categories that will initially be subject to bidding. We suggest that care be exercised in establishing the product categories for the future. Scope of practice limitations exist for our members and it would not make sense to require podiatric physicians to, for example, competitively bid to supply all off-the-shelf orthotics. Our members supply lower extremity orthotics and would be unable to supply upper extremity orthotics. Other specialties could be similarly challenged. For instance, it is unlikely that orthopedic hand surgeons would supply lower extremity orthotics. When

establishing product categories, we urge CMS to be realistic and avoid making the categories so broad that it actually prevents some specialties from bidding.

Quality Standards and Accreditation for Suppliers of DMEPOS

The APMA is concerned with the application of quality standards, as well as the establishment of an accreditation process, for all suppliers of DMEPOS. Specifically, if a uniform set of standards and a single accreditation process are utilized, it is conceivable that the standards and process could be so onerous or expensive that physician suppliers would be unable or unwilling to serve as DMEPOS suppliers. As a result, patient care could suffer.

While we recognize that the proposed rule was limited in its discussion of the quality standards and accreditation process, and we expect the release of the final quality standards in the near future, we believe physicians should have a unique set of quality standards and a separate accreditation process. At the very least, we object to a uniform set of standards and a single accreditation process for all suppliers of DMEPOS. We believe that the standards and accreditation process should be fair and reasonable and should be reflective of the amount of DMEPOS supplied to Medicare beneficiaries.

Podiatric and other physicians must obviously meet state licensing requirements, and subjecting them to additional or potentially duplicative requirements could be overly and unnecessarily burdensome. We believe that it is reasonable to utilize a process for physician suppliers that differs from the one used for traditional suppliers lacking professional licensure. To subject a licensed physician, who might supply $5,000 worth of DMEPOS to Medicare beneficiaries over the course of a year to the same standards and accreditation process that apply to an entity supplying $1,000,000 worth of DMEPOS seems unreasonable. We encourage CMS to be reasonable in establishing quality standards and an accreditation process for physician suppliers.

Additionally, if the costs associated with becoming accredited (including the fee paid to the accreditation organization) are excessive when compared to the amount of DMEPOS supplied, or the process is overly burdensome, physicians may decide against functioning as DMEPOS suppliers. Patient access and patient care could be compromised.

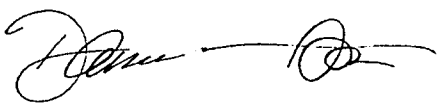
If accreditation is required for all suppliers, physicians must have equal and appropriate access to the accrediting organizations. A single accrediting body for podiatric physicians who supply DMEPOS does not exist. Since accreditation by suppliers will be required before the program starts, our members would be disadvantaged. Other physicians and qualified healthcare practitioners would likely face similar challenges. We believe that if CMS intends to require an

accreditation process for physicians beyond state licensing, the agency must ensure that a reasonable and fair pathway exists for physicians and other qualified healthcare professionals who wish to become accredited. The details of the accreditation process should be immediately communicated so that physicians and other qualified healthcare practitioners who wish to serve as suppliers in the new competitive bidding program understand the process they must follow.

Conclusion

The APMA appreciates the opportunity to offer these comments. The competitive bidding program, as proposed, is of significant concern to our members and we are hopeful that CMS will revise its proposals prior to issuing final regulations. If you have questions or require additional details, please contact Dr. Nancy L. Parsley, Director of Health Policy and Practice, at (301) 581-9233.

Sincerely,



David M. Schofield, DPM
President

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PRAXAIR
HEALTHCARE SERVICES

39 Old Ridgebury Road
Danbury, CT 05810
203-837-2037

June 30, 2006

Centers for Medicare & Medicaid Services
United States Department of Health & Human Services
Attention: CMS-1270-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

Re: Comments of Praxair on CMS Proposed Rule "Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (CMS-1270-P)

To the Centers for Medicare & Medicaid Services:

Praxair Healthcare Services, Inc. hereby submits the following comments in response to the above captioned proposed rulemaking. We have organized these comments with respect to the relevant "issue identifier" contained in the proposed rule. We have provided four types of comments as follows:

(1) Questions. These are items where our review of the proposed rule has caused us to identify an issue that does not appear to be addressed in the proposed rule. We are asking that our question be answered in the final rule.

(2) Clarification. These are items where we have identified an ambiguity related to an issue addressed in the proposed rule. We are asking that the issue be clarified in the final rule.

(3) Comments. These are items where we express a view regarding an aspect of the proposed rule. We would appreciate our view being considered and incorporated into the final rule.

(4) Recommendation. These are items where we have made an express suggestion as to how an issue should be addressed in the final rule. We would request that our recommendation be incorporated in the final rule.

Section II. Provisions of the Proposed Regulation

B. Implementation Contractor (Proposed Sec. 414.406)

- **Question**: Will the costs associated with hiring a competitive bidding implementation contractor (CIBC) to implement the proposed rule be included in the evaluation of overall costs to determine if competitive bidding in a Metropolitan Statistical Area (MSA) will result in significant savings?

- **Question**: What criteria will be used to select the CBIC? What safeguards will CMS implement to ensure an objective third party relationship with bidding suppliers?

- **Question**: How will CMS audit the CBIC's performance?

- **Question**: What are the service expectations of the CBIC relative to educating the DMERCs and suppliers (for example, number of training sessions per year or a 1-800 Hotline for questions)?

C. Payment Basis (Proposed Sec. 414.408)

- **Comment**: It is unreasonable to expect suppliers to furnish items to traveling beneficiaries at the CBA rate of their permanent residence. There are many vacation destinations (e.g. Palm Springs, CA) where the cost of providing an item is significantly higher than in the CBA. The supplier should not be forced to make up the cost difference.

C.3.a Process for Grandfathering Suppliers

"...the beneficiary could elect, at any time, to transition to a contract supplier and the contract supplier would be required to accept the beneficiary as a customer,"

  - **Comment**: Regarding the statement in the proposed rule that in order for CMS to achieve the economic benefit (i.e. economies of scale) of a true competitive bidding process, significant volume increases must be guaranteed to the winners. Only in those cases where volume shifts actually occur will it be economically viable for suppliers to offer the lowest price.

- **Question**: How can CMS estimate needed capacity in an MSA when it is not possible to determine how many beneficiaries will remain with their existing suppliers?

- **Question**: How will beneficiaries be informed of the winning contract suppliers?

  - **Recommendation**: The beneficiaries should be informed of the lowest composite bid score winners first.

- **Comment**: A transition plan needs to be outlined for those customers that suppliers choose not to service once competitive bidding begins in a specific MSA.

"Suppliers who agree to be grandfathered suppliers for a specific item must agree to be a grandfathered supplier for all beneficiaries who request to continue to use their service for that item".

  - **Recommendation**: There may be cases where it is unsafe to deliver to a beneficiary (e.g. patients smoking while on oxygen) and suppliers should have to right to refuse to provide service to those beneficiaries. Suppliers must be able to deny service for unsafe conditions or lack of co-payments from the beneficiary.

- **Question**: Will the CPI-U index used to determine payment increases to suppliers be based on national increases or MSA specific CPI-U price increases (there may be a 2.5% increase nationally, but much higher on a regional basis)?

- **Comment**: CMS should continue to use the increase in the cost of medical care versus the CPI – U index.

- **Question**: How will CMS account for dramatic cost increases in a particular quarter (the IRS adjusts its mileage allowance rate as needed to adjust for rising fuel costs)? More frequent inflation adjustments should be permitted.

C. 5 Authority to Adjust Payments in Other Areas (414.408(e))

- **Comment**: It is not appropriate to extrapolate the price from one competitive bidding area to another without engaging in a competitive bidding process. Regional factors must be considered such as population density, cost of labor and transportation infrastructure (etc).

C. 6 Requirement to Obtain Competitively Bid Items from a Contract Supplier (414.408(f))

- **Question**: If a company was the contract supplier in one CBA and the beneficiary traveled to another CBA where the company was not a contract supplier, would another company location (in the area where the beneficiary traveled to) be able to service that patient?
    - **Clarification**: This would allow companies to bill for the services as they do today providing seamless service for the beneficiary.

- **Comment**: Extending the bid area beyond the MSA creates unnatural geographic service areas that could be difficult to appropriately cover. The more CMS can clarify and make certain the proposed rules the better it will be for suppliers and beneficiaries. Using MSA boundaries is preferable to the proposed approach.

E. Criteria for Item Selection

"In addition, section 1847(a)(3)(B) of the Act grants us the authority to exempt items for which the application of competitive bidding is not likely to result in significant savings."

- **Clarification**: How does CMS plan to account for administrative costs and hospital readmissions in analyzing whether competitive bidding has resulted in significant savings? What factors will be applied?

- **Recommendation**: The degree of clinical service required should be one of the variables in determining which items should be competitively bid.

- **Comment**: The Deficit Reduction Act payment reductions that have occurred since the "demonstration" should be taken into consideration when determining if a product should be subject to competitive bidding. These are expected to reduce CMS expenditures by thirty percent, well beyond the CMS competitive bidding savings estimations. Therefore it is unlikely that savings will be achieved.

- **Comment**: Skilled Nursing Facilities should be required to competitively bid DMEPOS to participate in Medicare business. If not at the very least those facilities should be required to provide items at the competitively bid award price.

- **Comment**: Medicare should allow the supplier to supply new or used equipment on items that rent to purchase (with no discount). The ability to provide used items should be determined at the supplier's discretion. Title should not transfer to beneficiary in order to improve asset utilization and reduce overall healthcare costs.

- **Comment**: In order to fully understand the cost associated with accreditation, all suppliers should be required to obtain accreditation before they submit their bids. The competitive bidding process should be delayed until CMS identifies "accrediting bodies" and gives those "bodies" sufficient time to accredit all interested suppliers.
    - **Clarification**: Has CMS identified the capacities of the Accrediting Bodies for the 2007 and 2009 competitive bidding rounds?

"Each bidder must be enrolled with Medicare and be a current supplier in good standing with the Medicare program - not under any current Medicare sanctions."

- **Clarification**: Does that requirement apply to that for the supplier's location in the CBA or the company in general (all locations)? Please clarify that a company who is compliant with

an OIG approved Corporate Integrity Agreement or corporate integrity provisions in a settlement Agreement will not be a company considered under direct Medicare Sanctions.

- **Comment**: CMS must further clarify the financial information, key ratios or other metrics that will be used to determine supplier's potential capacity.

- **Question**: What specific methods will CMS use to calculate a supplier's true capacity?

    - **Recommendation**: For suppliers, basing calculations on volume is the best method for weighting individual items within a product category to determine the composite bid.

- **Comment**: Using the pivotal bid to determine supplier's capacity will not accurately reflect supplier capability due to the likelihood of misrepresentations.

    - **Recommendation**: A preferable approach would be to have a fixed reduction in the number of suppliers.

"Therefore, we would not accept any bid for an item that is higher than the current fee schedule."

    - **Clarification**: This may be a problem since the current price on some items may already be too low given the effects of the DRA and Medicare's current pricing methodology.

    - **Recommendation**: Medicare should base its savings on the total savings (including administrative costs) and not on savings at the item level.

- **Question**: Would winning companies that bid above the median of the winning bids be able to retract their bids if they did not want to supply product at the lower price?

    - **Recommendation**: A single payment price should be set at the pivotal bid as was done during the "demonstration". At the onset suppliers are going to submit their most competitive price. Using the Median bid will require 50% of the companies to reduce their price thus causing companies not to bid their most competitive price from the start.

H. Determining Single Payment Amounts for Individual Items (Proposed 414.416)

- **Comment**: The Rebate Program does not save Medicare money, it saves the beneficiaries money and the objective of the Medicare Modernization Act was for CMS to save money. As currently proposed the rebate program appears to provide no protections for the beneficiary, physician or supplier from current fraud and abuse legislation.

    - **Clarification**: Has CMS considered the administrative costs to follow up with patients to make sure the rebates did actually occur?

- **Question**: How will CMS handle reimbursement for repair or replacement of patient-owned equipment? Is it the patient's obligation to pay or Medicare's obligation?

- **Question**: What is the impact of the Deficit Reduction Act on competitive bidding?

    - **Clarification**: If a beneficiary decides to switch from a grandfathered supplier to a contract supplier in month 34, must the new contract supplier transfer title of the O_2 equipment after month 36, which in this case has only been providing revenue for the newly contracted supplier for two months?

- **Clarification**: If a beneficiary decides to switch from a grandfathered supplier in month 37 with dysfunctional equipment, what are the new supplier's obligations and payment schedules?

- **Question**: How does CMS define product integrity information?

- **Comment**: Industry consolidation is one of the ways the Homecare Industry has dealt with the successive severe reimbursement cuts in recent years. Requiring companies to notify CMS in writing 60 days prior to any changes in ownership (etc.) would be extremely difficult to manage as many acquisitions occur in a much shorter timeframe. In addition, by not allowing assignment of the contract to pass to the new owner automatically, CMS has diminished some the value associated with that business which is likely to hurt smaller suppliers.

- **Question:** What protections will CMS implement to ensure that no insider trading will occur given this knowledge of potential, undisclosed acquisition information between two publicly traded companies?

- **Comment**: It is highly unorthodox and unreasonable to make providers sign a contract to supply items when CMS could terminate the contract for convenience. This is particularly troubling as suppliers will have already hired employees and acquired assets to perform the services required to comply with the terms of that contract.

- **Comment**: A formal dispute resolution process should be defined for both CMS and the suppliers with regards to contract assignment, accreditation, or other issues that may arise under the competitive bidding rules.

L. Opportunity for Networks (Proposed 414.418)

- **Comment**: It appears that the ability to create networks may potentially cause companies to unintentionally collude. While it is logical that companies in a network should not be able to submit individual bids, is it unreasonable to expect as networks are being formed that there will not be some discussion of price before the legal entity is finalized. A safe harbor under applicable anti-trust rules must be created with clear guidelines.

    - **Clarification**: How will CMS assure that a subcontractor who serves several networks will not share price information amongst those networks?

    - **Recommendation**: Subcontractors must be accredited and this should be clearly defined in the rules.

- **Comment**: If CMS would allow appropriate substitution of like products higher savings could be achieved.

- **Question**: Is the cost of patient education properly reflected in the savings? Is the cost of the customer complaint monitoring system included in the benefits?

- **Question**: When will the final rules for quality standards be published? Adequate time is required to understand the quality standards and the impact to determine an appropriate price.

- **Question**: Would a product recall pose an immediate jeopardy to a beneficiary, and if that is the case, two days is not enough time to resolve the issue including a complete product recall. Additionally, if the accrediting body has two days to get back to CMS how much time do suppliers have to get the problem resolved? The final rule should recognize that an orderly recall may take different periods of time under different circumstances.

- **Question**: How will CMS audit accrediting organizations and is that cost reflected in the savings?

- **Question**: If a new type of technology is introduced after a competitive bidding award has taken place is a supplier obligated to supply that piece of equipment once CMS determines its reimbursement rate?

- **Comment**: Our experience with competitive bidding for managed care or provincial bids indicates that it takes on average more than 160 hours to prepare a bid, thus suppliers will need more than 70 hours to complete the process.

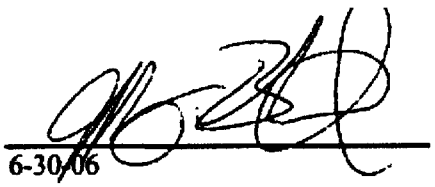
- **Comment**: The cost of accreditation and meeting the quality standards should be taken into consideration when determining the cost of a competitive bidding program.

- **Comment**: CMS has not included the savings from the Deficit Reduction Act in the proposed rules which will not allow CMS to be able to realize all the savings expected (after the DRA there is nothing left to reduce).

- **Comment**: By indicating that CMS expects a 10% savings from the competitive bidding process it appears that CMS is setting the price instead of allowing the competitive bidding process to determine the price.

We appreciate the opportunity to have our comments considered.

Sincerely,



6-30-06

Jeff Barnhard
VP, Business Development
Praxair Healthcare Services

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APRIA HEALTHCARE®

VIA COURIER

Ms. Kathleen H. McGuan
Office of General Counsel
U.S. Department of Health and Human Services
330 Independence Ave., S.W.
Room 5300
Washington, DC 20201-0002

June 30, 2006

Re: File Code CMS-1270-P - Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Ms. McGuan:

Apria Healthcare is the nation's largest provider of durable medical equipment ("DME"), respiratory care services and home enteral nutrition, as well as the third largest home infusion therapy provider. We are committed to providing Medicare beneficiaries with excellent quality products and services in an efficient, effective manner.

We are writing to the Office of General Counsel to highlight what we believe are significant legal issues implicated in the implementation of the competitive bidding program described in the Proposed Rule related to the Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues ("Proposed Rule"). 71 Fed. Reg. 25654 (May 1, 2006). Although we have prepared and are submitting extensive written comments to the Proposed Rule for the review and consideration of the Centers for Medicare & Medicaid Services ("CMS"), we also wanted to draw your attention to those topics that we believe raise unique legal questions.[1]

We are particularly concerned by the following five legal issues:

- **Rebate Program (Proposed Section § 414.416(c))** – CMS' proposal to allow contract suppliers who submitted bids for an individual item below the single payment amount to provide all beneficiaries with a rebate is

[1] For your information, we have attached a copy of the complete written comments that Apria has submitted to CMS. The points made in this letter are also included in that more comprehensive letter.

contrary to the Anti-Kickback Statute, the Beneficiary Inducement Statute, and the Medicare provisions governing the waiver of co-payments. We urge the Office of General Counsel to evaluate whether the rebate proposal needs to be eliminated or adjusted to fit the current regulatory framework concerning Medicare co-payment waivers.

- **Gap Filling (Proposed Section § 414.210)** – CMS proposes to modify its current gap-filling procedures in a manner that may exceed CMS' "inherent reasonableness" authority. Although Congress has granted CMS the specific authority to modify payment amounts upon the agency's determination that certain payment levels are grossly excessive or deficient, there are numerous procedural and substantive safeguards to ensure that CMS and its contractors do not act arbitrarily. We are concerned that the lack of those same safeguards in the current proposal on gap-filling procedures renders meaningless the scope and limitations of CMS' inherent reasonableness authority. According to the proposal, CMS, in effect, may use its gap-filling authority to change payment levels for existing products simply by changing the HCPC codes for those products. The Office of General Counsel should consider whether CMS is exceeding its authority with this aspect of the Proposed Rule and advise the agency accordingly.

- **Scope of a Competitive Bidding Area (Proposed Section 414.410)** – CMS proposes to define a competitive bidding area as a Metropolitan Statistical Area ("MSA"), plus certain contiguous counties or zip codes to be subsequently determined by CMS. This proposal is inconsistent with the clear statutory language that defines competitive bidding area, for at least the years 2007 to 2009, as an MSA.

- **Ability of Treating Practitioner to Order Brand-Specific Equipment (Proposed Section § 414.420)** – The Proposed Rule generally requires contract suppliers to provide brand-specific items and equipment as designated by the prescribing physician. The manner in which CMS has interpreted its authority to implement this process is more prescriptive, onerous and punitive than Congress intended. We urge the Office of General Counsel to re-evaluate the proposal in light of the Congressional intent and the practical effect this requirement would have upon contract suppliers.

- **Additional Comment Period** – We urge the Office of General Counsel to encourage CMS to exercise its discretion and offer interested parties an additional opportunity to comment on the key elements of the program before a final regulation is published. In light of the complexity of the new system, we expect any final rule will be very different from the initial proposal. The opportunity for additional public notice and comment is consistent with the scope of CMS' authority and, we believe,

will be required in light of the magnitude and scope of initial public comments.

Each of these issues is discussed below.

I. Rebate Program (Proposed Section § 414.416(c))

CMS proposes permitting contract suppliers who submitted bids for an individual item below the single payment amount determined through the bidding process to provide beneficiaries with a rebate. CMS states that such rebate, if provided, must be equal to the difference between the supplier's actual bid amount and the single payment amount. CMS's proposal, however, is contrary to the Anti-Kickback Statute, the Beneficiary Inducement Statute, and the Medicare provisions governing the waiver of co-payments. While there are other policy arguments why the rebate proposal raises concern, we highlight here only the legal issues that are implicated by this proposal.

A. Anti-Kickback Statute Implications

Permitting any rebates, no matter how determined, to lessen a beneficiary's co-pay obligations runs counter to guidance and direction provided by the OIG for many years and may well violate the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (the "AKS"). The AKS prohibits knowingly and willfully soliciting, receiving, offering or paying anything of value to induce referrals of items or services payable by a federal health care program. The waiver of beneficiary co-payments, or the economic equivalent, rebates of the co-payment, has long been identified by government enforcers as a possible violation of the AKS.

Indeed, the Office of Inspector General of the Department of Health and Human Services ("OIG") has highlighted the legal problems with routine waivers of beneficiary co-payments. *See, e.g.,* OIG, Special Fraud Alert, 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994). There, the OIG identified waivers of Medicare deductibles and co-payments as abusive violations of the AKS that likely lead to excessive utilization of items and services paid for by Medicare. The basis of this concern is equally applicable in the context of competitive bidding. The OIG states in its Special Fraud Alert that when "suppliers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase items or services from them." *See id.* The OIG acknowledges that at first glance, "it may appear that routine waiver of copayments and deductibles helps Medicare beneficiaries." *See id.* However, the OIG cites studies that show that patients who are required to pay a portion of their care become "better health care consumers, and select items or services because they are medically needed, rather than simply because they are free." *See id.*

Similarly, the OIG notes that the "routine waiver of all or a portion of the Medicare copayment is suspect under the anti-kickback statute," regardless of whether it is styled as a "discount" or a direct payment to a beneficiary. See OIG, Advisory Opinion No. 01-03 (May 3, 2001), at 5, *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/2001/ao01-03.pdf > (last visited May 18, 2006). The OIG concluded that waiver of co-pays was abusive because the federal government would not receive the full benefit of the discount provided under such a waiver and the waiver likely would lead to overutilization of services. *See id.* at 5-6.

Under the proposed rebate program, the federal government would not be receiving the benefit of the discount and the reduction in the beneficiary's out of pocket costs potentially would lead to overutilization of certain DME services.

The OIG Compliance Program Guidance for Durable Medical Equipment, Prosthetics, Orthotics, and Supply Industry ("DME Program Guidance") also highlights the OIG's "programmatic concerns when DMEPOS suppliers routinely waive deductibles and coinsurance." *See* 64 Fed. Reg. 36368, 36378 (Jul. 6, 1999). The DME Program Guidance states that DMEPOS suppliers are permitted to waive Medicare co-payment amounts only for cases of financial need. *See id.* Furthermore, the OIG recommends that a supplier's written policies and procedures should state that it will not routinely waive deductibles and coinsurance for Medicare beneficiaries. If a supplier plans to waive co-payment amounts, the OIG suggests that the supplier develop and maintain written criteria documenting its policy for determining financial need and attempting to collect this co-payment. *See id.*

For all of the reasons set forth in the OIG's prior guidance, both to the DMEPOS industry and in general to all Part B suppliers, CMS's proposal is contrary to law. Nothing in the statutory basis for the Competitive Bidding program authorizes CMS to authorize an action that would violate the AKS. Thus, we strongly urge the Office of General Counsel to assist CMS in reconciling the prior guidance regarding waivers of co-payment amounts with its proposed rebate program.

B. Beneficiary Inducement Statute Implications

In addition to violating the AKS, any rebate or waiver of co-payments also is contrary to the Beneficiary Inducement Statute, 42 U.S.C. § 1320a-7a(a), contained under the Civil Monetary Penalties statute. The Beneficiary Inducement Statute states, in relevant part, that:

> Any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5) of this section) that –...
>
> (5) offers to or transfers remuneration to any individual eligible for benefits under subchapter XVIII of this chapter, or under a State health care program (as defined in section 1320a-7(h) of this title) that such person knows or should know is likely to influence such individual in order to receive from a particular provider, practitioner, or supplier an item or service for which payment may be made, in whole or in part, under subchapter XVIII of this chapter, or a State health care program (as so defined);...
>
> shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $10,000 for each item or service.
>
> *See* 42 U.S.C. § 1320a-7a(a)(5).

For purposes of the Beneficiary Inducement Statute, the term "remuneration" includes the waiver of any partial coinsurance or deductible amounts. *See* 42 U.S.C. § 1320a-7a(i)(6); *see also* OIG, Advisory Opinion No. 00-5 (Jul. 7, 2000), at 4. The statute excludes

waivers of co-payments from the definition of "remuneration" *only if* (i) the waiver is not offered as part of any advertisement or solicitation; (ii) the person does not routinely waive coinsurance or deductible amounts; and (iii) the provider waives after determining in good faith that the individual is in financial need or fails to collect the coinsurance or deductible amounts after making reasonable collection efforts. *See* 42 U.S.C. § 1320a-7a(i)(6). The rebates proposed by CMS cannot satisfy these requirements. In particular, the proposed rule would equate to routine waivers of all or a portion of the co-payment without regard to financial need. Indeed, CMS is requiring that once a supplier decides to provide rebates, rebates must be provided to all beneficiaries regardless of an individual's financial situation.

The OIG has consistently expressed its concerns over waivers of co-pays in the context of the Beneficiary Inducement Statute. In Advisory Opinion No. 99-7, the OIG stated that "the statutory proscription in section 1128A(a)(5) of the Act [Beneficiary Inducement Statute] reflects serious programmatic concerns with waivers of coinsurance." *See* OIG, Advisory Opinion No. 99-7 (Jun. 30, 1999), at 3, *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_7.htm> (last visited May 18, 2006); OIG, Advisory Opinion No. 97-4 (Sep. 25, 1997), at 3-4, *available at* < http://oig.hhs.gov/fraud/docs/advisoryopinions/1997/97_4.pdf>. When "providers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be inducing the patient to use items or services that are unnecessary, simply because they are free." *See id.* Thus, the proposed rebate program is contrary to the prohibitions in the Beneficiary Inducement Statute. Nothing in the statutory basis for the Competitive Bidding program authorizes CMS to authorize an action that would violate the Beneficiary Inducement Statute. Thus, we have strongly urged CMS to reconsider this proposal. We request that the Office of General Counsel evaluate the issues raised under the Beneficiary Inducement Statute and coordinate with CMS to minimize confusion in this area of the law.

C. Medicare Requirements for Collecting a Twenty-Percent Co-Payment from Beneficiaries

The plan design for Medicare Part B benefits has always included beneficiary co-payments. The purpose behind the twenty (20) percent co-payment is to discourage excessive or unnecessary utilization. *See* 42 C.F.R. § 419.41 (calculating national beneficiary co-payment amounts and national Medicare program payment amounts); 42 U.S.C. § 1395e (requiring Medicare payments for inpatient and outpatient hospital services to be reduced by co-payment amounts). The rebate proposal runs counter to a fundamental principle of the Medicare program that requires beneficiary coinsurance. Nothing in the statutory basis for the Competitive Bidding program permits CMS to authorize an action that would fundamentally change the Part B plan design by eliminating some co-payments. Thus, we strongly urge CMS to reconsider this proposal.

For all the reasons stated above, permitting any beneficiary rebates will be inconsistent with previous government direction. We encourage the Office of General Counsel to provide guidance not only to CMS on the appropriateness of the rebate program but issue guidance to the public on how to reconcile the prior government guidance with the rebate program, if the proposal is included in the final rule.

II. Gap-Filling Proposal (Proposed Section § 414.210)

CMS proposes to modify its current gap-filling procedures for establishing fee schedule amounts for new DMEPOS items. While we agree that this process can benefit from further clarification, we are concerned that the gap-filling proposal exceeds CMS' "inherent reasonableness" authority. *See* 42 C.F.R. § 405.502. Although Congress has granted CMS the specific authority to modify payment amounts upon the agency's determination that certain payment levels are grossly excessive or deficient, there are numerous procedural and substantive safeguards to ensure that CMS and its contractors do not act arbitrarily. We are concerned that the lack of those same safeguards in the current proposal on gap-filling procedures renders the scope and limitations of CMS' inherent reasonableness authority meaningless. CMS, in effect, may use its gap-filling authority to change payment levels for any existing products simply by changing the HCPC codes for those products. As the legal counseling entity for CMS, the Office of General Counsel should consider whether CMS is exceeding its authority and advise the agency accordingly.

CMS' proposal for gap-filling procedures lacks specificity regarding the factors that it will use to determine gap-filling amounts. CMS simply lists a number of general factors for determining gap-filling amounts, without any indication how they would be used.

Given this lack of specificity and intention to apply this authority to new codes, we are concerned that CMS is proposing virtually unfettered authority to choose and apply payment criteria for any new product. CMS could conceivably trigger this authority by simply modifying a HCPC for a product category, thus reorganizing and creating a new code. By doing so, CMS could set aside the existing fee schedule and substitute its own judgment as to what is a reasonable payment level based on the general factors listed in the proposed rule.

Congress has provided CMS with the specific authority to modify payment amounts if CMS determines after a prescribed analysis that the payment levels are grossly excessive or grossly deficient. This so-called "inherent reasonableness" authority is set out at 42 CFR 405.502 and includes a number of procedural and substantive safeguards to ensure that CMS and its contractors do not act arbitrarily. None of those safeguards is present in the CMS proposal on gap-filling. The scope and limitations of CMS' inherent reasonableness authority will be meaningless if CMS can use its gap-filling authority to change payment levels for existing products merely by first changing the HCPC codes for those products.

Inherent reasonableness may only be used if payment levels are determined to be grossly excessive (or grossly deficient), which CMS has defined by regulation as being at least 15% more or less than a reasonable level of payment. CMS must use valid and reliable data in its analysis and its calculation of new payment levels. Part B suppliers must have the opportunity to comment on the finding that payments are grossly excessive and on the new payment level determined by CMS or its carriers. In addition, if CMS seeks to make an adjustment that will have a significant effect on a substantial number of small suppliers, it must publish an analysis in the Federal Register pursuant to the Regulatory Flexibility Act.

Further, CMS has defined to some extent how it will interpret various factors in its application of inherent reasonableness. CMS and its carriers also must consider the effects on the Medicare program, including:

1. The effects on the Medicare program, including costs, savings, assignment rates, beneficiary liability, and quality of care.

2. What entities would be affected, such as classes of providers or suppliers and beneficiaries.

3. How significantly would these entities be affected.

4. How would the adjustment affect beneficiary access to items or services.

In addition, the carriers must evaluate the comments received on the proposed notice. And, to ensure the use of valid and reliable data, CMS or the carrier must meet the following criteria to the extent applicable:

(i) Develop written guidelines for data collection and analysis.

(ii) Ensure consistency in any survey to collect and analyze pricing data.

(iii) Develop a consistent set of survey questions to use when requesting retail prices.

(iv) Ensure that sampled prices fully represent the range of prices nationally.

(v) Consider the geographic distribution of Medicare beneficiaries.

(vi) Consider relative prices in the various localities to ensure that an appropriate mix of areas with high, medium, and low consumer prices was included.

(vii) Consider criteria to define populous State, less populous State, urban area, and rural area.

(viii) Consider a consistent approach in selecting retail outlets within selected cities.

(ix) Consider whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population.

(x) Consider the products generally used by beneficiaries and collect prices of these products.

(xi) When using wholesale costs, consider the cost of the services necessary to furnish a product to beneficiaries.

Additional factors usually apply if CMS seeks to modify payment levels by more than 15 percent in a given year. Yet, none of these processes and criteria, which result directly from several statutes and recommendations of the Government Accountability Office, will have any applicability if CMS chooses to use its gap-filling authority instead of its inherent reasonableness authority to adjust payment rates.

We do not believe CMS has the legal authority to modify payment levels for existing, covered products by manipulating the particular HCPCs for those products. Where Congress sought to provide CMS with the authority to modify payment levels, it did so in an explicit and structured manner. The proposed rule on this issue appears to be little more than a reach for additional authority to undertake actions that could be precluded under the inherent reasonableness authority or would be more time-consuming under that authority. Congress, by its actions on inherent reasonableness, effectively limited CMS to the scope of that authority. We respectfully request that the Office of General Counsel review CMS' authority to modify payment levels for existing covered products and analyze CMS' proposed gap-filling proposal from a legal perspective.

III. The Scope of a Competitive Bidding Area Should Remain Consistent with the MSA Boundaries (Proposed Section 414.410)

The Medicare Modernization Act of 2003 ("MMA") states that competitive bidding will be implemented in a gradual fashion. CMS adopted this approach in the Proposed Rule and we support that decision. We disagree with how CMS intends to define the proposed competitive bidding areas and believe CMS has exceeded its statutory authority.

Until at least 2009, the scope of a competitive bidding area should be concurrent with a metropolitan statistical area ("MSA"). CMS is incorrect in its presumption that it has the authority to define a competitive bidding area as being anything other than concurrent with an MSA.[2]

From 2007 through 2009, the Social Security Act authorizes CMS to implement competitive bidding in some of the largest MSAs in the country. Specifically, section 18471(B) of the Social Security Act states that competitive bidding shall be phased in:

> among competitive acquisition areas in a manner so that the competition under the programs *occurs in*—
> (I) 10 of the largest metropolitan statistical areas in 2007;
> (II) 80 of the largest metropolitan statistical areas in 2009; and
> (III) additional areas after 2009; (emphasis added).

[2] Even if CMS were correct, it would be administratively very burdensome for suppliers to implement competitive bidding in geographic regions that meander outside of the clearly-defined MSA borders. This topic is discussed more fully in our complete written comments.

The statutory language clearly contemplated that the competitive activities would occur in an MSA. There is no discussion about the bidding areas occurring around an MSA or including an MSA. Based upon the clear statutory language, there is no authority for CMS to expand the program beyond the boundaries of an MSA until 2009. Only at that time, and not until then, may additional areas be included. It would be inappropriate and outside of CMS's statutory authority to design a competitive bidding area that exceeded the applicable MSA boundaries.

Even if CMS had the discretion to be creative with the boundaries of each competitive bidding area, it should not exercise that authority. In order for contract suppliers to efficiently furnish services in accordance with the program parameters, it is essential that the bidding area boundaries be clearly defined.

All parties agree that competitive bidding will add an additional layer of operational complexity for suppliers. This will be particularly true for those suppliers who service from one location Medicare beneficiaries in both traditional and competitive bidding programs because of the different reimbursement rates and scope of brand product that must be supplied. The business systems of most suppliers will not easily permit implementation of gerrymandering geographic boundaries. To avoid legal challenges, minimize unnecessary administrative burden and reduce the likelihood of confusion, CMS should establish competitive bidding areas with clearly defined borders. Adhering to the defined MSAs is the easiest and most appropriate approach.

IV. Ability of Treating Practitioner to Order Brand-Specific Equipment (Proposed Section § 414.420)

A. Current Proposed Rule

The Proposed Rule generally requires contract suppliers to provide brand-specific items and equipment as designated by the prescribing physician. Although a contract supplier may consult with the treating practitioner to find a suitable alternative product for the beneficiary, if the contract supplier is unable or unwilling to furnish the equipment the treating practitioner ultimately requests, the supplier must assist the beneficiary in finding another contract supplier in the competitive bidding area. CMS has proposed that the contract supplier still be required to support and service the item and the patient. If a supplier substitutes another item or equipment, the claim will be denied.

We believe that the way in which CMS has interpreted its authority is more prescriptive, onerous and punitive than Congress intended. We urge the Office of General Counsel to re-evaluate this provision of the Proposed Rule in light of the Congressional intent and the practical effect the proposal will impose upon suppliers.

B. Difficulty in Providing Brand-Specific Items Within the Context of Competitive Bidding

The proposal implementing the specific brand mandate raises serious financial consequences for suppliers and creates unnecessary uncertainty in the bids to be submitted. The primary bases for this concern are the unpredictability of the application of this new right to

make brand-specific requests and the wide range of costs among brands within a single HCPCS code. These issues are outside the control of the supplier who is going to be financially responsible for the outcome. Consequently, we strongly use the Office of General Counsel to support CMS' effort to implement the brand specific mandate in phases, requiring the designation of product categories and product codes that are distinct enough to allow suppliers to calculate realistic bids and product inventory assumptions. Alternatively, CMS should consider an exception process to fairly compensate suppliers for the provision of items that are very expensive in comparison to other products within the same HCPCS code.

C. High Level of Acquisition Cost Variance for DMEPOS Products Tied to Single HCPCS Codes

The right to brand specificity is a new concept within the Medicare program. We anticipate it will be very difficult for suppliers, even large, more sophisticated businesses, to accurately predict brand specific product utilization and fully incorporate these factors into their bids. The high level of price variance for certain types of products, such as oxygen concentrators, nebulizers, CPAP devices and masks, combined with an inability to predict prescribers' preferences and prescribing behavior, will make it difficult for suppliers to submit accurate bids. Extensive overbidding or extensive underbidding will not financially benefit the Medicare program, nor the level of care furnished to beneficiaries.

D. HCPCS Coding Process Has Challenges and CMS Should Delay Implementation of Brand-Specific Requirements Until the HCPCS Process is Revamped

In the Proposed Rule CMS states that it believes that "the HCPCS process has worked well in the past, and we believe that it adequately separates items based on their function." We do not agree with this assessment.

The advent of the Health Insurance Portability and Accountability Act's (HIPAA) Transaction Code Set (TCS) requirements forced a change in the role and relative importance of the HCPCS Coding Panel and new HCPCS code application/approval process. Prior to the TCS requirement, the HCPCS coding panel primarily focused on products and codes that were used in the Medicare population, while managed care payors allowed a much more broad array of customized codes to reflect different products, acquisition costs and service level variances.

Since HIPAA mandates that code sets be standardized among all payors – regardless of whether they are government or private managed care in nature – the HCPCS coding panel is now in a position to create codes that are more likely to be used in the private sector.[3] New HCPCS codes have been routinely denied to manufacturers who complete the application process after introducing new technology to the market and outlining the product features that differentiate the products from existing ones. Despite clear differentiation and

[3] Since 80% of the total Obstructive Sleep Apnea (OSA)/CPAP market is commercially insured, this is a good example of a product category for which HCPCS codes need to be modernized. Pediatric products used in Medicaid and commercial populations is another other example where the HCPCS codes available do not mirror current-day technology that is available and being used to treat children.

therapeutic benefits desired by both patients and physicians, the HCPCS coding panel has denied new codes and forced those new products into existing HCPCS categories with allowable reimbursement often far less than the acquisition cost.

The cost differences among brands within one HCPCS code can be significant and enforcing brand-specific delivery under the current proposal would almost certainly result in financial hardship for contract suppliers. For example, the more advanced, increasingly prescribed models of CPAP devices may cost five times as much as a standard CPAP that offers enough benefits to the patient to treat his/her condition less effectively. New technology, such as a portable oxygen concentrator, may cost as much as four times more than a traditional model. Yet, these products fall within the same HCPCS code and will be subject to the same single payment amount as their older generation predecessors. If a physician insists on prescribing the more expensive model, the supplier may face a dramatic financial shortfall if the single payment amount has not fully captured the anticipated volume and value of furnishing the much more expensive product. This may adversely impact the ability of the supplier to continue participating in the program or the level of patient care.

To address this concern, we have recommended that CMS consider delaying implementation of the brand-specific mandate until it ensures that the product categories and applicable HCPCS codes recognize the cost distinctions of these products. This could be accomplished through a phased-in approach to the brand mandate. For example, the entire product category of wheelchair coding already is being revised through new and revised codes and definitions. This phasing and more deliberate approach will minimize the onerous and unfair consequences to which suppliers otherwise will be subject and which we strongly believe was not Congress' intent when enacting the statutory language.

E. Exception Process Needed

Whether or not CMS implements a more refined product category and HCPCS classification, the Office of General Counsel should support CMS efforts to develop an exception process to protect suppliers when a physician orders a disproportionately more expensive brand. In other government program contexts such as the Medicare Part D program, CMS has recognized the importance of risk adjustments and risk corridors to decrease the exposure of Part D plans where the allowed cost exceeds the estimated plan payments for the Part D benefit. Similarly, CMS should take into consideration the potential exposure of suppliers who participate in the competitive bidding program and must handle unexpected requests (or an unpredicted request volume) for more costly items.

We anticipate there will be instances in which a physician refuses to modify a prescription and the contract supplier cannot provide the specifically requested item, or no contract supplier will furnish the specified item. Under the Proposed Rule, the contract supplier may furnish an alternative item within the same HCPCS code in an effort to meet a beneficiary's medical needs. Even though this item would be covered in a non-competitive bidding area and the item is considered equivalent to the ordered item because it falls within the same HCPCS code, the supplier will not be able to bill Medicare. Instead, the item will be considered a "non-covered item." It is unclear why the contract supplier should be left with the cost of the item in

these situations. This is an entirely inequitable result and, we believe, inconsistent with the Congressional intent.

In light of the grave concerns related to the implementation of this brand-specific provision, the Office of General Counsel should encourage CMS to delay implementation of the brand-specific component of the competitive bidding program until CMS develops a system that can more adequately distinguish supplies by relative cost and features. This approach will permit suppliers to calculate and offer realistic bids and, ultimately, receive fair reimbursement as they continue to supply high-quality services and items to Medicare beneficiaries.

F. Substitution Process and Documentation Requirements

If a physician or treating practitioner requests a specific brand, the contract supplier is allowed, under the current Proposed Rule, to consult with the prescriber concerning a suitable alternative. If the treating practitioner is willing to modify the original order, the Proposed Rule mandates the supplier receive a revised written prescription. Verbal orders are acceptable in most states. This proposal is well beyond the legal mandates of many states and imposes significant administrative burdens on suppliers and physicians.

First, many of the existing CMS documents, such as the CMN, have no place for a physician to specify a particular brand of equipment. Rather than requiring a supplier to obtain and store both a CMN and a separate prescription, CMS should modify its forms so that only one document is required. This approach is more efficient for physicians and suppliers, and is consistent with the general industry directive to reduce unnecessary paper.

Second, the proposed documentation requirements concerning order modification are not consistent with standard practice within the DME industry. Revised written prescriptions are not presently required for many DME items under state law. Thus, in appropriate circumstances, it is common for suppliers to furnish alternative products that physicians have orally approved without further physician documentation. Mandating a revised written prescription is an onerous and unnecessary burden on both the treating practitioner community and suppliers, and is likely to distract from the medical community's primary focus on patient care. The Proposed Rule should be modified so that a supplier is permitted to make appropriate notations in its internal documentation, such as system-generated prescriptions, in order to document a physician's oral consent to substitution of a particular product. A new physician prescription should not be required unless mandated under state law. Again, verbal orders are acceptable in most states. This suggested approach is consistent with industry practice and will improve the ability of suppliers to efficiently deliver necessary and proper items to beneficiaries.

Finally, the Proposed Rule should be clarified with respect to a contracted supplier's obligation to refer a beneficiary to an alternative supplier if the original supplier does not carry a requested item. The Proposed Rule suggests that in this situation the supplier is initially permitted to contact the treating physician and discuss an alternative product. Only if the supplier cannot fill the order must the supplier assist the beneficiary in locating an alternative source. The Proposed Rule Preamble, however, implies that the supplier must first contact other contract suppliers within the competitive bidding area ("CBA") before consulting with the physician. Since the language in the Proposed Rule is consistent with current industry practice

and minimizes disruption for the beneficiary, this would appear to be the most appropriate approach. CMS's clarification on this topic will minimize confusion among suppliers regarding the proper course of action.

G. Reasonable Effort Standard

The Proposed Rule states that if a supplier does not carry a requested item, the supplier may refer the beneficiary to another supplier in the CBA that does. CMS should specify the level of effort that a contract supplier must expend in locating another contract supplier. An appropriate standard would be to require contract suppliers that are unable to supply the requested item to use "commercially reasonable efforts" to locate an alternative supplier. CMS also should clarify a supplier's obligation to furnish a brand-specific item when no alternative suppliers can be located.

H. Perception of Discrimination and Unfairness

Implementation of the brand-specific provision of the Proposed Rule appears to be inconsistent with the Preamble discussion about the terms of a supplier contract. Specifically, the Preamble states that the supplier contract is likely to contain a requirement that the supplier not discriminate against beneficiaries in a CBA, so that "all beneficiaries inside and outside the CBA receive the same products that the contract supplier would furnish to other customers." 83 Fed. Reg. at 25681.

It is unclear how a contract supplier may comply with this directive while furnishing brand-specific items only to competitive bidding beneficiaries. It is also unclear how a supplier will be able to avoid potential beneficiary allegations of discrimination and unfairness when certain items will be covered in a non-competitive bidding area, but will be considered non-covered in the competitive bidding area if a physician insists on a specific brand, but the supplier is only able to furnish a different product. CMS should clarify these potential inconsistencies and ensure that suppliers will not be subject to inadvertent CMS and beneficiary liability.

In addition to these concerns, the current proposal will add administrative costs to those suppliers (including Apria) that have locations serving both competitive bidding and non-competitive bidding beneficiaries. These costs will include the need for additional training on the brand-specific issue, as well as the need to develop additional internal systems and protections to ensure appropriate implementation. It would be logistically impossible for every provider to train its employees on every single product available in the marketplace. Such training, if possible, would need to extend to our employees who must be able to set up, educate patients on and explain all brands of equipment. This is neither practical nor cost-effective for either the provider or the program.

I. CMS Cannot Consider an Item Non-Covered if it Has a HCPCS Code and is Reimbursed by Medicare Outside of the CBAs

The proposal also calls for the contract supplier to not bill Medicare for a product it supplies if it does not match the prescription as CMS would consider this a "non-covered item." This also represents and unfair and discriminatory business practice, as the supplier's

location might actually be providing that same product to beneficiaries who live outside of the CBA, and the supplier will have incurred the full expense burden associated with delivering that equipment to the patient's home within a very short period of time after the referral was received.

J. Brand-Specific Requirement Cuts Into Potential Program Savings

The competitive bidding program is designed to drive savings for the Medicare program. Homecare providers drive savings that they could pass on to the program by consolidating purchases among a few manufacturers. If this provision moves forward in its current form, it will undoubtedly result in reduced savings that may be attributed to the competitive bidding program. If a provider must account for higher product acquisition costs in the bids submitted during the application process, the savings levels will be lower. This certainly is not the result Congress intended when authorizing the competitive bidding program.

V. An Additional Comment Period is Needed and Justified

In light of the complexity of the new system the Proposed Rule attempts to implement, and the lack of enough detail in the Proposed Rule, we strongly urge the Office of General Counsel to require CMS to exercise its discretion and offer interested parties the opportunity to provide additional comments on key elements of the DMEPOS competitive bidding program before a final regulation is published. Not only is competitive bidding a new approach for the furnishing of DMEPOS to Medicare beneficiaries, it is a complex model whose operations and consequences remain relatively unfamiliar to CMS, suppliers, contractors and beneficiaries. It seems to raise more questions than it answers about the operations of competitive bidding, both this year and over the long-term lifespan of the program.

This lack of experience is reflected in the numerous critical topics discussed within the Proposed Rule that are proposed with minimal operational detail. These items include the criteria used to establish product categories and specific products, identification of the specific product categories and products that will be subject to competitive bidding in the first year, and identification of the geographic competitive bidding areas, among others. While the public can comment generally on the proposal CMS has put forth, without the details of these important topics it is difficult for the public and the providers to meaningfully and substantively evaluate the proposal.

The lack of existing detail is not the only reason that the public should have an additional opportunity for comment before the rule is finalized. The trade press has vocally noted the absence of any CMS guidance on critical non-competitive bidding topics that will have a direct impact on the ability of suppliers to successfully participate in the program. Until this information is available, it is difficult for a supplier to meaningfully evaluate the Proposed Rule. For example, the Proposed Rule requires a contract supplier to service beneficiary-owned items for any beneficiary who resides in the competitive bidding areas. The Deficit Reduction Act of 2005 permits CMS to make numerous and dramatic changes to what repair and maintenance services Medicare might cover. The Proposed Rule is silent about the application of these new statutory provisions, and fails to recognize or acknowledge in any manner that CMS has issued no guidance on these significant topics.

Due to the monumental changes the competitive bidding program is initiating, we expect the interim rule will be very different than the Proposed Rule on many topics. Thus, CMS should exercise its discretion and publish its initial responses to the public comments as a new proposed rule or, alternatively, an interim rule with an additional opportunity for comment. The parameters of the Administrative Procedure Act permit CMS to offer additional opportunity for public comment on proposed regulations. In fact, CMS recently exercised this discretion in the proposed regulations for the competitive acquisition program for Medicare Part B drugs ("CAP"). The DMEPOS competitive bidding program is far more complex than CAP and deserves a similar opportunity for a robust and thorough public discussion of actual CMS proposals. Implementing the final regulation in stages would provide further opportunity for meaningful public comment and facilitate successful implementation of the competitive bidding program.

This would be more than good and fair policy. It also would be consistent with applicable law. Section 1871(a)(4) of the Social Security Act provides that a final rule will be treated as a proposed rule if it includes provisions that are not "logical outgrowth(s) of a previously published notice of proposed rulemaking." Congress clearly was concerned about the type of situation where a proposed rule does not flesh out CMS' intent with enough specificity so that the final rule's provisions surprise the public that commented on the proposed rule. On several points, this proposed rule approaches this line.

An additional comment period will not significantly impact the overall implementation timeline. It is more important to implement the program correctly, given its magnitude and the facts that only two demonstrations were conducted and that the current Proposed Rule departs significantly from the approach tested in those demonstrations. Any rush to implement any aspect of the program will only result in beneficiary and referral agent dissatisfaction, not to mention an unknown disruption factor on suppliers themselves. The Office of General Counsel should encourage CMS to adopt a process for regulation development that is fair and consistent with due process.

* * *

Apria appreciates the opportunity to comment on the Proposed Rule and to share these legal concerns with you. Once you have had an opportunity to review these issues, we would like to meet with you in person to address any further comments or questions you may have. We look forward to speaking with you and continuing to work productively with CMS in order to support the successful and equitable implementation of the competitive bidding program.

Sincerely,

Robert S. Holcombe / T.C.S.

Robert S. Holcombe
Executive Vice President,
General Counsel and Secretary

Enclosure

APRIA HEALTHCARE®

June 30, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

VIA Hand Delivery in Washington, DC Office

DMEPOS Competitive Bidding Team
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Room 445-G
Hubert M. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Reference: File Code CMS-1270-P - Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan and DMEPOS Competitive Bidding Team:

On behalf of Apria Healthcare, thank you for the opportunity to provide written comments in response to the Notice of Proposed Rule Making (NPRM or Proposed Rule) for the competitive acquisition (competitive bidding) program for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) covered by Medicare Part B.

Development of the competitive bidding program is an incredibly complex undertaking and the Centers for Medicare & Medicaid Services (CMS) competitive bidding team certainly has invested significant time and thought in drafting the NPRM. We appreciate the opportunity to comment on its content.

We believe we offer a unique perspective on the DMEPOS industry that your team will find useful when preparing the final rule. As you may know, Apria Healthcare is the nation's largest provider of DME, respiratory care services and home enteral nutrition. We are the third largest home infusion therapy provider in the country.

In addition, as an active member of the Professional Advisory Oversight Committee (PAOC) that was formed to advise CMS on the competitive bidding program, I personally have a direct interest in ensuring that the program is implemented in the most appropriate, fair manner possible. Therefore, we believe that

Apria's comments reflect current competitive contracting experience and will be helpful to you as you finalize the plans for competitive bidding this summer.

ORGANIZATION OF OUR COMMENTS

We have organized our comments as follows:

1) An Executive Summary to highlight our most significant comments and general concerns about the Proposed Rule.

2) Background on Apria Healthcare.

3) Detailed comments and questions on each applicable section of the NPRM for which the Agency seeks comment, as well as many concrete suggestions and recommendations.

Per CMS' request, each major section starts on its own page with a boxed-in header that clearly identifies it.

CONTACT INFORMATION FOR QUESTIONS ABOUT COMMENTS

Due to the extensive nature of these comments, questions may arise about them as the bidding team undertakes its review. Please feel free to contact the following Apria Healthcare employees who are leading our efforts on competitive bidding:

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APRIA HEALTHCARE
COMMENTS ON COMPETITIVE BIDDING

EXECUTIVE SUMMARY

I. Background on Apria Healthcare

Apria Healthcare is the nation's largest provider of home respiratory, infusion and medical equipment services. With over 500 wholly-owned respiratory/medical equipment branch locations nationwide, Apria serves patients in all 50 states, including those covered by Medicare, Medicaid and managed care plans. We own and operate 32 home infusion pharmacies that provide extensive clinical and patient support services to patients who require intravenous therapies to treat a wide range of chronic and acute conditions.

Apria also owns and operates three centralized clinical respiratory pharmacies that serve patients who require inhalation drug therapies and support services necessary to treat Chronic Obstructive Pulmonary Disease (COPD), the fourth leading cause of death in the United States. The Company also provides custom rehabilitation equipment and services and diabetic supplies to patients covered by Medicare, Medicaid and certain managed care insurers.

All facilities are licensed by all of the states where we operate, and we fill orders and prescriptions written by physicians who are licensed in those states. We provide direct care to hundreds of thousands of Medicare beneficiaries each year, and are contracted with over 2500 managed care plans as well.

As part of our overall commitment to compliance, Apria operates a robust corporate compliance program that includes an employee hotline, disclosure methods, checks against debarment databases and other features. Our Board of Directors has been recognized nationally for its corporate governance measures and, recently, we were informed that Apria has won the Ethics in America Award in the category of "National Public Company." The awards are sponsored by the Passkeys Foundation, an Orange County-based organization that is dedicated to "building a nation of character."

II. Apria Healthcare Has the Most Managed Care Contracting Experience of Any Provider

Apria Healthcare has the most extensive managed care contracting experience in the RT/HME/IV industry, with over 2500 managed care contracts nationwide. As such, we believe strongly in the merits of our general comment that the Medicare program's planned implementation of "competitive bidding" is not analogous at all to what private sector health plans implement. In the managed care negotiation processes, health plans are willing to narrow the number of providers participating in their "panel" in exchange for guaranteed patient volume. The various panel participants may have different payment levels depending on their original bid rates and the potential patient volume from the health plan.

By contrast, the Medicare program would like to achieve "savings" through a bidding process that simply results in a lower, fixed fee schedule without directing any correlation to potential patient volume, and without consideration of what an individual supplier believes its own cost structures can withstand. This approach is inconsistent with standard competitive contracting practices.

III. General Comments

We support the five stated objectives for competitive bidding in the NPRM and believe that, if done correctly, the program can contribute to improved service quality. If implemented incorrectly, however, the program could result in an immense administrative structure imposed upon an already-complex Medicare Part B system without any associated savings.

A. Timeline of Implementation Needs to be Refined and Published

The general timeline that CMS has set for competitive bidding is aggressive. When one considers the body of work that must be completed before even the first phase of the program begins (that of issuing the Request for Bids (RFBs)), one realizes that the timeline may be too aggressive. Consider that the following steps must be completed in the next few months alone:

- The final quality standards must be published, including product-specific ones that may be fraught with problems;
- The accreditation organizations must be selected and they must undergo the application and review process with CMS;
- CMS must finalize its plans for actually implementing the accreditation requirement of the program;
- The stabilization of the new DMEMACs such as National Heritage Insurance Company (NHIC) and Noridian Administrative Services, which does not even take effect until October 2006. Neither one has ever processed DME claims;
- CMS must publish the interim final and final regulations;
- CMS must complete the proposed rule for the Deficit Reduction Act and project how it will interface with competitive bidding, and vice versa;
- The first 10 MSAs and product categories must be selected;
- The RFB package must be finalized and issued for the first 10 MSAs;
- CMS will need 72 FTEs to review the first round of bidding packages; and
- A major beneficiary and supplier education process must ensue.

B. Positive Aspects of the NPRM

In terms of positive attributes, we were pleased that the rule includes guidance on mandatory accreditation, reference to the quality, financial and compliance standards, and reasonable formulas for selecting geographic markets in which to institute the program and for calculating suppliers' composite bids.

C. Proposed Rule Lacked Detailed Plans on Which to Comment

In general, however, we are concerned about the lack of details surrounding the implementation of this critical program. We found that the NPRM raised more questions than it answered, and that there are several sections on which we cannot provide specific and detailed comments until further information is released by CMS.

Examples of sections that lacked sufficient detail include:

- Handling of MSP (Medicare as a Secondary Payor) claims – this was not addressed anywhere in the Proposed Rule;
- Final product-specific quality standards;
- Final list of DMEPOS products that will be included;

- Final list of Metropolitan Statistical Areas (MSAs) for 2007;
- Contract terms and conditions;
- Grandfathering Medicare Advantage patients and how to handle patients that transition between other payors and Medicare;
- Repair and Maintenance expectations in light of the Deficit Reduction Act of 2005 (DRA);
- Network development and implementation;
- Administration of the accreditation requirement;
- Satisfying the requirement to furnish brand-specific products; and
- The anticipated interface between the Competitive Bidding Implementation Contractor (CBIC) and the Durable Medical Equipment Medicare Administrative Contractors (DMEMACs).

We are also concerned that the Proposed Rule does not include any type of transition plan that describes how the impacted MSAs would shift from the existing method of reimbursement and payment to the new one under competitive bidding.

As a member of the PAOC, I am also personally concerned that a number of sections, ideas or proposed methodologies contained in the Proposed Rule were never discussed at prior PAOC meetings. While the recent May 22-23 meeting was the most productive one so far, such a surprise element should be avoided in the future. I know that my fellow PAOC members welcome the opportunity for more frequent dialogue with the agency on the development and implementation of the competitive bidding program, and we recommend that it take the form of more frequent conference calls or in-person meetings.

Since it is already late June, it appears that the PAOC will not have an opportunity to review the quality standards again before CMS issues its final formulation. This is really unacceptable given the likelihood of significant changes due to the 5600-plus comments CMS received. Moreover, the quality standards will have a direct impact on any provider's ability to comment on this rule in appropriate detail, especially as the comments relate to the critical issues of the bidding process itself and the establishment of a single payment rate. We hope that CMS will schedule another in-person PAOC meeting prior to the publication of the Final Rule for competitive bidding. We also strongly urge CMS to provide the public with the opportunity for additional written comments on the competitive bidding program, since we expect CMS to receive a large response to this NPRM.

IV. Primary Areas of Concern

Our primary areas of concern, which will be detailed further in the applicable sections of this letter, are as follows:

1. Proposed Calculation of Single Payment for a Competitively Bid Item Differs Significantly from Method Used in Two Demonstration Projects

CMS proposes to set the single payment rate for any competitively bid item at the median of the array of bids of the "winning suppliers." This means that some of the winning bidders will have to accept less than their bids in order to participate in the program, even if those winning bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. The result is simply a new fee schedule, and is contrary to basic principles of contracting and competitive bidding. It is also significantly different than the method used in the Polk County, FL and San Antonio, TX demonstration projects and therefore it probably is not what Congress intended in approving competitive bidding as part of the Medicare Modernization Act of 2003 (MMA).

The far better course would be to set the payment rate at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This is the method used in the two demonstration projects.

2. *CMS is Exceeding its Authority by Extending the Competitive Bidding Program Beyond the MSAs Authorized by Congress*

CMS states in the Proposed Rule that it has the authority to extend the scope of the competitive bidding program in 2007 to counties, zip codes or parishes that are contiguous to the metropolitan statistical areas (MSAs) that are selected for participation in the first phase of the competitive bidding program. This appears to be directly contrary to the MMA, which clearly limits the first phase of the program to 10 of the largest MSAs in 2007. In fact, the second phase of the program also is limited to MSAs - 80 of the largest MSAs in 2009. Areas outside of MSAs are not eligible for participation in the program until after 2009.

As discussed in our comments about the definition of MSA, we believe that section 1847(a)(1)(B) of the Social Security Act prohibits CMS from extending individual competition areas beyond the MSA boundaries in 2007 or 2009. Not only is the proposal beyond the statutory language, but supplier compliance will be impractical due to systems and other operational limitations. Since DMEPOS suppliers' physical locations often serve multiple counties, it would be logistically impossible to administer additional competitive bidding pricing, quality standards and other requirements in selective zip codes or areas. Neither the computer systems nor operations of suppliers, even sophisticated organizations like Apria, can support such selective add-ons. The hard boundary should be the MSA as defined by the Office of Management and Budget (OMB) and as described in the statute.

3. *CMS Has Not Clearly Defined or Differentiated Between "Supplier Coverage Area" and "Capacity"*

In numerous sections of the Proposed Rule, CMS refers to supplier coverage area and supplier capacity but has neither defined nor clarified those terms. The Proposed Rule requires a contract supplier to be able to service the entire competitive bidding area but does not specify any minimal capacity that it must have in order to participate and accept additional volume. These terms must be clarified before the Final Rule is issued.

4. *The Proposed Rule Exceeds the MMA's Directive Concerning Physician Authorization/Treating Practitioner – the Ability of the Physician to Order Brand Specific Items*

We understand that the MMA includes authority for the Secretary to establish a process for certain items under which a physician may prescribe a particular brand or mode of delivery of an item. We understand the intent was likely to prevent substandard products from being provided to beneficiaries under competitive bidding. However, we believe that CMS has overinterpreted the provision and proposed a process that is much too complicated and costly to both the program and providers.

CMS proposes that all participating suppliers must provide brand-specific items and equipment as designated by the prescribing physician. If a supplier substitutes another item or equipment, the claim will be denied, despite the fact that the same item would be covered in a non-competitive bidding area. This is counter to how all suppliers operate not only under the Medicare program, but with all payors. Never in the history of the Medicare Part B DMEPOS program has Medicare required brand-specificity. Suppliers often carry items and equipment that the FDA deems to be functionally equivalent to other products. Physicians are often not the most well-informed about the features and benefits of new

technologies; the homecare supplier is responsible for matching the patient's needs to the equipment or supplies. Having to carry all possible items and equipment is extremely costly and burdensome and will only drive up suppliers' costs and therefore reduce potential savings from competitive bidding. It is not a business model used today by any supplier.

In addition, the HCPCS process must be revamped in order to facilitate this provision's success. Today, single HCPCS codes exist for numerous products that have a wide range of clinical benefits, product differentiation and provider acquisition costs. One example is the over 400 CPAP mask interfaces available on the market, all tied to a single HCPCS code. Until the HCPCS process reflects the full array of products available on the market today, the brand-specific requirement will be very difficult to implement.

At Apria, all products provided to patients have been screened, evaluated, proven, approved and/ or accepted clinically, technically, and commercially. Physicians, for the most part, do not verify or validate the clinical, technical or commercial merits of scripted items or equipment. CMS should permit the substitution of items and equipment that meet or exceed specifications or requirements and are functionally equivalent or superior to the designated items and equipment. The FDA has clear guidelines on functional equivalence.

If CMS insists on pursuing the provision as planned, it should delay implementation until the 2008 round of competitive bidding, which would allow time for it to be further studied and possibly piloted before expanding to all CBAs. In addition, an exception process would be needed, as well as simplified documentation requirements. (Please refer to section "O" of our comments for more details on this issue.)

5. *CMS' Plans to Revise the Parenteral and Enteral nutrition (PEN) Schedule Without Formal Comments from the Industry are Inappropriate*

As an intravenous medication, parenteral nutrition was never intended to be included in competitive bidding. So, we are unclear as to why the agency feels the need to revise this reimbursement methodology at this time. In addition, with the advent of Medicare Part D, some patients are attempting to coordinate their intravenous therapy needs between Medicare Part B and Part D. The significant challenges some patients are already experiencing will be exacerbated by the Proposed Rule.

6. *The Beneficiary Rebate Proposal May be Illegal and Is Certainly Contrary to Existing Anti-Fraud and Abuse Initiatives by the Homecare Industry and the OIG*

CMS proposes to permit suppliers whose bids are lower than the median bid to rebate a portion of the difference to beneficiaries. CMS would publish a list of suppliers that provide rebates, although suppliers themselves would not be permitted to promote or advertise such rebates.

This proposal is completely contrary to federal law, OIG guidance, comments of government prosecutors, and the general compliance efforts of the DMEPOS industry. For years, providers have not been allowed to waive even a $5 co-pay. The industry has worked too hard to eliminate fraud and abuse and CMS will in no way be able to monitor appropriate rebating practices. CMS should be more concerned about tracking quality and services and encouraging beneficiary supplier selection on these bases. CMS resources should be targeted with auditing quality services from providers and not trying to police rebate programs, which have no savings to the government.

Rebates represent an open invitation for fraudulent and abusive practices, and CMS should withdraw this provision. Medicare, OIG, state and other policies exist today that prohibit such rebates from being provided to patients covered by government insurance. The industry is working hard to improve its

image and practices, and this provision would be a significant step backwards in that regard. CMS could not possibly monitor compliance. A system that encourages suppliers to provide monetary inducements as a way to influence patient choice is contrary to the fundamental principles of governance for the industry.

In addition, the rebate concept was never discussed at prior meetings of the Professional Advisory Oversight Committee (PAOC), which was formed to advise CMS on DMEPOS competitive bidding. The PAOC was surprised by its inclusion in the NPRM and, as evidenced by the discussion on this subject at the May meeting, the entire PAOC is opposed to this provision, not just Apria Healthcare.

CMS should focus its efforts and resources on supporting quality service and encouraging beneficiary supplier selection on that basis.

7. *CMS Proposes New Gap-Filling Procedures that Will Enable the Agency to Modify Payment Levels Without Due Process Protections for Homecare Providers*

Despite the length of this section, too many definitions remain unclear and details unknown about how CMS would move forward with this new methodology. It appears that CMS plans to grant itself authority, without any Congressional or other agency review, to revise the existing gap-filling methodology to apply to existing products. Again, this is an inopportune time when so many different reimbursement cuts are occurring concurrently, many of which have several outstanding regulatory questions. Their effects are not only unknown at this time, but also have not yet been quantified in terms of dollars saved.

The outmoded HCPCS system is directly linked to the challenges associated with gap-filling. Advanced, more costly technology used to treat homecare patients has been approved by the FDA in recent years. Yet CMS and the HCPCS coding panel have routinely denied the creation of new codes and different payment levels to recognize the higher research and development costs that manufacturers pass along to suppliers in the form of acquisition prices.

Using a technology assessment alone to adjust payment amounts would amount to CMS' circumvention of the requirements under section 1842b. Under the "inherent reasonableness" (IR) authority, Congress specifically included requirements for notice and comment so that valid and reliable data would be used. CMS must develop a method that reviews providers' <u>total</u> cost of providing certain technology to patients and not one that is based solely on product acquisition costs.

Gap-filling was another subject of much discussion at the PAOC, and none of the members endorsed CMS' plan as described in the Proposed Rule.

8. *The Overall Implementation Schedule for the Program Seems Overly Aggressive and the Estimated CMS Costs to Administer the Program Seem Understated*

CMS' own estimates for the amount of time it will take to review 16,000 bids for the 2007 program equates to 72 full-time equivalents (FTEs) working full-time, at an estimated cost of $3.6 million. The numbers for the 2008 program escalate significantly. Given the major milestones that have to be reached between now and when the Request For Bids (RFBs) are issued, we do not believe that the implementation timeline is realistic or can be achieved.

9. *Projected Savings Associated with Competitive Bidding are Overstated*

We believe that the savings projected for competitive bidding have been significantly overstated because the reimbursement cuts mandated by a different section of the MMA and the recently-passed Deficit Reduction Act of 2005 (DRA) have not been adequately studied or integrated into the financial model for competitive bidding. At the recent PAOC meeting, CMS staff admitted that the DRA was passed very late in the development of the competitive bidding NPRM. Therefore, they did not have time to adequately address its impact – from a patient care, service, quality standards or financial savings perspective – prior to the publication of the NPRM or PAOC meeting.

Indeed, the DRA received only cursory references in a few sections of the NPRM. Yet, the policy and reimbursement changes mandated by the DRA represent the most dramatic, and most draconian, changes associated with oxygen and other home medical equipment that have been implemented since the advent of Medicare Part B coverage for DMEPOS. The policy changes will shift burdens that are currently shouldered by DMEPOS suppliers onto Medicare beneficiaries. No impact studies have been performed to assess the increased burden on patients, potential increased out-of-pocket costs or how the suppliers will be paid to provide certain non-equipment services that continue beyond the capped rental/ownership period.

The American Association for Homecare (AAHomecare) sent a formal letter to Herb Kuhn of CMS on April 20, 2006, outlining a list of questions for the agency to answer about the DRA's implementation. We urge the agency to respond to those questions as soon as possible, and the competitive bidding team to fully account for the already-legislated savings that will accrue from the DRA in its Regulatory Impact Analysis (RIA) regarding competitive bidding. The entire makeup of the industry has changed with the new capped rental guidelines, yet no corresponding financial analysis has been performed by any government agency or independent consulting firm. It is quite concerning to us that CMS would move forward without a complete financial analysis considering the industry has gone through reimbursement cuts that were not part of the initial financial review when determining that competitive bidding should be implemented, *i.e.*, DRA and FEHBP. Please note that the list of questions sent to Mr. Kuhn is attached as Appendix A.

We strongly believe that the original savings estimates for competitive bidding will have been largely realized through the implementation of the MMA and the DRA by the time the competitive bidding program is initiated. Thus, after considering the significant costs of implementation, competitive bidding will result in no additional savings to the Medicare program.

10. *Additional Comment Period Needed and Justified*

In light of the complexity of the new system the Proposed Rule attempts to implement, and the lack of enough detail in the Proposed Rule, we strongly urge the Office of General Counsel to require CMS to exercise its discretion and offer interested parties the opportunity to provide additional comments on key elements of the DMEPOS competitive bidding program before a final regulation is published. Not only is competitive bidding a new approach for the furnishing of DMEPOS to Medicare beneficiaries, it is a complex model whose operations and consequences remain relatively unfamiliar to CMS, suppliers, contractors and beneficiaries. It seems to raise more questions than it answers about the operations of competitive bidding, both this year and over the long-term lifespan of the program.

This lack of experience is reflected in the numerous critical topics discussed within the Proposed Rule that are proposed with minimal operational detail. These items include the criteria used to establish product categories and specific products, identification of the specific product categories and products that will be subject to competitive bidding in the first year, and identification of the geographic

competitive bidding areas, among others. While the public can comment generally on the proposal CMS has put forth, without the details of these important topics it is difficult for the public and the providers to meaningfully and substantively evaluate the proposal.

The lack of existing detail is not the only reason that the public should have an additional opportunity for comment before the rule is finalized. The trade press has vocally noted the absence of any CMS guidance on critical non-competitive bidding topics that will have a direct impact on the ability of suppliers to successfully participate in the program. Until this information is available, it is difficult for a supplier to meaningfully evaluate the Proposed Rule. For example, the Proposed Rule requires a contract supplier to service beneficiary-owned items for any beneficiary who resides in the competitive bidding areas. The Deficit Reduction Act of 2005 permits CMS to make numerous and dramatic changes to what repair and maintenance services Medicare might cover. The Proposed Rule is silent about the application of these new statutory provisions, and fails to recognize or acknowledge in any manner that CMS has issued no guidance on these significant topics.

Due to the monumental changes the competitive bidding program is initiating, we expect the interim rule will be very different than the Proposed Rule on many topics. Thus, CMS should exercise its discretion and publish its initial responses to the public comments as a new proposed rule or, alternatively, an interim rule with an additional opportunity for comment. The parameters of the Administrative Procedure Act permit CMS to offer additional opportunity for public comment on proposed regulations. In fact, CMS recently exercised this discretion in the proposed regulations for the competitive acquisition program for Medicare Part B drugs ("CAP"). The DMEPOS competitive bidding program is far more complex than CAP and deserves a similar opportunity for a robust and thorough public discussion of actual CMS proposals. Implementing the final regulation in stages would provide further opportunity for meaningful public comment and facilitate successful implementation of the competitive bidding program.

This would be more than good and fair policy. It also would be consistent with applicable law. Section 1871(a)(4) of the Social Security Act provides that a final rule will be treated as a proposed rule if it includes provisions that are not "logical outgrowth(s) of a previously published notice of proposed rulemaking." Congress clearly was concerned about the type of situation where a proposed rule does not flesh out CMS' intent with enough specificity so that the final rule's provisions surprise the public that commented on the proposed rule. On several points, this proposed rule approaches this line.

An additional comment period will not significantly impact the overall implementation timeline. It is more important to implement the program correctly, given its magnitude and the facts that only two demonstrations were conducted and that the current Proposed Rule departs significantly from the approach tested in those demonstrations. Any rush to implement any aspect of the program will only result in beneficiary and referral agent dissatisfaction, not to mention an unknown disruption factor on suppliers themselves.

V. Summary

Competitive bidding for DMEPOS on a large-scale basis is a brand-new initiative for CMS. We believe that both the timeframe for implementation and the projected cost savings are overly aggressive and urge CMS to proceed with caution, using a phased-in approach to the program overall and certain elements contained therein. These include, for example, the brand-specific requirement, repair and maintenance of equipment that the contract supplier did not supply in the first place, and other elements that have never been studied or implemented before. These specific sections should be piloted in one MSA before expanding to the others in either 2007 or beyond.

Although two demonstration projects were performed, much has changed since the early part of this decade in terms of providers' total cost of caring for Medicare beneficiaries, policy changes implemented by CMS since the conclusion of the demonstrations, and new legislation that was passed since that time.

The negative impact on patients caused by this legislation – the Medicare Modernization Act of 2003's reduced fee schedules for oxygen, nebulizers, wheelchairs, patient lifts, hospital beds and diabetic supplies, and the Deficit Reduction Act of 2005 – cannot be emphasized enough. CMS has already realized a significant amount of savings from the MMA's reduced fee schedule and therefore little savings remain to be had from competitive bidding. Too much remains unknown about how CMS plans to address the major gaps in service coverage that will be caused by the DRA's forced equipment ownership provisions. Fuel, labor, insurance, health benefits, licensure and other non-equipment costs have risen dramatically since the demonstration projects were implemented. These costs will have to be reflected in providers' bids for the program in 2007 and every subsequent bidding cycle.

Finally, one of the other aspects of the demonstration projects that was never studied was that of Medicare patient rehospitalization and/or emergency room visit rates. This is a key outcome measure that CMS should have evaluated to determine if savings created through Part B were actually resulting in expenditures under Part A. It's possible that a price-oriented DMEPOS model actually led to higher levels of institutional care. It would be prudent for CMS to study this in the 2007 round of bidding.

Apria Healthcare has contracted with managed care organizations to provide a comprehensive array of DMEPOS products and services for over 20 years. If conducted correctly and in a truly competitive fashion, competitive bidding can indeed improve quality and consistency of service across a large patient population and geography, while delivering savings to the payor. We applaud CMS and Congress for adopting mandatory accreditation for DMEPOS suppliers, quality standards and other noble goals for the program. CMS' proposed plans for competitive bidding, however, do not reflect standard contracting procedures in this industry and unfortunately, the end result will simply be a reduced fee schedule not unlike what exists today. This is an extensive amount of work directed toward less than further reducing 3% of the total Medicare budget. The Inherent Reasonableness (IR) authority already provides CMS with a much less costly method by which to study and reduce fee schedules and we therefore believe that the planned infrastructure for competitive bidding is essentially unnecessary.

We appreciate the opportunity to provide you with these comments and recommendations and welcome any additional questions you may have in the coming months as you review what will likely be a significant number of comments from individual stakeholders. I look forward to seeing the Medicare DMEPOS Competitive Bidding Team at the next PAOC meeting.

Our more detailed comments, by section, begin on the next page.

B. Use of Terms
Proposed 414.400 and 414.402
71 Fed. Reg. 25654, 25660-61

In general we agree with the definitions of terms to be commonly used in the DMEPOS competitive bidding program. We were particularly pleased to read the definitions of "Bid" and "Item" since they recognize the services that are integrally involved in the safe delivery of products to the patients at home.

I. Definitions of "Bid" and "Item"

- Bid means an offer to furnish an item for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item.

- Item means one of the following products identified by a HCPCS code...and includes the services directly related to the furnishing of that product to the beneficiary.

We were pleased to see the reference to services because for years, the DMEPOS industry has been providing valuable non-equipment services that enable patients to use medical equipment at home in a safe and efficacious manner. For oxygen alone, a new study shows that providers spend $3 on non-equipment services for every $1 they spend on equipment provided to the patient. *See* American Association for Homecare, *Morrison Information Study*, June 2006.

Although the DMEPOS benefit was developed largely around the equipment itself, these services cannot be denied, and in fact they are the same services provided to millions of non-Medicare patients across the country. That is why we join the homecare community in reiterating our concerns about how CMS will ensure provision of and payment for these services after the capped rental period begins and patients are forced to take ownership of their equipment. Once the patient owns the equipment, the fiduciary relationship between the patient and homecare provider is essentially severed and the patient will be responsible for those problems the supplier addresses today as part of the bundled monthly payment rate.

The overall services that are included in the furnishing of DMEPOS, and that we believe are appropriately included in the proposed definitions of "bid" and "item" are:

- Intake/Patient Admission
- Insurance authorization/Verification of Medicare benefits and any secondary insurance
- Information systems processing
- In-home delivery (initial, recurring, emergency and while traveling to other areas)
- Vehicle costs, including lease expenses, insurance, fuel, maintenance/repair, Department Of Transportation (DOT), Food and Drug Administration (FDA) Medical Gases Division, Hazardous Materials and Homeland Security compliance
- Patient education in multiple languages
- Clinical support from licensed respiratory care professionals
- Warranty coverage, repairs, returns, maintenance, replacement, service and support
- All administrative functions
- Billing/Collection of the primary claim, the secondary insurer, any deductible amounts and co-pays
- Overhead, including facility rent, utilities, employee training (including that mandated by state or federal agencies), accreditation, licensing, legal fees, HIPAA compliance, information systems, etc.

So, in reviewing the bids, we urge CMS to recognize that the bid prices offered by suppliers must and do include the full range of services necessary to not only deliver the equipment to the home, but also to ensure that the patient has access to 24/7 on-call assistance, clinical professionals as necessary, emergency assistance on weekend, evenings and holidays, equipment exchanges, billing and collections on the patient's behalf, and an interface with the patient's physician.

II. Definition of Metropolitan Statistical Area (MSA)

We agree that the definition of Metropolitan Statistical Area (MSA) should be consistent with the meaning given by the Office of Management and Budget (OMB). Using this definition, the boundaries of MSAs are quite clear.

We do not support CMS' proposal to selectively add zip codes, parishes, counties or other areas outside of a given MSA. Not only does this proposal present difficulties for internal operational systems of suppliers, but it also will cause confusion and complexity with respect to employee education, referrals, and patients.

Congress' intent in approving DMEPOS competitive bidding as part of the MMA was quite clear in the language it used regarding MSAs. The statute specifically states that competitive bidding is to be implemented in 10 of the largest MSAs in 2007 and 80 additional MSAs in 2008. There is no exception language giving CMS the authority or discretion to add zip codes. We believe that CMS has incorrectly interpreted the statutory language on this matter and has exceeded its authority in this area.

C. Implementation Contractor
Proposed 414.406
71 Fed. Reg. 25654, 25661-25662

Section 414.406 of the Proposed Rule states that CMS plans to designate one or more Competitive Bidding Implementation Contractors ("CBICs") to implement the competitive bidding program. These CBICs would prepare the bid requests and participate in design function, oversight, access and quality monitoring among other administrative tasks. In addition, CMS has proposed that the CBICs will interact with the four DME regional carriers ("DMERCs"), now referred to as DME MACs, that currently process most of the Medicare DME claims. Apria strongly suggests that the criteria for the selection of CBICs include a provision that disallows DME market participants who could abuse their position from serving as CBICs as further described below. Ideally, CBICs should have no presence in the commercial managed care industry. In addition, CMS should take specific contractual and regulatory measures to ensure the independence of the contractors and strictly limit the use of any bidding data for any purposes beyond the competitive bidding program.

I. Clarification of CBIC Entities

Apria is concerned that the Proposed Rule does not state who these CBICs will be. The Proposed Rule only makes vague reference to the fact that "appropriate entities" will be used, without providing any explanation as to what types of entities will qualify or what criteria will be employed to establish that an entity is appropriate. Apria requests that CMS further specify the criteria that will be used to designate a CBIC.

II. Potential Conflicts of Interest with CBICs

CMS should carefully consider the potential conflicts of interests that may arise if entities that have existing relationships with suppliers are chosen to become CBICs, and CMS should implement certain protections through regulations and CBIC contract terms. Once an entity is selected as a CBIC, it will become privy to proprietary pricing information as well as other confidential financial information about the supplier. This type of data may be very useful to the CBIC in the context of other negotiations and commercial relationships the CBIC entity has with the supplier outside of the Medicare program. For example, a CBIC that also operates a commercial health insurance plan would be very interested in comparing supplier Medicare bids with the rates a supplier has proposed in a commercial context. This would provide the CBIC with a highly inappropriate and unfair commercial advantage over the supplier.

CMS already has recognized some of these potential conflicts through its decision to separate the functions of competitive bidding claims processing and bid evaluation. Though the Proposed Rule states that the confidentiality of information provisions in the Federal Acquisition Regulation ("FAR") will be enforced, this only prevents CBICs from giving or selling the information to other entities. It does not address the internal use of confidential information by CBICs, gained while serving in their capacity as CBICs, outside of the competitive bidding program and to the disadvantage of the bidding companies.

Consequently, we request CMS go even further than FAR to ensure that proprietary supplier information is not used inappropriately in other contexts. These efforts could include: preferential selection of an entity with no commercial relationships with suppliers, such as a healthplan or similar organization; specific regulations prohibiting CBIC use of proprietary data for any other purpose and requiring internal firewalls to prevent data sharing; and inclusion of similar protections and certifications in the final CBIC

contracts. These measures will minimize the conflicts of interest that may arise and ensure the overall success of the competitive bidding program and adequate protection of suppliers.

D. Payment Basis
Proposed 414.408
71 Fed. Reg. 25654, 25662-25664

I. Overview of Comments

Our overarching comment for this section is that the method that CMS has proposed for establishing the single payment rate is not the same as was used in the demonstration projects. We believe that the proposed methodology for establishing the single payment amount, for example, in no way matches what Congress intended for the DMEPOS competitive bidding program when it included the provision in the MMA.

It is clear that the CMS competitive bidding team has dedicated significant thought and time into the development of the "Payment Basis" section (Section 414.408(a)) of the NPRM. There are several subsections of this section that Apria supports. However, we also have serious concerns about CMS' intent to use a methodology or formula that differs greatly from those used in the two demonstration markets.

Our comments on this major section follow the same sub-headings used by CMS in the NPRM.

II. Payment Basis (Section 414.408(a))

In the private managed care sector, health plans contract with multiple DMEPOS suppliers at different payment levels based on their rates negotiated with each supplier. These rates reflect the following criteria:

- The amount of potential patient volume from the payor due to the payor's limitation on the number of contracted or preferred suppliers,
- The bundle of services expected from the supplier which does not allow for providers to selectively opt "in" or "out" of various products,
- The geographic area the health plan expects each supplier to cover,
- The service standards the health plan expects each supplier to meet,
- Any health plan-specific requirements, such as a drug or DME product formulary,
- Any customized reports the health plan expects of each supplier,
- Any incremental overhead, information systems, web site, telecommunications, billing/collections or other business support costs the suppliers incur that are specifically attributable to that health plans' unique needs or patient population.

The proposed competitive bidding program for DMEPOS – especially the establishment of a single payment amount for all contract suppliers regardless of their original bid amounts – is not competitive bidding at all. Rather, it represents arbitrary competitive fee-schedule-fixing. It is a model that is inconsistent with general free market principles that are the basis of competition and, in fact, it will not alter the existing model of using a single payment rate in any appreciable way. Moreover, we are doubtful that this approach will provide Medicare beneficiaries to access to high quality suppliers while also lowering Medicare program costs.

III. Beneficiary's Permanent Residence

We agree with CMS' proposal to base the payment to the contract supplier on the single payment amount for the item in the CBA where the beneficiary maintains a permanent residence. This is similar to how we handle snowbirds or temporary residents today.

However, it will be very difficult for the information systems of most suppliers to maintain two or three different sets of pricing terms for the same Medicare item. Consequently, we expect to incur a higher level of revenue adjustments, such as write-offs to the gross revenue line, due to this process. Such write-offs occur when the payment levels are not clear upon admission of the patient or when the guidelines/rules are confusing. (This is true for all payors, not just Medicare.) Such revenue adjustments are a cost of doing business and will be reflected in our bid if Apria chooses to participate in one or more CBAs.

IV. Grandfathering Methodology

A. Ownership and Rental Time Period Under DRA

We generally support the proposed grandfathering methodology, although we are concerned about the impact of the new DRA-mandated equipment ownership and capped rental change for oxygen. The AAHomecare submitted the aforementioned long list of questions to Mr. Kuhn on April 20, 2006 to seek clarification to important issues that arose after the passage of the DRA. Until CMS addresses those questions, and clearly communicates with the industry as to how it plans to fill the gaps in HCPCS codes, repair, maintenance, service, and in-home clinical visits that patients need past the 13-month and 36-month marks for HME and oxygen, respectively, we do not have sufficient information to offer informed comments.

If CMS expects a supplier to include in its bid the cost of providing 24/7 service to capped rental patients that were set up by another supplier, or to patients the contract supplier was forced to accept a few months prior to the end of the capped rental period, the following must and will occur:

1) A provider must have access to information through the Common Working File (CWF) or direct access to the information through the customer service lines to know whether or not the patient has had similar equipment. CMS cannot expect a provider to accept a patient in the eleventh month of rental, only to discover the Medicare claim is going to be denied because of same or similar equipment used in the past. How will a provider recover its equipment or obtain any reimbursement from Medicare? Additionally, it is critical that the DME MACs be current on recoupment activity, particularly when patients go in and out of the hospital or a skilled facility. In today's environment, suppliers sometimes receive refund requests up to two years after the equipment and services have been provided. With equipment capping at 13 months and the ownership transferring to the patient, this type of continuing backlog with the DME MACs will be unacceptable and will require suppliers to build these costs into their bids.

   In addition, in the Request for Bid (RFB) process, CMS must provide suppliers with the raw number of beneficiaries that are in each of the rental months for the equipment subject to bidding and provide contract suppliers with updated information 90 days before the "go live" date. This is needed particularly in light of the nine-month period that will elapse between the time the supplier bids on the MSA and the contracts are actually initiated.

   Using hospital beds as a product example and Orlando, FL as an MSA example, CMS must inform interested suppliers, during the bid process, that the Orlando MSA has 1,000 Medicare

beneficiaries using hospital beds in the market, and that 100 are in their first month, 200 are in their second month, 300 are in their third month, etc.

2) We anticipate that suppliers' bids will increase if they are expected to budget for the costs associated with accepting patients of non-contract suppliers who have "capped out" and therefore will need to be serviced with no corresponding monthly revenue;

3) As a result of the above, the savings associated with competitive bidding will be lower than what CMS has estimated.

B. Grandfathering Patients Who Transition Between Fee-for-Service and Medicare Part C (Medicare Advantage)

As the nation's largest managed care contractor, we process thousands of "payor changes" every single week. A payor change results when a patient's insurance plan changes in any way. It is very common for Medicare Advantage patients to elect to leave their Medicare Part C plan and re-elect fee-for-service coverage. The opposite occurs too, of course. Another unpredictable factor is the health plan's individual decision-making process for whether it will even continue to offer a Medicare Advantage plan at all; several years ago there was an almost wholesale exit from that market.

The rule is silent on how CMS expects these patients to be incorporated into the competitive bidding program. In a given MSA, the patients may be served by a provider who is not a contract supplier for competitive bidding. How does CMS propose that these patients obtain service? Will patients have the choice to continue using their existing provider or will they be forced to switch to another one? What rules will apply to this patient population under competitive bidding?

For purposes of avoiding patient abandonment and additional stress placed on patients, we recommend that patients who reenter the traditional Medicare program be allowed to remain with their existing provider under the grandfathering provisions outlined in the rule.

To minimize some of these unfair consequences, we suggest CMS consider specifying a firm transition period by which time a beneficiary must choose a contract supplier or a non-contract supplier chooses to grandfather. The option to make this decision cannot be an open-ended proposition. We see the potential for a non-contract supplier to elect to grandfather its patients as long as they are in the early months of a 13- or 36-month capped rental period. When the patients approach the end of that period, the supplier could inform the patient that they must transfer to a contract supplier, and that the equipment will be picked up. Then, in accordance with the Proposed Rule, the contract suppliers will be forced to (i) accept the patient on service and (ii) provide the patient with its owned equipment even though there may be only one or a few rental months left in the capped rental period.

Unless CMS establishes a firm deadline by which a decision to transfer is made, it will penalize the contract suppliers and reward the non-contract suppliers in a manner that surely was unintended.

We believe this deadline approach mirrors CMS' approach with Medicare Part D. Under Medicare Part D, CMS established a deadline by which beneficiaries were required to sign up for a Part D plan or face penalties.

In addition to establishing a deadline for electing whether or not to continue with a grandfathered supplier, we urge CMS to consider re-starting the rental counter when a contract supplier accepts a transfer patient, particularly one who is leaving a non-contract supplier. Even for a transfer patient, the receiving supplier must process the patient as a new patient, incurring all of the expenses associated with

new patient admissions such as administrative paperwork, patient and caregiver education, the procurement, provision and delivery of new equipment, and establishing billing and collection protocols. Even if CMS requires the previous supplier to furnish certain material information, such as the CMN, the processing costs for a new supplier may be significant. While this certainly is the cost of doing business, it may be disproportionately burdensome when the patient only has a very short rental period remaining for which the supplier may recover any funds. Thus, re-starting the rental period is a reasonable and fair approach to protect contracted suppliers.

CMS states that "the grandfathered supplier be paid the single payment amounts determined for those items under the competitive bidding program since beneficiaries rent these items for extended time periods ***as long as the items remain medically necessary***." *See* 71 Fed. Reg. at 25663 (emphasis added).

We take issue with the above section for three reasons:

1) The reference to "extended time periods" is outdated language thanks to the DRA.

2) The reference to "as long as the items remain medically necessary" is inaccurate. Patients have a medical need for HME today that extends beyond Medicare's capped rental period of 13-months as defined by the DRA. The DRA's unprecedented change to how oxygen treated, by capping it at 36 months, is going to leave over 250,000 Medicare beneficiaries per year who continue to have a medical need for the drug oxygen without any monthly reimbursement levels.

3) CMS does not recognize nor reimburse for the related services and support required and provided to patients when items remain medically necessary after the capped rental period.

The DRA includes provisions that now work in opposition to this language and still leaves many unanswered questions about how "rental agreement and supplier arrangements may be continued." The capped rental counter should begin at month one when a contract supplier accepts a patient after the noncontract supplier chooses not to accept CMS' single payment rate through the grandfathering provisions.

As Appendix A, we are providing a copy of the list of questions that AAHomecare sent to Herb Kuhn in April.

C. Suppliers That Lose Their Contract Status in a Subsequent Competitive Bidding Program

Comments, concerns, issues and exceptions to 1847(a)(4) of the Act as they apply to Grandfathering of Suppliers should follow suit when applying 1847(a)(4) of the Act to Suppliers that Lose their Contract status. *See* 71 Fed. Reg. at 25663.

D. Payment for Accessories for Items Subject to Grandfathering

This section generally makes sense except that it does not adequately reflect the unknown implementation aspects of the Deficit Reduction Act of 2005. For example, oxygen cannulas and tubing which must be changed frequently, as well as backup oxygen tanks, are currently supplied and reimbursed under the monthly bundled reimbursement rate for oxygen. Although there are HCPCS codes for these supplier (A4615 and A4616), there are no corresponding Medicare allowables. Unless CMS addresses the shortcomings of the DRA between now and the time when the 2007 competitive bidding RFBs are issued, providers will not know how to incorporate this unknown factor into their bids.

It is unrealistic to expect either a contract supplier or a grandfathering supplier to continue supplying oxygen tubing, cannulas or other accessories/supplies for free to beneficiaries after the capped rental period commences and patients own their equipment.

By that time, warranty coverage, service and support from the manufacturer will have expired. It is imperative that CMS issue the answers to the questions posed by AAHomecare in its letter to the Agency so that providers may incorporate that information into their bids later this year.

The only major item now left in the frequent and substantial servicing category is a ventilator, which provides life support in the home. Almost every other item is now in the capped rental category or inexpensive and routinely purchased category.

However, if a supplier is forced to pick up another patient base that has already capped out, that is not a fair proposal. While it would have made sense under the historical payment mechanism for oxygen and durable medical equipment where the equipment either rented as long as the patient had a medical need or in the 15-month capped rental plus every-six-month service and maintenance fee scenario, it no longer makes sense in light of the Deficit Reduction Act of 2005.

E. Payment Adjustment to Account for Inflation (proposed section 414.408(b))

The rule states that the fee schedule payment amounts for DMEPOS items are updated by annual update factors related to the percentage change in the CPI-U for the 12-month period ending June of each year.

However, it is important to note that oxygen and DME fee schedules have been frozen since 2004. Looking closely at even earlier years, a freeze has applied for most of the past 15 years. So, it is misleading to state that the DMEPOS fee schedule is updated annually by a CPI-U factor.

Nevertheless, the rule states that an annual inflation update to the single payment amount would be applied to the single payment amount each year of the three-year contract associated with competitive bidding. We agree with this plan since operating costs such as labor, fuel, vehicle lease, rent, utilities and insurance continue to increase with each passing year.

F. Authority to Adjust Payments in Other Areas (section 414.408(e))

In the Rule, CMS argues that it has the discretion to apply the payment information determined under the competitive bidding program to adjust the payment amounts for the same DMEPOS in areas not included in a competitive bidding program. The Proposed Rule asserts the same proposal for enteral nutrition but that the detailed methodology for doing so has not yet been developed by CMS.

We are vehemently opposed to this approach. We believe it is beyond CMS' authority until at least 2009, and even then, the methodology for competitive bidding does not support application in very different markets.

The general theme of our comments in this section centers around four main facts:

1) Providers' TOTAL costs of caring for patients who need a particular DMEPOS item may vary considerably in different parts of the country.

2) Although we believe the competitive bidding payment methodology is somewhat flawed, the program seeks price concessions from suppliers in exchange for some, perhaps very small reduction, in the number of competitors. This exchange does not exist in the non-competitive bidding areas, thus, it is inappropriate to apply the pricing beyond the CBA.

3) Instead of using competitive bidding pricing in these other areas, CMS should apply the existing processes of Inherent Reasonableness and the related notice process for changing prices.

4) It is entirely too premature for CMS to even contemplate this approach. Too much remains unknown with the DRA and competitive bidding in terms of the scale that CMS is embarking on in 2007.

CMS proposes to incorporate a threshold or amount or level of savings that the Medicare program must realize for an item or group of items before it would use payment information from a competitive bidding program to adjust payment amounts for those items in other areas. This is essentially government price-fixing and not competitive bidding at all.

In addition, providers' total costs of providing certain DMEPOS products and services in different geographic areas may differ greatly from the original competitive bidding area where a certain single payment rate applied. Examples of variable costs in different states include fuel, utilities, rent, labor, overtime, regulatory compliance, and licensure.

Finally, the single payment rate that a supplier agreed to in a given competitive bidding area may have been notably less than the supplier's original bid in that market.

CMS would determine whether adjustments of payment amounts in these areas would be on a local, regional or national basis, depending on the extent to which the single payment amounts and price indexes for an item or group varied across different areas of the country.

Again, the single payment amount that bidders use reflects their TOTAL costs for providing that item of DMEPOS and its related support services in a specific MSA. These can vary dramatically in different areas of the country and it would be unfair and unrealistic to apply rates from one area to another for this reason.

CMS would also consider whether adjustments of payment amounts in other areas would be based on a certain percentage of the single payment amount(s) from the competitive bidding area(s). This is anti-competitive and simply wrong. CMS proposes no studies, no methodology, and no process for arriving at a certain percentage.

G. Requirement to Obtain Competitively Bid Items from a Contract Supplier (section 414.408(f))

Most of our payors have a difficult time enforcing this same requirement for open-choice managed care products such as Preferred Provider Organizations (PPOs) and Point of Service plans (POS). Many noncontracted suppliers eventually pay a claim related to a noncontract supplier through a process usually described as "contract leakage." In this situation, when a patient has already visited a noncontracted provider, the claim is usually billed at retail and then the payor reimburses the noncontracted provider a non-par amount (usually 50-60% of billed charges). Unless CMS is going to build a system that has strict exclusion provisions, providers could still get paid even if they are noncontracted. (However, we do not support CMS' plan, stated elsewhere, to "flag" Medicare supplier numbers, since a single location could serve both CBA- and non-CBA Medicare patients. See below.)

H. Limitation on Beneficiary Liability for Items Furnished by Noncontract Suppliers (section 414.408(f))

We are very concerned about the long-term effectiveness of the proposed supplier flagging process at the NSC. This process is flawed because we anticipate that many contract suppliers may serve broad geographic areas that include both competitive and non-competitive bidding areas. Apria operates branches, each with its own supplier number, that currently service beneficiaries in geographic areas that include the proposed competitive bidding areas.

Another example where this process would be problematic is that of a centralized (*i.e.*, "mail order") pharmacy from which diabetic supplies are provided to patients in numerous states. While the pharmacy requires applicable state licenses to serve patients in those states, it usually requires only one Medicare supplier number. Therefore, Medicare could not flag its supplier number as a non-contracted supplier in one market if it serves hundreds of other markets nationwide.

Instead, we suggest that flagging occur at the patient level based on his/her permanent residence. This is a preferable approach because it addresses the challenges associated with suppliers' geographic coverage beyond a given MSA and the issues associated with patients who reside temporarily in another part of the country or travel frequently.

Suppliers would need to be given access to this patient-level flag through some electronic means that could be verified during the routine Medicare insurance/secondary insurance verification process that all suppliers implement upon the referral of a patient from a referral agent.

E. Competitive Bidding Areas
Proposed 414.410
71 Fed. Reg. 25654, 25665-25669

I. Phase-In Approach

We agree with CMS' planned approach to phase-in competitive bidding. However, we are concerned about the aggressive nature of the plans, especially for 2008, when CMS is proposing to expand the competitive bidding program to eight times as many markets as in 2007. This is a huge undertaking and we strongly suggest that CMS consider a more moderate approach. In our experience, it takes a supplier approximately ninety days to appropriately coordinate implementation for a brand new contract. In addition, this program involves new Medicare carriers. CBICs have yet to be selected or identified, and an entirely new mindset for both beneficiaries, suppliers, and referral agents is required. It remains unclear how CMS itself, and its internal support systems such as the ombudsman, will fare under the new program. Consequently, we recommend CMS consider no more than 50 MSAs in 2008. If the first markets are not implemented until late 2007, CMS should consider further reducing the 2008 projection.

II. Proposed Methodology for MSA Selection for 2007 and 2009 Competitive Bidding Programs

A. The Scope of a Competitive Bidding Area Should Remain Consistent with the MSA Boundaries

The MMA states that competitive bidding will be implemented in a gradual fashion. CMS adopted this approach in the Proposed Rule and we support that decision. We disagree with how CMS intends to define the proposed competitive bidding areas and believe CMS has exceeded its statutory authority.

Until at least 2009, the scope of a competitive bidding area should be concurrent with a metropolitan statistical area ("MSA"). CMS is incorrect in its presumption that it has the discretion to define a competitive bidding area as being anything other than concurrent with an MSA. Even if CMS were correct, it would be administratively very burdensome for suppliers to implement competitive bidding in geographic regions that meander outside of the clearly-defined MSA borders.

From 2007 through 2009, the Social Security Act authorizes CMS to implement competitive bidding in some of the largest MSAs in the country. Specifically, section 18471(B) of the Social Security Act states that competitive bidding shall be phased in:

> among competitive acquisition areas in a manner so that the competition under the programs *occurs in—*
> (I) 10 of the largest metropolitan statistical areas in 2007;
> (II) 80 of the largest metropolitan statistical areas in 2009; and
> (III) additional areas after 2009; (emphasis added).

The statutory language clearly contemplated that the competitive activities would occur in an MSA. There is no discussion about the bidding areas occurring around an MSA or including an MSA. Based upon the clear statutory language, there is no authority for CMS to expand the program beyond the boundaries of an MSA until 2009. Only at that time, and not until then, may additional areas be included. It would be inappropriate and outside of CMS' statutory authority to design a competitive bidding area that exceeded the applicable MSA boundaries.

F. 2007 Program Should be Fully Evaluated Before Proceeding to 2009 Round of Bidding

Regarding the selection of markets for 2009, we generally agree with the selection methodology. Since 2005 data will be more current, projected savings levels could change (downward). However, we believe that the 2007 round of bidding should be thoroughly evaluated, with official reports generated for Congress, the Administration and the DMEPOS community before CMS proceeds with the 2009 round.

We do have concerns about CMS' idea to modify the ranking of MSAs for 2009 based on allowed DMEPOS charges per beneficiary so that it focuses on items that experienced the largest payment reductions or savings under the initial round of competitive bidding in 2007. They include:

- Suppliers' overall costs will change over time. For example, for Apria alone, fuel rose over 30% in the fourth quarter of 2005 alone, and 19% year-over-year. So, CMS should not assume that savings levels would be the same from year to year or contract to contract.

- Other policy, regulatory or statutory changes could occur during the 2007 contract period, such as capped rental, coverage criteria, local coverage determinations (LCDs), etc. could greatly impact savings.

- CMS stated that they "do not propose limiting the number of MSAs that can be selected from any one state." We disagree since it would be too burdensome for suppliers to have different prices and policies in the same state, not to mention the amount of resources required to bid on and participate in numerous markets with different cost structures in the same state.

- We anticipate that the dramatic changes impacting patients and the industry in 2007-2008 in conjunction with the DRA will further impact the perceived success of competitive bidding.

III. Establishing the Competitive Bidding Areas for 2007 and 2009 (414.410(b))

As discussed in our comments about the definition of MSA, we believe that section 1847(a)(1)(B) of the Social Security Act prohibits CMS from extending individual competition areas beyond the MSA boundaries in 2007 or 2009. Not only is the proposal beyond the statutory language, but supplier compliance will be impractical due to systems and other operational limitations. No "adjoining" area (which CMS did not define), parish, county, or zip code should be added to an existing MSA. *See* 71 Fed. Reg. at 25669.

We request that CMS refrain from using the term "competitive" interchangeably with "price savings." The two concepts are different and should be applied accordingly.

The bullet point that says "the area is part of the normal service area or market for suppliers who also serve the MSA market or areas within the boundaries of an MSA in which a competitive bidding program will be operating in 2007 or 2009" describes another mistaken assumption. Service areas vary by each individual company and can change at any given time, such as when a provider decides to close or relocate a branch operation. Such a closure or relocation may be unrelated to the Medicare beneficiaries it serves and be based on other reasons.

IV. Nationwide or Regional Mail Order Competitive Bidding Program (section 414.410(d)(2))

One general aspect of this section is that it does not define "mail order." Most suppliers that provide centralized pharmacies STILL have to employ a large clinical and administrative staff to support the non-

nutrition involves liquid nutrients delivered directly into the gastrointestinal tract through either a surgically-implanted feeding tube or a nasal feeding tube.

Patients who require infusion therapy and/or enteral nutrition typically suffer from a chronic, acute or terminal illness such as Crohn's Disease, Ulcerative Colitis, Motility Disorders, Multiple Sclerosis, Lupus, Rheumatoid Arthritis, Bacteremia, Septicemia, Endocarditis, Osteomyelitis, Lyme Disease, all kinds of cancers, leukemias and lymphomas.

Infusion therapies generally fall into major categories such as total parenteral nutrition (TPN), antibiotic/antifungal/antiviral therapy, chemotherapy, pain management, intravenous immune globulin (IVIG), hydration, colony stimulating factors, hemophilia therapies and others. Therapy may be needed continuously (daily) over a long period of time, or it may be intermittent in nature, as in the case of chemotherapy treatments. Such therapies are almost always prescribed after an oral or other course of treatment fails.

Examples of the complexity involved are frequent prescription changes in either dosage, drug or frequency; intensive patient admission and monitoring processes, intensive patient/caregiver education and 24/7 service supporter, coordination of care between a physician's office, an outpatient setting and the homecare setting for care and other unique aspects of care.

Therefore, we strongly oppose the inclusion of these two product categories in any round of competitive bidding.

IV. Infusion Therapy is Too Complex for Medicare Competitive Bidding to Be Successful

Only specialized home infusion pharmacies that are licensed and/or accredited by the Joint Commission or another accrediting body may provide home infusion to patients in any given state. Only high-tech nurses may administer IV therapies to patients at home; these nurses usually have advanced education, training or certification in their area of expertise, such as cancer, pediatrics, nutrition or pain management.

All medications must be prepared in a sterile environment, where clinical pharmacists who again have specialized training and education prepare each medication according to the individual patient's prescription. The clinical team routinely consults with the patient's physician to serve as his/her "eyes and ears" at home.

There are also policy reasons why infusion drugs and pumps should not be considered for competitive bidding. In some ways, infusion drugs have been "shoehorned" into the Medicare DMEPOS benefit simply due to the way that the benefit is structured for "pure" DMEPOS products or the infusion pumps used in conjunction with IV therapies. Managed care plans, on the other hand, usually include home infusion therapy coverage under either their major Medical benefit or their prescription drug benefit.

The matter is made more complicated by Medicare Part D. While 23 drugs may be covered in the home under Part B, hundreds of home IV drugs are now coverable under Part D (although it is important to note that only the drugs are covered; unlike the private sector that appropriately recognizes the full range of services and supplies needed to safely administer these drugs at home, the Part D program only covers the drugs.) Medicare Part D plans and home infusion providers alike are still working through operational and implementation issues and shortcomings associated with the Part D program and IV drugs. There are already patients who require both Part B and Part D drugs and experience tremendous confusion. To add competitive bidding to the mix would only serve to confuse both patients and referral agents further.

they were in 2002. Clearly, this is not an area that requires immediate action and attention from CMS to restrain inexplicable increases in the rates of Medicare expenditures. If this factor truly is an important criterion in CMS' product selection, then enteral nutrition is a poor choice for inclusion in the 2007 phase of competitive bidding on that basis.

IX. Potential for Savings

Throughout the rule, CMS refers to "significant" or "large savings" potential associated with the program. Yet, it does not define these terms. We request that CMS explain what specific measure will be used to identify an item's true potential savings, after accounting for any recent policy changes and rate cuts.

Our questions include the following:

Is there a minimum threshold of savings or expenditure level that will trigger a particular item's inclusion in competitive bidding?

When CMS reviews annual growth in product expenditures, is there a threshold growth percentage and does it vary by any measure?

Regarding supplier capacity, CMS has not provided enough detail needed to calculate reliable supplier capacity numbers. Is CMS using a supplier capacity threshold to determine the final number of suppliers in a particular MSA?

Since only a limited number of product categories were included in the two demonstration markets and the number of categories for future rounds is likely to be larger, what savings threshold will CMS use to determine whether other categories should be included or not?

X. New Product Categories Are Not Needed

We are greatly concerned that CMS is proposing to create new product categories subject to competitive bidding, especially if the plan is to increase the number of categories. The existing product categories have guided coverage and reimbursement for many years; CMS' own web site is organized by product category and suppliers access the site frequently for information. It would be far too confusing for the categories to be modified, especially when a provider operates multiple sites. Such providers usually operate a single information systems platform and keeping track of old categories and new categories in a single market or state would be next to impossible. Much more information is needed about CMS' plans before we can comment further.

Policy changes made in recent months or years will further reduce potential savings that can be attributed to competitive bidding. A new 2006 policy will significantly bring down the $131.1 million in 2003 allowed charges for the following three HCPCS codes:

- E0470 (Respiratory assist device (RAD), bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device);

- E0471 (Respiratory assist device, bi-level pressure capability, with backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device), and,

- E0472 (Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device).

CMS uses nebulizers as an example, but again, FEHB brought those expenditures down substantially. CMS should republish allowed 2004 and 2005 charges post-FEHB.

CMS has proposed a number of variables it would consider when making determinations about an item's potential savings as a result of the application of competitive bidding. Our comments on each are noted below:

- Annual Medicare DMEPOS Allowed Charges – We agree

- Annual Growth in Expenditures – It is important to note that certain products may show a negative growth rate from 2004 to 2005 based on the FEHB cuts. In addition, growth could be attributed to other factors unrelated to "inappropriate" supplier behavior, such as an increase in the number of new beneficiaries or elimination of Part C in various markets.

- Number of Suppliers – We do not agree that savings should be measured using the available number of suppliers. Rather, savings should be based on capacity.

- Savings in the DMEPOS Demonstrations – Any savings should be adjusted for after FEHB and DRA methodology before the impact of it is calculated.

- Reports and Studies -- We are concerned that CMS does not always use reports and studies that are comparable to the industry or specific situations being evaluated. It appears that at least 7 of the 10 proposed markets are significantly more complex than Polk County, based upon total (all payors) revenues, not just Medicare.

We disagree with the CMS presumption and corresponding language that "Medicare overpays for specific items" at 71 Fed. Reg. at 25671. The studies that OIG and GAO conduct often collect data on only a portion of a supplier's total costs. (See comparison data from Muse & Associates in 2004 and 2005 vs. OIG on inhalation drugs.) Government studies from GAO and OIG are important data sources, but CMS should not rely upon them exclusively and without critical assessment. CMS should ensure that OIG conducts robust studies that capture what we believe is a complete and accurate reflection of a supplier's TOTAL costs, not just equipment costs. We are also concerned that some of the studies upon which CMS seems to rely are outdated and do not reflect changing markets and realistic price pressures.

Pending or future changes to likely competitively bid products include:

- The revision to the power wheelchair product category– currently underway and includes major changes to HCPCS codes, product descriptions and mobility assist equipment as well

- The proposed LCD that would effectively eliminate patient and physician access to the inhalation drugs DuoNeb and Xopenex could also impact nebulizers

- CPAP was impacted by a National Coverage Determination (NCD) in 2006

- Respiratory Assist Devices (RADs) were moved to the capped rental category

G. Submission of Bids Under the Competitive Bidding Program
Proposed 414.412
71 Fed. Reg. 25654, 25672-25674

I. Physicians (proposed section 414.404, 414.422)

In this section, CMS requires that "[p]hysicians that do not become contract suppliers must use a contract supplier to furnish competitively bid items to their Medicare patients."

We recommend that the Office of Inspector General (OIG) eliminate one of the last remaining loopholes of physician self-referral by preventing their ability to own sleep laboratories and provide Part B DMEPOS items in their offices. By studying the impact of physician ownership on overnight sleep study expenditures incurred by Medicare Part A and the growth rates of the past few years, the OIG will likely conclude that such ownership needs to be eliminated just as it was for clinical laboratories and traditional home medical equipment (HME) operations.

A. Physicians as DMEPOS Suppliers

Regarding specific language in this section, CMS should replace the phrase "must use" with the phrase "must refer to." Use the term "refer" because it is illegal and against our compliance program to enter into certain non-safe harbored relationships with physicians. In most cases, physicians cannot own businesses that provide DMEPOS to government-insured patients.

Apria strongly believes that any contracted supplier should satisfy the standards CMS has established, including accreditation, quality standards, Medicare supplier standards, financial and compliance standards, and other requirements associated with being a DMEPOS supplier under Medicare Part B competitive bidding. This obligation should apply to any physician or physician's practice that wants to participate in competitive bidding. There should be no exceptions.

B. Financial Information Required of Large Suppliers

We also agree with CMS' plan to require suppliers to submit a minimum of financial information with their bids. We ask CMS to consider the logistical difficulties and practicalities for large or publicly-traded organizations. As a publicly-traded organization, Apria already has supplied a significant amount of financial information to public markets and the Securities and Exchange Commission (SEC). This includes consolidated information for our multiple locations, since balance sheet, debt, interest and other financial data are not typically available at the branch or supplier number level. This type of public, consolidated information should be sufficient for the CMS bidding process. Organizations like Apria should not be required to prepare unique reports for CMS, and we request that this be made clear in the final rule.

C. Physical Location Within the MSA

CMS has proposed that a supplier must be physically located within a competitive bidding area in order to submit a bid to furnish items in that area. We agree with and strongly support this approach, even for items and services that could be furnished from another company-owned centralized location or via the mail. We do believe that even if a supplier has a centralized pharmacy for providing, for example, diabetic supplies and testing strips, the corporate parent should also operate a physical location within the

MSA. The purpose of this site would be to ensure that beneficiaries have access to contact employees who work for the same corporate entity in the event of a time zone or other limitation.

Without such a requirement, CMS runs the risk of contracting with suppliers that simply drop-ship into the MSA's zip codes without any additional local support whatsoever. They could "cherry-pick" certain product categories without having to make any investment in the MSA. While certain products lend themselves to centralized pharmacy or operations management, others do not and if CMS does not provide some guidance in this area, all kinds of medical equipment may be shipped interstate with or without an appropriate level of patient and caregiver education. This may seriously jeopardize patient safety or violate state licensing and shipping laws and regulations.

II. Product Categories for Billing Purposes (proposed section 414.412)

A. Use of Same 55 Product Categories or Policy Groups

In the Proposed Rule, CMS suggests that it may establish all new "product categories" solely for the purpose of competitive bidding. Although much more detail is needed before we can comment more comprehensively, this proposal is unwieldy and unnecessary given the fact that the existing product categories have been in existence for decades and are commonly-referenced by the industry and DMERC employees alike. We are uncertain why CMS would like to develop alternative categories, and CMS offered no reasonable explanation in the Proposed Rule.

Although the competitive bidding program will launch in 10 markets in 2007 and more in 2008, many markets will continue to operate under the existing product categories. Parallel systems will add unnecessary confusion for suppliers, DMERC claims processing employees and patients. A branch operation may find itself serving patients with the same exact DMEPOS item, but the item could fall into two different categories depending on the zip code of the patient's permanent residence. Few information systems would be able to accommodate such bifurcation.

Before we can make extensive comments on this section, we need to understand how CMS plans to create separate product categories specifically for competitive bidding purposes. CMS was not clear as to the rationale behind the creation of all-new product categories. The 55 categories work for most other reasons, such as how coverage criteria is currently organized, so we need more information on CMS' detailed plans.

B. Submitted Bids: What Do They Include?

CMS states that the submitted bid must "include all costs related to the furnishing of each item such as delivery, set-up, training and proper maintenance for rental items." *See* 71 Fed. Reg. at 25672. This list does not reflect the full range of services or associated costs of the services, such as 24/7 on-call/emergency availability and responsiveness, new patient admission/insurance verification costs, coordination of traveling patients' needs between locations, billing/collections, rent, utilities and regulatory compliance. Most importantly, it does not reflect what might or might not be contained in the proposed quality standards for competitively bid items.

Thus, we ask CMS to clearly specify that these additional costs should be factored into a supplier's bid. While CMS has defined "bid" to recognize these costs, we believe reemphasizing the point here will eliminate future confusion and increase the likelihood of bids that reflect a similar bundle of products and services.

C. Requiring Suppliers to Submit a Bid for All Items in Every Defined Product Category

We are unpersuaded by at least one rationale CMS has offered for the use of new product categories. CMS asserted at 71 Fed. Reg. at 25673 that it believes that "the use of product categories will allow Medicare beneficiaries to receive all of their related products (for example, hospital beds and accessories) from one supplier, which will minimize disruption to the beneficiary."

This is not necessarily true. It is only true if a supplier who is capable of providing all or most of the items being included in that MSA's product list bids on and wins the contract with CMS for the MSA. If not, a patient who requires oxygen, a hospital bed, a wheelchair, a walker, nebulizer and commode chair could, theoretically, have to interact with six different suppliers. This means they would receive six separate monthly bills or statements, six different sets of patient education materials and possibly policies to follow, and other examples of mass confusion. So, any patient who requires multiple DMEPOS products – and many do – will still have to coordinate care with multiple suppliers. This inherently adds additional costs to the entire healthcare system. Referral agents will also be very confused by this process. This seems to be an extremely inefficient and confusing approach and in no way mirrors how private sector managed care organizations handle this.

On the other hand, CMS also stated that in regard to design options, it considered requiring suppliers to submit a bid for all items in every defined product category. *See* 71 Fed. Reg. at 25672. CMS asserted that it would like to "accommodate DMEPOS suppliers who want to specialize in one or a few product categories." *See* 71 Fed. Reg. at 25683.

While there are certainly suppliers that currently specialize in one or a few product lines (diabetic supplies and power wheelchairs are two good examples), we believe that certain suppliers who offer a broader range of DMEPOS may elect to "cherry-pick" the system and directly or indirectly manipulate the CBA's referral patterns. If suppliers focus on one or two product lines and leave other products out of their bids, even though they provide them in that market, it could cause problems when the referral agents apply their "rotation system" in the hospitals. It is well-understood that different product categories have different cost structures and service requirements, accreditation standards, labor and other operating expenses. Therefore, the profit margins for each may vary and some providers may "cherry-pick" if this policy is not thoroughly reviewed. We provide the following scenario for your consideration:

- Supplier A COULD bid on oxygen, standard wheelchairs and walkers, but elects to only bid on oxygen. Supplier A wins the bid on oxygen.

- Supplier B bids on oxygen, standard wheelchairs and walkers, and wins on all three. However, once the discharge planner in the local hospital learns which suppliers they have to choose from for the different products and applies the "rotation system" under which the employee goes down the list in either alphabetical or chronological order, Supplier A could receive a disproportionate share of the hospital's oxygen referrals, while Supplier B could receive a disproportionate share of wheelchairs and walkers. Depending on the final single payment rate for these products, and the associated quality standards, a provider could find itself upside down financially and have to either withdraw from the competitive bidding program or request an increase in the single payment rate.

CMS states that the Act grants the authority to exempt "items for which competitive bidding is unlikely to result in significant savings. We would propose not to include items in a product category if they are rarely used or billed to the program." CMS builds on its earlier plan to create separate product categories specifically for competitive bidding by going on to say that it "may establish different product categories from one CBA to another, as well as in different rounds of competitive bidding in the same CBA." *See* 71 Fed. Reg. at 25673.

We urge CMS to define "significant" when used in reference to potential savings. It is used throughout the document but is never defined.

We agree that items that have low utilization should be excluded from consideration for competitive bidding.

We also provided extensive comments on why infusion therapy and enteral nutrition should be excluded from competitive bidding.

D. Small and Large Suppliers' Ability to Furnish All Product Categories

CMS asserts that "a supplier may be able to furnish a bundle of items at a lower cost than it can product each individual item. This approach is also more favorable to small suppliers because they can choose to specialize in only one product category. It would be more difficult for a small supplier rather than a large supplier to furnish all product categories. This approach is also more convenient for Medicare beneficiaries, as they can choose to receive all their related supplies from one supplier and would not have to deal with multiple suppliers to obtain the proper items for their condition." *See* 71 Fed. Reg. at 25673.

We also disagree with your assertion that it would be more difficult for a small supplier to furnish all product categories. Apria Healthcare purchased 42 independent, private home DMEPOS companies in 2004-2005. Many offered a broader array of DMEPOS products than what Apria offers. While large suppliers may have greater access to capital, everything is scalable and relative to individual financial structures. Some small suppliers' cash flow is at a higher rate than for large suppliers; others may have incurred too much debt to be able to expand rapidly.

This section was not clear to us, but we refer to you to our comments from the immediate section above regarding the need for CMS to guard against "cherry-picking."

Regarding convenience for beneficiaries, again we reiterate that allowing suppliers to selectively participate in competitive bidding by product line could create havoc for beneficiaries who require multiple DMEPOS products to support their health condition. It is not uncommon for a patient with COPD to require, either upon hospital discharge or admission to our service, or as his/her condition worsens due to the natural progression of the disease, oxygen, nebulizer, inhalation therapies, a hospital bed, wheelchair and walker or other assistive device. If the patient also has obstructive sleep apnea (OSA) or diabetes, he/she may need a CPAP and diabetic supplies. In this case, the patient could find the need to use up to six separate suppliers. No patient or referral agent is going to be able to coordinate this easily.

If CMS is truly interested in adopting time-proven methods of contracting for home healthcare services as in the private sector, it should mandate that a supplier bid on all products that they typically supply in an MSA.

E. Relationship Between the DMEPOS Supplier and the Medicare Beneficiary

We appreciate that CMS recognizes the importance of the relationship between the patient and the supplier. However, we believe that CMS oversimplified that relationship by describing the services involved as "...deliver[ing] the item to the beneficiary, set[ting] up the equipment and also educat[ing] the beneficiary on the proper use of the equipment."

This oversimplification was further reinforced at the recent PAOC meeting when Linda Smith shared the results of the very small sample-sized focus groups by indicating that beneficiaries primarily view their supplier as a "delivery person."

1. Comments

Several industry studies have documented a much broader range of services. A June 2006 study conducted by Morrison Informatics, Inc., of Mechanicsburg, Pennsylvania, documents that for oxygen alone, the following services are provided in conjunction with the "furnishing" of the equipment.

Moreover, private managed care payors have been relying on homecare provider patient satisfaction survey results for decades. These surveys have been time-tested for statistical significance and the dimensions that are measured are commonly accepted as the primary services associated with the provision of DMEPOS to all patients, regardless of their insurance source. These dimensions include:

- ***Customer Service***, including the admission process, overall customer service, telephone interactions, the insurance benefits verification process, scheduling the in-home care, responsiveness to the patient after hours or on weekends, issue resolution, coordination of travel, etc.
- ***Clinical respiratory therapists*** – access to this care at home, timeliness, courtesy and professionalism of the therapist involved in educating the patient and/or caregiver
- ***Patient/caregiver education*** – in both printed and verbal form, and in regard to both the equipment's operation, trouble-shooting, patient safety instructions, emergency preparedness, how to reach the DMEPOS supplier with questions, etc.
- ***In-Home Delivery*** – timeliness, courtesy, professionalism, appearance, quality of instruction, etc.
- ***Billing/Collection*** – the extent to which the patient was informed of his/her financial responsibilities in terms of co-pays or deductibles, the accuracy of the billing, the responsiveness of the billing department if the patient had questions, etc.
- ***24/7 Emergency Service and Availability*** – Accrediting bodies require that suppliers offer around-the-clock service. Patients frequently access homecare providers on weekends and during natural disasters.
- ***Overall value of homecare*** – the patient assesses the overall value to his/her life, the degree to which homecare aids in the performance of activities of daily living, etc.

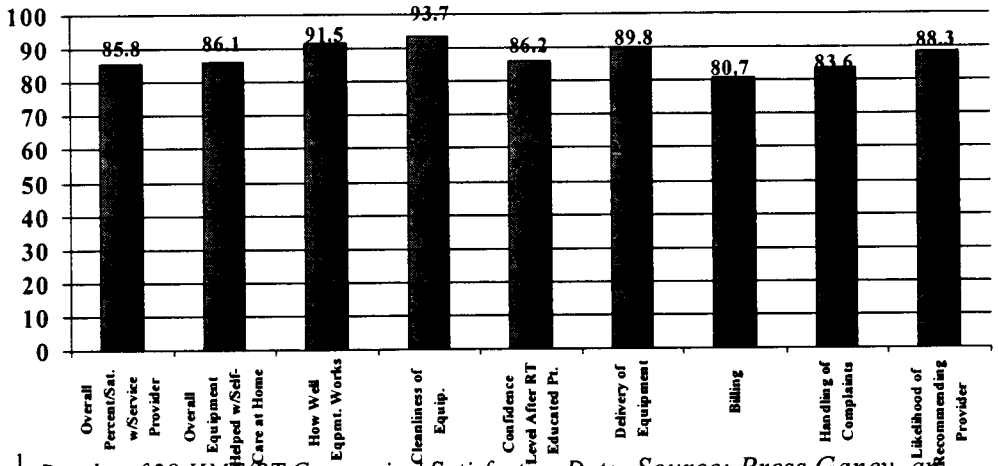
The above list only includes the services most obvious to the patient and does not, of course, account for numerous behind-the-scenes services that are required to ensure a smooth interaction between the company and the patient. Examples of the latter include accreditation, licensure, repair/maintenance and equipment cleaning/disinfecting functions, employee training and certification, telecommunications, regulatory compliance, management information systems, HIPAA compliance, SOX compliance, and more.

Below is a chart that shows the major service dimensions that are involved in measuring patient satisfaction with HME providers:

Patients Are Very Satisfied with HME Providers' Services

(75 Points is Considered "Satisfied")

Very Good	Good	Fair	Poor	Very Poor
5	4	3	2	1
100 points	75 points	50 points	25 points	0 points



[1] *Results of 29 HME/RT Companies' Satisfaction Data. Source: Press Ganey, an independent satisfaction measurement firm. Data represents approximately 580 physical locations. Data also represents multiple product lines and all payor sources.*

We do not see how the use of product categories will "facilitate the transition for those beneficiaries who have to change suppliers." CMS needs to provide much more background on how and why this is needed before we could change our views on this matter.

III. Bidding Requirements (section 414.408)

A. Inexpensive or other routinely purchased DME items

CMS states that "the current fee schedule amounts for these items are based on average reasonable charges for the purchase of new items, purchase of used items, and rental of items from July 1, 1986 through June 30, 1987. *See* 71 Fed. Reg. at 25673. In those cases where reasonable charge data from 1986/87 is not available, the fee schedule amounts for the purchase of new items are generally based on retail purchase prices deflated to the 1986/1987 base period by the percentage change in the CPI-U..."

1. Comments/Recommendations

Using data from 20 years ago or applying a deflation factor associated with the same surely must represent one of the most archaic fee schedule systems in the entire Medicare/Medicaid program. The home DMEPOS industry is remarkably different today than it was 20 years ago – the sheer number of new products and technologies introduced since 1986 could not possibly be reflected in a 20-year-ago fee structure.

Moreover, a CPI-U freeze has been in effect for the majority of the years since 1986, so the rates do not reflect either the cost of inflation or large increases in certain operating costs that providers must incur, such as fuel, vehicle expense, liability insurance or costs associated with state or federal legislation that has occurred since then. These examples include COBRA expenses, Sarbanes-Oxley compliance, HIPAA compliance, compliance with requirements of the Department of Homeland Security, the Department of Transportation, the Food and Drug Administration, the Occupational Safety and Health Administration, state pharmacy and licensure boards.

B. DME items requiring frequent and substantial servicing

We have no comment on continuous passive motion exercise devices as the plan appears acceptable.

C. Oxygen and oxygen equipment

CMS states:

> If included under a competitive bidding program, we would propose that the single payment amounts for oxygen and oxygen equipment be calculated based on separate bids submitted and accepted for furnishing on a monthly basis of each of the oxygen and oxygen equipment categories of services described in section 414.226(b)(1)(I) through 9b)(1)(iv).

1. Comment

It is important to state here that oxygen and oxygen equipment are facing the most dramatic policy and reimbursement changes in the history of coverage for this life-sustaining drug therapy and equipment. The Deficit Reduction Act of 2005 will limit reimbursement for oxygen to 36 months regardless of a patient's ongoing medical need, which flies in the face of how every other drug is covered and paid for in America.

The DRA's negative consequences on patients include:

- It forces patients to take ownership of their equipment and be responsible for identifying when preventive maintenance or repairs are needed.
- It will prevent patients from exercising their right to switch providers due to a move or dissatisfaction, since a provider will be unlikely to accept a patient who has reached the 36-month cap and for which there is no associated monthly reimbursement to care for that patient.
- It represents significant patient safety risks in the form of forcing them to own, maintain and dispose of FDA-regulated medical devices that are subject to manufacturer recalls and intensive regulatory scrutiny by the FDA, DOT and accrediting bodies.
- When patients might benefit from a different oxygen technology due to a change in their condition or their physician's preference, they will not have access to such technology because they will own the one they had during the 36-month period.
- Despite a reduction in benefits, there is no corresponding decrease in the patients' Part B premiums. In fact, the premiums will likely rise due to physician fees.

The NPRM in general is very "light" on how the DRA will interrelate to the competitive bidding program. Since over 23% of Medicare beneficiaries who require home oxygen therapy exceed the 36th

month, it is imperative that CMS address the numerous open questions about how the agency plans to address the gaps caused by the DRA.

The American Association for Homecare submitted a list of questions to the agency on April 20, 2006 . As an active member of AAH, Apria respectfully requests the agency to respond to that list of questions as soon as possible as the patients impacted by the Act's changes will feel that effect in just six short months when providers are required to inform them of the change in ownership and their associated responsibilities, effective February 2007. *(See Appendix A – "AAHomecare List of Questions About the Implementation of the Deficit Reduction Act of 2005)*

IV. Capped rental items

A. The Deficit Reduction Act of 2005 Dramatically Changes the Landscape for HME and Competitive Bidding's "Success" Will be Negatively Impacted by Its Provisions

This section marks the first reference to the DRA. We hope CMS understands that despite the fact that homecare providers are required to inform patients of their right to take ownership of their equipment at the current policy of month 15 of their rental period, less than 10% elect to do so. Patients were not asking for more ownership or "control" over their equipment; they need it just to get through the day, sleep through the night or walk to the mailbox.

Therefore, CMS needs to prepare for another 90% of patients who will take ownership of their equipment and all that it entails.

B. Payment for Maintenance and Servicing

CMS has proposed that suppliers submit a separate bid for all items in a particular product category. The bid must include all costs related to the furnishing of the item, including proper maintenance for rental items. The Proposed Rule suggests that a supplier's bid need not cover the costs for maintenance of an item once a beneficiary purchases it. 42 C.F.R. §§ 414.408(g), (i). On the other hand, CMS has proposed that a supplier must agree to service, repair, and replace all beneficiary owned items. 42 C.F.R. § 414.422(c).

These conflicting directives are confusing and make it difficult for suppliers to accurately determine their responsibilities under competitive bidding. While CMS might refer suppliers for guidance to the historic repair and replacement obligations of DME suppliers, enactment of the DRA has significantly modified the coverage terms. Under the DRA, Medicare will cover service and maintenance only if the Secretary had determined the payment is reasonable and necessary, and appropriate for the equipment. The Secretary has issued no guidance on this topic, and, with respect to certain items, such as oxygen equipment and supplies, this is an area of potentially significant supplier liability. Until suppliers know what service and maintenance activities Medicare expects suppliers to furnish, it is almost impossible for suppliers to accurately project costs of participation in the competitive bidding program. CMS should clarify the maintenance and repair obligations for suppliers in the final rule. CMS also should initially exclude those products from competitive bidding where the impact of this uncertainty is most troubling, such as oxygen equipment and supplies.

CMS states that "under the Medicare DMEPOS Competitive Bidding Program, we propose that separate payment for reasonable and necessary maintenance and servicing only be made for beneficiary-owned DME. Payment for maintenance and servicing of rented equipment would be included in the single payment amount for rental of the item." *See* 71 Fed. Reg. at 25674.

1. Question

Is CMS proposing to establish codes tied to product categories down to the labor and parts level or expecting providers to bid on a lump-sum basis for repair and maintenance?

We are unclear on CMS' intent for this area.

2. Comment

The current fee schedule and HCPCS codes for maintenance and repair is woefully inadequate. It has not been updated in years and in no way reflects the full range of maintenance, repair and "servicing" that providers currently perform for patients, largely under the monthly bundled payment rate. The fee schedules for labor and parts have not kept pace with the actual cost of providing such services.

Because the payment rate for HME and oxygen has been bundled, and because suppliers retained ownership to the equipment for all the years leading up to 2007 (re: HME), most providers merely exchanged the patient's equipment when it was broken, damaged or otherwise in need of repair. They took the patient's existing equipment back to their facility where it was then repaired and returned to inventory, or, if unsalvageable, they have to write the equipment off as an inventory loss. In other words, most providers have not billed the Medicare program for all of the repair and maintenance that the equipment actually would need under an ownership situation.

The DRA also eliminated the semi-annual payments for service and maintenance that Medicare paid if the patient with a capped rental item was still using the equipment after the monthly payments ended. This service and maintenance fee essentially covered providers' costs of providing patients with telephonic support, troubleshooting, additional patient or caregiver education in the home, an equipment exchange involving an in-home delivery, ongoing infrastructure costs and 24/7 emergency availability.

We are very concerned that CMS and certain members of Congress believe that a "seamless web of services" will continue to be available to patients once they own their equipment and are 100% responsible for it. Due to the elimination of the semi-annual payments – which were very nominal in the big picture of Medicare expenditures – as well as the inadequacy of the current HCPCS codes available concerning repair, maintenance and servicing, many providers will have no choice but to eliminate or dramatically scale back their repair functions. Moreover, if CMS does not create new HCPCS codes and reasonable payment allowables to address the other services that patients require after they own their equipment, providers will have to charge patients for such services and request payment up-front since the service will essentially be a non-covered item.

Examples are:

1) Emergency assistance on a weekend when their equipment malfunctions,
2) Coordination of travel needs between company-owned locations or between providers that are not legally related,
3) In-home reinforcement of patient education/instruction on how to use the equipment,
4) Safe pickup and disposal if the patient or family cannot handle this on their own (currently this is a service we provide because we own the asset),
5) An in-home clinical assessment performed by a licensed respiratory therapist per an order from the patient's physician. Who is going to pay for a clinical visit or telephonic counseling sessions?

3. Recommendation

There are several steps that CMS must take immediately to fix the problems associated with the DRA's provisions related to equipment ownership. The Act provides the Secretary with a broad level of authority to create appropriate methods to ensure that patients continue to have access to necessary service above and beyond repair/maintenance:

1) Convene a panel of industry experts to work with CMS to create a list of new HCPCS codes that address the myriad "a la carte" service needs of a patient beyond the capped rental period.
2) Create a fair fee schedule associated with the current and new HCPCS codes which fairly reflects providers' fully-loaded costs of providing those specific services. Such allowables should be subject to an annual CPI-U.
3) Establish a monthly service and maintenance fee and associated HCPCS codes for oxygen patients who continue to have a medical need beyond the 36th month. Such codes and fees could reflect the type of oxygen system they have at home since the service intensity of each may vary, e.g., liquid oxygen requires more frequent in-home deliveries.
4) Clarify that the portable oxygen tanks themselves, or those that are used as backup systems in the event of power failures, are not to be owned by the patients. There are significant FDA and DOT medical gas policy concerns, chain of custody and drug adulteration concerns that cannot be ignored. In addition, there exists no separate payment mechanism for the back-up oxygen tanks that patients require for daily safety measures and in the event of a power outage. Congress clearly did not consider the regulatory constraints surrounding this issue when it passed the legislation quickly in late 2005/early 2006.
5) Establish a clear process for how CMS expects to handle patients who move or desire to switch providers after the capped rental period. We recommend that the "rental counter" start over if the patient either switches providers after the capped rental period begins, or in the case of a patient obtaining new equipment in the home prior to the onset of the capped rental period.
6) Any patient who moves his/her permanent residence from one home to another (not to a skilled nursing facility (SNF) or other institution where this would not apply) and, as a result, switches homecare suppliers, should also represent the restart of the rental counter. This is due to the fact that the new supplier must admit that patient to service using all-new paperwork, patient education, etc. and thus incurs a significant amount of costs associated with the transfer. In the case of a patient who moves before the capped rental period, the patient would have to return the equipment to the original supplier and obtain new equipment from the new supplier. In the event where there were only a few months left on the "rental counter," there would be no motivation for the new supplier to accept that patient on service.

C. "Purchase Bids and "New Items"

CMS states that it proposed "purchase" bids be submitted for the furnishing of new items in this category. Based on these bids, a single payment amount for purchase of a new item will be calculated for each item in this category for the purpose of determining both the single payment amount for the lump sum purchase of a new power wheelchair, and for calculating the single payment amounts for the rental of all items in this category." *See* 71 Fed. Reg. at 25674.

1. Question

What is CMS' definition of "new" in this context? Does it mean a never-used item or new technology that may include different or better features/benefits for the patient? Since both definitions could apply to DMEPOS, we ask for clarification before we can comment effectively.

D. Enteral nutrition equipment and supplies

1. Comments

Apria Healthcare opposes the inclusion of enteral nutrition equipment, nutrients and supplies in competitive bidding for the following reasons:

1) The demonstration projects for competitive bidding proved that enteral was not a suitable product for competitive bidding because the majority of patients who require it reside in skilled nursing facilities. We outlined our reasons why enteral should be excluded from competitive bidding in the applicable section.
2) Enteral nutrients cannot be "rented;" they represent life-sustaining nutritional products that are prescribed much like a drug by a licensed physician; caloric requirements can fluctuate and therefore dosing can vary much like pharmaceuticals.
3) Patients' condition may change over time, requiring them to move between the four enteral product categories and payment levels, thus making it very difficult for providers to project their total costs and therefore bids.

The current HCPCS codes and allowables for certain enteral supplies are outdated and inadequate. They do not reflect the more modern supplies that are on the market today, such as low-profile or "Mic-Key" buttons which cost providers significantly more than the older products covered by the existing HCPCS codes.

Several years ago when the HIPAA standardized coding rules went into effect, Apria Healthcare, the Coalition of Wound Care Manufacturers and several manufacturers applied for a separate HCPCS code and allowable for "Mic-Key" buttons. Despite proof sources that showed the extent to which the products are prescribed and used in the U.S. market, and the fact that private managed care payors were willing to pay a differential amount for that product when it was ordered by a physician, the HCPCS coding panel denied the request.

If the HCPCS coding process is not modernized to reflect the changing nature of products available in the U.S. market, providers will have no choice but to reflect the higher costs associated with them in their bids for competitive bidding, and savings will be further eroded.

Finally, we oppose the gap-filling methodology that CMS proposes to grant itself for existing products such as enteral and parenteral nutrition. Our detailed comments on this can be found in the gap-filling section.

E. Maintenance and servicing of enteral nutrition equipment

CMS describes its current authority to pay for maintenance and servicing of enteral nutrition equipment after monthly rental payments have been made. It goes on to say that "maintenance and servicing payments are to be made in amounts that we determine are reasonable and necessary to ensure the proper operation of the equipment." *See* 71 Fed. Reg. at 25674.

1. Question/Comment

What methodology does CMS use to determine what is "reasonable and necessary" in terms of ensuring the proper operation of equipment? CMS should not be in the equipment maintenance business when all pump manufacturers have issued service, repair and preventive maintenance guidelines based on years of product testing, quality control programs, FDA inspections, etc.

The whole section at 71 Fed. Reg. at 25674 where CMS describes how specialized testing equipment should be available for enteral nutrition illustrates how CMS is overextending its reach into equipment maintenance rather than focusing on medical coverage and payment policies.

Please provide the methodology that CMS plans to use to determine "reasonable and necessary."

F. Supplies used in conjunction with DME

CMS states briefly that "We propose that bids be submitted for the purchase of supplies necessary for the effective use of DME, including drugs (other than inhalation drugs)." 71 Fed. Reg. at 25673. Based on the bids submitted and accepted for these items, we would calculate payment amounts for the furnishing of these items on a purchase basis.

1. Question/Comment

Again referencing the impact of the Deficit Reduction Act, we ask CMS to clarify how oxygen supplies such as tubing and cannulas, both of which must be changed frequently for patient hygiene and efficacy reasons, will be reimbursed once the patient reaches the 36-month cap. Today, these supplies have HCPCS codes but do not have a corresponding Medicare allowable and are not reimbursed separately as they are included in the monthly bundled rate.

Separate HCPCS codes with an appropriate reimbursement allowable should be established for these supplies using current industry data (not data deflated back to 1986).

In addition, certain oxygen patients receive their oxygen through a trans-tracheal catheter directly into their airway as opposed to through their nose via a cannula. Despite the fact that there is a separate HCPCS code for the catheters, there is no separate allowable that appropriately reflects the higher acquisition cost of the catheters. Therefore, Medicare's current policy effectively limits patient access to this important technology.

Trans-tracheal catheters are not for everyone, but since a small portion of the oxygen patient population does benefit from this modality versus the cannulas, CMS should modernize the HCPCS schedule to reflect their use in the Medicare patient population and providers' actual acquisition costs. Today, the Medicare allowable for A4608 is $58.15, while providers costs simply to procure the catheters are at least 30% greater than the allowable, and that is before any accompanying service is provided to the patient. Unless the system is modernized, again, providers will be reluctant to refill the patients' catheters or accept those patients on to service in the first place if they are going to be reimbursed below the acquisition cost of the necessary supplies.

Finally, oxygen conserving devices (OCDs) are another integral part of an overall oxygen patient's care. These devices conserve oxygen, thus enabling a patient to be out of the house or ambulatory within the house for longer periods of time. For payors that pay for oxygen contents, they also appreciate the value of OCDs.

However, Medicare currently does not reimburse providers separately for OCDs. The monthly bundled payment rate is considered to cover the devices, which can sometimes cost 50% or more of the total acquisition cost of the primary oxygen system in the home. After the DRA takes effect, providers will be unable to provide such expensive devices free on a stand-alone basis, so again a HCPCS code and allowable is needed.

G. OTS Orthotics

Apria has no comments on this section.

H. Conditions for Awarding Contracts
Proposed 414.414
71 Fed. Reg. 25654, 25674-79

I. Quality Standards and Accreditation (proposed section 414.414 (c))

Pages 82-83 of the NPRM outline the Act's requirement that a contract may not be awarded to any entity unless the entity meets applicable quality standards and that this requirement is applicable to all DMEPOS suppliers in all geographic areas, not just CBAs. The section goes on to describe a possible grace period that may be granted for suppliers that have not had sufficient time to obtain accreditation before submitting a bid and requests comments on such a grace period.

A. Apria Was The First HME Provider to Seek and Obtain Accreditation 18 Years Ago

Apria Healthcare has been a long-term advocate for mandatory accreditation in the home medical equipment industry. In fact, Apria was the first HME provider to seek and obtain accreditation from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) 18 years ago.

From the ten-year period from 1996 through May 31, 2006 Apria has paid $4.9 million in application fees for JCAHO accreditation. Prior to the 1995 merger that formed Apria, we estimate that the two constituent companies invested another $3.1 million, for a total of $8 million over those 18 years. When one adds the costs of policy implementation to meet JCAHO accreditation standards, conducting internal pre-survey audits and other preparatory costs, we estimate that the company invests well over $750,000 per year in accreditation-related costs.

We have expanded the number of JCAHO-accredited sites to over 500 since then. In the ensuing years, we have competed with independently-owned HME providers that have never been accredited, never complied with any independent accrediting bodies' standards and, in some cases, never followed certain laws and regulations. Therefore, we strongly support the development of quality standards and the requirement that all DMEPOS providers obtain accreditation as a condition for supplying and billing the Medicare program on behalf of Medicare beneficiaries.

Another reason we support mandatory accreditation is that private sector managed care organizations with whom we contract have insisted that HME providers be accredited for over 15 years. Although the Medicare beneficiaries cared for by Apria and other accredited providers have essentially been receiving the same quality-oriented benefits as managed care patients, the same cannot be said for those beneficiaries cared for by a non-accredited organization. We believe Medicare beneficiaries deserve the same level of quality-oriented care as all others.

B. No Grace Period

Regarding a grace period, we oppose it for the following reasons:

1) The Medicare Modernization Act was passed in December 2003, thus giving all suppliers at least three years' notice of the need for accreditation prior to the initiation of the competitive bidding application process.

2) For suppliers outside of the first 10 CBAs slated for 2007, they will actually have four years' notice.

3) Thus, there has been plenty of advance notice for suppliers to select an accrediting body, apply and complete the accreditation process.

4) Since accreditation fees are on a sliding scale based on the provider's total patient census and number of physical locations, the smaller the provider, the lower the accreditation fees. In addition, the smaller providers will have lower internal costs to audit, prepare and undergo the accreditation itself.

5) Unless a supplier has undergone the accreditation process, it cannot properly estimate its costs associated with seeking and maintaining accreditation and therefore it cannot submit an accurate bid to CMS to participate in competitive bidding. Examples of incremental costs that might be incurred include: improved warehouse operations management, increased levels of tracking patient satisfaction and complaints; increased reporting to the accrediting body; increased internal audit and travel costs; increased medication and incident reporting; increased performance improvement documentation and management; and state or federally mandated licenses.

C. CMS Should Select up to Three Well-Established National Accreditors to Which to "Deem" Authority

There are three national accrediting bodies that have a track record of experience in accrediting home medical equipment/respiratory/infusion suppliers. They are:

- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- Accreditation Commission for Health Care (ACHC)
- Community Health Accreditation Program (CHAP)

We do not believe that CMS should experiment with such a new and important program by including any Internet-based or other relatively new accreditation organization. It is very important for the accrediting body to have a level of experience with the industry and be able to prove to CMS that it has a rigorous process that does not automatically "rubber-stamp" accreditation. For example, JCAHO's rate of non-accreditation for its homecare division is a documentable 6 percent.

D. Grandfathering Already-Accredited Providers

We agree with CMS' plan to recognize that a provider that already holds a valid accreditation with a CMS-approved accreditation organization should be "grandfathered" to participate in the application and bid process.

E. Multi-Site Providers Must Conform to Medicare Supplier Number Requirements

We want to emphasize that CMS should ensure that multi-site providers conform to National Supplier Clearinghouse (NSC) requirements by applying for and obtaining a Medicare supplier number for any and all locations that will physically provide DMEPOS to beneficiaries through competitive bidding. It is possible that there are still providers that hold one Medicare supplier number to bill on behalf of several different but still company-owned branch locations. This may be true for smaller, not larger, suppliers. While this is not directly related to accreditation in terms of quality standards, it is something CMS should incorporate into its application and audit process.

However, a physical site visit by the accrediter is not needed for every single location. The NSC already has a process in place to ensure that the Medicare supplier standards are met before a supplier number is issued. This site inspection is designed to ensure that the supplier actually has a physical location. That

is not the function of an accreditation organization. All three of the major accrediting organizations have a process in place that statistically samples sites, patients, records and other documentation associated with the provider. The statistical sampling process, coupled with the fact that the branches that may not receive an on-site visit do not know it in advance and therefore must be prepared for such a visit, has been proven as an effective method and should be adopted by CMS.

F. Quality Standards: General Comments

We were very concerned about the nature of the draft standards that were published by CMS in the Fall of 2005. Those standards appeared to be lifted from some provider's operational policy and procedure manual as opposed to reflecting commonly-accepted standards of care in the home respiratory and HME industry. We filed formal comments critiquing the standards and hope that the revised standards reflect the input of the over 5600 organizations that filed comments on the quality standards.

The standards even go so far as to prohibit certain methods of delivery, which is outside of the purview of this process; the standards should not dictate operational decisions of homecare providers who elect to participate in competitive acquisition. The direct-to-home delivery of CPAP/Bi-Level replenishment supplies, for example, is a well-established standard in the industry and has never been a concern of private managed care organizations, including those that serve Medicare Advantage patients. If CMS insists on dictating certain operational standards, providers' costs will INCREASE compared to today's levels and the direct result of that will be a lower level of savings than what has been ascribed to the competitive acquisition process for HME starting in 2007.

It was very disappointing that most recommendations that were made by the true homecare industry experts in the area of quality standards were not included in the report issued to the PAOC and CMS by the consulting organization. We are not clear on why the consulting organization completely disregarded the input of the homecare industry, when it has shown a significant level of commitment to cooperate with CMS by providing draft standards that conform to the current HME industry professional practice standards and the requirements of private sector managed care payors nationwide.

Quality standards need to be the standard measurement of overall quality of a provider; they should not describe how a provider should handle each piece of equipment (that is considered one of the most basic aspects of any homecare operation and no payor in America specifies such things). As a reminder, Medicare does not "officially" reimburse providers for service and policymakers have repeatedly gone on the record to say that it pays for equipment only under the Part B DMEPOS benefit. If CMS' intent is to increase the breadth of service requirements, providers should be compensated for this service separately from and in addition to the monthly rental or purchase amount for the equipment.

G. Independent Accrediting Bodies Already Mandate and Monitor Quality Standards That Meet and Often Exceed the HME Industry and Professional Standards; CMS Should Simply Add Financial and Compliance Standards to Existing Accreditation Standards to Consider a Homecare Provider to Have Met CMS Standards

Frankly, as a company that has literally spent millions of dollars in both accreditation fees and the higher operating costs associated with preparing for and maintaining accreditation by the JCAHO since 1987, Apria Healthcare questions why CMS cannot simply deem between one and three already-existing accrediting organizations to meet its expectations and then require any provider that desires to participate in competitive acquisition to become accredited by one of those three organizations. It is much simpler to administer, will save American taxpayers the cost of redundant and unnecessary standards development at CMS and is the way that private sector managed care organizations have operated for years.

As one example, JCAHO currently has over 400 standards that we must comply with to obtain accreditation. Non-compliance could result in the suspension of the accreditation.

Standards should establish the benchmark that a provider must meet, but should not be so specific that they dictate specific operating policies, care or service. Moreover, standards this specific become obsolete when technology or clinical standards of practice change. CMS would never be able to keep up with changing standards as specific as they are currently written, while the accrediting bodies whose very history, mission and livelihood depends on monitoring and amending such standards already incorporate such an update process into their accreditation models.

Because the current draft standards do not reflect industry input and will create additional administrative or labor burdens on DMEPOS suppliers, the program is going to be very difficult to operationalize and such an extra burden would simply have to be reflected in suppliers' bid prices. Therefore, the projected savings could be less. Who at CMS is going to keep the quality standards up-to-date and who will be auditing these standards? What type of financial analysis has been done?

Because the current draft standards do not reflect industry input and will create additional administrative or labor burdens on DMEPOS suppliers, the program is going to be very difficult to operationalize and such an extra burden would simply have to be reflected in suppliers' bid prices. Therefore, the projected savings could be less.

Based on the above concerns, we strongly recommend that CMS approve two or three of the long standing accrediting bodies and request that these CMS approved accrediting bodies add CMS' draft standards for Financial Management and the requirement for a Corporate Compliance Program. We believe that more than 95% of the draft standards in the balance of Section 1 are addressed by the established accrediting bodies. We believe that CMS should delete the "Appendices for Supplier Product Specific Service Requirements" from the quality standards as JCAHO, CHAP and ACHC have rigorous standards that address this section of the proposed draft standards. In addition, all three organizations have industry clinical experts that review both the standards and the emerging technology as part of their continuous review process.

II. Eligibility

CMS proposes that "all bidders must meet eligibility rules to be considered for selection under the...program. Also, each bidder must be enrolled with Medicare and be a current supplier, in good standing with the Medicare program, and not under any current Medicare sanctions. Again we ask CMS to more clearly define "sanctions." 71 Fed. Reg. at 25675. Each bidding supplier must certify in its bid that it, its high level employees, chief corporate officers, members of board of directors, affiliated companies and subcontractors are not now and have not been sanctioned by any governmental agency or accreditation or licensing organization. In the alternative, the bidding supplier must disclose information about any prior or current legal actions, sanctions, or debarments by any Federal, State or local program, including actions against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, and subcontractors."

A. Question Regarding Definition of "Current" Supplier

In the above section, CMS references "current" supplier. How does CMS define "current" and how will it handle a situation where a contract supplier decides to add a physical location in a part of the MSA that might improve overall Medicare patient access and responsiveness in that area?

Our recommendation is that CMS allow any winning contract supplier to add a physical location to its competitive bidding contract as long as 1) the physical location obtains its own Medicare supplier number and meets all eligibility requirements, 2) the location is considered accredited by that organization's accrediting body, and 3) the location is linked to the same tax ID # as the location(s) listed on the original application.

This approach should apply even to acquisitions pending at time of the contract application or award process, or acquisitions after a contract is awarded.

We definitely support CMS' goal of eliminating "fly-by-night" suppliers that enter and exit markets, but the Agency also needs to allow for expansions in a given MSA.

B. Corporate Compliance Program

Apria Healthcare strongly agrees with CMS' direction regarding eligibility. We have incorporated a multi-faceted Corporate Compliance Program into our daily business operations since the 1990s. We were recently notified that we will receive an award for ethical business practices in the "National Public Company" category, sponsored by the Passkeys Foundation.

Our Compliance Program includes several different vehicles for stakeholders to express concerns about the company's practices, policies, operations, etc. These disclosure mechanisms include the following:

Toll-Free Hotline –For employees that is untraceable and unrecordable. Employees have the right to remain anonymous and many do exercise that right, despite the company's explicit written policy regarding retaliation, for which the company has zero tolerance.

Exit Interviews – All employees who separate from the company are sent an Exit Interview and asked to complete it.

Annual Regulatory Compliance Certification by Middle and Senior Management – The Compliance Officer issues an annual mailing to all mid-level and senior managers requesting an attestation of the company's compliance with all applicable regulations and laws to the best of their knowledge.

Website, Letters and Other Correspondence – Employees, patients and other stakeholders have been known contact Apria via the Contact_Us@apria.com email address, direct correspondence via letters or other methods.

Regardless of the disclosure mechanism, all communicated concerns are reviewed closely by either the Compliance Officer or the Legal Department and, if applicable, added to the Company's corporate compliance process for further follow-up.

C. Compliance with Medicare Rules and Licensing Rules

Medicare regulations require suppliers with multiple locations to obtain separate supplier numbers for each location. The Proposed Rule requires each bidder to be properly enrolled with Medicare and to be a supplier in good standing. In the Proposed Rule, CMS states that the bidder must have all State and local licenses required to furnish the items that are being bid. *See* 71 Fed. Reg. at 25675.

Compliance with Medicare regulations and licensing requirement adds administrative and operational costs to a supplier's operations. CMS should make every effort to ensure that bidders with multiple locations that are seeking a contract as a single bidder comply with all existing regulations, including

appropriate enrollment of each location. This will ensure a level playing field for all suppliers and lead to more accurate bids.

We urge CMS to review the FDA's medical gas registration requirements for those providers who supply compressed gas and liquid oxygen. Our acquisition experience has shown that there are small providers who may not fully understand all of the federal registration requirements and may not have the appropriate medical gas registrations on-hand. Part of the application process should review this.

D. "Good Standing" Needs to be Defined as It Relates to CMS' Authority to Terminate a Contract

CMS states "we would suspend or terminate a contract if a supplier loses its good standing with us or any other government agency." *See* 71 Fed. Reg. at 25675.

While we agree with this concept of terminating or suspending contract suppliers who have lost their standing, it would help if CMS would define "good standing" as it relates to other government agencies. A provider could be involved in a tax dispute with the Internal Revenue Service (IRS) or something else that has nothing to do with their Medicare program participation. Such a dispute does not constitute "bad standing" and therefore we request that CMS issue clarifying language.

III. Financial Standards

CMS outlines the financial standards for the program. *See* 71 Fed. Reg. at 25675. We applaud CMS' efforts to establish financial standards as part of the competitive bidding program. Again using Apria's acquisition experience as an example, we have seen the occasional situation where a bankrupt or near-bankrupt provider does not have the capital or cash flow necessary to procure new medical equipment or comply with the basic preventive maintenance and repair that it requires. We have seen situations where payroll was held or delayed.

A. Allowing Existing Reports to Suffice

The basic financial information that CMS described is certainly applicable to small businesses that use independent accountants, law firms, third party billing services, etc.

However, in terms of public companies that already file extensive financial reports with the Securities and Exchange Commission, comply with Sarbanes-Oxley requirements and conform to Generally Accepted Accounting Principles (GAAP), we recommend that CMS allow existing reports to suffice when a public company submits its competitive bidding application. Examples include:

- 10-K Annual Report
- 10-Q Quarterly reports for the quarters since the last annual report
- 8-K reports for current developments

In addition, we recommend that in the case of any company – public or private – that has more than one physical location attached to a competitive bidding application, the financial information should only have to be provided once as long as the applicant attests that it applies to all locations. Most national and regional providers cannot produce a balance sheet , for example, at the individual location level. On the other hand, the parent corporation's strong financial position will help each individual location in the event of a natural disaster, emergency or other problem where access to capital and assets are critical to continuing to service patients (e.g. Hurricane Katrina).

B. Formula to Determine "Business Capacity" Needs to Be Defined More Clearly

This is one area that needs much more definition and clarity by CMS.

We are very concerned that the rule is too vague on the subject of business capacity. Contrasted with the very detailed formulas that CMS provided for calculating DMEPOS suppliers per Medicare beneficiary, prioritization of the MSAs, etc., business capacity was left too vague. In addition, we are concerned that if a provider is permitted to commit to almost any increase in capacity without have some assessment mechanism on CMS' part, an access-to-care problem could arise when the patients are unable to obtain that service or product from the supplier.

Apria Healthcare has extensive experience in business capacity planning. In late 2005, we were awarded the national contract to serve one of America's largest managed care plans. The contract was set to "go live" on February 1. In the intervening months, Apria embarked on an extensive capacity planning process that accounted not only for the medical equipment needed (or "units," as CMS described in one section of the rule), but also the incremental labor, telecommunications equipment, facilities, vehicles, supplies, etc. that would be needed to meet the expected demand.

A better capacity planning process to enable providers to meet the demand in any given MSA would be as follows:

BID PROCESS:

1) During the bid process, CMS provides total number of beneficiaries likely to require service

2) CMS provides data on the number of patients in each rental month for any capped rental item (e.g. 120 patients with hospital beds are in rental month one, 100 are in month two). One key is that providers must know how many patients (not a percentage) have already or will reach the cap period and therefore own their equipment per the DRA.

3) This data must be updated again 90 days before the contract goes "live," especially since CMS states that a nine-month period could elapse between the time when bids are submitted and when the contract goes live.

4) CMS would assess the standard financial information that suppliers provide on the RFB application.

5) The RFB application must require that the supplier provide a detailed business expansion plan that addresses how it will increase its capacity not only in terms of additional equipment it can procure, but more importantly, how it will attract additional staff, telecommunications and computer equipment, facilities, vehicles and other support services needed to support the increased volume.

AFTER CONTRACT SUPPLIERS ARE SELECTED:

1) Since nine months may have elapsed, provider should have to affirm that nothing has changed financially since the application date.

2) CMS must provide updated data on which suppliers are electing to grandfather their patients and inform the contract suppliers of the number of patients for each product category. CMS must also provide the names of the other winning suppliers and their capacity. This will help contract

suppliers understand what the "adjusted" increase in volume is likely to be, if any, and plan accordingly.

Because there is a downstream effect of this program, in terms of increased demand that could be placed on manufacturers of medical equipment, vehicles, etc., and because leases can take up to a year to negotiate, we recommend that CMS build in the 90-day transition period that was described earlier. Most managed care payors allow such a period to facilitate joint planning between the contracted supplier(s), the noncontracted suppliers and the plan itself.

C. Days Sales Outstanding/Accounts Receivable Performance

CMS lists certain financial indicators that are important for evaluating financial stability. *See* 71 Fed. Reg. at 25675. We recommend using Days Sales Outstanding (DSO), which is a measure of the company's performance in accounts receivable and can impact cash flow that otherwise would be used to purchase equipment, hire staff, etc. There is no need to ask for Medicare DSO – a blended rate will suffice for your purposes.

D. Expertise of Staff to Evaluate Financial Standards Conformance

The rule is reasonably clear about the financial data that will be requested of suppliers who wish to participate in competitive bidding. Such financial data is "cut-and-dry" when it comes to what the indicators suggest about a business.

However, the financial standards are not "standards" at all since they do not specify a minimum threshold, range of acceptable performance or other criteria that is defined as "acceptable. Moreover, at the May PAOC meeting, we grew concerned when certain CMS staff members described a less objective, more subjective review process in which they might decide to select one supplier over another based on financial performance in one area or another. This concerns us because CMS has not stated what the financial standards or range of performance need to be, such as Cash Flow of X, DSO of Y, what defines a "positive credit history," etc.

The ability for CMS to subjectively discard one supplier's application over another, especially if the bid prices vary significantly, could be fraught with problems and lead to allegations of unfair business practices and single payment rate ("price") manipulation against CMS.

We urge CMS to either hire or consult with financial experts who may assist in determining an acceptable range for each of the indicators and then publish them so that all suppliers will understand the exact financial standards they have to meet.

IV. Evaluation of Bids

We refer you to the comments already supplied in another section, in which we urge you to consider how best to avoid situations where providers could "cherry-pick" a market. And we reiterate the fact that a patient who needs oxygen, a CPAP, a hospital bed and wheelchair could STILL find themselves receiving service from four different suppliers. This is neither efficient nor how it is done in the private managed care sector.

A. Market Demand and Supplier Capacity (proposed section 414.414 (e))

CMS describes, in more detail, how it plans to address market demand and supplier capacity. *See* 71 Fed. Reg. at 25675-76. Regarding the calculation of expected demand, CMS proposes to:

1) Examine claims data to determine the number of units of each item supplied...during the past two years;

2) Determine the number of new beneficiaries that have entered the market during the last two years;

3) Gather data on the number of new fee-for-service Medicare enrollees coming into a competitive bidding area and use this number to project the number of new enrollees;

4) Calculate two years worth of claims on a monthly basis to determine beneficiary demand;

5) Take into consideration the expected demand over the total duration of the contract and the seasonal effects;

6) Use two years of data to identify any time trends.

1. *Comments on Market Demand Calculations*

Again we agree in principle with all of the above criteria, but we do have some concerns and guidance for the Agency to consider.

- Historical claims data is one criteria for projecting future volume

- Although the number of new beneficiaries is important, CMS should also look at disease prevalence and age-related data, since there could be a higher ratio of new beneficiaries with, for example, COPD, and therefore the utilization would be higher

- The effect of seasonality, especially on patients with chronic respiratory illnesses, cannot be emphasized enough. A provider could experience a substantial increase in demand solely due to a bad flu season, large fluctuations in temperature, etc. It is a proven fact that COPD patients utilize more oxygen in the summer and less in the winter and more nebulizer medications in the winter than in the summer. This variance is solely related to the specific disease and seasonal effects.

2. *Estimating Supplier Capacity*

CMS then states, on page 86-87, its proposed approach for estimating supplier capacity. The proposal is for CMS to:

1) Analyze Medicare claims to determine how many items a supplier is currently providing in the competitive bidding area, as well as in total.

2) Ask suppliers to say how many units they are willing and capable of supplying at the bid price in the CBA.

3) Compare this information to what the supplier has dispensed to Medicare beneficiaries in the past and what it specified in its response to the RFP as its projections.

B. Question

Will CMS provide the number of projected patients, by product category, that will be encompassed in the entire CBA? In addition, suppliers will need to know – prior to submitting their bid -- the number of patients, by product category, in each month or episode of care so that they will have visibility to the number of patients who have either "capped out" or are approaching their rental cap where they will then own their equipment and no monthly revenue will accrue.

It is important for this data to be issued to all suppliers at the time of the RFB. Otherwise, the supplier will not know what kind of capacity is expected from CMS and it will not be able to formulate an effective bid. In managed care contracting, the payor almost always issues the projected future volume during the bidding process.

C. Comments on Estimating Supplier Capacity

We refer to the comments made earlier in this section and add the following comments.

The method CMS proposed above is severely flawed for several reasons:

1) A supplier might have obtained a new supplier number within the two years prior, gained a significant amount of market share and have a lot of additional capacity. That would not show up if CMS were looking only at supplier numbers that have been in existence since 2004.

2) A supplier might be caring for a very large number of patients who are not covered by Medicare and have much larger capacity to double or triple the number of Medicare patients they care for. If CMS only reviews Medicare claims and Medicare "units," it will not capture the true picture of a supplier's capacity in any given market.

3) Managed care organizations switch suppliers without looking back to see if they billed the plan in the past – the key is to determine the future capacity correctly.

4) This process does not allow for the situation where a large provider might have covered the CBA from another location and then decided to put a new physical location in an area. Because Medicare's proposed method is at the supplier number level, it would cause the new site to show a very low Medicare utilization/expenditure level and could be very misleading if historical claims alone were used to assess capacity.

D. "New" Suppliers

CMS writes, "For new suppliers, we would ask them for their expected capacity, look at trend data for new suppliers in that area, and examine the capacity of other suppliers in that area. We would need to use this data to make estimates about capacity because suppliers may have more capacity potential than they are currently exhibiting. During the DMEPOS demonstration, demonstration suppliers were able to expand their output to meet market demand and replace market share previously provided by non-demonstration suppliers; indeed, some demonstration suppliers were disappointed that they did not gain more market share during the demonstration." *See* 71 Fed. Reg. at 25676.

1. *Comment*

CMS' use of the term "new supplier" in this section conflicts with its earlier statement from the section where it stated essentially that only those suppliers that had a Medicare supplier number in 2004 or billed the program a minimum of $10,000 may participate in the bidding process. If we are misinterpreting that section, it is because it is not clear and should be further detailed by CMS.

Any new supplier should also have to provide its ability to accept additional capacity. Other language also causes us to infer that once the contracts have been awarded, no "brand-new" supplier would be able to contract with CMS. "Brand-new," and "expansion or acquired "new" locations associated with existing contract suppliers" need to be clearly defined by CMS in order to avoid confusion and should be included.

In regard to demonstration suppliers who were disappointed that they did not gain more market share, this only reinforces the assertions we made earlier in the document:

1) Today, Medicare reimbursement is the same for every supplier.

2) Therefore, providers compete on many more dimensions other than price, such as ease of doing business, depth and breadth of payor contracts, product availability, geographic coverage and overall service.

3) Under the competitive bidding program, since a single payment rate will be established, reimbursement will again be fixed.

4) Unlike managed care organizations that guarantee providers certain volume in exchange for pricing discounts which enables providers to set up and plan their infrastructure investments, Medicare does not guarantee any volume. Capacity has nothing to do with the volume the provider will actually receive.

5) **Therefore, providers will continue to compete on the basis of service, not on price, and some will win more market share than others! Price is not the prevailing factor in Medicare market share growth.**

2. *Recommendations*

We recommend the following definitions and guidelines:

1) **"Brand-new" supplier/location** – Defined as a start-up business tied to a tax ID number/company that has never billed the Medicare program before. This type of provider should not be able to participate in a competitive bidding contract that is already underway but should be allowed to bid in any subsequent round in that market.

2) **"Expansion or acquired "new" locations associated with existing contracted suppliers"** – Defined as a new physical location and associated Medicare supplier number that came about due to an expansion of an existing contract supplier or the acquisition of an existing supplier in the market. As long as these two examples are tied to the same existing supplier's tax ID #, they should be allowed to participate in competitive bidding after the contract begins, as long as they meet all eligibility criteria and agree to accept the single payment rate in that CBA.

E. Composite Bids (proposed section 414.414 (e))

In this section, CMS describes the methods for computing:

- Composite bid
- Item weight

1. *Comments on Composite Bid*

Apria agrees with CMS' intent to compute a composite bid in the manner in which it has suggested: multiply a supplier's bid for each item in a product category by the item's weight and sum these numbers across items.

2. *Item Weight*

Apria also agrees that the weight of an item should be based on the utilization of the individual item compared to other items within that product category based on historic Medicare claims. However, we want to emphasize that the utilization used as the weight should be CBA-specific and not based on nationwide Medicare claims, since age, the patients' illnesses or conditions and a number of other demographic or clinical/community standards of care could cause variations in utilization among disparate MSAs.

We have grave concerns about the following sentence:

"We would select item weights that ensure that the composite bid is directly comparable to the costs that Medicare would pay if it bought the expected bundle of items in the product category from the supplier." *See* 71 Fed. Reg. at 25676.

This sentence, which follows the paragraphs that describe the weighting methodology that would be based on utilization of the individual item compared to other items, based on historic claim data, implies that CMS would not use that methodology but would manipulate the item weights in order to change the composite bids. If this is CMS' plan, this is an unacceptable and unfair variation on the plan.

We believe that the best method of weighting individual items within a product category is to set the weight for each item based on the volume of the individual item's share compared to the total utilization of the product category. This is how the managed care sector handles weighting.

We want to emphasize the following:

1) The weighting should be MSA-specific.

2) Individual suppliers have different contracting and pricing strategies. Some suppliers use "loss leader" strategies where they purposefully price certain items within a category lower and other items higher so that the blended rate in that category helps them win a bid for a larger-scale contract. We advise CMS not to read too much into prices that are submitted for individual items. There are several references in the NPRM where CMS implies that a low price means that the item requires less service and associated costs when in fact that may not be true. Every individual company has a different pricing philosophy and strategy.

3) If an item's utilization is increasing due to an increase in beneficiaries or a particular condition in a certain geographic area, but CMS uses utilization data based on 2003 claims, this could create an unfair outcome based on an inaccurate weighting methodology. For example, the incidence of obesity and obstructive sleep apnea (OSA) in America has led to a nationwide increase in prescriptions for CPAPs and related supplies. This is true for all payors across the United States; neither Medicare nor any other payor is alone in this experience.

We would like to bring several other concerns about the weighting methodology to CMS' attention for your consideration:

- The current HCPCS system is outdated, does not reflect the current broad range of products and technology that physicians and patients want/need and does not reflect the wide range of acquisition costs providers incur.

- The new brand-specific requirement described in that applicable section will cause providers' operating costs to rise and therefore those costs will have to be reflected in providers' composite bids. Or, an unsophisticated bidder who does not understand his/her cost of doing business could win a bid with an unrealistically low bid price.

- Both of the above factors will result in a lower level of savings associated with the competitive bidding program.

- There are geographic preferences for certain brands or type of equipment and supplies. In this case, composite bids will reflect the same and again, savings could vary greatly if providers incur higher operating costs than under the current program.

We use the following simplified example to illustrate the potential effect of brand specificity or unreasonable quality standards for a particular item. This data is illustrative only and does not represent either an actual allowable or actual provider costs.

Current Medicare Allowable for Item =	$100
Provider bids, brand specificity not required, achieves savings @ 12%	-12
New single payment rate in CBA	$ 88
Savings vs. current allowable	12%

But, now providers are forced to provide a brand-specific item that does not necessarily offer any incremental features, advantages or benefits to the patient. However, it costs the provider 10% more to provide that item to the beneficiary than it would today.

Current Medicare Allowable for Item =	$100
Provider bids, brand specificity is required, achieves savings @ 2%	-2
New single payment rate in CBA	$ 98
Actual savings vs. current allowable	2%

F. Determine the Pivotal Bid (proposed section 414.414 (e))

We also agree that prior to bid selection, CMS should first ensure that suppliers meet quality and financial standards prior to arraying the bids and selecting suppliers. In fact, CMS should look at suppliers' bids on the basis of meeting the accreditation, quality and financial standards first before wasting valuable time to review bids from suppliers who do not meet the eligibility criteria.

We also agree with CMS' final proposal to base the pivotal bid on the point where expected combined capacity of the bidders is sufficient to meet expected demands of beneficiaries. All of the alternative methods that CMS considered but did not propose, such as pre-determining a number of suppliers, allowing those providers whose bids are "close" and making the pivotal bid dependent on a summary statistic such as the mean, median or 45th percentile, are inappropriate. They do not reflect a true competitive bidding process such as what we see in the private sector, and they artificially manipulate the number of suppliers and the single payment rate.

If CMS were to base the pivotal bid on a target composite bid such as the 20 percent below the DMEPOS fee schedule that was described at 71 Fed. Reg. at 25678, we believe that would be tantamount to government price-fixing and thus quite undesirable for both the government and suppliers.

We are also very concerned about several aspects related to the pivotal bid:

1) "Supplier Capacity" is much too loosely defined and the formula that CMS briefly outlined is an inaccurate method for calculating and validating supplier capacity.

2) Since supplier capacity is one of the most critical variables in the entire competitive bidding process, we urge CMS to adopt a more formal process for calculating, assessing and validating supplier capacity.

3) When all the bids are received, the FIRST thing the CMS bid team should review is whether or not the provider meets eligibility criteria such as the quality, accreditation and financial standards. Only after the team has determined that the supplier meets the eligibility criteria should the team then move on to review the bid submitted.

4) What happens if the bidder refuses to supply the products at the lower price?

And, of most grave concern to us:

5) **CMS is proposing to use a different method to establish the single payment rate than what was used in the demonstration projects. This runs counter to what Congress intended when including competitive bidding in the MMA language.**

CMS' definition of the pivotal bid seems acceptable, but our careful scrutiny of this section causes us to restate our serious concerns about the formula itself and the validation method CMS plans to adopt for "Supplier Capacity." *See* 71 Fed. Reg. at 25678. Since "Supplier Capacity" is one of the three primary criteria to be used to determine the pivotal bid, we believe that CMS should adopt the capacity planning formula that we described in an earlier section.

Unless CMS tightens up the definition of supplier capacity, suppliers could underestimate the operational and financial resources required to meet a significant increase in volume. This could lead to an access-to-care problem for beneficiaries.

G. Homecare Providers Are Often "First-Responders" In A Disaster or Emergency

Another aspect of supplier capacity that CMS must validate is that of emergency preparedness or a local disaster plan. In the case of Hurricane Katrina, some suppliers lost their businesses, telecommunication or information systems and had no way to replace their displaced patients' equipment, communicate with them or assist them in the aftermath. A managed care plan in Florida called on Apria to assist by helping current and new patients because their contracted provider did not have the resources. During Katrina and all other natural disasters, Apria was able to transport extra equipment, supplies, bottled water, emergency generators and employees into the stricken areas so that operations could continue and patients could be served.

On September 11 and in the days that followed, New York and Washington, DC area hospitals called on Apria to donate a large volume of home medical and respiratory equipment. In rapid response, Apria's area teams were able to deploy the necessary equipment to the hospitals, police and fire rescue teams.

Other examples of emergencies or disasters where homecare providers have been among the first to respond and enable patients to remain at home or be evacuated safely are the great blackout of the Northeast/Midwest (Summer of 2005), deep freezes/ice storms in the Northeast, floods throughout the U.S. and Southern California wildfires.

Regarding other possible methods of determining the pivotal bid, CMS should not determine a competitive range for the composite bid. This would only be appropriate if CMS were going to allow each supplier within the competitive range to bill Medicare at that level, as in the case of private managed care contracting. However, since CMS plans to establish one single payment rate anyway, such a range would be arbitrary and inappropriate. It could lead to allegations of small business and other discrimination.

H. Review Supplier on Quality/Financial Standards FIRST, Then Look at Bids

CMS describes the demonstration process for evaluating quality and financial standards as "time-consuming for the bid evaluation panel and required bidders to provide extensive information on quality and finances." *See* 71 Fed. Reg. at 25677. Apria asserts that the evaluation of the quality and financial standards is more important than the evaluation of the prices submitted. Almost any supplier can bid a low price, but meeting the quality and financial standards will require a higher level of commitment on the part of any winning or contract supplier.

1. *Reviewing Adherence to Quality Standards*

CMS could minimize the time involved in reviewing suppliers' adherence to the quality standards if it would simply adopt or "deem" the accrediting bodies' standards of accreditation. CMS should simply accept JCAHO, ACHC and CHAP accreditation as a proxy for meeting quality standards. Then, it could focus the bid review team on the financial standards and bids themselves. This is how the private managed care sector works; payors do not try to reinvent quality standards or conduct time-wasting validation surveys.

2. *Accredited Multi-Site Providers Require Less Review Time*

Another way for CMS to minimize the amount of time spent reviewing the bids is to recognize that if a multi-site provider is accredited in a particular geographic area or state, it is likely that ALL owned locations in that state are accredited based on the same standards and accreditation cycle. For example, if an accreditation application includes all branches in Florida and two MSAs in Florida go through competitive bidding, CMS would only have to review that supplier's accreditation/quality standards for one MSA and not waste time doing so for the other MSA.

I. Assurance of Savings (proposed section 414.414 (f))

Throughout the document, CMS asserts that Section 1847(b)(2)(A)(iii) of the Act prohibits awarding contracts to any entity for furnishing items unless the total amounts to be paid to contractors in a competitive bidding area are expected to be less than the total amounts that would otherwise be paid. Therefore, CMS would not accept any bid for an item that is higher than the current fee schedule amount for that item.

While this makes sense conceptually, it is another form of price-fixing since it is quite possible that current Medicare allowables for certain DMEPOS items do not adequately cover providers' costs. Moreover, the CPI freeze put in place by the MMA for most DME has exacerbated the problem because fuel, insurance, labor and other operating costs continue to rise. Even the competitive bidding

demonstration projects illustrated the effect of requiring bidders to bid below the existing allowable. In regard to incontinence and ostomy supplies, the bidders bid too low, experienced financial challenges and the single payment rates had to be raised.

We believe that CMS will find that some suppliers will not choose to bid on certain product categories because they already represent unprofitable business once all of the non-product costs are factored in. Therefore, savings would again be reduced.

Net program savings should be viewed at the product category level by comparing the savings to a "snapshot picture" of expenditures, not at the HCPCS level. Again, some suppliers use certain items as loss leaders, while others have a "no loss leader" pricing philosophy.

Also, CMS needs to realize that individual HCPCS expenditures may decrease, but the overall spending in a particular category could still increase after accounting for the following factors that could ensue during the competitive bidding contracting period:

- An increase in beneficiary enrollment,
- An increase in the number of patients with particular conditions in the area, such as COPD,
- A severe flu season or other seasonal effect,
- Changes in community standards of care,
- Changes in physician prescribing patterns,
- The introduction of new technology to be used at home, such as portable oxygen concentrators, higher-featured CPAP devices, low profile enteral tubes and portable ventilators,
- CMS medical coverage policy changes, and/or,
- Changes with Medicare Part C/senior risk plan enrollment that could result in a situation where patients move from Part C back to traditional Medicare coverage.

J. Assurance of Multiple Contractors (proposed section 414.414 (g))

Apria agrees that the program must offer choices to beneficiaries, referral agents and treating practitioners that order DMEPOS for Medicare beneficiaries. We also agree that CMS would neither generate the "significant savings" it desires nor reduce its own administrative costs of claims processing, etc., if it selects too many suppliers to service a competitive bidding area.

Again we reinforce the importance of supplier capacity and the need for CMS to formalize a process for calculating and assessing supplier capacity. We suggest a method within this comment letter.

K. Selection of New Suppliers After Bidding (proposed section 414.414 (h))

CMS states that it could determine that the number of contract suppliers it selected to furnish a product category was insufficient to meet beneficiary demand for those items. *See* 71 Fed. Reg. at 25678. It then goes on to describe how it would handle situations where a contracted supplier's contract was terminated. CMS suggests that a new supplier that would be added to the process would have to agree to accept the already determined single payment amounts for the individual items within the product category in the CBA.

Section 414.414(h)(1) of the proposed rule provides that "Subsequent to the awarding of contracts under this subpart, CMS may award additional contracts if it determines that additional contract suppliers are needed to meet beneficiary demand for items under a competitive bidding program." (71 Fed. Reg. 25701.) To select additional contractors, CMS plans to use bids previously submitted by bidders in the specific product category for which additional contract suppliers are needed to make award. *Id.* CMS

plans to offer award first to the disappointed bidder whose composite bid is the first composite bid above the pivotal bid for that product category. *Id.*

This is an inappropriate method for the acquisition of additional contractors following award. First, by awarding contracts after award without competition, CMS would violate the clear language of the statute, which requires that CMS conduct a competition for the award of any contracts for the items specified by the statute. The statute states: "[t]he Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services." (Section 302(b)(1) of the Medicare Modernization Act of 2003; Sec. 1847(b)(1) of the Social Security Act.) A post-award contract award to the next-in-line disappointed bidder who participated in the initial competition is not a competitive acquisition. It is not a continuation of the original competition. It is a sole-source acquisition. (*See* 41 U.S.C.A. § 253(a),(c) (West 1987 and Supp. 2006); *see* 48 C.F.R. 2.101 for the definition of sole source acquisition.) Sole-source awards to contractors for items and services within competitive acquisition areas are not authorized by the statute.

1. *Question*

How will CMS determine that capacity is insufficient? This must be formalized because if CMS decides to add other suppliers to a given MSA after the competitive bidding program is already underway, it would essentially constitute a "bait and switch" practice for the suppliers that bid at the beginning and were awarded contracts. Managed care companies usually go to their existing contracted providers FIRST to gain a commitment that they can handle additional volume before electing to add any other suppliers to their network.

2. *Comment*

We do not agree with CMS' intent to require a new supplier to accept the already determined single payment amount. CMS should also not choose the option to conduct a new round of bidding to select additional suppliers as this is too administratively burdensome for everyone involved and again constitutes a "bait and switch" for the suppliers who bid initially and won.

In the event that CMS proceeds with adding other suppliers to the MSA after it has already been launched, the fairest method is for CMS to re-array all of the suppliers' bids from lowest to highest, recalculate the pivotal bid and recalculate the single payment rate accordingly.

Another option would be for CMS to split up the volume of the terminated supplier fairly among the remaining contract suppliers in order to expedite the transition process and avoid a major disruption in patient care.

If CMS does not follow these methods, it will likely find itself hard-pressed to persuade additional suppliers who obviously bid at a rate even higher than the original pivotal bid who are willing to accept the existing single payment rate. Suppliers' internal costs could have increased since the time the contract was initiated, as in the case of fuel, labor and other expenses. Or, the Medicare program might have implemented a policy change or required more paperwork that also drives providers' costs up. Therefore, they might bid differently 12 or 18 months later than they did initially. The gap between the single payment rate and what they bid might be too great for them to accept since they have to cover their costs.

The same comment applies if a contracted supplier's contract is terminated by CMS – the new supplier(s)' original bids should be re-arrayed and a new single payment rate re-calculated.

I. Determining Single Payment Amounts for Individual Items
Proposed 414.416
71 Fed. Reg. 25654, 25679-80

I. Setting Single Payment Amounts for Individual Items (proposed 414.416 (b))

Beginning on page 97, CMS describes the process for determining single payment amounts and the options it considered on this subject. On page 98, CMS describes its preferred approach to use the median of the supplier bids that are at or below the pivotal bid for each individual item within each product category.

A. We strongly disagree with CMS' preferred approach because it does not reflect the method used in the two demonstration projects, on which Congress based its legislative approval.

CMS proposes to set the single payment rate for any competitively bid item at the median of the array of bids of the "winning suppliers." This means that 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. The result is simply a new fee schedule, and is contrary to basic principles of contracting and competitive bidding. It is also significantly different than the method used in the Polk County, FL and San Antonio, TX demonstration projects and therefore it probably is not what Congress intended in approving competitive bidding as part of the MMA.

The far better course would be to set the payment rate at the pivotal bid level using the adjustment factor described on page 99-100 of the NPRM. This method defined the pivotal bid as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This is the method used in the two demonstration projects.

Using the pivotal bid in this manner still meets the statutory requirement that CMS should expect to pay less and that single payment amounts are to be based on bids submitted and accepted. It is also still consistent with the intent of competitive bidding.

Two additional flaws in the method that CMS has proposed are:

1) The single payment method and projected savings is highly dependent on whether there is an even or odd number of suppliers in the final array. This is a meaningless variable.

2) Individual supplier capacity, rather than quality or even bid prices, is one of the key variables in how the single payment method is calculated.

Another option that CMS considered was to take the minimum winning bid for each item. This does not make sense and does not reflect true competitive bidding processes. So, we agree that CMS should not pursue this option either.

B. CMS' Principles for Setting Single Payment Amount

Despite the fact that this entire method of setting single payment amounts and selecting contractors varies greatly from the time-tested, proven methods used by private managed care organizations, we agree on

the first principle used to determine the single payment amounts for individual items in a product category:

1) Bid amounts from all winning bids for an item in a CBA will be used to set the single payment amount for that item in the CBA.

2) We do not agree with principle #2 despite the reference in the statutory language:

3) [CMS] must expect to pay less for each individual item than we would have otherwise paid for that item under the current fee schedule. Single payment amounts cannot be higher than our current fee schedule amounts for individual items within a product category.

In the earlier section, we commented on the fact that there are many product categories or HCPCS codes today where providers are in an unprofitable situation after all of their costs are accounted for. The CPI for DMEPOS has been frozen for most years in the past decade-plus. Yet, providers' costs have risen in almost every cost category. The demonstration project proved that such a requirement could have a deleterious effect on the market, suppliers, patient and physician access to suppliers and products (incontinence and ostomy supplies).

C. HCPCS Process Flaws and Brand-Specific Requirements Will Negatively Impact Potential Savings

Again we reiterate earlier comments about the current HCPCS coding process flaws and concerns about the unprecedented requirement to fulfill brand-specific prescriptions. The current HCPCS codes for some of the most frequently-utilized DMEPOS are too limited in number and definition. The HCPCS codes, application process for the same and Medicare allowable-setting process have not kept pace with advances in technology and manufacturers' practice of constantly introducing new products to the market.

As an example, we reference the continuous positive airway pressure (CPAP) mask HCPCS code. There are over 100 masks manufactured today that tie to this single HCPCS code. Yet, the acquisition cost that providers incur for the masks varies by as much as 400% from the low end to the high end of the cost spectrum. Medicare's current allowable for the mask causes many instances where the provider is "upside down" from a cost perspective, even before other non-product costs are considered. *(See Appendix B, CPAP Masks).*

If CMS intends to implement the brand-specific requirement in the manner it described in another section, and a single HCPCS code exists for these several hundred masks, well-managed providers will have to incorporate the increased costs associated with the brand-specific requirement into the bids they submit for competitive bidding. That is, of course, if they CAN estimate what percentage of total masks will be for certain brands. Because there has never been a brand requirement under Medicare in the history of the program, this is an unknown factor and could cause suppliers to underestimate their costs of providing CPAP masks after the program launches and manufacturers begin detailing physicians about how to write brand-specific prescriptions.

D. Single Payment Amount Should be Set for Three-Year Contract Period Regardless of New OIG or GAO Reports or Any Subsequent Legislation, and CPI-U Applied

Since the competitive bidding program was mandated by the MMA and indirectly augmented by the DRA, we believe that those Acts' provisions are the ones that should take precedent. Because CMS and the competitive bidding contract suppliers will essentially enter into a three-year contract in good faith, it would be wrong for CMS to adjust the single payment amount downward based on any OIG, GAO, MedPAC or other report. In addition, regardless of any new legislation or Medicare coverage policy

changes that might ensue after a contract is initiated, the agreed-upon single payment rate should prevail through the entire contract period.

Of course, the CPI-U that CMS described in an earlier section would still apply to the single payment amount in each of the contract years.

II. Rebate Program (proposed section 414.416 (c))

CMS proposes permitting contract suppliers who submitted bids for an individual item below the single payment amount determined through the bidding process to provide beneficiaries with a rebate. CMS states that such rebate, if provided, must be equal to the difference between the supplier's actual bid amount and the single payment amount. CMS' proposal, however, is directly contrary to several laws. In particular, permitting the proposed rebates is contrary to the Anti-Kickback, the Beneficiary Inducement Statute, and the Medicare provisions governing the waiver of co-payments.

We have grave concerns about the proposed rebate program and its inherent risks for four primary reasons that we detail below:

1) We believe it violates existing laws and regulations,

2) It would be logistically impossible for a provider to implement in its information system, branch operation and accounts receivable processes,

3) The industry has worked hard to improve compliance and eliminate fraud and abuse. The rebate program would not only set the industry back in this area but would also be impossible for the agency to monitor. It would recreate the "uneven playing field" of years ago before the OIG issued strong guidelines in this area.

4) Patients will already realize savings from the program through the reduction in the fee schedules.

5) Discrimination Issues

A. Anti-Kickback Statute Implications

Permitting any rebates, no matter how determined, to lessen a beneficiary's co-pay obligations would violate the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (the "AKS"). The AKS prohibits knowingly and willfully soliciting, receiving, offering or paying anything of value to induce referrals of items or services payable by a federal health care program. The waiver of beneficiary co-payments, or the economic equivalent, rebates of the co-payment, has long been identified by government enforcers as a violation of the AKS.

Indeed, the OIG has highlighted the legal problems with routine waivers of beneficiary co-payments. See, e.g., OIG, Special Fraud Alert, 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994). There, the OIG identified waivers of Medicare deductibles and co-payments as abusive violations of the AKS that likely lead to excessive utilization of items and services paid for by Medicare. The OIG states in its Special Fraud Alert that when "suppliers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase items or services from them." See id. The OIG acknowledges that at first glance, "it may appear that routine waiver of copayments and deductibles helps Medicare beneficiaries." See id. However, the OIG cites studies that show that patients who are required to pay a portion of their care become "better health care

consumers, and select items or services because they are medically needed, rather than simply because they are free." See id.

Similarly, the OIG notes that the "routine waiver of all or a portion of the Medicare copayment is suspect under the anti-kickback statute," regardless of whether it is styled as a "discount" or a direct payment to a beneficiary. See OIG, Advisory Opinion No. 01-03 (May 3, 2001), at 5, available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2001/ao01-03.pdf. The OIG concluded that waiver of co-pays was abusive because the federal government would not receive the full benefit of the discount provided under such a waiver and the waiver likely would lead to overutilization of services. *See id.* at 5-6. Under the proposed rebate program, the federal government would not be receiving the benefit of the discount and the reduction in the beneficiary's out of pocket costs potentially would lead to overutilization of certain DME services.

The OIG Compliance Program Guidance for Durable Medical Equipment, Prosthetics, Orthotics, and Supply Industry ("DME Program Guidance") also highlights the OIG's "programmatic concerns when DMEPOS suppliers routinely waive deductibles and coinsurance." See 64 Fed. Reg. 36368, 36378 (Jul. 6, 1999). The DME Program Guidance states that DMEPOS suppliers are permitted to waive Medicare co-payment amounts only for cases of financial need. See id. Furthermore, the OIG recommends that a supplier's written policies and procedures should state that it will not routinely waive deductibles and coinsurance for Medicare beneficiaries. If a supplier plans to waive co-payment amounts, the OIG suggests that the supplier develop and maintain written criteria documenting its policy for determining financial need and attempting to collect this co-payment. See id.

For all of the reasons set forth in the OIG's prior guidance, both to the DMEPOS industry and in general to all Part B suppliers, CMS' proposal is contrary to law. Nothing in the statutory basis for the Competitive Bidding program authorizes CMS to authorize an action that would violate the AKS. Thus, we strongly urge CMS to reconsider this proposal.

B. Beneficiary Inducement Statute Implications

In addition to violating the AKS, any rebate or waiver of co-payments also is contrary to the Beneficiary Inducement Statute, 42 U.S.C. § 1320a-7a(a), contained under the Civil Monetary Penalties statute. The Beneficiary Inducement Statute states, in relevant part, that:

> Any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5) of this section) that:
>
> > (5) offers to or transfers remuneration to any individual eligible for benefits under subchapter XVII of this chapter, or under a State health care program (as defined in section 1320a-7(h) of this title) that such person knows or should know is likely to influence such individual in order to receive from a particular provider, practitioner, or supplier and item or service for which payment may be made, in whole or in part, under subchapter XVIII of this chapter, or a State health care program (as so defined);...
> >
> > shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $10,000 for each item or service.
>
> *See* 42 U.S.C. § 1320a-7a(a)(5).

For purposes of the Beneficiary Inducement Statute, the term "remuneration" includes the waiver of any partial coinsurance or deductible amounts. *See* 42 U.S.C. § 1320a-7a(i)(6); *see also* OIG, Advisory Opinion No. 00-5 (Jul. 7, 2000), at 4. The statute excludes waivers of co-payments from the definition of "remuneration" *only if* (i) the waiver is not offered as part of any advertisement or solicitation; (ii) the person does not routinely waive coinsurance or deductible amounts; and (iii) the provider waives after determining in good faith that the individual is in financial need or fails to collect the coinsurance or deductible amounts after making reasonable collection efforts. *See* 42 U.S.C. § 1320a-7a(i)(6). The rebates proposed by CMS cannot satisfy these requirements. In particular, the proposed rule would equate to routine waivers of all or a portion of the co-payment without regard to financial need. Indeed, CMS is requiring that once a supplier decides to provide rebates, rebates must be provided to all beneficiaries regardless of an individual's financial situation.

The OIG has consistently expressed its concerns over waivers of co-pays in the context of the Beneficiary Inducement Statute. In Advisory Opinion No. 99-7, the OIG stated that "the statutory proscription in section 1128A(a)(5) of the Act [Beneficiary Inducement Statute] reflects serious programmatic concerns with waivers of coinsurance." *See* OIG, Advisory Opinion No. 99-7 (Jun. 30, 1999), at 3, *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_7.htm; OIG, Advisory Opinion No. 97-4 (Sep. 25, 1997), at 3-4, *available at* < http://oig.hhs.gov/fraud/docs/advisoryopinions/1997/97_4.pdf>. When "providers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be inducing the patient to use items or services that are unnecessary, simply because they are free." *See id.* Thus, the proposed rebate program is contrary to the prohibitions in the Beneficiary Inducement Statute. Nothing in the statutory basis for the Competitive Bidding program authorizes CMS to authorize an action that would violate the Beneficiary Inducement Statute. Thus, we strongly urge CMS to reconsider this proposal.

C. Medicare Requirements for Collecting a Twenty-Percent Co-Payment from Beneficiaries

The plan design for Medicare Part B benefits has always included beneficiary co-payments. The purpose behind the twenty (20) percent co-payment is to discourage excessive or unnecessary utilization. See 42 C.F.R. § 419.41 (calculating national beneficiary co-payment amounts and national Medicare program payment amounts); 42 U.S.C. § 1395e (requiring Medicare payments for inpatient and outpatient hospital services to be reduced by co-payment amounts). The rebate proposal runs counter to a fundamental principle of the Medicare program that requires beneficiary coinsurance. Nothing in the statutory basis for the Competitive Bidding program permits CMS to authorize an action that would fundamentally change the Part B plan design by eliminating some co-payments. Thus, we strongly urge CMS to reconsider this proposal.

D. Harm to Quality and Disadvantaging Smaller Suppliers

The nature of the CMS competitive bidding proposal is that winning bidders, on average, will be able to recoup their costs from their bid proposal in supplying the full range of services. While some items might have competitive bidding pricing less than bid of some suppliers, other items will have prices higher than the bid. On average, the winning bidders should recoup at least their overall bid amount. Under the proposed rebate structure, however, there is a risk that rather than focusing on supplying all items for which the bidder has submitted a bid, the supplier will instead focus on those items where the reimbursement price is greater than the supplier's bid amount. For those items, the supplier can provide the inducement of a rebate, while still not falling below the bid price. By providing the rebates, the supplier will have less of a profit margin to support the provision of those items for which the supplier's bid was higher than the reimbursement amount. Suppliers paying rebates are likely to be less inclined to provide service in those areas where the supplier has bid above the contract price.

Moreover, the rebates will not benefit the Medicare program. By its terms, all of the rebate will go to beneficiaries, none to the Medicare program. It is hard to see how such a system will have any benefit at all to reducing the government's expenditures on Medicare, the key objective behind the competitive bidding program.

For all the reasons stated above, permitting any beneficiary rebates will be unwise and contrary to existing law.

E. Logistical Challenges with Implementation of Proposed Rebate

As it relates to rebates, CMS' proposal would create significant logistical and management information systems challenges for providers. These are sample factors that would make it almost impossible to implement such a program in a given branch operation:

1) Since CMS has indicated that it may implement competitive bidding in a portion of an MSA, that could mean that the beneficiaries within the CBA would be eligible for a rebate but beneficiaries who live one zip code or town away would not. Yet, they would be served by the same location under two different sets of rules.

2) Competitive bidding will only apply to certain DMEPOS items, not to all. Keeping rebates straight on certain items will be challenging. Patients who have a competitively-bid item in their home and a non-competitively bid item in their home (e.g. oxygen that might be in and a walker that might be out) would be confused by the process. We would still be required to make a good-faith effort to pursue a $5 co-pay on a non-competitively bid item but could rebate $2 on a competitively bid one in their home. The whole idea is impractical.

3) Physicians would have no way of keeping this information straight either. Research has shown they want a very easy referral process when working with homecare providers.

4) If only CMS may inform referral sources and patients about the suppliers that have chosen to provide rebates, how is the supplier's representative supposed to answer a direct question about this subject when posed by a referral source or patient? How would CMS inform POTENTIAL patients of the rebate offered by some suppliers, when the beneficiaries may not yet realize they will need DMEPOS in the future? The entire secrecy shroud is fraught with potential problems, not to mention the fact that CMS should not waste valuable taxpayer dollars on this program by advertising or marketing rebate-related information.

5) Certain beneficiaries may elect to "supplier-hop" between suppliers simply to obtain a $5 rebate. This adds additional cost to the healthcare system because the new supplier would have to invest all of the same up-front admission time and costs as had already been invested by the first supplier.

6) It often costs more to issue a rebate check than the value of the check itself. Most businesses cannot issue a check for less than $15 in labor and processing expenses, so again the concept only adds to suppliers' cost structure, regardless of whether it is voluntary or not.

7) A recent national industry study of 74 home respiratory providers showed that patient bad debt expense already runs 5% of total revenues on average for home respiratory care providers. That means for every $100 Medicare dollars a supplier bills in revenue, it writes off $5 to bad debt. CMS has not historically acknowledged bad debt for home respiratory providers, but it is a real cost of doing business, which cannot be ignored.

8) How would CMS expect a provider to integrate such a rebate with the patient's Part B supplemental insurance plan where the plan pays 100% of the 20% co-pay amount? Or integrate it with a "Financial Hardship" waiver policy where the patient has to attest to his/her financial situation before the provider could grant a full or partial waiver of the co-pay amounts due?

F. Competition Should be Based on Quality and Service, Not on Price. Rebate Concepts Represents "Backsliding" In Area of Compliance Expectations for Program.

The competitive bidding program should be one that advances competition among suppliers on the basis of quality and service, not on price in the form of either the single payment amounts or nominal rebate amounts. In future years, CMS should be able to publish comparative patient satisfaction or other outcome data. This would be much more meaningful data on which patients and referral sources could make a decision to use one supplier over another in any given CBA.

Given the strides that the homecare industry has made in recent years in terms of promoting Codes of Ethical Business Conduct, implementing formal compliance programs and adopting the guidelines, recommendations and rules issued by the Office of Inspector General (OIG), United States Sentencing Commission (USSC) and American Health Lawyers Association (AHLA), we are concerned that the rebate concept would set the industry back substantially.

For all of the reasons cited, we urge CMS to eliminate the rebate concept from either consideration or implementation.

J. Terms of Contract
Proposed 414.422
71 Fed. Reg. 25654, 25680-82

I. Termination of the Contract

The statute, 42 U.S.C. § 1395w-3(b)(3)(A), requires the Secretary to specify the "terms and conditions" to govern contracts between CMS and suppliers under the competitive bidding process. Under the Proposed Rule, CMS may terminate a contract with a supplier based on ill-defined, unduly subjective reasons, which include:

1) CMS' determination that Medicare is not realizing "significant savings;"

2) A change in the ownership of a supplier from merger or acquisition, even if the successor entity meets all the necessary qualifications and standards;

3) Breach of contract by a supplier, which includes failure to comply with "governmental agency or licensing organization requirements";

4) For the "convenience" of CMS. The Proposed Rule further states that suppliers are bound for the full length of the contract period, which CMS proposes to specify for each item when it requests bids.

The Proposed Rule's provision governing the terms of the contract raises several concerns. The Proposed Rule grants CMS the unilateral right to terminate the contract without cause merely if it is "convenient" for CMS to do so. There is no definition of "convenience" under the Proposed Rule. A contract supplier that has not breached its contract, has dutifully followed all applicable federal and state regulations and licensing requirements, and incurred significant cost to submit an accepted bid should not have its contract terminated without cause. Such a right to unilaterally terminate without grounding in any articulated economic contravenes CMS' goal of broad participation by suppliers in the competitive bidding program and reduction of cost for DMEPOS supplies. Permitting CMS to terminate without cause eliminates the principal advantage for winning bidders. Without modification of the Proposed Rule, bidders would be dissuaded from submitting the lowest bid possible because they would have to calculate the financial risk of termination and compensate for this uncertainty in their bid price.

A. Varying Length of Contracts for Different Product Categories Too Confusing to Administer

On page 103, CMS references the section of the Social Security Act that gives the Secretary the authority to recompete contracts at least every three (3) years and then indicates that it would award contracts for different lengths of time for different product categories. This is much too confusing and administratively burdensome for both CMS and suppliers to administer. The private sector generally locks in long-term contracts for two or more years. Private sector plans also have a much simpler bidding process up-front. Given the extremely burdensome method that CMS is pursuing to issue RFBs by individual product category, define all-new product categories specifically for competitive bidding (which we oppose), evaluate bids and arrive at a single payment rate for each individual CBA, and develop duplicative processes for accreditation, we believe that for every given MSA selected for competitive bidding, the length of the contract should be the same for each product category included in that market.

B. Supplier Must be Given Right to "Cure" the Alleged Breach of Contract

CMS should be permitted to terminate contracts on the basis of a "material breach," subject to a contract supplier's right to cure the breach within a specified time upon notification of such breach. This is consistent with CMS' right to terminate agreements with entities participating in other government-run programs. For example, under the Medicare Part D Final Rule, CMS may terminate its contract with a Part D sponsor if the Part D sponsor "[s]ubstantially fails" to carry out the terms of the contract or meet various Part D regulation requirements. See 42 C.F.R. § 423.509. All of the stated reasons for termination are limited to substantial failure to perform expected duties or comply with applicable law.

C. Contract Should Lock in Pricing for Entire Contract Term

One significant flaw in the Proposed Rule is that it does not explicitly prohibit the Secretary from unilaterally changing the price of an item in a competitive bid area during the term of the competitive bidding contract. If CMS holds such a right, the suppliers, who accepted their contracts based on the bids they submitted and not this new price, should be given the option of continuing their contract or terminating the contract without being subject to breach of contract remedies. If CMS believes that it has the right to re-price during the term of the contract, suppliers should have the opportunity to terminate the portion of their contract subject to re-pricing without any penalty or negative consequence.

The Proposed Rule states that contract suppliers are held to their contracts for the full length of the contact period or they are considered to be in breach. There are no provisions that allow suppliers to terminate their contracts for any reason no matter how meritorious it may be. There should be a provision that allows suppliers to terminate, without being in breach of contract, in cases of hardship or material change in circumstances that are not the fault of or within the control of the supplier. For example, the availability of new equipment that is frequently prescribed and significantly more expensive than that existing at the time of the bid submission may raise sufficient financial hardship to merit a contract termination. Certainly, CMS has proposed such a right for itself. The lack of parity in the ability of the contracting parties to terminate may serve as an impediment to many potential bidders' submission of the lowest possible bid.

D. Supplier Contract Termination Rights

Therefore, CMS should implement regulations that (1) eliminate any right of CMS to terminate a supplier's contract without cause or for convenience; (2) allow suppliers the choice of voluntary termination if the Secretary changes the price of an item outside of the bidding process; and (3) permits a supplier to terminate its contract without penalty if unexpected circumstances arise that hinder its ability to render performance.

E. Competitive Bidding Contract Review Process

CMS lists the minimum provisions that contracts will address, such as subcontracting rules and potential onsite inspections. *See* 71 Fed. Reg. at 25680-81. Two sections cause concern:

1) "Compliance with changes in Federal laws and regulations during the course of the agreement"

We assert that if such regulations or laws either change the then-current coverage guidelines and corresponding payment levels or cause the supplier to incur substantially higher costs to care for the beneficiary who requires a particular item, the supplier should have a right to renegotiate that line item of the contract since it would represent a material change to the information the supplier used to bid for the contract at the outset. A current example of such a regulatory change is related to the Respiratory Assist

Device (RAD) policy and local coverage determination (LCD). Other examples include the pending changes to Power Wheelchair codes, coverage guidelines and payment levels, and a proposed FDA requirement concerning how medical gases such as oxygen are handled in the home. These changes would significantly increase providers' costs over and above today's levels.

2) "Non-discrimination against beneficiaries in a competitive bidding area (so that all beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier would provide to other customers)."

This requirement is in direct contrast to CMS' proposed inclusion of selective rebates, since only certain beneficiaries would be eligible for such a rebate and others would not. In addition, it conflicts with the brand-specific product language found in the applicable section of the NPRM. As we commented in that section, the brand-specific requirement is fraught with problems. It could cause a supplier to provide the lowest quality product simply because a physician writes a prescription for that brand. And, since the Medicare program has never mandated brand specificity before and will continue to adhere to this guideline in the non-CBAs, it is possible that beneficiaries will receive different products than before CBA, and this would have nothing to do with whether or not the product is of the same level of "quality," however that term might be defined.

F. Preamble's Terms Not Found Within Regulation, Require A Separate NPRM

Finally, we note that the Preamble discussion contains a number of different proposed contract terms that are not found within the regulation itself. We presume the actual contract provisions will be subject to a separate Notice of Proposed Rule-Making in order to permit suppliers to offer more productive comments.

II. Furnishing of Items (proposed section 414.422(c))

CMS states that "a contract supplier must agree to furnish the items included in its contract to all beneficiaries who maintain a permanent residence or who visit the competitive bidding area and request those items from the contract supplier. *See* 71 Fed. Reg. at 25681. Later in the paragraph it states that "a physician that is also a contract supplier must only agree to furnish the items included in its contract to his or her patients." *See id.*

A. Question

If five or 20 bidders win a contract, does one have a choice not to accept the patient? An extreme example, but one that occurs occasionally, is when the patient is not a suitable candidate for homecare services according to the individual supplier's policies and procedures. For example, a patient may not have a caregiver at home, or there may be an insurmountable language barrier that would represent a patient safety risk if patient education could not be conducted adequately. Medical records may indicate that the patient is combative and non-compliant with the homecare regimen their physician has prescribed in the past. Each provider's policy and procedure manual differs slightly from the next; each has different "patient admission criteria" for certain respiratory, HME and infusion products/services.

In addition, most suppliers have trained their employees to provide, repair and maintain a certain list of products. It would be logistically impossible for a provider to train its employees to effectively provide the full range of products available on the market today. Therefore, the supplier should have the right to refer the patient to another contract supplier to provide a certain product if that other supplier is known to provide that particular brand.

B. Comments

Physicians that are also contract suppliers should also be required to furnish items to visiting or traveling patients, just as homecare suppliers do today. They should not be given the option to only provide the products to their own patients as this does not address the issue of a patient who winters in or travels to another area, and then finds himself/herself in need of a particular item from a physician. This is especially true in an emergency situation.

III. Repairs and Replacements of Patient Owned Items Subject to Competitive Bidding

This section, although short in length in the NPRM, represents a significant area of concern and unanswered questions. The section does not address how the repair and replacement of patient-owned items subject to competitive bidding will be addressed after the Deficit Reduction Act's forced ownership takes effect.

The NPRM states that "repair or replacement of patient-owned DME and enteral nutrition equipment...must be furnished by a contract supplier because only winning suppliers can provide these items in a competitive bidding area. The contract supplier cannot refuse to repair or replace patient-owned items subject to competitive bidding. This proposed policy...is consistent with the CB program in that it directs business to contract suppliers."

A. Question

We have numerous questions about repair and replacement after the DRA's provisions take effect. They were not answered in any section of the NPRM. AAHomecare submitted a long list of questions to Herb Kuhn on April 20, and we hope they will be answered very soon, since the first impact will be felt by patients in February 2007. This is the month in which the first Medicare beneficiaries will take forced ownership of their hospital beds, patient lifts, wheelchairs and other HME.

Sample questions already posed to CMS include:

- How will CMS pay for an in-home service visit that does not involve any repair or maintenance? Telephonic support requested by the patient? A patient assessment ordered by a physician and performed by a licensed clinical respiratory therapist? Coordination of services between several locations in the event of patient travel, a move or other need? These are everyday occurrences that have not been addressed by CMS and are not covered at all by existing HCPCS codes for repair and maintenance.

- Does the requirement for a contract supplier to not refuse to repair or replace patient-owned items apply to equipment that the contract supplier did not originally provide? This cannot be the case, since the contract supplier would essentially be required to use its own assets to replace equipment that was provided by another supplier.

- How does CMS plan to pay for a replacement item once it is owned by the patient under the new DRA rules? How does CMS expect a provider to explain to a patient that he/she cannot access new technology that has been launched since he/she took ownership of the original oxygen equipment? None of this has been specified in any rule issued thus far.

CMS' proposed requirement that a contract supplier must repair or replace patient-owned items solely because the supplier won a contract and therefore would be interested in that particular volume is flawed. To repair or replace such an item could represent a financial loss to the supplier and therefore risk the

supplier's overall financial viability if only repairs or replacements were directed its way by the Medicare program.

B. Recommendation

When a beneficiary switches to a contract supplier, CMS should allow a new period of continuous use to begin since beneficiary access is a key goal of CMS in implementing this program. Such a decision would also protect the contract supplier who may have to furnish equipment to the beneficiary without compensation.

In addition, rather than request a supplier to include the cost of repairing patient-owned equipment in an overall HCPCS bid category, CMS should treat this as a separately-bid line item on the RFB.

IV. Furnishing Items to Beneficiaries Whose Permanent Residence is Within a CBA

In this section, CMS proposes that "the contract supplier must agree to accept as a customer a beneficiary who began renting the item from a different supplier regardless of how many months the item has already been rented. This is particularly important in those cases where a supplier or noncontract supplier does not elect to continue furnishing the item in accordance with the grandfathering provisions...Suppliers must factor the cost of furnishing items in these situations into their bid submissions."

A. Comment

We vehemently oppose this requirement in light of the passage of the DRA. Under the prior reimbursement methodology, a supplier who "inherited" a patient from another supplier could at least attempt to cover his costs through the semi-annual service and maintenance fee that would ensue after the capped rental period.

The DRA's provisions for forced ownership makes dramatic changes that make CMS' proposal for competitive bidding a "non-starter." As an example of this problem, the following is a very real situation that occurs every day in the homecare community:

TODAY

- Patient starts on liquid oxygen with a portable stationary with supplier A and uses oxygen for 33 months.
- In that 33-month period, patient may have tried other oxygen systems, asked for more or less tanks, tanks of different sizes purely for convenience.
- At month 34, patient decides to move permanently from one state to another.
- In this case, patient returns oxygen system to supplier A and is admitted to supplier B's service in the new state. Supplier B provides patient with all-new oxygen system it has purchased and, because it is a separate business with a separate Medicare supplier number, must incur all of the expenses associated with admitting and servicing a brand-new patient. This is even true of multi-site providers. Supplier B continues providing oxygen system and support as long as patient has a medical need. If patient's condition changes or his/her physician orders a different system, supplier provides it or one that is functionally equivalent.

UNDER THE DRA

- Patient starts on liquid oxygen with a portable stationary with supplier A and uses oxygen for 33 months.

- At month 34, patient decides to move permanently from one state to another.
- Patient returns oxygen system to supplier A.
- CMS expects supplier B to provide an all-new oxygen system asset and supporting service in the new state and yet the supplier will receive only three (3) months of reimbursement.
- If patient's condition changes or his/her physician orders a different system, supplier provides it or one that is functionally equivalent.

It is unrealistic for CMS to expect a contract supplier to be forced to accept a patient if, thanks to the DRA, it cannot cover the cost of providing the equipment and associated service to the patient.

In addition, CMS favors the non-contract suppliers who elect to non-grandfather, and penalizes the contract suppliers! The supplier that decides to non-grandfather should not relinquish its responsibility and force a winning supplier to pick up all responsibility and liability for that patient at either no charge or only a limited number of rental months.

B. Recommendation

When a patient elects to change suppliers for any reason, the "rental counter" should start over at month one. That way, CMS can ensure that there is patient access and that a supplier will be able to cover the costs of admitting a new patient to service. Unless the oxygen section of the DRA is repealed, this is the only way to administer this section.

CMS needs to address the issue of how the contract supplier is essentially being penalized under this section, while the supplier that refuses to grandfather is "rewarded." Surely CMS did not intend these incentives to be so misaligned and the challenge is directly related to the DRA.

V. Furnishing Items to Beneficiaries Whose Permanent Residence is Outside a CBA

On page 106, CMS proposed that "...a beneficiary whose permanent residence is located outside of a CBA must use a contract supplier to obtain all items subject to competitive bidding in the competitive bidding area that he or she visits."

A. Comments

We are confused by this requirement in that it infers that certain products might be drop-shipped into the temporary geographic location where the beneficiary is visiting. Oxygen is one example of equipment and service that should not be drop-shipped from one area to another. There are many more. This section requires clarification by CMS.

VI. Information Collection from the Supplier

On page 107, CMS lists the terms, conditions and information it proposes a supplier must agree to provide to CMS for purposes of assessment prior to becoming a contract supplier. In general, we agree with the items on the list, but we are concerned that CMS has not defined certain terms which, if not defined properly in advance of the contracting process, allow too much room for interpretation. These include:

- Information on product integrity – Define "integrity" of products.
- Information on business integrity – Define "integrity" as it relates to business. Does CMS intend for all suppliers to have a corporate compliance program? A Mission Statement and Operating Principles? Other ethical aspects of their business? This must be clarified.

- Organizational conflicts of interest – Must be clearly defined.
- NSC number of any affiliated company – For public companies with multiple locations tied to a single tax ID #, the definition of "affiliate" must be simplified so that we do not have to provide the names or supplier numbers of all 500+ locations on an application form for a single CBA.
- Employee information – Specify the level of employee information you expect, e.g. highest ranking local manager, title, etc., or CEO, COO of public company.
- Customer service protocol – Needs to be defined since different companies define the customer service process differently.

In addition to the list CMS provided and the comments on the six listed above, we recommend that CMS also require suppliers to provide:

- A description of the provider's corporate compliance program;
- The company's procedure for checking to ensure that it does not knowingly employ any individuals who have been debarred from participating in government programs;
- The company's procedure for conducting background checks on employees who will have direct contact with patients;
- Awards, honors or other distinction issued to the company;
- A description of the provider's credentialing program if a subcontractor will be used to care for patients;
- A description of the provider's emergency preparedness plan;
- A description of the provider's process for selecting products and, if applicable, independently testing them through objective metrics.

VII. Change In Ownership (proposed section 414.422 (d))

The Proposed Rule requires contract suppliers to notify CMS sixty (60) days prior to any changes in ownership, mergers or acquisitions. There are no assurances that CMS will ultimately permit the successor entity to assume the contract, even if the successor entity meets all CMS bidder requirements. Or, if the transaction is structured as a sale of stock, CMS apparently may terminate the arrangement with the supplier even though the supplier has a contract with CMS and continues to meet all of the requirements. If CMS determines that there is no longer a need for the acquired entity to function as a contractor to ensure Medicare's capacity to meet, CMS may no longer recognize the acquired entity as a contract supplier. Unfortunately, CMS' proposal will act as a disincentive for companies to participate in the bidding program by dramatically reducing the marketability of such companies. Obviously, winning a CMS contract is an economic asset that should be recognized in a sale. If CMS will not recognize the buyer as a supplier, however, companies desiring or needing to sell for whatever reason will be penalized for having been a successful bidder. Limiting the ability of successful bidders to sell the company can hardly be in the best interests of the Medicare program. Indeed, penalizing successful bidders by making a portion of their business non-transferable in a sale will discourage competitive bidding.

A. <u>CMS Must Allow an Acquirer to Participate as Long as it Continues to Meet Eligibility Requirements After the Transaction</u>

Moreover, CMS' articulated concerns for denying contractor status to an acquired successful bidder are misplaced. CMS states that it does "not want to allow suppliers to adopt a strategy of circumventing the regular bidding process by gaining winning status through acquisitions of or mergers with contract suppliers or to violate any anticompetition prohibitions." CMS fails to recognize that companies are sold for varying reasons at varying times in their life cycle and that the competitive bidding process is a repetitive event, whereas a merger or acquisition is a one-time transaction wholly unrelated to the bidding

process. Sometimes a provider's founder retires, passes away or must liquidate its investment for personal financial reasons such as medical costs, a divorce or college education (all of which we have experienced when buying small providers in recent years). While a losing bidder might be able to stay in business in an area during the term of the contract by acquiring a winning bidder, in order to stay in business in the area, the acquirer will need to submit competitive bids in the future. Any company that acquires a winning bidder is likely to be committed to doing whatever it takes, including submitting competitive bids in the future, to retain the business. Clearly, the acquisition of a winning bidder should not adversely impact the initial bidding process, since by definition the bid process has been completed and the contract awarded to the winning bidders. Nor could the acquisition adversely impact any subsequent bids, since to retain the business, the acquired entity will need to continue submitting competitive bids.

It also is highly unlikely that a company would fail to submit an initial competitive bid with the expectation that if it did not get a contract, it could just acquire a company that did acquire a contract in the area. A company operating in the area of competitive bids cannot reasonably expect that it can stay in business by failing to submit a competitive bid and instead acquiring a winning bidder. There is no way to know post bidding whether any successful bidders will be for sale, or whether the price for a winning bidder will be reasonable. Thus, if a company wants to get the business in an area, the only practical strategy for doing so is to initially submit a competitive bid. We cannot think of a plausible scenario under which the ability subsequently to acquire a winning bidder to get the business would adversely impact the prior bidding process.

B. Sixty-Day Prior Notice Requirement is Unrealistic and Burdensome

A sixty-day prior notice requirement is a burdensome restraint on legitimate corporate transactions. Acquisitions and mergers frequently occur in a much more compressed time frame. But for the proposed requirement, there generally is no advance notice requirement prior to completing and acquisition and/or merger. Note Hart-Scott-Rodino requirements generally are not applicable in small DME company transactions.

C. Recommendation

We suggest CMS revise the proposed rule to require no more than thirty (30) days prior notice or, if the transaction is set to close within less than thirty days, then the parties should have an obligation to provide notice as soon as the parties sign a letter of intent to change ownership.

CMS should be able to assure itself that the acquired entity continues to meet all obligations and requirements for eligible suppliers. However, CMS' review should be limited to a consideration of whether post acquisition, the entity: (1) meets all the requirements of a contracting supplier; (2) is willing to assume all obligations under the contract; and (3) has executed a novation agreement. The only limited circumstances where CMS may have a legitimate concern over a transfer of ownership is in a case where the acquirer, through the acquired entity, does not satisfy one of the foregoing three requirements. Thus, the presumption should be that the entity post acquisition will be acceptable to CMS unless it fails to satisfy the requirements applied to all contract suppliers, refuses to assume the obligations and liabilities borne by the prior contract supplier, or declines to execute a novation agreement. Thus, there should be an explicit presumption that unless the entity post acquisition fails to meet these listed conditions, the entity will be able to continue acting as the contract supplier following the acquisition.

Winning a bid should not diminish the marketability of any supplier. Companies need to be able to preserve their marketability, and a key component of the marketability is that the acquisition not jeopardize the pre-sale business of the entity. CMS' proposed regulations actually punish the winning

bidders by making a potentially significant portion of the business unmarketable. If this aspect of the proposed regulations is not changed, companies that might need to contemplate a change in ownership (for family, tax, or economic reasons) will be discouraged from bidding. If CMS desires to encourage all companies to bid, the contract supplier's status as the winning bidder should be preserved as a valuable asset for consideration in any commercial transaction. Accordingly, CMS should change the prior notification requirement and modify the scope of its review of an acquisition.

VIII. Suspension or Termination of a Contract (proposed section 414.422 (f))

It is reasonable for CMS to expect that contract suppliers will be held to all the terms of their contracts for the full length of the contract period.

However, we are concerned about a few aspects of this section:

1) CMS states that it may include reprocurement costs if a supplier's contract is terminated for breach – this is not how the private sector handles it and is unreasonable since the supplier cannot know CMS' reprocurement cost structure.

2) CMS states that it could "preclud[e] the supplier from participating in the competitive bidding program," but it does not specify if that is only for that certain competitive bidding area or for the entire competitive bidding program.

3) CMS states that it would have the right to terminate the contract for "convenience." This is not defined anywhere in the document and must be so defined in the final rule. Otherwise, this is much too one-sided and again, patient care could be at risk if CMS were to simply terminate a supplier's contract after it invested a significant amount of time and money in preparing to participate in competitive bidding.

4) There must be a clear "cure" period, process and timeframe (this is how private managed care plans handle such contracts). This must include a written and/or verbal appeal process such as those that exist with the Joint Commission, the FDA, state licensing agencies, etc.

K. Administrative or Judicial Review
Section 414.424
71 Fed. Reg. 25654, 25682

I. Administrative or Judicial Review (Proposed § 414.424)

The statute restricts the bases for seeking administrative or judicial review within the competitive bidding program context. However, these limitations do not preclude the establishment of some process in which suppliers may communicate with CMS regarding grievances and seek redress. In addition to the recommendations previously made regarding the scope of CMS' termination rights and the need for a cure period for a supplier's breach, CMS should consider mechanisms that allow suppliers to provide feedback and seek redress for grievances. Consistent with Constitutional due process rights, this should include the opportunity for suppliers to have at least some administrative appeal mechanism with respect to CMS contract termination decisions.

L. Opportunity for Participation by Small Suppliers 71 Fed. Reg. 25654, 25682-83

In principle, we agree that small suppliers should be given every opportunity to participate in competitive bidding. Numerous small suppliers across America provide a consistently high level of quality service to over 50% of the Medicare DME/respiratory market and obviously play a key role in doing so.

We believe that CMS should make the results of the focus groups conducted with small suppliers public as the agency refers to them at 71 Fed. Reg. at 25683 but does not provide the summary in any appendix.

A. General Comments

We want to emphasize the following points related to small suppliers:

1) Accreditation fees and related internal operating costs to prepare for, undergo and maintain accreditation are on a sliding scale based on the size of the individual supplier. So, a small supplier incurs significantly lower out-of-pocket costs for accreditation than a large supplier and therefore the argument that mandatory accreditation is too costly for small providers is, in our opinion, unsupportable.

2) Two other accreditation options exist for small suppliers to access today, when compared to a decade ago when the Joint Commission "owned" the accreditation market. Therefore, we believe that if a small supplier made plans to become accredited by the 2007 competitive bidding timeframe, or the 2010 year in which it will be mandatory for all Part B suppliers, ample time and resources exist for these suppliers to seek and obtain accreditation prior to the 2007 competitive bidding launch in only 10 markets.

3) Regarding applicable financial standards, which again have not been clarified by CMS for providers of ANY size, we believe that the entities either meet the standards or they do not – there should not be any room for interpretation based solely on size. Operating cash flow, access to capital, and ability to expand capacity are factors that all suppliers should be able to address. Only the scale differs.

4) Regarding applicable quality standards, we believe that Medicare beneficiaries deserve no less than their managed care counterparts. Every managed care organization in America requires accreditation as a minimum condition of participation in serving its members. Again, the cost of conformance to the quality standards should be viewed on a sliding scale according to the supplier's size.

B. Small Business Definition

CMS' definition of a small DME supplier as an entity that is generating less than $6 million in revenue per year, ironically appears to include over 75% of Apria Healthcare's individual locations. *See* 71 Fed. Reg. at 25691-92. In addition, CMS notes that "at least 90 percent of DMEPOS suppliers had Medicare allowed charges of less than $1 million in 2003." Again, Apria would have a significant number of individual branch locations that fall under this definition. Surely this is not how CMS intended to define a "small business" in terms of participating in competitive bidding. We recommend that CMS view individual supplier size by the cumulative revenues they generate across all supplier numbers tied to the tax ID number to which they are commonly linked. In this manner, CMS and the Small Business

Administration (SBA) would be able to truly assess the size of various suppliers that participate in the program.

C. Requirement to Service an Entire CBA

We also agree that all contract suppliers should be expected to service the whole competitive bidding area. We do NOT agree that CMS should allow a supplier with fewer than 10 employees to carve out a geographic service area that is smaller than the entire CBA. The number of employees does not directly correlate to a supplier's ability to service an area. Beneficiaries WOULD be confused as CMS described, and the issue of "cherry-picking" certain geographic areas would once again be likely. We note that CMS considered and rejected that carve-out option and we fully support this decision.

D. Participation by Small Suppliers in the Demonstration Projects

CMS notes that some small suppliers were able to increase their market share substantially during the demonstration, while others experienced little change in market share. Again we want to emphasize that suppliers in any given market – today or in the future under competitive bidding – compete on SERVICE and not on price. A large national provider with a small local branch usually offers the same local flavor, community involvement and medical community knowledge as a truly small competitor. Therefore, the size of the supplier has little relevance; a small supplier can certainly out-service a large one, or vice versa, and frankly it is all dependent on the people, business processes, responsiveness and relationships at the local level – not only on the equipment itself.

E. Proposal to Conduct Separate Bidding Competitions for Product Categories

We understand CMS' intent behind its proposal to allow suppliers to decide how many product categories for which they want to submit bids, rather than conducting a single bidding competition for all DMEPOS items and other equipment. CMS seems to believe that this will also allow small supplier that specialize in one or a few product categories to participate more easily.

However, there are flaws with this proposal:

1) Conducting separate bidding processes for individual product categories is the most administratively burdensome method CMS could select. Private managed care plans – including senior risk plans – issue RFPs for a comprehensive list of products and services. The paperwork alone is going to add significantly to the cost burden of CMS and bidders.

2) CMS may find little bidding interest in certain product categories that already represent a financial loss to suppliers, regardless of their size. These are categories where suppliers' service or product costs have risen while the Medicare allowables have decreased or been frozen for many years. Examples are ventilators, CPAP devices and supplies and ambulatory aids such as walkers, canes, commode chairs, etc.

3) The assumption that large suppliers could expand their product offering easier or more quickly than small suppliers is oversimplified and overstated. Privately-owned, small providers may be able to move more quickly than large organizations that must seek approval from their Board or other stakeholders before certain business expansion occurs.

M. Opportunity for Networks
71 Fed. Reg. 25654, 25683

In general we agree that the network model would enable small providers to better cover an entire CBA and that the entity should be formalized through a legal contractual relationship. CMS noted that networks were an option in the demonstration projects, but none were submitted. *See* 71 Fed. Reg. at 25683. In Polk County, that could be due to the fact that the geographic area was small enough for a single provider or location to cover the entire county and therefore it had nothing to do with the competitive bidding program itself. Obviously, other markets will require some degree of networking due to their sheer geographic reach, population density or number of Medicare beneficiaries to be served.

I. Recommendations

A discrete legal entity – rather than an informal referral network – is needed in order to prevent the commingling of Medicare funds, unintentional or intentional violations of anti-kickback, self-referral rules and regulations, and allegations of unfair business practices among the participating providers.

II. Networks Must Satisfy Same Conditions as Individual Suppliers

CMS proposes to allow suppliers to form networks for bidding purposes. In the event that CMS permits networks of independent suppliers, it is crucial, as CMS recognizes, that each supplier in a network satisfy the same conditions that suppliers who are not participating in a network must satisfy. In particular, each member of a network should be independently eligible to bid and satisfy the applicable accreditation and quality standards.

III. CMS Needs to Address Open Questions About How Network Entity Will Obtain Medicare Supplier Number and Be As Accountable as a Single Supplier

The requirements proposed by CMS, however, may not be sufficient to prevent networks from being formed that do not provide beneficiaries with appropriate levels of service and quality of items. Where a network of unrelated suppliers serve an area, there is a real risk that beneficiaries will fall through the cracks. Where a single supplier is responsible for the entire area, there is a single entity that can be held accountable. There is a substantial risk that, absent appropriate safeguards, no single entity will have the same level of accountability as with a single supplier. CMS needs to both add requirements to ensure that contracting networks are as accountable and responsible in the aggregate as single bidders and scrutinize bids submitted by networks to ensure that each network has appropriate mechanisms to ensure accountability and that each beneficiary has a single point of contact that ensures satisfactory resolution of any performance problems or other issues across the stated geographic region.

In addition, the PAOC raised the question about how a network entity would obtain a Medicare supplier number. Since all 21 Medicare supplier standards must be met before an entity can obtain such a number from the National Supplier Clearinghouse (NSC), and the network entity, as proposed, would merely represent the individual members of the network, it is not clear how the network entity will obtain that number. There should be no exceptions in terms of requiring an entity to meet the 21 supplier standards that exist today.

IV. Contractor/Subcontractor Relationship as an Option

We agree that this should be an option in those cases where a beneficiary resides in an area that is simply un-serviceable by a contract supplier, but CMS should recognize that the contract supplier is likely to find itself in an unprofitable situation when it must subcontract. This is due to the fact that the service costs far outweigh the equipment costs and the subcontractor would therefore negotiate a high price in order to take care of that patient. With shrinking single payment levels and rising fuel/labor costs, this scenario may be even more untenable under competitive bidding.

If a subcontracting arrangement is used, CMS should require the contract supplier to describe its formal credentialing process in the RFB process before contracts are awarded. Such a process should clearly define the roles and responsibilities that is appropriate for employees and subcontractors, outline the training required, and require the adoption of certain policies and procedures to ensure consistency with our own service and liability limitations.

V. Calculating a Network's Collective Market Share

CMS states that a network cannot be anti-competitive, a principle with which we agree. *See* 71 Fed. Reg. at 25683. The Proposed Rule states that "the network members' market share for competitive bid item(s) when added together, cannot exceed 20 percent of the Medicare market within a CBA. See id.

We have questions for CMS' consideration:

1) How will CMS calculate the market share and monitor changes in it over the course of the contract?

2) What does CMS propose to do to the network or its members if the market share grows to, for example, 40 percent?

VI. Networks Should be Subjected to Pre- and Post-Payment Audits

Just as individual suppliers are subject to pre- and post-payment audits, the same process should apply to networks. The Program Integrity Unit should include networks in their sampling methodology to ensure that regardless of their size in terms of Medicare allowed charges, they are audited in exactly the same manner as those suppliers that generate higher levels of allowed charges.

N. Education and Outreach
71 Fed. Reg. 25654, 25683-84

In general, we agree that education and outreach are key components of the competitive bidding program. We are very concerned about the aggressive timeframe which CMS has outlined in order to implement the program in 2007 and beyond, and believe that the level of beneficiary, supplier and referral agent education required may actually surpass CMS' expectations and budgeted resources.

I. 90-Day Notice Period Needed from Contract Award to Implementation Date in Every CBA

Therefore, we request that the supplier community be given a minimum of 90 days notice prior to implementation of the CB program from the bid award process to the actual "go-live" implementation date. This 90-day period is common in the private managed care sector and benefits all stakeholders involved:

1) It will allow CMS to fine-tune its launch plans by CBA, reprogram its computer systems, communicate with DMEMACs, the NSC and other government agencies as applicable.

2) Providers will have time to re-program their computer systems, make changes to operating policies and procedures, attempt to sign new contracts or secure additional facilities to support the contract, notify patients and referral agents of the upcoming CB program and its implications for them;

3) Referral agents will have time to become acclimated to the new process in their market and will be more likely to support the program than if they are caught by surprise due to a short implementation phase;

4) Patients will experience less disruption if their supplier has time to analyze the applicability of the grandfathering provisions if it does not win a contract and to learn more about the competitive program in general before it becomes effective.

II. Supplier Education

We agree with CMS' overall plan to involve the CBIC, DMEMAC, customer service support and the claims processing system to notify and educate all parties regarding competitive bidding. We agree that bidders' conferences should be held to provide an open forum for suppliers to exchange information with CMS.

We request that CMS collaborate with industry groups, such as the American Association for Homecare ("AAH"), to develop appropriate communications to be sent to suppliers to minimize confusion in the supplier community. Organizations like the AAH have extensive collective knowledge about suppliers' day-to-day operations and can provide expertise that may help CMS streamline its communications with the supplier industry.

The PAOC should also review any materials that relate to DMEPOS competitive bidding to avoid mistakes and reflect the expertise of the industry.

III. Beneficiary Education

We also agree that beneficiary education will be critical to the success of the program. However, CMS mischaracterizes some of the patient-directed messages that would be associated with competitive bidding. *See* 71 Fed. Reg. at 25684. CMS states that the benefits of the Program include "lower out-of-pocket expenses and increased quality of products." *See id.* These two alleged benefits are not necessarily true. The Deficit Reduction Act's forced equipment ownership requirement may actually increase patients' out-of-pocket expenses for certain services that are currently included in the monthly bundled rental payment rate. Since CMS has not issued any rule or guideline regarding, for example, a Saturday evening emergency delivery to a home after the equipment has reached its capped amount and is owned by the patient, the supplier will likely need to charge the patient an after-hours in-home delivery rate – something that it does not do under the current system.

Regarding "increased quality products," we caution CMS about using such a statement since Medicare beneficiaries across America already receive quality products. Since it is illegal to discriminate against patients based on payor source in most U.S. states, most suppliers go through a formal product selection process and then provide those products to all patients, regardless of payor. This is also more logistically sensible than trying to maintain multiple separate sets of inventory, etc., and again goes to the point that providers will continue to compete on service, not price or equipment.

IV. Direct Mail and other Direct Marketing Should be Used, Not Mass Media

However, we do not believe that CMS should waste taxpayers' resources by investing in expensive direct-to-consumer televisions or media advertising on this subject. Rather, targeted direct mail or information dissemination through high-Medicare volume physicians' offices would be more effective. In addition, CMS should relay on the homecare supplier community itself to educate beneficiaries, since we visit patients' homes every single day of every year.

V. Suppliers Should Use Their Own Homecare Education Materials

In another section of the NPRM, CMS references the possibility that patient education materials for the homecare services and equipment itself would be developed and standardized in the competitive bidding markets. This is unnecessary and would be problematic for providers who serve multiple payors. At Apria, for example, our patient education materials have been reviewed thoroughly by the Joint Commission, our Legal Department, insurance carriers and certain manufacturers' Legal departments since some content relates to their equipment's safety, troubleshooting tips and maintenance schedules. They are all written at the sixth grade reading level and many have been translated into Spanish and other prevalent languages.

We certainly hope that CMS does not intend to impose a requirement on providers to create and print all-new patient education materials. This represents a waste of resources. Instead, CMS should simply require that providers give patients written and in-person education that is appropriate to their health condition and that meets the expectations of the supplier's accreditation organization.

O. Monitoring and Complaint Services for the Competitive Bidding Program 71 Fed. Reg. 25654, 25684

We agree that an effective complaint monitoring system is needed as part of the competitive bidding program. We believe this should be a simple process that incorporates existing channels for Medicare beneficiaries to voice complaints – such as the Ombudsman program – and should not attempt to either recreate what exists in another section of the program or overcomplicate the process.

CMS has cited examples of potential problems that CMS would consider to be serious, such as contract suppliers refusing to furnish items to beneficiaries in the CBA and contract suppliers furnishing items of inferior quality.

CMS concludes this short section by stating that "claims data will be monitored to identify trends, spikes or decreases in utilization and changes in utilization patterns within a product category." 71 Fed. Reg. at 25684.

I. Comments/Recommendations

1) Current Medicare supplier standards require that suppliers show the NSC the complaint resolution process through the site inspection required prior to the issuance of a provider number.

2) Patients should be directed to call their supplier FIRST regarding any alleged service issues before calling the Medicare Ombudsman or other contact, since the majority of issues are easily resolved at the local branch office location and do not require escalation.

3) CMS must define "items of inferior quality" and other terms used in this section, since our experience suggests that patients will complain if their oxygen tubing is clear instead of their preferred blue, even if the quality is exactly the same. They may not be familiar with all of the features and benefits of a certain product, or new technology that makes their old product obsolete, and therefore believe that the supplier is providing them with something other than their typical quality product. Typically we resolve these questions and concerns quickly and easily without the need for any outside involvement.

4) In determining whether a supplier is experiencing a high level of complaints, CMS must view complaints not in an isolated, numerical manner but expressed as a percentage of the total number of in-home deliveries made to Medicare patients in a given month. Otherwise, CMS could misconstrue the level of complaints if an individual supplier were to have, for example, the largest Medicare market share in a given CBA and thus the raw number of complaints were to appear large. Expressing the complaints as a ratio of total in-home deliveries is how the private sector now looks at complaint monitoring.

II. CMS Cannot Force a Supplier to Furnish an Item it Does Not Routinely Supply

In terms of furnishing items, again we ask CMS to address the quite-common situation where a supplier does not carry a particular item or know how it works, must be maintained, etc. It is not uncommon for a supplier to contract with a few quality manufacturers to provide the majority of the products patients need, making it difficult and more costly for that supplier to obtain a non-contracted items from another manufacturer, especially on short notice. Mandating that supplier to furnish that item could raise patient

safety, employee safety and other liability concerns. As long as SOME contract supplier in the CBA can supply that particular item, it should be acceptable to CMS; that is part of the reason why multiple suppliers are needed to service a given CBA.

III. Product Utilization May Have Nothing to Do with Competitive Bidding

While claims monitoring may be effective for some purposes, using it to suggest that a spike in certain items' utilization may be attributable to competitive bidding is narrow-minded. As we stated in an earlier section, certain areas of the country are experiencing rapid Medicare beneficiary population growth, the baby boomers are entering the program in disproportionately high numbers, the incidence of certain diseases is higher in some parts of the U.S. than others, and new products/technologies are introduced every year which enables a larger number of patients to remain independent at home.

P. Physician Authorization/Treating Practitioner and Consideration of Clinical Efficiency and Value of Items in Determining Categories for Bids (proposed 414.420) – Also known as "Brand-Specificity" 71 Fed. Reg. 25654, 25684

CMS describes its proposed plan for fulfilling the Act's authority granted to the Secretary as intending to "establish a process for certain items under which a physician may prescribe a particular brand or mode of delivery of an item within a particular HCPCS code if the physician determines that use of the particular item would avoid an adverse medical outcome on the individual." *See* 71 Fed. Reg. at 25684.

We have serious concerns about this entire requirement, as it is the first time in the history of Medicare DMEPOS coverage that the agency has ever concerned itself with brand-specific products, and it will add to both the administrative burden and cost of the entire program. Moreover, we believe that the way in which CMS has interpreted its authority is more prescriptive, onerous and punitive than Congress may have originally intended.

The phrase "avoid an adverse medical outcome on the individual" must be clearly and carefully defined. Currently, neither the CMN nor any other Medicare document contains a space for the physician to either prescribe by brand-name or document that the product is needed to "avoid an adverse medical outcome." Physicians cannot be expected to remain abreast of all new products on the market, warranties, commercial status, problems experienced with each, manufacturer product recalls, backorders, shortages, etc. Therefore, they could actually prescribe a product that would cause an adverse medical outcome if the homecare provider were to supply it to the patient! Finally, our experience shows that certain brands are prescribed purely due to manufacturers' sales efforts, market perception or features of the equipment that solely offer comfort and convenience to patients.

Based on historical experience, the Medicare program has not paid for "convenience" items and product features. Product aspects such as color, weight, portability, battery-operation, etc., have never been considered valuable by Medicare before, and we are concerned that Medicare will discriminate against beneficiaries in non-CBAs if it approves of products with these features in the CBAs but still does not approve of such products in the non-CBAs.

Three examples are (1) battery-operated, portable nebulizers, (2) ambulatory enteral nutrition pumps and (3) CPAP devices featuring C-FLEX technology. We also find this requirement interesting and in conflict with the recent Local Coverage Determination (LCD) issued by the three DMEMACs in regard to Medicare Part B inhalation drug therapies. In it, Medicare suggested that physicians' brand-specific prescriptions for Xopenex® and DuoNeb® would not be recognized or honored by the Medicare program. Yet, patients who are forced to switch to another drug in lieu of Xopenex or DuoNeb could actually experience a true "adverse medical outcome." The program cannot require that brand-specific prescriptions be honored in one part of the DMEPOS program and disregarded entirely by another. We provided extensive comments on this subject under separate cover to the three DMEMAC medical directors in May 2006. Also, keep in mind that a high percentage of patients receiving products under the competitive bidding program may be the same ones who use Xopenex and DuoNeb, so confusion would reign among physicians, patients and providers alike.

With Apria's extensive experience working with national and regional managed care plans, brand-specificity is very rarely, if ever, a requirement of the contract.

I. Current Proposed Rule

The Proposed Rule generally requires contract suppliers to provide brand-specific items and equipment as designated by the prescribing physician. Although a contract supplier may consult with the treating practitioner to find a suitable alternative product for the beneficiary, if the contract supplier is unable or unwilling to furnish the equipment the treating practitioner ultimately requests, the supplier must assist the beneficiary in finding another contract supplier in the competitive bidding area. CMS has proposed that the contract supplier still be required to support and service the item and the patient. If a supplier substitutes another item or equipment, the claim will be denied.

We believe that the way in which CMS has interpreted its authority is more prescriptive, onerous and punitive than Congress intended.

II. Difficulty in Providing Brand-Specific Items Within the Context of Competitive Bidding

The proposal implementing the specific brand mandate raises serious financial consequences for suppliers and creates unnecessary uncertainty in the bids to be submitted. The primary bases for this concern are the unpredictability of the application of this new right to make brand-specific requests and the wide range of costs among brands within a single HCPCS code. These issues are outside the control of the supplier who is going to be financially responsible for the outcome. Consequently, we strongly use the Office of General Counsel to support CMS' effort to implement the brand specific mandate in phases, requiring the designation of product categories and product codes that are distinct enough to allow suppliers to calculate realistic bids and product inventory assumptions. Alternatively, CMS should consider an exception process to fairly compensate suppliers for the provision of items that are very expensive in comparison to other products within the same HCPCS code.

III. High Level of Acquisition Cost Variance for DMEPOS Products Tied to Single HCPCS Codes

The right to brand specificity is a new concept within the Medicare program. We anticipate it will be very difficult for suppliers, even large, more sophisticated businesses, to accurately predict brand specific product utilization and fully incorporate these factors into their bids. The high level of price variance for certain types of products, such as oxygen concentrators, nebulizers, CPAP devices and masks, combined with an inability to predict prescribers' preferences and prescribing behavior, will make it difficult for suppliers to submit accurate bids. Extensive overbidding or extensive underbidding will not financially benefit the Medicare program, nor the level of care furnished to beneficiaries.

IV. HCPCS Coding Process Has Challenges and CMS Should Delay Implementation of Brand-Specific Requirements Until the HCPCS Process is Revamped

In the Proposed Rule CMS states that it believes that "the HCPCS process has worked well in the past, and we believe that it adequately separates items based on their function." We do not agree with this assessment.

The advent of the Health Insurance Portability and Accountability Act's (HIPAA) Transaction Code Set (TCS) requirements forced a change in the role and relative importance of the HCPCS Coding Panel and new HCPCS code application/approval process. Prior to the TCS requirement, the HCPCS coding panel primarily focused on products and codes that were used in the Medicare population, while managed care payors allowed a much more broad array of customized codes to reflect different products, acquisition costs and service level variances.

Since HIPAA mandates that code sets be standardized among all payors – regardless of whether they are government or private managed care in nature – the HCPCS coding panel is now in a position to create codes that are more likely to be used in the private sector.[1] New HCPCS codes have been routinely denied to manufacturers who complete the application process after introducing new technology to the market and outlining the product features that differentiate the products from existing ones. Despite clear differentiation and therapeutic benefits desired by both patients and physicians, the HCPCS coding panel has denied new codes and forced those new products into existing HCPCS categories with allowable reimbursement often far less than the acquisition cost.

The cost differences among brands within one HCPCS code can be significant and enforcing brand-specific delivery under the current proposal would almost certainly result in financial hardship for contract suppliers. For example, the more advanced, increasingly prescribed models of CPAP devices may cost five times as much as a standard CPAP that offers enough benefits to the patient to treat his/her condition less effectively. New technology, such as a portable oxygen concentrator, may cost as much as four times more than a traditional model. Yet, these products fall within the same HCPCS code and will be subject to the same single payment amount as their older generation predecessors. If a physician insists on prescribing the more expensive model, the supplier may face a dramatic financial shortfall if the single payment amount has not fully captured the anticipated volume and value of furnishing the much more expensive product. This may adversely impact the ability of the supplier to continue participating in the program or the level of patient care.

To address this concern, we have recommended that CMS consider delaying implementation of the brand-specific mandate until it ensures that the product categories and applicable HCPCS codes recognize the cost distinctions of these products. This could be accomplished through a phased-in approach to the brand mandate. For example, the entire product category of wheelchair coding already is being revised through new and revised codes and definitions. This phasing and more deliberate approach will minimize the onerous and unfair consequences to which suppliers otherwise will be subject and which we strongly believe was not Congress' intent when enacting the statutory language.

V. Exception Process Needed

Whether or not CMS implements a more refined product category and HCPCS classification, the Office of General Counsel should support CMS efforts to develop an exception process to protect suppliers when a physician orders a disproportionately more expensive brand. In other government program contexts such as the Medicare Part D program, CMS has recognized the importance of risk adjustments and risk corridors to decrease the exposure of Part D plans where the allowed cost exceeds the estimated plan payments for the Part D benefit. Similarly, CMS should take into consideration the potential exposure of suppliers who participate in the competitive bidding program and must handle unexpected requests (or an unpredicted request volume) for more costly items.

We anticipate there will be instances in which a physician refuses to modify a prescription and the contract supplier cannot provide the specifically requested item, or no contract supplier will furnish the specified item. Under the Proposed Rule, the contract supplier may furnish an alternative item within the same HCPCS code in an effort to meet a beneficiary's medical needs. Even though this item would be covered in a non-competitive bidding area and the item is considered equivalent to the ordered item

[1] Since 80% of the total Obstructive Sleep Apnea (OSA)/CPAP market is commercially insured, this is a good example of a product category for which HCPCS codes need to be modernized. Pediatric products used in Medicaid and commercial populations is another other example where the HCPCS codes available do not mirror current-day technology that is available and being used to treat children.

because it falls within the same HCPCS code, the supplier will not be able to bill Medicare. Instead, the item will be considered a "non-covered item." It is unclear why the contract supplier should be left with the cost of the item in these situations. This is an entirely inequitable result and, we believe, inconsistent with the Congressional intent.

In light of the grave concerns related to the implementation of this brand-specific provision, CMS should delay implementation of the brand-specific component of the competitive bidding program until CMS develops a system that can more adequately distinguish supplies by relative cost and features. This approach will permit suppliers to calculate and offer realistic bids and, ultimately, receive fair reimbursement as they continue to supply high-quality services and items to Medicare beneficiaries.

VI. Substitution Process and Documentation Requirements

If a physician or treating practitioner requests a specific brand, the contract supplier is allowed, under the current Proposed Rule, to consult with the prescriber concerning a suitable alternative. If the treating practitioner is willing to modify the original order, the Proposed Rule mandates the supplier receive a revised written prescription. Verbal orders are acceptable in most states. This proposal is well beyond the legal mandates of many states and imposes significant administrative burdens on suppliers and physicians.

First, many of the existing CMS documents, such as the CMN, have no place for a physician to specify a particular brand of equipment. Rather than requiring a supplier to obtain and store both a CMN and a separate prescription, CMS should modify its forms so that only one document is required. This approach is more efficient for physicians and suppliers, and is consistent with the general industry directive to reduce unnecessary paper.

Second, the proposed documentation requirements concerning order modification are not consistent with standard practice within the DME industry. Revised written prescriptions are not presently required for many DME items under state law. Thus, in appropriate circumstances, it is common for suppliers to furnish alternative products that physicians have orally approved without further physician documentation. Mandating a revised written prescription is an onerous and unnecessary burden on both the treating practitioner community and suppliers, and is likely to distract from the medical community's primary focus on patient care. The Proposed Rule should be modified so that a supplier is permitted to make appropriate notations in its internal documentation, such as system-generated prescriptions, in order to document a physician's oral consent to substitution of a particular product. A new physician prescription should not be required unless mandated under state law. Again, verbal orders are acceptable in most states. This suggested approach is consistent with industry practice and will improve the ability of suppliers to efficiently deliver necessary and proper items to beneficiaries.

Finally, the Proposed Rule should be clarified with respect to a contracted supplier's obligation to refer a beneficiary to an alternative supplier if the original supplier does not carry a requested item. The Proposed Rule suggests that in this situation the supplier is initially permitted to contact the treating physician and discuss an alternative product. Only if the supplier cannot fill the order must the supplier assist the beneficiary in locating an alternative source. The Proposed Rule Preamble, however, implies that the supplier must first contact other contract suppliers within the competitive bidding area ("CBA") before consulting with the physician. Since the language in the Proposed Rule is consistent with current industry practice and minimizes disruption for the beneficiary, this would appear to be the most appropriate approach. CMS's clarification on this topic will minimize confusion among suppliers regarding the proper course of action.

VII. Reasonable Effort Standard

The Proposed Rule states that if a supplier does not carry a requested item, the supplier may refer the beneficiary to another supplier in the CBA that does. CMS should specify the level of effort that a contract supplier must expend in locating another contract supplier. An appropriate standard would be to require contract suppliers that are unable to supply the requested item to use "commercially reasonable efforts" to locate an alternative supplier. CMS also should clarify a supplier's obligation to furnish a brand-specific item when no alternative suppliers can be located.

VIII. Perception of Discrimination and Unfairness

Implementation of the brand-specific provision of the Proposed Rule appears to be inconsistent with the Preamble discussion about the terms of a supplier contract. Specifically, the Preamble states that the supplier contract is likely to contain a requirement that the supplier not discriminate against beneficiaries in a CBA, so that "all beneficiaries inside and outside the CBA receive the same products that the contract supplier would furnish to other customers." 83 Fed. Reg. at 25681.

It is unclear how a contract supplier may comply with this directive while furnishing brand-specific items only to competitive bidding beneficiaries. It is also unclear how a supplier will be able to avoid potential beneficiary allegations of discrimination and unfairness when certain items will be covered in a non-competitive bidding area, but will be considered non-covered in the competitive bidding area if a physician insists on a specific brand, but the supplier is only able to furnish a different product. CMS should clarify these potential inconsistencies and ensure that suppliers will not be subject to inadvertent CMS and beneficiary liability.

In addition to these concerns, the current proposal will add administrative costs to those suppliers (including Apria) that have locations serving both competitive bidding and non-competitive bidding beneficiaries. These costs will include the need for additional training on the brand-specific issue, as well as the need to develop additional internal systems and protections to ensure appropriate implementation. It would be logistically impossible for every provider to train its employees on every single product available in the marketplace. Such training, if possible, would need to extend to our employees who must be able to set up, educate patients on and explain all brands of equipment. This is neither practical nor cost-effective for either the provider or the program.

IX. CMS Cannot Consider an Item Non-Covered if it Has a HCPCS Code and is Reimbursed by Medicare Outside of the CBAs

The proposal also calls for the contract supplier to not bill Medicare for a product it supplies if it does not match the prescription as CMS would consider this a "non-covered item." This also represents and unfair and discriminatory business practice, as the supplier's location might actually be providing that same product to beneficiaries who live outside of the CBA, and the supplier will have incurred the full expense burden associated with delivering that equipment to the patient's home within a very short period of time after the referral was received.

X. Brand-Specific Requirement Cuts Into Potential Program Savings

The competitive bidding program is designed to drive savings for the Medicare program. Homecare providers drive savings that they could pass on to the program by consolidating purchases among a few manufacturers. If this provision moves forward in its current form, it will undoubtedly result in reduced savings that may be attributed to the competitive bidding program. If a provider must account for higher product acquisition costs in the bids submitted during the application process, the savings levels will be

lower. This certainly is not the result Congress intended when authorizing the competitive bidding program.

Here is a very real and practical scenario that could occur:

1) The provider conducts a formal product reviews among various manufacturers of CPAP masks and selects three or four masks that fit the clinical, comfort and overall needs of 80% to 90% of all patients (regardless of payor source) likely to need them. The provider signs a contract with two manufacturers to secure product availability and pricing associated with those three or four masks.

2) In CBA A, a competitive manufacturer's sales representative persuades the local sleep management physicians and/or sleep laboratory technicians to write a brand-specific prescription for a mask that 1) does not offer any incremental benefits to those 80% to 90% of all patients, but 2) costs the provider three times more than the ones they've selected as standard.

3) The provider would need to make attempts to educate physicians and/or beneficiaries about availability and quality of masks that are contracted. If the physician does not write an all-new prescription, the provider would need to supply that more costly mask.

4) If the more costly masks were to constitute a significant percentage of total Medicare CPAP mask patients served, the provider would have to reflect the higher acquisition cost in its bid to Medicare.

XI. Section Summary and Recommendations

In summary, this entire requirement is fraught with many adverse consequences, presumably unintended. While Congress may have believed it was ensuring that patients continued to have access to "quality" products (again, not defined anywhere), the way in which CMS has interpreted this section will cause a significant increase in administrative burden, decreased cost savings associated with competitive bidding and possibly even low-quality products being provided to beneficiaries solely because a physician writes a prescription for them.

We urge CMS to delay the implementation of the brand-specific requirement until 2008 after the 2007 program is up and running in all 10 initial markets. In addition, CMS must:

1) Clearly define the phrase "to avoid an adverse medical outcome."

2) Adopt the FDA's definition of "functional equivalence" used to approve medical devices that are similar to already-approved ones and allow a provider to substitute such a device without extensive documentation;

3) Eliminate the financial penalty aspect of the proposal by allowing a supplier to bill Medicare for a substitute product that meets the functional equivalent standard;

4) Phase in the requirement by piloting it in one CBA in 2008 to study the ramifications of implementing it;

5) Allow enough time for the HCPCS system to be updated to reflect the broad range of products and associated provider acquisition costs within certain categories;

6) Further consult with the homecare community to develop the most streamlined, least punitive method for implementing such a provision;

7) Build safeguards into the process that are designed to prevent product manufacturers from taking advantage of this provision to drive up unnecessary costs associated with certain brand specificity;

8) Study the discrimination aspects of this rule, since Medicare patients in non-CBAs will not be subject to the same brand-specific requirements.

Q. Quality Standards and Accreditation for Suppliers of DMEPOS 71 Fed. Reg. 25654, 25684-87

As stated in our opening comments, Apria Healthcare is an ardent supporter of the need for quality standards and mandatory accreditation as part of the Medicare Part B DMEPOS program. Both requirements will "level the playing field" among all suppliers, regardless of whether they participate in the competitive bidding program or not.

However, we are concerned about several aspects of the proposed methods that CMS would use to implement these two very important components of the program:

1) The quality standards are not yet finalized and therefore we, along with every other supplier, are unable to adequately and comprehensively comment on their content or their impact on our operations and cost structure once competitive bidding is launched;

2) The proposed quality standards are too abstract and "policy and procedure" in nature, demonstrating a lack of understanding of the homecare industry from the consulting organization, and do not reflect actual quality standards that have long been used in the private sector;

3) Rather than "recreate the wheel" in terms of accreditation, CMS should simply designate the three large national DMEPOS accrediting bodies to have "deemed status" and, by virtue of a provider's successful accreditation from one of the three, CMS could assume that the provider essentially meets all standards associated with the program.

4) CMS' proposed "Validation Review" process is much too duplicative with the existing accreditation process and questions remain as to the background, experience and training of any CMS employees who would perform such validation surveys. No managed care plan in America conducts such a validation survey as the costs far outweigh the benefits.

5) No grace period should exist in which a supplier would obtain accreditation. The Medicare Modernization Act was passed in December 2003, so suppliers will have had three years to seek and obtain accreditation by the time the competitive bidding program is underway later this year.

6) Cost savings will be further eroded if CMS proceeds with its plan to implement a redundant Validation Review process of accreditation surveys.

I. Special Payment Rules for Items Furnished by DMEPOS Suppliers and Issuance of DMEPOS Supplier Billing Privileges (section 424.57)

We strongly urge CMS to select the three national, well-established accrediting organizations to implement and monitor the standards. These are the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Accreditation Commission for Health Care (ACHC) and Community Health Accreditation Program (CHAP). All three have a proven track record of developing standards in order to meet the changing realities of homecare services, surveying DMEPOS providers and developing a success/failure rate over time. Newer organizations do not have such a track record and we therefore recommend that they develop at least three years of data before being considered for inclusion in the Medicare Part B accreditation program.

In this section, CMS also states that proposed new paragraph (c) (22) would specify that all suppliers of DMEPOS and other items be accredited by a CMS approved accreditation organization before receiving a supplier billing number.

II. Questions

Regarding this latter point, CMS must clarify how acquisitions of existing suppliers would be handled. Currently, if an accredited supplier buys a non-accredited supplier and keeps that physical location open, the acquirer's accreditation status and process would ensue, meaning that the accrediting organization would likely conduct a survey of the acquired location(s) subsequent to the acquisition. The schedule of that survey hinges almost completely on the accrediting body's availability to conduct the survey. CMS should not delay either the issuance of a supplier number or payment for patients served through that location where the acquiring organization is fully accredited while the individual acquired location is pending a post-acquisition accreditation survey. Evidence of notification to the accrediting body should be adequate proof to move forward with issuance of the provider number.

CMS has also not accounted for the very real situation where an accredited supplier would open a new physical location providing like services as those provided by the accredited organization to better serve Medicare beneficiaries in a particular part of the CBA. Today, the accrediting body would consider the new location to be accredited since it is owned by the same parent organization, follows the exact same policies and procedures, uses the exact same information system, accounting procedures, compliance program, complaint monitoring program, etc. It would do so without necessarily conducting an on-site visit. We recommend that CMS make an allowance for this situation and consider any start-up location associated with an already-accredited organization to qualify for the immediate issuance of a Medicare supplier number, followed up by a subsequent accreditation survey. Since this situation occurs every single month in markets across America, it cannot be ignored, especially if the expansion helps to serve Medicare beneficiaries better.

III. Accreditation (section 424.58)

We generally with the plan that CMS describes to use existing procedures for the application, reapplication, selection and oversight of accreditation organizations and apply them to organizations accrediting suppliers of DMEPOS seems to make sense.

A. CMS Must Not "Force-Fit" Part A Processes On To Part B DMEPOS

However, CMS must not try to "force-fit" existing Part A home health procedures into the DMEPOS industry. It must recognize the differences between Part A and Part B. One section references the deemed status authority related to Part A and the state surveys that are performed on Part A agencies. This is inapplicable to Part B, since many states impose completely different state licensing requirements and the FDA, DOT and other state/federal agencies are involved in providing oversight to and audits of DMEPOS suppliers.

B. Adopt Existing Accrediting Bodies' Survey Procedures, Do Not Duplicate or Add Burden

Again, we urge CMS to rely on the Joint Commission and other accrediting bodies to seek their counsel on any standards, audit procedures, self-evaluations, etc., rather than recreate the wheel. The quality standards for competitive bidding should not differ very much from the 400-plus performance standards that the Joint Commission and others already have in place. The "crosswalk" that CMS references on page 122 should be brief since the standards should be the same.

Also, CMS must adopt the accreditation organizations' processes and procedures for notifying suppliers of compliance or noncompliance with accreditation requirements, monitoring the correction of deficiencies found during the survey, coordinating surveys with another accrediting organization and quality review processes for deficiencies. CMS must NOT create additional administrative burdens on either the accrediting bodies or the suppliers since again, this will have to be reflected in the cost structure of the program. If CMS adds significantly to the accrediting bodies' operating costs by, for example, requiring them to conduct a physical audit of each and every location of a national accredited provider that follows the exact same policies and procedures, the accrediting body will have to pass those increased costs on to suppliers. The suppliers, in turn, will have to reflect those increased costs in the bids they develop for competitive bidding, and savings will be eroded.

C. Other Information CMS Should Seek from Accreditors

In addition to the professional background information that CMS may request from the surveyors themselves, the agency should also ask the accrediting bodies for their conflict of interest disclosure policies, since some surveyors also have consulting businesses that may conflict with certain clients.

D. Notice Requirements for Accrediting Organizations

On page 123, CMS outlines some of the other data requests it may make of accreditation organizations. While most of the requests make sense, some of the reporting that CMS is referencing does not exist today. For example, accrediting bodies do not currently notify ombudsmen programs or the National Supplier Clearinghouse (NSC) of unfavorable accreditation decisions related to DMEPOS.

Any such notice process must be preceded by or include an appropriate appeal and "cure" process for providers to access prior to any punitive action being taken against the organization. The Joint Commission currently has a stair-step appeal and escalation process which is appropriate given the importance of accreditation to an individual supplier's ability to participate (today) with managed care organizations and (future) with the Medicare program.

E. Revocation of Supplier Number Should Not be Performed Wholesale Since Supplier May Serve Non-CBA Medicare Beneficiaries

CMS indicates that it would revoke the supplier's billing number and re-evaluate the accreditation organization's approved status.

These two plans need careful evaluation and a phased-in approach because any given supplier may be serving both competitively bid and non-competitively bid patients. While quality standards are going to be implemented for all suppliers, mandatory accreditation is not required until 2010. In addition, if competitive bidding only applies to certain products and quality standards are ascribed to only those products, CMS should not revoke the supplier number permitting a supplier to bill for non-competitive bid patients if compliance with the competitively-bid quality standards is in question.

Also, CMS needs to consider the situation where the supplier has another physical location in the CBA that is in full compliance with all applicable standards and could absorb the existing patient volume of the location that loses its supplier number without any interruption in patient care. In this case, CMS should allow the parent company/supplier to transfer the patients into another owned location that meets the applicable standards. Of course, that new location will bill under its own Medicare supplier number per standard operating procedures that exist today.

In sum, there are a number of issues associated with the application of some of the accreditation requirements. Accordingly, any requirements for CBA suppliers absolutely must be phased in and not implemented across the board upon the launch of competitive bidding.

IV. Ongoing Responsibilities of CMS Approved Accreditation Organizations

While we understand the deemed status process that applies to Part A or other areas may require certain documentation from independent accrediting bodies, we believe that with regard to DMEPOS, CMS should mirror the private sector, not other Medicare programs. For example, requiring the approved accreditation organizations to provide copies of all written surveys, corrective action plans and summaries represents a significant paperwork burden to the accrediting organization and CMS. CMS will be inundated with volumes of paper that it could not possibly review without adding a significant number of new staff members, thus further eroding potential program savings.

Moreover, the current format of the survey reports is not necessarily self-explanatory. Scoring methodologies differ among the three major accrediting organizations; slightly different standards and requirements may be assessed. The degree of narrative description to accompany the scores is often limited. Without an executive summary written by either the accrediting organization or the provider itself, CMS might find itself unable to accurately interpret the results of the survey.

The key information CMS needs is that the supplier has or has not achieved accreditation or renewal. Of course any significant change in accreditation status should be reported to CMS, but we urge CMS to forego the need for copies of the surveys themselves. No private payor in America requires copies of the actual survey results. The copy of the cover letter from the accreditation organization should suffice.

V. Notice of Beneficiary Complaints Should Be Limited to Clearly-Defined "Serious" Ones

CMS should not require the accrediting organization to provide notice of all complaints related to suppliers of DMEPOS since certain complaints may be minor in nature and easily resolved between the accrediting organization and the supplier. Examples of minor complaints might be a curt telephone manner used by a supplier's employee and the patient, delivery on Tuesday instead of Thursday, the color of their tubing changed, etc.

Only the most serious complaints should be reported to CMS. We would be pleased to work with CMS and JCAHO to define "serious complaint" and a method for sending CMS this information.

VI. Notice of Changes in Accreditation Standards, Requirements or Survey Process

While it is reasonable for CMS to expect the accrediting organizations to inform the agency of changes in standards, etc., it is unreasonable to penalize the organization by withdrawing its approval if it implemented the changes before or without CMS' approval.

Keep in mind that accreditation standards apply to all patients cared for by suppliers, regardless of their payor source. If CMS in any way delays review or approval of amended or new standards, it could impact a much larger number of patients and payors than those covered by Medicare competitive bidding.

Since most accreditation organizations update their standards annually, develop an appropriate annual calendar to ensure that appropriate notice is given to all parties.

In this section, CMS also alludes to the fact that it would be allowed to change the quality standards at any time during the contract period. This is another "bait and switch" proposal since such changes could

cause a substantial increase in providers' cost structure, which would impact the amount they bid if they had known the change would occur. Quality standards should remain intact for at least a calendar year before amending or changing them, unless of course patient safety is the crux of the issue.

VII. Continuing Federal Oversight of Approved Accreditation Organizations

A. Equivalency Review

CMS' plan to conduct an equivalency review seems reasonable as briefly described in this section. Again, however, we are concerned that CMS infers that it could impost new requirements at any time throughout the contract, causing additional burdens on suppliers that may not have been revealed by the agency during the RFB process. Annual updates would be acceptable.

B. Validation Review

The accreditation organizations' procedures are time-tested and have been in place for many years, if not decades. The Joint Commission's survey failure rate for DMEPOS is 6%, which proves that it is not a "rubber-stamp" process. Each accrediting body has its own performance improvement and evaluation process in which it consults with industry advisors to modify and add to its standards every year.

The 10% disparity guideline outlined on page 127 is irrelevant and unneeded. Accreditation organizations all have slightly different philosophies in their scoring methods, the standards they deem most or least important (weighting), etc. Because CMS has not outlined the background, experience level, survey experience or any other aspect of the team that would be assigned to perform the validation survey, we cannot endorse this process in any way. If there were no independent accreditation organizations or if DMEPOS represented an all-new product category for them to survey, our opinion might differ. We believe it is an unnecessary incremental burden on the government cost structure for this program.

1. *CMS' Plan to Conduct Validation Survey of Accredited Suppliers is Redundant*

It is a waste of time and taxpayer resources for CMS to perform validation surveys. No other payor in America – including senior risk plans – conducts such duplicative surveys. CMS is not in the business of conducting DMEPOS accreditation surveys, and the Rule did not specify the background or experience of the people it would rely on to conduct such critical surveys. By contrast, the accrediting bodies have comprehensive training, development and monitoring programs for their surveyor employees. These programs are updated regularly and CMS has not described any comparable process in the Rule or any other document.

We are especially concerned that CMS would conduct such surveys in response to allegations of supplier noncompliance with quality standards. Even before the competitive bidding program is launched with all of its new requirements that will surely evolve over time, Medicare rules and regulations are very complex; inexperienced employees, competitors and surveyors can often misconstrue them. This causes some allegations to be unsubstantiated and unsupportable once the facts are made clear.

Instead of conducting validation surveyors, CMS should do two things:

1) Direct the supplier's accrediting organization to conduct follow-up with the supplier on any allegation of supplier noncompliance with quality standards. The accrediting organization is best-equipped to conduct such follow-up and mechanisms exist today for them to follow-up on complaints that reach their office. Accrediting organizations such as the Joint Commission already have mechanisms in place that require providers to develop and implement corrective

action plans. We urge CMS to rely on the expertise of the private sector for all of these services, just as it relied on private sector specialists to implement the complex Medicare Part D program.

2) Take the resources that would be used to conduct validation surveys and direct them toward conducting unannounced billing audits of suppliers that have not had such an audit in the past year. The Program Integrity Unit's current plan of auditing only high-volume, claims-generating DMEPOS suppliers causes a situation where those suppliers are audited over and over again, with largely successful outcomes, while the suppliers that may not be following Medicare guidelines go unaudited for many years. Audits represent a large administrative burden for suppliers, and those that pass "successfully" should be moved on to some kind of representative sampling methodology to ensure ongoing compliance. If the PIU continues its current sampling methodology, it will continue to overlook those suppliers that are more likely to be violating rules and regulations than the ones that have high volume and pass audits successfully time after time.

If CMS insists on performing validation surveys, it should focus only on those accrediting organizations that have been performing DMEPOS surveys for two years or less. Again, a mediation or "cure" process must be included in the overall plan so that a provider or an accreditation organization would have a channel for appealing CMS' validation survey findings.

2. *Notice of Intent to Withdraw Approval for Deeming Authority*

Individual suppliers have too much at stake if CMS were to withdraw its approval of one or more accreditation organizations without an appropriate notice and transition period. Suppliers would need to contact another organization to discuss accreditation through that organization, and depending on the volume of displaced suppliers involved, a serious backlog could occur.

On page 127, an example of the lack of specificity of this entire rule exists when CMS states that "if an equivalency review...or our concerns with the ethical conduct of the accreditation organization suggest [it] is not meeting the requirements..." How does CMS define "ethical conduct of the accreditation organization"? This too-vague description provides too much risk to the supplier, since it could lose its right to participate in the Medicare program purely due to actions of the accrediting group and CMS' perceptions thereof.

3. *Withdrawal of Approval for Deeming Authority*

CMS states that it could essentially withdraw approval of an accreditation organization at any time. No grace period, transition period or other notice to the supplier was described by CMS in this section.

Individual suppliers should not lose their ability to participate in a competitive bidding program solely due to the fact that their accrediting body is sanctioned by CMS due to noncompliance with the administrative or paperwork requirements that CMS has outlined. The supplier has no control over the accrediting body's compliance in this area. It can only be responsible for its own performance in meeting the expectations of the accrediting body and CMS.

CMS needs to outline an appropriate transition period that would facilitate a supplier's ability to continue participating in the program. How does CMS propose to handle a situation where the accrediting body is sold to another group? Undergoes a merger? Goes bankrupt?

4. *Reconsideration*

The written reconsideration process described on page 128 appears to be reasonable. However, we are concerned that the accrediting organization would only be entitled to an "informal hearing conducted by a hearing officer appointed by the Administrator of CMS." The word "informal" is then used repeatedly throughout this section.

The hearing process needs to be formal and involve a more independent, objective mediator than one that is appointed by the CMS Administrator. It should allow testimony and other evidence to be accepted and admissible under the usual rules of court procedures. The process, as described, would afford all legal benefits to CMS and none to either the accrediting organization or the supplier. This one-sidedness represents unfair business practices.

Hundreds of thousands of Medicare beneficiaries' care could be disrupted by a negative outcome concerning the accrediting body, and we doubt that is CMS' intention by limiting the appeal process to such an informal process. A stair-step method of escalation is required for such an important aspect of the Medicare Part B program.

The current Joint Commission appeal process should be used as a model for escalating appeals in order to ensure a fair presentation of all of the facts involved in the situation. Its method is stair-step in nature and involves an objective review board composed of independent members when the appeal reaches a certain level.

R. Low Vision Aid Exclusion
(proposed section 414.15)
71 Fed. Reg. 25654, 25687.

Apria Healthcare has no comments on this section.

S. Establishing Payment Amounts for New DMEPOS Items (Gap-filling) (proposed section 414.210(g)) 71 Fed. Reg. 25654, 25687-89.

I. Gap-Filling Proposal

CMS proposes to modify its current gap-filling procedures and instead use far more subjective criteria in developing payment levels for new products and for new HCPCs. We agree that the current gap-filling practices should be revised – they are not well understood and often result in payment levels that are significantly lower than the payment levels found in the private sector.

CMS also states that "there is an inherent responsibility to pay enough for beneficial new technologies to ensure beneficiary access to care, while also being a prudent payor. To increase the Medicare program's ability to ensure fair treatment across technologies, we have focused on developing strategies that recognize those technologies that provide a demonstrated clinical benefit and clearly identify the additional benefits over existing technologies."

II. Medicare Part B Structure and Coding Process Has Not Kept Pace With Changing Technology

Frankly, our experience in recent years suggests that CMS does not follow the philosophy described immediately above. Numerous examples of advanced, more costly technology used to treat homecare patients have been approved by the FDA. Such technology has clear differential advantages over certain existing technology, offering demonstrated clinical benefits. Yet, CMS and the HCPCS coding panel have routinely denied the creation of new codes and different payment levels to recognize the higher research and development costs that the manufacturers pass along to suppliers in the form of acquisition prices. Examples include: The Pulmonetic® (now Viasys) portable ventilator, portable oxygen concentrators, portable liquid oxygen systems, ambulatory infusion pumps, ambulatory enteral pumps, transfilling oxygen concentrator systems, auto-titrating CPAP devices, non-traditional CPAP masks, low-profile enteral tubes and more.

In this section, CMS proposes to use three main areas to study new products. Our comment for each of the three is written in italics below:

1) **Functional assessment** – *Who were the healthcare providers interviewed? What was their background? Were they experienced in ordering the devices for use at home or solely in the hospital? What was the background of the people who evaluated device operations? No information about the contractor CMS hired was provided in the NPRM.*

2) **Price Comparison Analysis** – *What data source is used for cost? Medicare cannot solely look at the cost to acquire equipment. It must incorporate the total costs borne by suppliers to take care of patients who require that equipment. A recent industry study on oxygen, for example, shows that for every $1 providers spend on equipment, they spend $3 on support services and overhead. Did the group incorporate costs such as managing product recalls, complying with FDA and other government requirements, etc., in their cost analysis? No detail was provided in the NPRM.*

3) **Medical Benefit Assessment** – *Again, what was the background of the "health care providers" interviewed? Are they familiar with homecare or simply institutional or office-based care? We*

need to understand how CMS or its contractors defined "significantly improved clinical outcomes" before commenting further on the effectiveness of the Medical Benefit Assessment.

Using a technology assessment to adjust payment amounts would amount to CMS' circumvention of the requirements under section 1842b and the related regulations for implementation. Under the Inherent Reasonableness (IR) authority, Congress specifically included requirements for notice and comment so that valid and reliable data would be used. The goal was to protect the interest of beneficiaries and providers and prevent an access-to-care problem. The technology assessment that CMS has proposed appears to use a method that would look solely at the cost of acquiring a particular technology and not the total cost providers incur to take care of patients who require it.

III. Recommendation

If CMS proceeds with the use of a technology assessment to establish a payment amount or a new HCPCS code, we believe that an appropriate notice and comment period should proceed for all stakeholders to provide input into the process.

A. CMS Should Not Grant Itself Authority to Alter Gap-Filling in This Manner

We must strongly oppose the particular gap-filling modification proposed by CMS. CMS simply listed a number of general factors for determining gap-filling amounts, without any indication how they would be used. CMS is proposing to give itself what appears to be virtually unfettered authority to choose and apply payment criteria for any new product. Perhaps of greater concern is CMS' intention to apply this broad authority to new codes. It would appear that CMS could trigger this authority by simply modifying a HCPC for a product category, thus reorganizing and creating a new code. By doing so, CMS could set aside the existing fee schedule and substitute its own judgment as to what is a reasonable payment level based on the general factors listed in the proposed rule.

There is no reason to expect that the payment for new technologies under a competitive bidding proposal should be determined on the basis of bids for products that were specifically included in the competitive bidding proposal. In submitting a bid for existing products, a DMEPOS supplier knows what its costs are and can bid appropriately. Use of a gap-filing process to determine competitive bid reimbursement for new technologies is likely to establish prices for new technologies that do not cover the costs of the DMEPOS supplier in providing those new technologies. If new technologies are developed, it is more appropriate to not include the new technologies under the existing competitive bidding agreement, but rather to wait until the next bidding period to determine the competitive bidding level of reimbursement for the new technologies. Any attempt to impute a competitive bidding price for new technologies is likely to force DMEPOS suppliers to incur losses in supplying the new technologies.

B. CMS Already Has Authority to Modify Payment Amounts

Congress has provided CMS with the specific authority to modify payment amounts if CMS determines after a prescribed analysis that the payment levels are grossly excessive or grossly deficient. This so-called "inherent reasonableness" authority is set out at 42 CFR 405.502 and includes a number of procedural and substantive safeguards to ensure that CMS and its contractors do not act arbitrarily. None of those safeguards is present in the CMS proposal on gap-filling. The scope and limitations of CMS' inherent reasonableness authority will be meaningless if CMS can use its gap-filling authority to change payment levels for existing products merely by first changing the HCPC codes for those products.

Inherent reasonableness may only be used if payment levels are determined to be grossly excessive (or grossly deficient), which CMS has defined by regulation as being at least 15% more or less than a

reasonable level of payment. CMS must use valid and reliable data in its analysis and its calculation of new payment levels. Part B suppliers must have the opportunity to comment on the finding that payments are grossly excessive and on the new payment level determined by CMS or its carriers. In addition, if CMS seeks to make an adjustment that will have a significant effect on a substantial number of small suppliers, it must publish an analysis in the Federal Register pursuant to the Regulatory Flexibility Act.

Further, CMS has defined to some extent how it will interpret various factors in its application of inherent reasonableness. CMS and its carriers also must consider the effects on the Medicare program, including:

1) The effects on the Medicare program, including costs, savings, assignment rates, beneficiary liability, and quality of care;

2) What entities would be affected, such as classes of providers or suppliers and beneficiaries;

3) How significantly would these entities be affected; and

4) How would the adjustment affect beneficiary access to items or services.

In addition, the carriers must evaluate the comments received on the proposed notice. And, to ensure the use of valid and reliable data, CMS or the carrier must meet the following criteria to the extent applicable:

- Develop written guidelines for data collection and analysis.
- Ensure consistency in any survey to collect and analyze pricing data.
- Develop a consistent set of survey questions to use when requesting retail prices.
- Ensure that sampled prices fully represent the range of prices nationally.
- Consider the geographic distribution of Medicare beneficiaries.
- Consider relative prices in the various localities to ensure that an appropriate mix of areas with high, medium and low consumer prices was included.
- Consider criteria to define populous State, less populous State, urban area and rural area.
- Consider a consistent approach in selecting retail outlets within selected cities.
- Consider whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population.
- Consider the products generally used by beneficiaries and collect prices of these products.
- When using wholesale costs, consider the cost of the services necessary to furnish a product to beneficiaries.

C. Additional Factors Apply to Modify Payment Levels in a Given Year

Additional factors apply if CMS seeks to modify payment levels by more than 15% in a given year. Yet, none of these processes and criteria, which result directly from several statutes and recommendations of the Government Accountability Office, will have any applicability if CMS chooses to use its gap-filling authority instead of its inherent reasonableness authority to adjust payment rates. We do not believe CMS has the legal authority to modify payment levels for existing, covered products by manipulating the particular HCPCs for those products. Where Congress sought to provide CMS with the authority to modify payment levels, it did so in an explicit and structured manner. The proposed rule on this issue appears to be little more than a reach for additional authority to undertake actions that could be precluded under the inherent reasonableness authority or would be more time-consuming under that authority. Congress, by its actions on inherent reasonableness, effectively limited CMS to the scope of that authority.

D. Too Many Definitions Unknown in This Section

The entire gap-filling section of the NPRM is filled with terms that are not clearly identified. CMS must clarify them before moving ahead. Here is a list of terms that may be interpreted very differently by different readers:

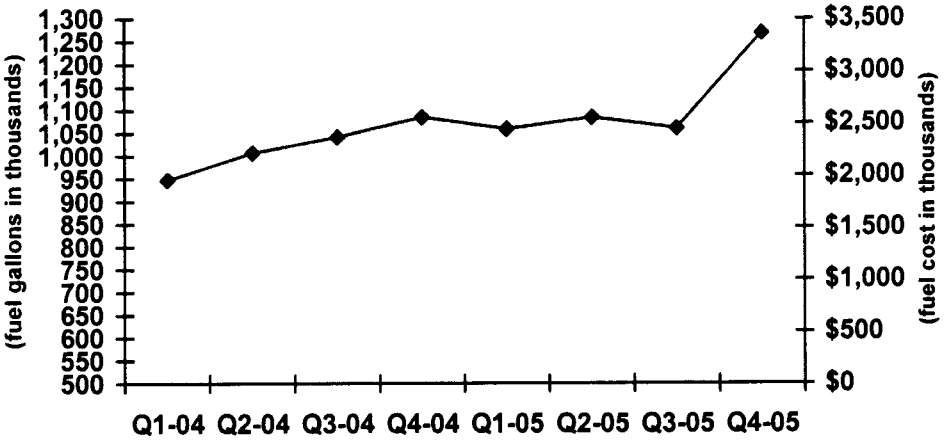
- Comparable item
- Prices in effect at the time that the fee schedule amounts are established
- Manufacturer pricing information
- Retail pricing
- Wholesale prices
- Appropriate mark-up
- Cost comparison analysis
- Middle of a bidding cycle
- New item
- Related or similar items

E. Renegotiation of Contract if Gap-Filling Results in Change of >2% in Single Payment Rate

If CMS moves ahead with this plan despite vocal opposition by the industry, suppliers must be offered certain protections that would ensure continuity of care for patients. While CMS appears to be studying acquisition costs of technology, the Rule is silent on how it plans to assess the non-equipment costs that providers incur in providing that technology to the patient.

In addition, CMS should adhere to a standard calendar for making changes to anything associated with the competitive bidding contract for the next calendar year. Providers may need to reprogram their information systems, train or retrain staff on anticipated changes, notify physicians or beneficiaries of the changes and implement other operational requirements. If CMS moves ahead, suppliers should be given notice of any contractual changes by October 1 of the year prior to a January implementation date.

To illustrate how non-product costs impact providers, below is a chart that shows how fuel costs at Apria escalated from 2004 to 2005, despite a significant improvement in overall productivity among our delivery personnel. Unless CMS accounts for providers' non-equipment costs, the system for assigning new codes and payment levels for each will continue to be flawed well into the future.


(fuel gallons in thousands)
1,300
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1,200
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950
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(fuel cost in thousands)
Q1-04 Q2-04 Q3-04 Q4-04 Q1-05 Q2-05 Q3-05 Q4-05

T. Fee Schedules for Home Dialysis Supplies and Equipment (proposed section 414.107) 71 Fed. Reg. 25654, 25689.

Apria Healthcare has no comments on this section other than to observe that since these supplies are subject to a CPI-U, the products we provide should be eligible too, as the same inflationary cost factors impact our products as those supplied by home dialysis suppliers. We also find it interesting that CMS uses data for allowed services furnished in calendar year 2005 on which to base the CPI-U. This is certainly more reflective of dialysis suppliers' current costs than the archaic gap-filling methodology that CMS applies to DMEPOS products.

U. Fee Schedules for Therapeutic Shoes (proposed section 414.228 (c)) 71 Fed. Reg. 25654, 25689.

Apria Healthcare has no comments on this section.

V. COLLECTION OF INFORMATION REQUIREMENTS (COMMENTS ON PAPERWORK) 71 Fed. Reg. 25654, 25689-90.

ALSO COPY THIS SECTION TO:

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs,
Regulations Development and Issuances Group
Attn: William Parham
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

And

Office of Information and Regulatory Affairs
Office of Management and Budget
Room 10235, New Executive Office Building
Washington, DC 20503
Attn: Carolyn Lovett, CMS Desk Officer, carolyn_lovett@omb.eop.gov, Fax (202) 395-6974

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In this section, CMS solicits comments on each of four issues related to the information collection requirements associated with the competitive bidding program.

We will expound further on the regulatory impact of this program under Section V: Regulatory Impact Analysis, and submit a copy of those comments to the above-named CMS employees in addition to the comments on this particular section.

Our general comments on this section fall into five categories:

1) Due to the lack of specificity of the proposed rule, it is impossible for either Apria or CMS to accurately estimate the amount of incremental time required to complete the bid process and participate in the program. Only two demonstration projects were performed, and they did not include many of the requirements that CMS has proposed in the next round of implementation. This is true for both the application/bid review process as well as the quality and financial standards review, mandatory accreditation, etc.

2) Overall, competitive bidding is an administratively burdensome program for suppliers, CMS and its contractors. It represents an incremental administrative process that is layered on top of an already complex Medicare Part B system. The more manual processes, reports, documents, interviews and visits that CMS integrates into this program, the more administratively burdensome it will be for all parties.

3) In order to reduce both a paperwork and administrative burden, we have provided recommendations in other sections of this document that urge the agency to adopt existing

accreditation standards, existing patient satisfaction tools, existing patient complaint and resolution processes and existing financial reports rather than attempt to "recreate the wheel."

4) Competitive bidding will add costs to both suppliers and especially CMS, in the form of increased staff and reporting procedures.

5) The projected savings associated with competitive bidding are overstated and have not been adjusted to adequately reflect the savings that Medicare began realizing from another section of the MMA in 2004 and will realize from the DRA, beginning in 2007.

I. Section 414.412 Submission of Bids Under the Competitive Bidding Program

In this section CMS provides an estimate of 70 hours per bid on each supplier's part. CMS arrived at this number by using the median of the hours that suppliers estimated they required during the two less complicated demonstration projects. We assume this is per location, which for Apria could represent quite an arduous task. We are unclear as to whether this 70-hour estimate includes time spent attending bidders' conferences and preparing internal analyses or simply the amount of time needed to complete the application process.

However, if one includes the time spent reviewing, analyzing and responding to the NPRM, Apria has invested over 250 hours of executive and mid-level management time on this portion of the program alone. At the local branch level, if it indeed takes 70 hours to complete the application process, and Apria has an estimated 25 branches impacted by the first round of competitive bidding in 2007, our company would need to invest 1750 hours in preparing bids.

II. Competitive Bidding Layers on Over $4.1 Million to Provider Cost Structures in 2006-2007, Escalates to $178 Million in 2007-2008

In regard to the total number of hours that suppliers would invest in 2006 in regard to the 2007 round of bidding, CMS' own estimate on page 142 of the Rule is that 1,158,150 hours would be needed by the industry (16,545 bids). If a conservative, fully-loaded $35 per hour average salary rate is used, this amounts to an incremental $41 million attributable to the first 10 CBAs alone. In 2008, this escalates dramatically to an incremental 5,100,550 hours needed to prepare 72,865 bids, which in turn computes to $178.5 million in supplier labor!! These costs have to be accounted for in the bids suppliers submit to Medicare.

We agree that the cost associated with the requirements pertaining to the accreditation program should not formally be included as part of the cost or burden for the competitive bidding program. However, there are numerous other incremental costs that we have described in individual sections of this document.

III. Recommendation

The proposed application process and certain provisions described in the rule appear to be too paper-intensive. CMS could save a significant amount of paperwork for itself and suppliers (and thereby, time), if it adopted the following recommendations:

1) Automate the supplier application process by making it Web-based. Allow an attachment feature for the financial reports and other supplemental information specified.

2) Automate the accreditation organization application process by making it Web-based. Allow an attachment feature.

3) The bid review team should start reviewing those bids that meet the quality and financial standards first before proceeding on to review the bid prices. Any supplier's bid package that does not meet these two standards would be eliminated from further review. This will eliminate a significant amount of time and paper that CMS would have to review.

4) Any multi-site provider that is owned by the same corporate parent or tied to the same tax ID# should be allowed to provide certain standard information only one time. Examples include a financial summary filed with the Securities and Exchange Commission (SEC), JCAHO accreditation report for a specific geographic area, list and background of corporate officers, etc.

5) Adopt a standardized Medicare patient satisfaction questionnaire for DMEPOS, such as that developed by the independent firm Press-Ganey Associates, to assess patient satisfaction with DMEPOS suppliers.

6) Keep the beneficiary and supplier education simple and low-cost.

7) Eliminate the brand-specific requirement and associated paperwork that is described in section "O."

8) Rather than requiring a separate application for every competitively-bid product category in a given MSA, consolidate the application form itself into a check-box format where the supplier would check (a) the products it is bidding on, and (b) the MSA it is bidding on. See example below:

9) Rather than creating an all-new government infrastructure that essentially duplicates what exists in the private sector (including senior risk plan oversight and management), we recommend that CMS consider subcontracting with several large managed care organizations to administer this program for Medicare beneficiaries nationwide. This checkbox format is also how the National Supplier Clearinghouse (NSC) has customized Apria's application process in order to reduce administrative burdens for both parties.

SAMPLE APPLICATION FORM CONTENT

Please check the box(es) next to each product category on which you are bidding in this MSA.

☐ Oxygen and oxygen equipment
☐ CPAP and CPAP supplies
☐ Wheelchairs
☐ Walkers

Please check the MSA(s) on which you are bidding via this application.

☐ Miami
☐ San Juan, Puerto Rico
☐ Dallas
Etc.

Are you bidding on the same products in all of the MSAs you have checked above?

☐Yes ☐No EXPLAIN_____

10) After a supplier has successfully completed round one of competitive bidding, it should only have to provide an attestation statement regarding its compliance with quality standards, financial standards, etc. and report any major changes that would impact its ability to participate in round 2, such as a change in ownership or some other large event. It should not have to complete an all-new application simply to participate in the second round of bidding in the exact same MSA.

IV. RESPONSE TO COMMENTS

Apria Healthcare has complied with CMS' deadline for submitting these comments. If any reader has any questions, feel free to contact the Apria executives below:

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Executive Vice President
Government Relations, Clinical Services,
Investor Services & Corporate Compliance Officer
Apria Healthcare
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Kimberlie Rogers-Bowers
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250 Technology Drive
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(724) 873-7804 Office
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SUMMARY

Competitive bidding for DMEPOS on a large-scale basis is a brand-new initiative for CMS. We believe that both the timeframe for implementation and the projected cost savings are overly aggressive and urge CMS to proceed with caution, using a phased-in approach to the program overall and certain elements contained therein. For example, the brand-specific requirement, as well as repair and maintenance of equipment that the contract supplier did not supply in the first place and other elements have never been studied or implemented before. These specific sections should be piloted in one MSA before expanding to the others in either 2007 or beyond.

Although two demonstration projects were performed, much has changed since the early part of this decade in terms of providers' total cost of caring for Medicare beneficiaries, policy changes implemented by CMS since the conclusion of the demonstrations and new legislation that has been passed since that time.

The negative impact caused by the MMA's reduced fee schedules for oxygen, nebulizers, wheelchairs, patient lifts, hospital beds and diabetic supplies, and the DRA of 2005, cannot be emphasized enough. The DRA in particular will have unintended, negative consequences on beneficiary access to care and new technology, which seem contrary to the goals publicly-stated by the Secretary. CMS has already harvested a significant amount of savings from the MMA's reduced fee schedule and more will accrue from the DRA. Therefore, the savings that remains to be gleaned from competitive bidding is not likely to be "significant" or "large" as the rule suggests. Too much remains unknown about how CMS plans to address the major gaps in service coverage that will be caused by the DRA's forced equipment ownership provisions. Fuel, labor, insurance, health benefits, licensure and other non-equipment costs have risen dramatically since the demonstration projects were implemented. These costs will have to be reflected in providers' bids for the program in 2007 and every subsequent bidding cycle.

Apria Healthcare has contracted with managed care organizations to provide a comprehensive array of DMEPOS products and services for over 20 years. If conducted correctly and in a truly competitive fashion, competitive bidding can indeed improve quality and consistency of service across a large patient population and geography, while delivering savings to the payor. We applaud CMS and Congress for adopting mandatory accreditation for DMEPOS suppliers, quality standards and other noble goals for the program. CMS' proposed plans for competitive bidding, however, do not reflect standard contracting procedures in this industry. This represents an unbelievable amount of work directed toward further reducing what amounts to less than 2% of the total Medicare budget.

We appreciate the opportunity to provide you with these comments and recommendations and welcome any additional questions you may have in the coming months as you review what will likely be a significant number of comments from individual stakeholders.

I look forward to seeing the Medicare DMEPOS Competitive Bidding Team at the next PAOC meeting and again want to reiterate that you and any member of the CMS team are invited to visit one of our branches in the greater Baltimore/Washington area or any part of the country.

Sincerely yours,

Lawrence M. Higby

Lawrence M. Higby
Chief Executive Officer

Attachments (Electronically and by Mail)

Appendix A – Letter from AAHomecare to Mr. Herb Kuhn with questions about the Deficit Reduction Act
Appendix B – Master List of all CPAP Products, by Brand

Cc: Herb Kuhn, CMS (Executive Summary Only)
Leslie Norwalk, CMS (Executive Summary Only)

V. REGULATORY IMPACT ANALYSIS
71 Fed. Reg. 25690-96.

ALSO COPY THIS SECTION TO:

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs,
Regulations Development and Issuances Group
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7500 Security Boulevard
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And

Office of Information and Regulatory Affairs
Office of Management and Budget
Room 10235, New Executive Office Building
Washington, DC 20503
Attn: Carolyn Lovett, CMS Desk Officer, carolyn_lovett@omb.eop.gov, Fax (202) 395-6974

Dear Mr. Parham and Ms. Lovett:

Thank you for the opportunity to provide comments on the Regulatory Impact Analysis (RIA) associated with the Notice of Proposed Rule Making (NPRM) for the Medicare Part B DMEPOS Competitive Bidding Program. Apria Healthcare is the nation's largest provider of home respiratory services, medical equipment and home infusion, and our managed care contracting experience is extensive. We believe that experience provides us with expertise in the area of competitive bidding that is valuable as Medicare embarks on this program.

In addition, I am a member of the Professional Advisory Oversight Committee (PAOC) that was established by the Medicare Modernization Act of 2003 (MMA) in order to advise CMS on the implementation of the program. As such, I am very interested in providing you and your colleagues with concrete feedback, recommendations and suggestions for how this program should be implemented most efficiently and cost-effectively.

Under separate cover, we provided comprehensive comments on the entire NPRM and submitted them to the DMEPOS competitive bidding team as well as to Dr. McClellan. The purpose of this document is to provide our comments specifically as they relate to the RIA and the program's impact on numerous stakeholders.

We have organized our comments according to the order in which the applicable sections of the RIA were presented in the Proposed Rule. Due to the extensive nature of these comments, you may have questions about them as the bidding team reviews the document this summer. Feel free to contact the following Apria Healthcare employees who are leading our efforts on competitive bidding:

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A. Overall Impact

This section describes the intent of a Regulatory Impact Analysis (RIA) in terms of directing agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). It also references the fact that an RIA is required for any final rule that would have an annual effect on the economy of $100 million or more in any one year, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or communities.

CMS' own comments in this section indicate that until the product categories and markets are selected, potential savings, implementation costs, the number of affected suppliers and supplier bid costs all remain unknown. We again express our disappointment about the fact that after 18 months, CMS did not publish the product list or MSAs as part of the proposed rule.

COMMENTS

Timeline of Implementation Needs to be Refined and Published

The general timeline that CMS has set for competitive bidding is aggressive. When one considers the body of work that must be completed before even the first phase of the program begins (that of issuing the Request for Bids (RFBs)), one realizes that the timeline may be too aggressive. Consider that the following steps must be completed in the next few months alone:

- The final quality standards must be published, including product-specific ones that may be fraught with problems;
- The accreditation organizations must be selected and they must undergo the application and review process with CMS;
- CMS must finalize its plans for actually implementing the accreditation requirement of the program;

- The stabilization of the new DMEMACs such as National Heritage Insurance Company (NHIC) and Noridian Administrative Services, which as you may know, does not even take effect until October 2006. Neither one has ever processed DME claims.

- CMS must publish the interim final and final regulations;

- CMS must complete the proposed rule for the Deficit Reduction Act and project how it will interface with competitive bidding, and vice versa;

- The first 10 MSAs and product categories must be selected;

- The RFB package must be finalized and issued for the first 10 MSAs;

- CMS will need 72 FTEs to review the first round of bidding packages; and,

- A major beneficiary and supplier education process must ensue.

We Do Not Believe $100 Million in Savings Will Be Achieved in 2007/2008

The NPRM contained DMEPOS expenditures for 2003 and a list of the top MSAs' expenditures in that year. Since the data was for 2003, it did not reflect the reimbursement cuts (savings) that Medicare began realizing from the fee schedule reductions associated with the Federal Employee Health Benefits Program (FEHBP) in January 2005 for HME and April 2005 for oxygen. The oxygen reduction, for example, was over 10% and the reductions for individual HME line items ranged from 12% to 24%. Nebulizers, for example, were cut 18%.

Added to this, the Deficit Reduction Act will also deliver savings to the program. Apparently the Congressional Budget Office (CBO) scored the Act's provision at zero over five years, and we are unclear why, since oxygen savings begin to accrue in 2009. Meanwhile, the reimbursement structure for power wheelchairs and a few other product categories is undergoing a major change, which will result in savings to the program that cannot be attributed to competitive bidding.

Therefore, if one reviews the expenditures for the top 10 MSAs that will most likely be included in the 2007 round of bidding, the most likely product categories to be included and then accounts for the significant savings that have already been realized and applies a conservative rate of savings that might accrue from competitive bidding, the actual savings will not likely meet the defined goal of being "significant" or "large."

We urge the OMB and CMS actuaries to ensure that savings are not counted "twice." That is, savings which are generated from the DRA in 2007, 2008, 2009 and beyond should not be counted toward both the DRA and competitive bidding.

Negative Impact on Patients

We do believe that the competitive bidding program could have a negative impact on patient care, productivity, competition, jobs and public health, especially when it is viewed in conjunction with the Deficit Reduction Act's provisions related to oxygen and home medical equipment. While this document is likely requesting comment related solely to competitive bidding's impact on these areas, we have yet to see a proposed rule on how CMS plans to implement the DRA's requirements to force ownership of FDA-approved medical equipment on to patients who have not asked for such responsibility.

Patients will be impacted negatively in the following ways:

- Patient choice among providers in a community could be eliminated
- Patients who reach a rental cap and own their HME or oxygen equipment would have difficulty finding a provider to repair or service their equipment
- Due to the DRA, patients will not be able to access the non-equipment support services that are typically included in a monthly rental rate structure. They will own their equipment and therefore the fiduciary relationship between the supplier and the patient is severed.
- Patients will not be able to obtain new technology that might improve their condition once they own their medical equipment and oxygen equipment.
- Patients may have to obtain multiple DMEPOS products and services from multiple providers solely due to the convoluted bidding mechanism that has been proposed. This translates to multiple bills every month, multiple co-pays to be paid and more confusion.

CMS Already Has a Simpler Method Available to Reduce Fee Schedule Reductions

In addition, we believe that CMS has had the authority to effect fee schedule reductions in a much simpler, less paperwork-intensive and less administratively burdensome. It does not need to proceed with competitive bidding in order to achieve savings. This is an unbelievable amount of work directed toward less than 3% of the total Medicare budget. The Inherent Reasonableness (IR) authority already provides CMS with a much less costly method by which to study and reduce fee schedules and we therefore believe that the planned infrastructure for competitive bidding is essentially unnecessary. Although we generally disagreed with the MMA's provision to apply the median rate of FEHBP reimbursement levels to the very different Medicare program, such a process, if performed with an appropriate level of detailed research by an independent agency or research firm, could also provide CMS with a more simplified mechanism for adjusting payment levels.

It seems obvious that the Office of Management and Budget (OMB) and CMS' Office of Strategic Operations and Regulatory Affairs would want to see a side-by-side comparison of the cost/benefit analysis associated with Inherent Reasonableness versus competitive bidding. Has such a comparison been requested of CMS?

No Public Health and Safety Impact Analysis Yet Performed Re: DRA's Forced Equipment Ownership Provisions

Also, we have seen no public health and safety impact analysis associated with the DRA's forced equipment ownership provisions. Forced equipment ownership has never been piloted, studied or analyzed from any angle. No other payor in America has adopted such draconian measures as they relate to oxygen patients and those who require home medical equipment to remain at home instead of in an institution. We urge the Agency and the OMB to require that such a study be performed before proceeding with forced ownership, set to begin in February 2007 with certain HME items and then in 2009 for oxygen.

Flawed Assumption on DMEPOS Fee Schedule Inflation Rate Increases

CMS assumes that the Medicare DMEPOS fee schedule will increase at the rate of inflation for those years in which a statutory freeze has not been put in place by the MMA, and that total charges will increase at the same rate as Part A and Part B.

We do not agree with this assumption at all. The Medicare Part A increases are largely attributable to rate and utilization increases in inpatient hospitalization. Medicare Part B increases are almost exclusively attributable to physicians' rate increases and increased utilization of physicians' office services. Non-DME, non-home health nursing costs are the segments that are driving the huge increase in overall Medicare expenditures. Moreover, once CMS accounts for savings realized in 2004 and 2005, it will see that expenditures based on a base year of 2003 have resulted in flat to decreased spending in most of the key categories that are being considered for competitive bidding.

B. Anticipated Impacts

CMS Underestimates the Impact on Referral Agents

CMS indicates that although the workload of referral agents appeared to increase during implementation of the demonstration, it does not anticipate that competitive bidding will result in an appreciable, ongoing burden on referral agents.

We are unclear as to why CMS would draw this conclusion when the demonstration projects clearly showed that the burden on referral agents increased. Moreover, the Polk County MSA in particular is a relatively small market with clearly definable borders. Once competitive bidding takes place in larger markets, and if CMS proceeds with its plan to bid each product category individually, it will be very difficult for referral agents such as hospital discharge planners, physicians, physicians' office staff and case managers to keep the details of the program straight. For example, they may have to refer hospital beds to one of 20 suppliers, nebulizers to one of 15 different suppliers and oxygen to one of still 10 other suppliers. A patient who requires all three will pose an interesting challenge to the discharge planner who was used to calling one company to arrange for homecare services.

In addition, certain new provisions of competitive bidding that did not exist in the demonstration projects will also add to the administrative and cost burden of referral agents. The brand-specific product requirement that would require all-new paperwork from a physician's office rather than allowing the homecare provider to substitute another quality product of functional equivalence is one example. Another would be the confusion surrounding the philosophically-flawed rebate concept; referral agents could not possibly remember which suppliers offer the rebate, at what level and how to explain it to sick patients being discharged from the hospital.

In addition, CMS has suggested that it would selectively add zip codes, parishes and areas outside of the official MSA boundaries. Although we oppose such indiscriminate amendments to government-defined MSAs, if the plan were to proceed, it would result in massive confusion among referral agents who would be discharging patients.

We believe that OMB or another government agency, such as the Government Accountability Office (GAO) should perform a more concrete analysis of the increased burden on referral agents and assign a cost accordingly.

DMEPOS Suppliers to Be Impacted Most by Program

We agree with CMS' assertion that DMEPOS suppliers that provide at least one product category will be impacted most. However, CMS' data that suggests that approximately 90 percent of registered suppliers are considered small is flawed. Because this data was likely studied at the Medicare supplier number level and not at the tax ID # level, it implies that over 75% of Apria Healthcare's 500 locations meet the definition of a small business. The same would hold true for other large homecare providers, whether public or private.

Regardless of size, if an individual location were to lose its ability to participate in the Medicare program because of not winning a competitive bidding contract, that location would be impacted significantly. It would have to lay off employees, consider closing the facility in that community, consider selling to another provider, risk bankruptcy if Medicare is its primary source of revenue or make other difficult business decisions.

Therefore, we urge OMB to reassess the true impact on small businesses nationwide, since it appears that the number of businesses impacted may have been grossly, albeit inadvertently, overstated. OMB should utilize the tax ID # to determine the size of a given DMEPOS business.

Fixed Costs Required to Undergo the Bidding Process Also Are Relative to Size of Business

CMS asserts that the fixed costs required to undergo the bidding process may be a larger deterrent to small businesses than larger firms. Similar to accreditation survey fees and internal operating costs to prepare and maintain accreditation, we believe that the fixed costs associated with participating in competitive bidding are relative to the size of the business. Therefore, a $2 million provider with one location will spend substantially less money and time preparing for and participating in competitive bidding, while a $1 billion provider with multiple impacted locations will spend a higher amount that is still relative to the size of its business.

CMS' Own Estimates Suggest That by 2008, DMEPOS Suppliers Will Incur Direct Costs of $178 Million

The data that CMS provided in the sections related to paperwork requirements and the regulatory impact analysis regarding the amount of time it would take for the supplier industry to prepare bids for the 2008 round of bidding suggests that the total cost would be $178 million. This DOES exceed the $120 million per year that the Unfunded Mandates Reform Act (UMRA) addresses. CMS may believe that since suppliers can choose whether to submit a bid for the competitive bidding program and therefore collectively they may not cross the $120 million threshold of the UMRA, the reality is that the majority of small and medium suppliers of DMEPOS actually rely on Medicare revenues for a majority of their business. Even a few national providers rely heavily on Medicare, while Apria represents a more diversified payor base that includes managed care plans nationwide.

Accordingly, it is likely that few suppliers will sit on the sidelines and not participate in the program. Therefore, we urge the OMB to review the competitive bidding program's incremental and fixed costs placed on the industry in light of UMRA regulations.

CMS Offered No Detail on Resources Needed for Overseeing Program Operations

On p. 149 of the rule, CMS outlines the government contractors that would be impacted by the program. However, it offered only one cursory reference to a "...need to devote resources necessary for overseeing program operations."

This is very concerning to us because it is clear from the rule's provisions that CMS will need to incur a significant amount of expense attributable to program oversight. Examples of provisions that represent incremental costs to the program include:

- An estimated 72 full-time equivalents (FTEs) needed to review 16,500 bids in 2007 alone, escalating in 2008 when the number of impacted MSAs increases eightfold.
- The accreditation validation survey process – where CMS would employ a group of people to conduct redundant, random accreditation surveys that mirror what the professional accrediting organizations already know how to perform.
- Financial expertise/employees who have the right background to review bidding suppliers' adherence to the financial standards and who can make the right judgment call about financial performance
- Additional claims processors to handle the influx of questions, problems and issues associated with the brand-specific requirement
- CBICs layered on top of the DMERCs
- Additional Medicare ombudsmen to answer an increase in questions, complaints and problems associated with beneficiaries' confusion about the new program
- Resources to support beneficiary and supplier education, in the form of printed materials, direct mail and potentially other media
- Monitoring ongoing compliance with quality, financial and other standards throughout the life of the contract
- The additional staffing/auditors to ensure overall compliance with the contractual requirements of competitive bidding

None of these costs has been described by CMS to date, nor has CMS ever issued the costs associated with contracting with Research Triangle Institute (RTI), the Apt Group and other consultants; managing the Professional Advisory Oversight Committee (PAOC), and developing the operations framework, Request for Bids (RFBs) and administration of the CIBCs.

C. Implementation Costs

It is disappointing that CMS made no attempt to estimate bid solicitation and evaluation costs at this time. Using CMS' own data, we estimated that CMS will need 72 full-time equivalents (FTEs) to evaluate 16,500 bids in the 2007 bid cycle. At a conservative $50,000 per FTE (fully loaded, with fringe benefits included), this will cost CMS $3.6 million in incremental labor. The next round of bidding, in which 75,000 bids will be received, could cost CMS an incremental $16.2 million in labor.

Viewed in the context that competitive bidding may not generate $100 million in savings per year, that labor ratio, coupled with other operating costs of the program, will greatly erode the net savings that may be generated.

CMS also estimates the start-up costs to CMS and its contractors will include $1 million in immediate fixed costs for contractor startup and system changes for the initial phase. Again, we believe these costs are grossly understated and urge the OMB to require an update from CMS on the total costs of

implementing this program, an updated cost/benefit analysis and quarterly updates as program implementation continues.

CMS states that it will only incur bid solicitation and evaluation costs in the years in which competitive bidding is conducted. Even if one amortizes the almost $4 million in estimated bid costs for the first round and $16 for the next, that will cost between $1.3 and $5.5 million per year for CMS – numbers that do not correlate to the low estimates provided by CMS on page 149-150.

On page 150, CMS goes on to state that maintenance costs will include a "small staff to oversee the program," office costs for the staff, travel costs, three new Ombudsmen, education/outreach expenses, printed materials and overhead. CMS did not provide any detail on these costs and we respectfully ask that they be published in the final rule.

CMS believes that the time required to evaluate bids will be lower than in the demonstration, and ultimately depend on the number of suppliers that choose to submit bids. We believe that other factors will impact the amount of time needed, such as the number of counties served, the number of beneficiaries impacted, crossover into other states, etc.

Also, CMS plans to have the CBICs administer the bidding process. Since the CBICs have not yet been made public, we cannot comment on their individual experience in contracting for DMEPOS services. However, given their newness to the Medicare Part B program, it is likely that they will need to spend more time per bid than the reviewers did in the two demonstration, at least initially.

D. Program Savings

On page 151, CMS once again states that it "estimates large savings" from the competitive bidding program. Yet, it does not define "large" and it does not account for savings already "in the bank" due to the MMA and in the future due to the DRA. Quoting savings ranges from nine to 30% and an average of 20 percent is misguided since so many things have changed since the early part of the decade (Refer to comments found in the section entitled "Paperwork Requirements.") If the MMA had not contained the FEHBP fee schedule cuts and if the DRA had never been passed, such a starting point might be appropriate, even though meanwhile, providers' costs have risen as well. That is not the case – savings of well over 10% have already been realized and therefore the projected savings, especially netted against the same-sized fixed infrastructure needed for the program, will not be "large" despite CMS' assumption that they will still achieve the same net savings levels as though the FEHBP and other cuts had never taken place.

In addition, Medicare's own data, found in a table on page 151, shows that nebulizer drugs accounted for 22% of the total savings in the San Antonio demonstration market. As you may know, inhalation drugs were addressed through separate reimbursement cuts associated with the MMA and have experienced a reduction of well over 50% since 2004. They are also statutorily excluded from being included in competitive bidding, so again the potential savings associated with competitive bidding has been reduced.

CMS' chart on page 152 reinforces our assertion under an earlier section regarding the Unfunded Mandates Reform Act (UMRA) that this program must be reviewed in light of UMRA since it does not begin to achieve savings over that level until 2009.

"Spillover Effect" From Competitive Bidding Onto the Medicare Advantage Program

In its fiscal year presentation of savings data, CMS states that it expects lower prices for DME products in the fee-for-service (FFS) program will lead to lower prices in the Medicare Advantage market. It states that most managed care plan rates are linked to FFS expenditures

While historically this may have been true, in recent years, most managed care contracts have converted from a "Medicare-minus" pricing methodology to a fixed fee schedule methodology. This is due to the fact that private plans operate differently than Medicare in terms of guaranteed market share, different medical coverage policies (for example, private health plans cover a full range of home infusion therapy services, while Medicare does not) and because suppliers' costs increase for fuel, labor, etc., may fluctuate over time. We speak from extensive managed care contracting experience on this issue.

Frankly, we are shocked that CMS would attempt to credit savings in Medicare Advantage (Medicare Part C) toward the DMEPOS expenditures reimbursed by Medicare Part B. This is a new variable in the total cost/benefit analysis and we again urge OMB to evaluate the Part B competitive bidding infrastructure costs and potential savings in their own "silo." When the home infusion industry conducted an independent study that proved that significant savings would be realized under Medicare Part A if only the home infusion benefit were structured correctly under Medicare Part B, it was advised that the agency does not look at savings in that manner. They stated that our study merely showed an increase in Part B spending and that they could not claim savings from Part A.

E. Effect on Beneficiaries

In general we agree that if done correctly, beneficiaries should have access to suppliers and experience more consistent quality throughout any given market. However, CMS uses another term it doesn't define – "showed minimal adverse results" – and we need to know how it defines "adverse."

To reinforce another point made numerous times throughout this document, the Deficit Reduction Act changes the entire situation for patients, referral agents and providers. Until CMS addresses the DRA's impact on beneficiaries both on its own and as it ties into the competitive bidding program, it would be reckless to assume that beneficiaries will experience "minimal adverse results." Regardless, it is too broad to say that there will be "no negative impacts on beneficiary access..." A very personal relationship develops between a beneficiary and homecare provider over time. If the beneficiary's provider is not selected through the competitive bidding process and chooses not to grandfather, a very disruptive and stressful experience could ensue for the beneficiary. If the beneficiary has to obtain three different products from three different suppliers in the future, that will also cause confusion and increased paperwork for people who are frail and elderly.

The MMA's requirement concerning mandatory accreditation for DMEPOS suppliers by 2010 already provides a platform by which beneficiaries would receive increased or consistent quality services and products. CMS seems to be crediting the competitive bidding program with that goal when in fact it is already covered in a separate provision of the MMA.

Regarding beneficiary co-insurance savings, we again ask the OMB to calculate the savings that will already result from the changes in capped rental payments as mandated by the DRA. On page 154, CMS shows beneficiary co-insurance savings levels that are likely overstated since the DRA will already capture a certain amount. An updated table is needed.

F. Effect on Suppliers

CMS lists three primary impacts of the competitive bidding program on suppliers. In addition to the three, we add the following:

- Contract suppliers may incur additional labor and other operating costs associated with meeting product-specific quality standards. Since they are not yet published, we can only assume that they will result in higher costs.

- Contract suppliers will incur costs to transition patients and ramp up capacity via new capital expenditures, facility expansions, additional staff and overhead.

- Accreditation fees and preparatory costs will be incremental for non-accredited suppliers.

- An increase in referral agent frustration with the new administrative burden could have a spillover effect on suppliers who also care for non-Medicare patients.

CMS confirms that "because [it does] not know [whether suppliers will increase or decrease volume], the net effect on an individual contract supplier's revenue is uncertain prior to bidding.

This is a primary reason why we believe that the GAO, MedPAC or another independent agency should conduct a thorough review of the 2007 competitive bidding program before proceeding in 2009. Two demonstration markets in two relatively uncomplicated areas of the country do not provide either the agency or the industry with enough information to predict what will happen to suppliers once the program is scaled up substantially. We believe that the 2007 program should be thoroughly analyzed in terms of its impact on all stakeholders and the savings actually, not theoretically delivered, before proceeding with the additional 80 markets.

1. Affected Suppliers

In this section, CMS estimates that 50 percent of bidding supplier will be selected as winners. It states that there will be 8272 contract suppliers in the CBAs that CMS initially designates. It also assumes that if a supplier submitted a bid in multiple product categories, its probability of winning would increase.

We are concerned about a few of these assumptions. First, the business has changed dramatically since the demonstration projects were conducted. The cost of fuel, labor, insurance, certain new technology has risen, while HME and oxygen have been subjected to a CPI-U freeze for most of the years.

Medicare has changed its coverage policies for several key product categories that may be included in competitive bidding, such as mobility assistive equipment (MAEs) such as walkers, canes and wheelchairs; respiratory assist devices (RADs) and CPAPs. MAEs in particular represent extensive policy and documentation changes that took effect in 2005. In addition, the MMA and DRA both affected suppliers outside of the competitive bidding provisions, as in the case of inhalation drugs, the reimbursement structure for which has undergone a massive transformation in the past three years.

In addition, numerous suppliers are no longer in business. At Apria alone, we acquired over 40 small or medium providers in 2004 and 2005.

This is the first reference that CMS makes to selecting 50 percent of the suppliers that bid. Yet, in another section of the rule, CMS states that it must select two or more suppliers and purposefully stated that it would not select a predetermined number of suppliers but rather, capacity would be the key. Using

CMS' 8272 number, that translates to 827 contracted suppliers per each of the 10 initial MSAs. The 44,705 contract suppliers projected for 2008, based on 70 additional MSAs, translates to a net of 36,400 suppliers per 80 markets, or 455 contracted suppliers per market.

We simply do not understand why CMS would contract with that many suppliers in a given MSA if it is expecting to achieve any level of savings. Perhaps we misunderstood how this number was derived; if, for example, the 8272 counts the same supplier multiple times if it bids on multiple products, that may account for it.

Obviously, more clarification is needed.

CMS uses Bureau of Labor Statistics (BLS) data to estimate the average hourly wage for an accountant and auditor. Given the importance of competitive bidding to a supplier's overall livelihood, it is likely that a higher-salaried employee or team of employees will be responsible for preparing the company's bids. Our earlier estimate used $35 per hour is on the conservatively low end, and that translates to provider costs of $41 million in the first year and $178 million in the next round.

The number of suppliers per CBA is really not as relevant as the size of those suppliers. In recent years, a significant number of acquisitions took place in the DMEPOS market. We estimate that by buying 40 companies in a two-year period of time, over 300 Medicare supplier numbers were eliminated by consolidating those sites into our own. Other major acquirers of the past few years include Lincare, OmniCare and certain integrated healthcare systems.

2. Small Suppliers

Again we urge both CMS and the SBA to re-review their definition of a "small supplier." Because CMS must have used supplier number data rather than tax ID number data, Apria actually owns and operates over 400 "small supplier" locations that generate less than $6 million per year. The same would hold true for all of the major public companies which collectively only account for about 40% of the total DMEPOS market in the United States (all payors).

The team needs to derive a method for looking at supplier size by tax ID # and also must realize that many suppliers may be much larger in size and capacity if they serve non-Medicare patients whose revenue does not appear on any Medicare report.

We find Medicare's equation involving the cost of bidding expressed as a share of Medicare revenue to be odd and irrelevant.

Regarding how CMS considered minimizing the burden of competitive bidding on small businesses, we have already expressed our comments about networking. We want to reinforce that any network should be formally organized in a legal manner, that the network's members must meet all applicable Medicare supplier standards, be accredited, meet the quality standards and those related to financial performance and compliance. The latter topic may be more important in a network scenario than the quality standards, since a network of providers who all operate individually could lend itself to inconsistent sales practices, inducements or kickbacks.

We agree that CMS should not exempt small suppliers from the requirement that a contract supplier must service an entire CBA. Doing so could lend itself to the "cherry-picking" phenomenon described in an earlier section and cause confusion among referral agents and patients.

We agree that CMS should not allow a small supplier to submit a bid and then decide after the bidding whether or not they would accept the new competitive bidding single payment amounts. This would represent a significant "workaround" to the standardized bid submission and review process. Managed care would never allow such an exception, and we appreciate that Medicare recognizes this too.

G. Accounting Statement

In the final section of the Regulatory Impact Analysis, CMS presents a table in which it provides an "Accounting Statement – Classification of Estimated Expenditures, from FY 2007 to FY 2011." Since there was little explanation surrounding this table, we offer the following questions and comments:

1) Does the $570.3 million in savings double-count savings already effected by the MMA/FEHBP and the DRA? If yes, the savings are overstated.

2) Using $570.3 million over five years, that translates to $114 million per year.

3) Does the $570.3 million include earlier-referenced "spillover" savings attributed to the Medicare Advantage program? If yes, this is overstated.

4) CMS will incur well over $10 million per year to implement the program, and suppliers, by 2007, will expend $178 million simply preparing bids, excluding other program-related costs.

5) How does the $570.3 million compare to the original CBO score that was used as a basis for including the provision in the MMA?

6) Has CMS accounted for any delay in the implementation schedule in these numbers?

Summary

We appreciate the effort that CMS made in estimating the regulatory impact and cost/benefits associated with competitive bidding. Given the concurrent reimbursement cuts that have occurred in the past few years, we understand that it is challenging to develop certain estimates that reflect future savings and costs directly attributable to this program.

However, given the length of time that CMS staff has had to develop the proposed rule and all of its various provisions, we are disappointed in the lack of detail in the Regulatory Impact Analysis. As a large supplier that has already invested a significant amount of management and executive time in reviewing the NPRM and preparing comprehensive comments, we believe that CMS has:

1) Underestimated suppliers' total costs of participating in competitive bidding

2) Underestimated CMS' start-up costs for the program

3) Underestimated CMS' ongoing program maintenance, monitoring costs and those associated with the CBICs, DMERCs, new Ombudsmen, etc.

4) Overestimated the number of small suppliers by counting large companies' individual locations that generate less than $3 million per year in Medicare revenues

5) Overestimated the number of suppliers that will be contracted in each area

6) Not accounted for numerous Medicare policy changes that will further erode the savings originally estimated for this program

7) Not accounted for the large increase in providers' costs for fuel, labor, insurance and other expenses since the demonstration projects were conducted

8) Not accounted for a much more complex program than what was implemented in San Antonio and Polk County, and, ultimately,

9) Overestimated the total savings that will result from the program

We appreciate the opportunity to provide these comments on the Paperwork Requirements and the Regulatory Impact Analysis directly to the Office of Management and Budget and the Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group of CMS.

If you have any questions, please contact one of the Apria representatives listed in the opening section of these comments.

Sincerely,

Lawrence M. Higby

Lawrence M. Higby
Chief Executive Officer
Apria Healthcare

Appendix A

Letter from the American Association for Homecare (AAHomecare) to Herb Kuhn, CMS on April 20, 2006, regarding implementation questions associated with the Deficit Reduction Act of 2005 (DRA)

(See PDF File)

Appendix B

Master List of Continuous Positive Airway Pressure (CPAP) Medical Devices and Masks Associated with Treating Obstructive Sleep Apnea (OSA)

EXAMPLE OF FLAWS WITH BRAND-SPECIFIC REQUIREMENTS OF PROPOSED RULE

Note how many unique manufacturers' products are linked to the single HCPCS code EO601

Ops Class	HCPC	Category	Vendor Name	Model No	Product Description
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC231JHU	CPAP UNIT HC231 CONVERTIBLE
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC232JHU	CPAP UNIT HC232 CONVERTIBLE
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC233JHU	CPAP UNIT HC233JHU W/HEATED HUMIDIFIER
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC234JHU	CPAP UNIT HC234JHU W/HEATED HUMIDIFIER
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	9000D	CPAP UNIT NASAL SYSTEM HORIZON
248	E0601	CPAP UNIT	RESPIRONICS INC	1017453	CPAP UNIT REMSTAR AUTO W/CFLEX
248	E0601	CPAP UNIT	RESPIRONICS INC	1005960	CPAP UNIT REMSTAR PLUS
248	E0601	CPAP UNIT	RESPIRONICS INC	1009586	CPAP UNIT REMSTAR PLUS W/C FLEX
248	E0601	CPAP UNIT	RESPIRONICS INC	1012668	CPAP UNIT REMSTAR PLUS W/HTD HUMIDIFIER
248	E0601	CPAP UNIT	RESPIRONICS INC	1020923	CPAP UNIT REMSTAR PRO II W/C-FLEX
248	E0601	CPAP UNIT	RESMED INC	14307	CPAP UNIT
248	E0601	CPAP UNIT	RESMED INC	20000102	CPAP UNIT
248	E0601	CPAP UNIT	RESMED INC	90000103	CPAP UNIT
248	E0601	CPAP UNIT	RESMED INC	14314	CPAP UNIT SULLIVAN III W/ SMART START
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	9001D	CPAP UNIT 9001
248	E0601	CPAP UNIT	RESMED INC	14009	CPAP UNIT APD 2 FLOW GENERATOR
248	E0601	CPAP UNIT	RESPIRONICS INC	532034	CPAP UNIT ARIA
248	E0601	CPAP UNIT	RESPIRONICS INC	622094	CPAP UNIT ARIA LX
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	Y-GK418ANA	CPAP UNIT AUTO GOODNIGHT 418A
248	E0601	CPAP UNIT	RESMED INC	30001	CPAP UNIT AUTO SET SPIRIT
248	E0601	CPAP UNIT	RESMED INC	30034	CPAP UNIT AUTOSET RESPOND
248	E0601	CPAP UNIT	RESPIRONICS INC	30245	CPAP UNIT CLINICAL
248	E0601	CPAP UNIT	VIASYS	9258	CPAP UNIT CLINICAL NIGHTBIRD
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC200-JHU-KL	CPAP UNIT COMB HEAT HUMIDIFIER W/CASE
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	126826	CPAP UNIT COMPANION 314
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	126828	CPAP UNIT COMPANION 314 W/METER
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	126804	CPAP UNIT COMPANION 318
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	126800	CPAP UNIT COMPANION 318 W/ CASE
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	418	CPAP UNIT COMPANION 418
248	E0601	CPAP UNIT	RESPIRONICS INC	40001	CPAP UNIT CPAP-200 120V
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	9054D	CPAP UNIT DEVILBISS AUTO ADJUST
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	Y-GK418S-NA	CPAP UNIT GOOD KNIGHT S RECORD
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	S-126831-00	CPAP UNIT GOODKNIGHT 318
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	S-126844-00	CPAP UNIT GOODKNIGHT 418
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	418G	CPAP UNIT GOODKNIGHT 418G W/COMPL MNTR
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	Y-GK420ENA	CPAP UNIT GOODKNIGHT 420E
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	Y-GK420GUS	CPAP UNIT GOODKNIGHT 420G
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	Y-GK420S-NA	CPAP UNIT GOODKNIGHT 420S
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	Y-420EH20	CPAP UNIT GOODKNIGHT F/HEATED HUMIDIFIER
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	126831-01	CPAP UNIT GOODNIGHT 318 PLUS
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	126831-00	CPAP UNIT GOODNIGHT 318 PLUS W/METER
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	Y-GK418PNA	CPAP UNIT GOODNIGHT 418P
248	E0601	CPAP UNIT	MALLINCKRODT INC	Y-GK420GUS	CPAP UNIT GOODNIGHT 420
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC201JHU	CPAP UNIT HC201 W/HEATED HUMIDIFIER
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC211JHU	CPAP UNIT HC211 CONVERTIBLE
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC220JHU	CPAP UNIT HC220 W/HEATED HUMIDIFIER
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC221JHU	CPAP UNIT HC221 W/HEATED HUMIDIFIER
248	E0601	CPAP UNIT	RESPIRONICS INC	7001	CPAP UNIT HOME SYSTEM
248	E0601	CPAP UNIT	RESPIRONICS INC	7000	CPAP UNIT HOME SYSTEM
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	7353D	CPAP UNIT HORIZON
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	7354D	CPAP UNIT HORIZON AUTO ADJ
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	8054B	CPAP UNIT HORIZON AUTO ADJUST
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC200	CPAP UNIT NASAL
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	7352D	CPAP UNIT NASAL
248	E0601	CPAP UNIT	MOUNTAIN MEDICAL EQUIP	411-001-801	CPAP UNIT NASAL
248	E0601	CPAP UNIT	RESPIRONICS INC	307400	CPAP UNIT NASAL
248	E0601	CPAP UNIT	RESMED INC	14105	CPAP UNIT NASAL APD2S
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	8000-RD	CPAP UNIT NASAL SYSTEM HORIZON
248	E0601	CPAP UNIT	RESPIRONICS INC	7100-10	CPAP UNIT NASAL W/O CASE
248	E0601	CPAP UNIT	RESMED INC	14006	CPAP UNIT NASAL W/O MASK
248	E0601	CPAP UNIT	VIASYS	9460	CPAP UNIT NIGHT BIRD
248	E0601	CPAP UNIT	INVACARE CORPORATION	ISP9800	CPAP UNIT POLARIS
248	E0601	CPAP UNIT	RESPIRONICS INC	367580	CPAP UNIT RELIANCE CHOICE

Ops Class	HCPC	Category	Vendor Name	Model No	Product Description
248	E0601	CPAP UNIT	EVO MEDICAL SOLUTIONS	C2002	CPAP UNIT REMREST W/CORD
248	E0601	CPAP UNIT	RESPIRONICS INC	367100	CPAP UNIT REMSTAR
248	E0601	CPAP UNIT	RESPIRONICS INC	1018547	CPAP UNIT REMSTAR
248	E0601	CPAP UNIT	RESPIRONICS INC	1007381	CPAP UNIT REMSTAR AUTO
248	E0601	CPAP UNIT	RESPIRONICS INC	367500	CPAP UNIT REMSTAR CHOICE
248	E0601	CPAP UNIT	RESPIRONICS INC	367575	CPAP UNIT REMSTAR CHOICE EXPRESS
248	E0601	CPAP UNIT	RESPIRONICS INC	367550	CPAP UNIT REMSTAR CHOICE LS
248	E0601	CPAP UNIT	RESPIRONICS INC	367200	CPAP UNIT REMSTAR CSA APPROVED
248	E0601	CPAP UNIT	RESPIRONICS INC	1012657	CPAP UNIT REMSTAR LITE W/CARRYING CASE
248	E0601	CPAP UNIT	RESPIRONICS INC	1000920	CPAP UNIT REMSTAR LX
248	E0601	CPAP UNIT	RESPIRONICS INC	DS100	CPAP UNIT REMSTAR M SERIES
248	E0601	CPAP UNIT	RESPIRONICS INC	DS100H	CPAP UNIT REMSTAR M SERIES W/HH
248	E0601	CPAP UNIT	RESPIRONICS INC	DS200S	CPAP UNIT REMSTAR PLUS C-FLEX W/CARD
248	E0601	CPAP UNIT	RESPIRONICS INC	DS200	CPAP UNIT REMSTAR PLUS C-FLEX W/O CARD
248	E0601	CPAP UNIT	RESPIRONICS INC	1000921	CPAP UNIT REMSTAR PLUS LX
248	E0601	CPAP UNIT	RESPIRONICS INC	1005961	CPAP UNIT REMSTAR PRO W/C-FLEX
248	E0601	CPAP UNIT	RESMED INC	21104	CPAP UNIT RESMED S6 ELITE
248	E0601	CPAP UNIT	RESMED INC	21102	CPAP UNIT RESMED S6 LTWT
248	E0601	CPAP UNIT	RESMED INC	21101	CPAP UNIT RESMED S6 LTWT W/HOUR METER
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	7351D	CPAP UNIT REVITALIZER
248	E0601	CPAP UNIT	RESMED INC	21127	CPAP UNIT S6 LTWT II W/HOUR METER
248	E0601	CPAP UNIT	RESMED INC	30002	CPAP UNIT S7 ELITE
248	E0601	CPAP UNIT	RESMED INC	30011	CPAP UNIT S7 LTWT W/HR MTR& ALTITUDE ADJ
248	E0601	CPAP UNIT	RESMED INC	33112	CPAP UNIT S8 AUTOSET VANTAGE F/APAP
248	E0601	CPAP UNIT	RESMED INC	33021	CPAP UNIT S8 ELITE
248	E0601	CPAP UNIT	RESMED INC	33007	CPAP UNIT S8 ESCAPE
248	E0601	CPAP UNIT	RESPIRONICS INC	307600	CPAP UNIT SLEEPEZE III
248	E0601	CPAP UNIT	RESPIRONICS INC	622206	CPAP UNIT SOLO LX
248	E0601	CPAP UNIT	RESPIRONICS INC	622207	CPAP UNIT SOLO LX W/METER
248	E0601	CPAP UNIT	RESPIRONICS INC	622209	CPAP UNIT SOLO PLUS LX
248	E0601	CPAP UNIT	RESPIRONICS INC	622043	CPAP UNIT SOLO PLUS W/TIMEMETER
248	E0601	CPAP UNIT	RESPIRONICS INC	622002	CPAP UNIT SOLO W/ACSRY KIT/MASK
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC210JHU	CPAP UNIT STD W/HOUR METER & 6' HOSE
248	E0601	CPAP UNIT	RESMED INC	17102	CPAP UNIT SULLIVAN AUTOSET T
248	E0601	CPAP UNIT	RESMED INC	14316	CPAP UNIT SULLIVAN IIID
248	E0601	CPAP UNIT	RESMED INC	21001	CPAP UNIT SULLIVAN V
248	E0601	CPAP UNIT	RESMED INC	21009	CPAP UNIT SULLIVAN V ELITE
248	E0601	CPAP UNIT	RESMED INC	21042	CPAP UNIT SULLIVAN V HM
248	E0601	CPAP UNIT	RESMED INC	21005	CPAP UNIT SULLIVAN V PLUS
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC604JHU	CPAP UNIT THERMOSTART W/HEATED HUMIDIFIE
248	E0601	CPAP UNIT	RESPIRONICS INC	7410	CPAP UNIT TRANQUILITY AUTO
248	E0601	CPAP UNIT	RESPIRONICS INC	7200-10	CPAP UNIT TRANQUILITY MP-R
248	E0601	CPAP UNIT	RESPIRONICS INC	7100	CPAP UNIT TRANQUILITY PLUS
248	E0601	CPAP UNIT	RESPIRONICS INC	7400	CPAP UNIT TRANQUILITY PLUS
248	E0601	CPAP UNIT	RESPIRONICS INC	7100MH	CPAP UNIT TRANQUILITY PLUS W/MASK/HEADGR
248	E0601	CPAP UNIT	RESPIRONICS INC	7300HE	CPAP UNIT TRANQUILITY QUEST
248	E0601	CPAP UNIT	RESPIRONICS INC	7300	CPAP UNIT TRANQUILITY QUEST
248	E0601	CPAP UNIT	RESPIRONICS INC	7300HMH	CPAP UNIT TRANQUILITY QUEST CMPLT W/MTR
248	E0601	CPAP UNIT	RESPIRONICS INC	7300MH	CPAP UNIT TRANQUILITY QUEST COMPLETE
248	E0601	CPAP UNIT	RESPIRONICS INC	7300H	CPAP UNIT TRANQUILITY QUEST W/HOUR METER
248	E0601	CPAP UNIT	RESPIRONICS INC	7300E	CPAP UNIT TRANQUILITY QUEST W/HVY TUBING
248	E0601	CPAP UNIT	RESPIRONICS INC	7300HL	CPAP UNIT TRANQUILITY QUEST W/METER
248	E0601	CPAP UNIT	RESPIRONICS INC	7300L	CPAP UNIT TRANQUILITY QUEST W/O CASE
248	E0601	CPAP UNIT	RESPIRONICS INC	7202-20	CPAP UNIT TRANQUILITY W/ 10" HOSE/METER
248	E0601	CPAP UNIT	RESPIRONICS INC	622093	CPAP UNIT VIRTUOSO LX
248	E0601	CPAP UNIT	RESPIRONICS INC	532326	CPAP UNIT VIRTUOSO T SMART
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	9001D-HH	CPAP UNIT W/HEATED HUMIDIFIER
249	E0601	CPAP UNIT	REDLINE HEALTHCARE	AC1005960	CPAP UNIT REMSTAR PLUS CIGNA ONLY
252	A7030	FULL FACE MASK	RESPIRONICS INC	302433	CPAP KIT FULL FACE
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	HC431A	CPAP KIT FULL FACE FLEXFIT HC431
252	A7030	FULL FACE MASK	FISHER & PAYKEL HEALTHCARE INC	HC431A	CPAP KIT FULL FACE FLEXFIT HC431
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	302433	CPAP KIT FULL FACE RES
252	A7030	FULL FACE MASK	RESMED INC	16670	CPAP KIT MIRAGE FULLFACE LG SHLW SER II
252	A7030	FULL FACE MASK	RESMED INC	16666	CPAP KIT MIRAGE FULLFACE SM SHLW SER II
252	A7030	FULL FACE MASK	RESMED INC	60604	CPAP KIT ULTRA MIRAGE FULL LG STD
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	60604	CPAP KIT ULTRA MIRAGE FULL LG STD RMD
252	A7030	FULL FACE MASK	RESMED INC	60603	CPAP KIT ULTRA MIRAGE FULL MED SHLW
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	60603	CPAP KIT ULTRA MIRAGE FULL MED SHLW RMD
252	A7030	FULL FACE MASK	RESMED INC	60602	CPAP KIT ULTRA MIRAGE FULL MED STD
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	60602	CPAP KIT ULTRA MIRAGE FULL MED STD RMD
252	A7030	FULL FACE MASK	RESMED INC	60600	CPAP KIT ULTRA MIRAGE FULL SM STD
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	60600	CPAP KIT ULTRA MIRAGE FULL SM STD RMD
252	A7030	FULL FACE MASK	RESPIRONICS INC	1010870	CPAP MASK COMFORT FULL FACE LG
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	1010870	CPAP MASK COMFORT FULL FACE LG RES
252	A7030	FULL FACE MASK	RESPIRONICS INC	1010869	CPAP MASK COMFORT FULL FACE MED
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	1010869	CPAP MASK COMFORT FULL FACE MED RES
252	A7030	FULL FACE MASK	RESPIRONICS INC	1010868	CPAP MASK COMFORT FULL FACE SM
252	A7030	FULL FACE MASK	RESPIRONICS INC	452036	CPAP MASK FULL FACE DISP MED

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252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452036	CPAP MASK FULL FACE DISP MED RES
252	A7030	FULL FACE MASK	RESPIRONICS INC	452034	CPAP MASK FULL FACE DISP SM
252	A7030	FULL FACE MASK	RESPIRONICS INC	452038	CPAP MASK FULL FACE LG DISP
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452038	CPAP MASK FULL FACE LG DISP RES
252	A7030	FULL FACE MASK	RESPIRONICS INC	452037	CPAP MASK FULL FACE LG REUSE
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452037	CPAP MASK FULL FACE LG REUSE
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452035	CPAP MASK FULL FACE MED REUSE
252	A7030	FULL FACE MASK	RESPIRONICS INC	452035	CPAP MASK FULL FACE MED REUSE
252	A7030	FULL FACE MASK	RESPIRONICS INC	452032	CPAP MASK FULL FACE PETITE DISP
252	A7030	FULL FACE MASK	RESPIRONICS INC	452031	CPAP MASK FULL FACE PETITE REUSE
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452033	CPAP MASK FULL FACE SM REUSE
252	A7030	FULL FACE MASK	RESPIRONICS INC	452033	CPAP MASK FULL FACE SM REUSE
252	A7030	FULL FACE MASK	RESMED INC	16630	CPAP KIT MIRAGE FULL FACE LG
252	A7030	FULL FACE MASK	RESMED INC	16669	CPAP KIT MIRAGE FULL FACE LG
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16669	CPAP KIT MIRAGE FULL FACE LG
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16669	CPAP KIT MIRAGE FULL FACE LG II RES
252	A7030	FULL FACE MASK	RESMED INC	16629	CPAP KIT MIRAGE FULL FACE MED NO REORDER
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16629	CPAP KIT MIRAGE FULL FACE MED NO REORDER
252	A7030	FULL FACE MASK	RESMED INC	16668	CPAP KIT MIRAGE FULL FACE MED SHLW SERII
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16668	CPAP KIT MIRAGE FULL FACE MED SHLW SERII
252	A7030	FULL FACE MASK	RESMED INC	16628	CPAP KIT MIRAGE FULL FACE SM
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16628	CPAP KIT MIRAGE FULL FACE SM
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16665	CPAP KIT MIRAGE FULL FACE SM SER II RES
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16665	CPAP KIT MIRAGE FULL FACE SM SER II RES
252	A7030	FULL FACE MASK	RESMED INC	16667	CPAP KIT MIRAGE FULL FACE STD MED SER II
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16667	CPAP KIT MIRAGE FULL FACE STD MED SER II
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16667	CPAP KIT MIRAGE FULL FACE STD MED SER II
252	A7030	FULL FACE MASK	RESMED INC	16665	CPAP KIT MIRAGE FULL FACE STD SM SER II
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16670	CPAP KIT MIRAGE FULLFACE LG SHLW SER II
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16666	CPAP KIT MIRAGE FULLFACE SM SHLW SER II
252	A7030	FULL FACE MASK	RESMED INC	60605	CPAP KIT ULTRA MIRAGE FULL LG SHLW
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	60605	CPAP KIT ULTRA MIRAGE FULL LG SHLW RMD
252	A7030	FULL FACE MASK	RESMED INC	60601	CPAP KIT ULTRA MIRAGE FULL SM SHLW
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	60601	CPAP KIT ULTRA MIRAGE FULL SM SHLW RMD
252	A7030	FULL FACE MASK	SUNRISE MEDICAL HHG INC	113237	CPAP MASK FULL FACE LG
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452037	CPAP MASK FULL FACE LG REUSE
252	A7030	FULL FACE MASK	SUNRISE MEDICAL HHG INC	113238	CPAP MASK FULL FACE MED
252	A7030	FULL FACE MASK	HANS RUDOLPH INC	113304	CPAP MASK FULL FACE PETITE F/7600
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452035	CPAP MASK FULL FACE REUSE MED
252	A7030	FULL FACE MASK	CARDINAL HEALTH	16707	CPAP MASK FULL FACE SM
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452033	CPAP MASK FULL FACE SM REUSE
252	A7030	FULL FACE MASK	RESPIRONICS INC	1012572	CPAP/BIPAP MASK PERFORMANCE FULL LG DISP
252	A7030	FULL FACE MASK	RESPIRONICS INC	1012624	CPAP/BIPAP MASK PERFORMANCE FULL MED DIS
252	A7030	FULL FACE MASK	RESMED INC	M02B014	MASK BUBBLE KIT
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1030493	CPAP KIT COMFORT LITE 2 W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1030495	CPAP KIT COMFORT LITE 2 W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1007931	CPAP KIT COMFORT SELECT SM WIDE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1025112	CPAP KIT COMFORTLITE 2 COMBO
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1030494	CPAP KIT COMFORTLITE 2 SM/MED W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1014913	CPAP KIT COMFORTLITE S,M,L W/HDGR & SMPL
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	HC481A	CPAP KIT INFINITY 481 W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	HC481A	CPAP KIT INFINITY 481 W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	RESMED INC	16549	CPAP KIT LG ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16549	CPAP KIT LG ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	RESMED INC	60505	CPAP KIT MIRAGE SWIFT NASAL PILLOW
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	60505	CPAP KIT MIRAGE SWIFT NASAL PILLOW RMD
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	LG305	CPAP KIT NASAL AIRE II LG
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	MD303	CPAP KIT NASAL AIRE II MED
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	SM302	CPAP KIT NASAL AIRE II SM
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	XL306	CPAP KIT NASAL AIRE II XLG
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	XS301	CPAP KIT NASAL AIRE II XSM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16550	CPAP KIT SHALLOW ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	RESMED INC	16550	CPAP KIT SHALLOW ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002759	CPAP KIT SIMPLICITY MED W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002759	CPAP KIT SIMPLICITY MED W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002757	CPAP KIT SIMPLICITY SM W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002757	CPAP KIT SIMPLICITY SM W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	RESMED INC	16548	CPAP KIT STD ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16548	CPAP KIT STD ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1007965	CPAP MASK COMFORT CLASSIC MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1007965	CPAP MASK COMFORT CLASSIC MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1007966	CPAP MASK COMFORT CLASSIC SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1007966	CPAP MASK COMFORT CLASSIC SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1007932	CPAP MASK COMFORT SELECT MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1007932	CPAP MASK COMFORT SELECT MED RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1007933	CPAP MASK COMFORT SELECT SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1007933	CPAP MASK COMFORT SELECT SM RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1007934	CPAP MASK COMFORT SELECT SM WIDE

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252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1014916	CPAP MASK COMFORTLITE COMBO S, M, W/O HE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1004215	CPAP MASK CONTOUR DELUXE MED NO REORDER
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16560	CPAP MASK FRAME ULTRA MIRAGE ONE SZ RMD
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302356	CPAP MASK GEL GOLD SEAL LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302356	CPAP MASK GEL GOLD SEAL LG RES
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302354	CPAP MASK GEL GOLD SEAL MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302354	CPAP MASK GEL GOLD SEAL MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302355	CPAP MASK GEL GOLD SEAL MED WIDE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302355	CPAP MASK GEL GOLD SEAL MED WIDE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302353	CPAP MASK GEL GOLD SEAL MED/SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302353	CPAP MASK GEL GOLD SEAL MED/SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302352	CPAP MASK GEL GOLD SEAL SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302352	CPAP MASK GEL GOLD SEAL SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302357	CPAP MASK GEL LARGE/NARROW GOLD SEAL
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302351	CPAP MASK GEL PETITE GOLD SEAL
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1004213	CPAP MASK LG-NO RE ORDER
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1010641	CPAP MASK NASAL COMFORT GEL LG
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1010640	CPAP MASK NASAL COMFORT GEL MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1010640	CPAP MASK NASAL COMFORT GEL MED RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1010518	CPAP MASK NASAL COMFORT GEL PET
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1010519	CPAP MASK NASAL COMFORT GEL SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1010519	CPAP MASK NASAL COMFORT GEL SM RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302188	CPAP MASK NASAL LG REUSE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302188	CPAP MASK NASAL LG REUSE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302218	CPAP MASK NASAL LG/NRW REUSE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302218	CPAP MASK NASAL LG/NRW REUSE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	312103	CPAP MASK NASAL MED DISP
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302180	CPAP MASK NASAL MED REUSE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302180	CPAP MASK NASAL MED REUSE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302186	CPAP MASK NASAL MED/SM REUSE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302186	CPAP MASK NASAL MED/SM REUSE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302183	CPAP MASK NASAL MED/WIDE REUSE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302183	CPAP MASK NASAL MED/WIDE REUSE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302219	CPAP MASK NASAL PETITE REUSE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302219	CPAP MASK NASAL PETITE REUSE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302187	CPAP MASK NASAL SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302279	CPAP MASK NASAL SM CHLD REUSE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	312102	CPAP MASK NASAL SM DISP W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302187	CPAP MASK NASAL SM REUSE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002373	CPAP MASK PROFILE LITE LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002373	CPAP MASK PROFILE LITE LG RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002374	CPAP MASK PROFILE LITE LG/NARROW
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002374	CPAP MASK PROFILE LITE LG/NARROW RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002371	CPAP MASK PROFILE LITE MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002371	CPAP MASK PROFILE LITE MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002370	CPAP MASK PROFILE LITE MED/SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002370	CPAP MASK PROFILE LITE MED/SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002372	CPAP MASK PROFILE LITE MED/WIDE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002372	CPAP MASK PROFILE LITE MED/WIDE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002849	CPAP MASK PROFILE LITE PETITE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002849	CPAP MASK PROFILE LITE PETITE RES
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002850	CPAP MASK PROFILE LITE SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002850	CPAP MASK PROFILE LITE SM
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-232101-00B	CPAP MASK SHELL NARROW W/O THERMISTOR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	S-232101-00B	CPAP MASK SHELL NARROW W/O THERMISTOR NP
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-231700-00B	CPAP MASK SHELL W/O PRESSURE TAP
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	S-231700-00B	CPAP MASK SHELL W/O PRESSURE TAP
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1004217	CPAP MASK SM- NO RE ORDER
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7030-20	CPAP MASK SOFT SERIES LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7030-20	CPAP MASK SOFT SERIES LG
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7035-20	CPAP MASK SOFT SERIES LG NARROW
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7035-20	CPAP MASK SOFT SERIES LG NARROW RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7020-20	CPAP MASK SOFT SERIES MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7020-20	CPAP MASK SOFT SERIES MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7025-20	CPAP MASK SOFT SERIES MED NARROW
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7025-20	CPAP MASK SOFT SERIES MED NARROW
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7022-20	CPAP MASK SOFT SERIES MED/WIDE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7022-20	CPAP MASK SOFT SERIES MED/WIDE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7010-20	CPAP MASK SOFT SERIES SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7010-20	CPAP MASK SOFT SERIES SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1019185	CPAP KIT COMFORT CURVE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1026880	CPAP KIT COMFORT SELECT SM,MED SM/WD
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1026880	CPAP KIT COMFORT SELECT SM,MED SM/WD
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1016691	CPAP KIT CONTOUR DELUX W/HDGR MD/LG 5/PK
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	NPMD103	CPAP KIT FREESTYLE NASAL PAP MED
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	NPSM101	CPAP KIT FREESTYLE NASAL PAP SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16549	CPAP KIT LG ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	RESMED INC	60101	CPAP KIT MASK ACTIVA LG

Ops Class	HCPC	Category	Vendor Name	Model No	Product Description
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	60101	CPAP KIT MASK ACTIVA LG RMD
252	A7034	NASAL INTERFACE MASK	RESMED INC	60102	CPAP KIT MASK ACTIVA SHALLOW
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	60102	CPAP KIT MASK ACTIVA SHALLOW RMD
252	A7034	NASAL INTERFACE MASK	RESMED INC	60100	CPAP KIT MASK ACTIVA STD
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	60100	CPAP KIT MASK ACTIVA STD RMD
252	A7034	NASAL INTERFACE MASK	SLEEPNET	50739	CPAP KIT MASK NASAL IQ W/HOLEY HEADGEAR
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	669132	CPAP KIT MASK SM 7600
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16501	CPAP KIT MIRAGE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16501	CPAP KIT MIRAGE
252	A7034	NASAL INTERFACE MASK	RESMED INC	16501	CPAP KIT MIRAGE
252	A7034	NASAL INTERFACE MASK	RESMED INC	16502	CPAP KIT MIRAGE LARGE NO REORDER
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16502	CPAP KIT MIRAGE LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16502	CPAP KIT MIRAGE LG
252	A7034	NASAL INTERFACE MASK	RESMED INC	16537	CPAP KIT MIRAGE SHALLOW
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16537	CPAP KIT MIRAGE SHALLOW RMD
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	MP304	CPAP KIT NASAL AIR II MED PLUS
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	MP304	CPAP KIT NASAL AIR II MED PLUS
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	LG305	CPAP KIT NASAL AIRE II LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	MD303	CPAP KIT NASAL AIRE II MED
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	PA401	CPAP KIT NASAL AIRE II PETITE PA
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	PB402	CPAP KIT NASAL AIRE II PETITE PB
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	PC403	CPAP KIT NASAL AIRE II PETITE PC
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	PD404	CPAP KIT NASAL AIRE II PETITE PD
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	PE405	CPAP KIT NASAL AIRE II PETITE PE
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	K2A	CPAP KIT NASAL AIRE II PT SET UP XS-XL
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	SM302	CPAP KIT NASAL AIRE II SM
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-102444-00	CPAP KIT NASAL AIRWAY ASSY W/O NASAL PIL
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	NPLG105	CPAP KIT NASAL PAP FREESTYLE LG
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	NPMP104	CPAP KIT NASAL PAP FREESTYLE MED PLUS
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	NPM5102	CPAP KIT NASAL PAP FREESTYLE MED SM
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	NPXL105	CPAP KIT NASAL PAP FREESTYLE XLG
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS3033	CPAP KIT NASAL SNAPP MED
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS3022	CPAP KIT NASAL SNAPP SM
252	A7034	NASAL INTERFACE MASK	THE AFTERMARKET GROUP	WM25830	CPAP KIT NASAL SOMNOPLUS W/HEADGEAR LG
252	A7034	NASAL INTERFACE MASK	THE AFTERMARKET GROUP	WM25820	CPAP KIT NASAL SOMNOPLUS W/HEADGEAR MED
252	A7034	NASAL INTERFACE MASK	THE AFTERMARKET GROUP	WM25810	CPAP KIT NASAL SOMNOPLUS W/HEADGEAR SM
252	A7034	NASAL INTERFACE MASK	SENSORMEDICS CORP	467077	CPAP KIT NASAL W/HEADGEAR SPIRITUS MED
252	A7034	NASAL INTERFACE MASK	SENSORMEDICS CORP	467148	CPAP KIT NASAL W/HEADGEAR SPIRITUS SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	LG1001	CPAP KIT PM NASAL AIRE LG
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	LG1001	CPAP KIT PM NASAL AIRE LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	MD1002	CPAP KIT PM NASAL AIRE MED
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	MD1002	CPAP KIT PM NASAL AIRE MED
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	SM1003	CPAP KIT PM NASAL AIRE SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	SM1003	CPAP KIT PM NASAL AIRE SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	XL1000	CPAP KIT PM NASAL AIRE XLG
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	XL1000	CPAP KIT PM NASAL AIRE XLG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	XS1004	CPAP KIT PM NASAL AIRE XSM
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	XS1004	CPAP KIT PM NASAL AIRE XSM
252	A7034	NASAL INTERFACE MASK	RESMED INC	60201	CPAP KIT PROTEGE LG
252	A7034	NASAL INTERFACE MASK	SUNRISE MEDICAL HHG INC	9352D	CPAP KIT SERENITY
252	A7034	NASAL INTERFACE MASK	SUNRISE MEDICAL HHG INC	9352G	CPAP KIT SERENITY GEL
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16550	CPAP KIT SHALLOW ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002759	CPAP KIT SIMPLICITY MED W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002757	CPAP KIT SIMPLICITY SM W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16548	CPAP KIT STD ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	RESMED INC	60001	CPAP KIT VISTA DEEP
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	60001	CPAP KIT VISTA DEEP RMD
252	A7034	NASAL INTERFACE MASK	RESMED INC	60000	CPAP KIT VISTA STD W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	60000	CPAP KIT VISTA STD W/HEADGEAR RMD
252	A7034	NASAL INTERFACE MASK	RESMED INC	60930	CPAP KIT VISTA W/DEEP CUSH W/O HEADGEAR
252	A7034	NASAL INTERFACE MASK	RESMED INC	60929	CPAP KIT VISTA W/STD CUSH W/O HEADGEAR
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	776239	CPAP MASK
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	900HC402	CPAP MASK ACLAIM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	900HC402	CPAP MASK ACLAIM FISHER & PAYKEL
252	A7034	NASAL INTERFACE MASK	RESMED INC	BB35	CPAP MASK ADULT SM BUBBLE CUSH SERIES 3
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-2540	CPAP MASK ADVANTAGE HUSH LG
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-2520	CPAP MASK ADVANTAGE HUSH SM
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-2530	CPAP MASK ADVANTAGE REG
252	A7034	NASAL INTERFACE MASK	RESMED INC	16302	CPAP MASK ASSY
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	211009	CPAP MASK ASSY NASAL W/STRAP LG
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	211007	CPAP MASK ASSY W/SWIVEL PORT SM
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	211118	CPAP MASK ASSY W/VFOAM HEADGEAR SM
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	400HC505	CPAP MASK BASE INFINITY 481
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	400HC505	CPAP MASK BASE INFINITY 481
252	A7034	NASAL INTERFACE MASK	RESMED INC	16010	CPAP MASK BUBBLE MED
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-133331-00	CPAP MASK BUBBLE SYSTEM
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-133332-00	CPAP MASK BUBBLE SYSTEM LG
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-133330-00B	CPAP MASK BUBBLE SYSTEM MED

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252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1007965	CPAP MASK COMFORT CLASSIC MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1007966	CPAP MASK COMFORT CLASSIC SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1025121	CPAP MASK COMFORT LITE 2 W/O HDGR
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1014919	CPAP MASK COMFORTLITE S,M,L W/O HDGR
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-616462-00	CPAP MASK CUSH BUBBLE
252	A7034	NASAL INTERFACE MASK	RESMED INC	M02B923	CPAP MASK CUSH LG FLAT BUBBLE
252	A7034	NASAL INTERFACE MASK	VITAL SIGNS INC	9002	CPAP MASK DOWNS
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-102617-00	CPAP MASK DREAMSEAL ASSY
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-103076-00A	CPAP MASK DREAMSEAL NASAL AIRWAY SHALLOW
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	400HC510	CPAP MASK FLEXIFIT F/HC406
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	400HC510	CPAP MASK FLEXIFIT F/HC406
252	A7034	NASAL INTERFACE MASK	RESMED INC	16089	CPAP MASK FRAME KIT MODULAR
252	A7034	NASAL INTERFACE MASK	RESMED INC	16728	CPAP MASK FRAME ULTRA MIRAGE LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302354	CPAP MASK GEL GOLD SEAL MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302353	CPAP MASK GEL GOLD SEAL MED/SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302355	CPAP MASK GEL GOLD SEAL MED/WIDE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302376	CPAP MASK GEL LARGE/NARROW
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302375	CPAP MASK GEL LG
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302373	CPAP MASK GEL MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302374	CPAP MASK GEL MED WIDE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302372	CPAP MASK GEL MED/SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302370	CPAP MASK GEL PETITE
252	A7034	NASAL INTERFACE MASK	INVACARE CORPORATION	IQ50160S	CPAP MASK GEL SLEEPNET IQ
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302371	CPAP MASK GEL SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302352	CPAP MASK GEL SM GOLD SEAL
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1010871	CPAP MASK IMAGE III W/HEADGEAR LG
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	776257	CPAP MASK INERFACE
252	A7034	NASAL INTERFACE MASK	RESMED INC	16723	CPAP MASK INTERFACE FULL MED STD RPLCMNT
252	A7034	NASAL INTERFACE MASK	AG INDUSTRIES	AG100371	CPAP MASK INTERFACE MED/LG F/AURA
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-3040ADJ	CPAP MASK INTERFACE SNAPP W/HEADGEAR LG
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-3030ADJ	CPAP MASK INTERFACE SNAPP W/HEADGEAR MED
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-3020ADJ	CPAP MASK INTERFACE SNAPP W/HEADGEAR SM
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	DF301	CPAP MASK INTERFACE W/LG DREAM SEAL
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	DF303	CPAP MASK INTERFACE W/SMALL DREAM SEAL
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	DF302	CPAP MASK INTERFACE W/STNRD DREAM SEAL
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-800	CPAP MASK IQ GEL ONE SIZE
252	A7034	NASAL INTERFACE MASK	SUNRISE MEDICAL HHG INC	7351D-670	CPAP MASK LG
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7030-10	CPAP MASK LG
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	669130	CPAP MASK LG 7600
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7035-10	CPAP MASK LG NARROW
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302218-DISC	CPAP MASK LG NARROW
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	6938	CPAP MASK LOW BRIDGE SEAL LG
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	069370	CPAP MASK LOW LG
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	776239-05-DISC	CPAP MASK MED
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-133338-00	CPAP MASK MED
252	A7034	NASAL INTERFACE MASK	AIRSEP CORP	MS001-3	CPAP MASK MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7020-10	CPAP MASK MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1004849	CPAP MASK MED DO NOT ORDER HOSP ONLY
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7025-10	CPAP MASK MED NARROW
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7025-10	CPAP MASK MED NARROW HLT
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	133338	CPAP MASK MED NPB
252	A7034	NASAL INTERFACE MASK	AIRSEP CORP	MS001-2	CPAP MASK MED REMEDY
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7020-10	CPAP MASK MED RESP
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7022-10	CPAP MASK MED WIDE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7022-10	CPAP MASK MED WIDE HLT
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	572003	CPAP MASK MINI MONARCH
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	572004	CPAP MASK MINI MONARCH
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	572022	CPAP MASK MONARCH ULTRA W/O PORT
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	572026	CPAP MASK MONARCH ULTRA W/PORT
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-133335-00	CPAP MASK NARROW SOFT SM
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-232102-00B	CPAP MASK NARROW W/THERMISTOR PORT
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	LG2001	CPAP MASK NASAL AIRE BASIC LG
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	MD2002	CPAP MASK NASAL AIRE BASIC MED
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	SM2003	CPAP MASK NASAL AIRE BASIC SM
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	XL2000	CPAP MASK NASAL AIRE BASIC XL
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	XS2004	CPAP MASK NASAL AIRE BASIC XS
252	A7034	NASAL INTERFACE MASK	SYSTEMS 2000, INC	VF86040L	CPAP MASK NASAL COMFO-SEAL
252	A7034	NASAL INTERFACE MASK	RESMED INC	M02B948	CPAP MASK NASAL CUSH SM
252	A7034	NASAL INTERFACE MASK	RESMED INC	M02B937	CPAP MASK NASAL CUSHION MED
252	A7034	NASAL INTERFACE MASK	SUNRISE MEDICAL HHG INC	9353D	CPAP MASK NASAL FLEXAIRE DEVILBISS
252	A7034	NASAL INTERFACE MASK	VIASYS	776780	CPAP MASK NASAL INTERFACE LYRA
252	A7034	NASAL INTERFACE MASK	SLEEPNET	50160	CPAP MASK NASAL IQ
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	312104	CPAP MASK NASAL LG DISP
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302188	CPAP MASK NASAL LG REUSE RES
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302218	CPAP MASK NASAL LG/NRW REUSE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	312103	CPAP MASK NASAL MED DISP
252	A7034	NASAL INTERFACE MASK	SENSORMEDICS CORP	467078	CPAP MASK NASAL MED PLUS SPIRITUS
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302180	CPAP MASK NASAL MED REUSE RES

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252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	312105	CPAP MASK NASAL MED/SM DISP
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302186	CPAP MASK NASAL MED/SM REUSE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	312124	CPAP MASK NASAL MED/WIDE DISP
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302047	CPAP MASK NASAL MED/WIDE REUSE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302183	CPAP MASK NASAL MED/WIDE REUSE RES
252	A7034	NASAL INTERFACE MASK	SLEEPNET	50220	CPAP MASK NASAL MINI ME
252	A7034	NASAL INTERFACE MASK	CARDINAL HEALTH	60404	CPAP MASK NASAL NON VENTED ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	312122	CPAP MASK NASAL PETITE DISP
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302219	CPAP MASK NASAL PETITE REUSE RES
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302187	CPAP MASK NASAL SM REUSE RES
252	A7034	NASAL INTERFACE MASK	SENSORMEDICS CORP	467081	CPAP MASK NASAL SPIRITUS LG
252	A7034	NASAL INTERFACE MASK	INVACARE CORPORATION	ISP2000L	CPAP MASK NASAL W/HEADGEAR TWLIGHT LG
252	A7034	NASAL INTERFACE MASK	INVACARE CORPORATION	ISP2000	CPAP MASK NASAL W/HEADGEAR TWLIGHT ST
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	400HC503	CPAP MASK NASAL W/O HEADGEAR
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	400HC502	CPAP MASK NASAL W/O HEADGEAR
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	211067	CPAP MASK NASAL W/O HEADGEAR ALIZES LG
252	A7034	NASAL INTERFACE MASK	ROSCOE MEDICAL INC	CPAP-NPTUB	CPAP MASK NOSE INTERFACE
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	900HC406	CPAP MASK ONLY FLEXIFIT SERIES
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	900HC406	CPAP MASK ONLY FLEXIFIT SERIES F&P
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7015-10	CPAP MASK PED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7015-20	CPAP MASK PED SOFT SERIES
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	669134	CPAP MASK PETITE 7600
252	A7034	NASAL INTERFACE MASK	SLEEPNET	50215	CPAP MASK PETITE MINI ME W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	SLEEPNET	50402	CPAP MASK PHANTOM
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-700	CPAP MASK PHANTOM GEL ONE SIZE
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	232101	CPAP MASK PILLOW STEEL NARROW
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-101699-00	CPAP MASK PLENUM ASSY W/O PRESSURE TAP
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1001527-DISC	CPAP MASK PROFILE LARGE NARROW
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1001526-DISC	CPAP MASK PROFILE LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002371	CPAP MASK PROFILE LITE MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002370	CPAP MASK PROFILE LITE MED/SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002372	CPAP MASK PROFILE LITE MED/WIDE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002850	CPAP MASK PROFILE LITE SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1006322	CPAP MASK PROFILE LITE SM W/O EXHAL VALV
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1001524-DISC	CPAP MASK PROFILE MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1001525-DISC	CPAP MASK PROFILE MED WIDE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1001523-DISC	CPAP MASK PROFILE MED/SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1001521-DISC	CPAP MASK PROFILE PETITE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1001522-DISC	CPAP MASK PROFILE SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302187 A	CPAP MASK REORDER M124878
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	900HC432	CPAP MASK SEAL KIT MED/LG
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	900HC431	CPAP MASK SEAL KIT SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	S-232101-00B	CPAP MASK SHELL NARROW W/O THERMISTOR NP
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	S-231700-00B	CPAP MASK SHELL W/O PRESSURE TAP
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-231701-00B	CPAP MASK SHELL W/PRESSURE TAP
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-102637-00	CPAP MASK SHELL W/PRESSURE TAP
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-133336-00	CPAP MASK SM
252	A7034	NASAL INTERFACE MASK	AIRSEP CORP	MS001-1	CPAP MASK SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7010-10	CPAP MASK SM
252	A7034	NASAL INTERFACE MASK	SUNRISE MEDICAL HHG INC	7351D-668	CPAP MASK SM
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-133329-00	CPAP MASK SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	133336	CPAP MASK SM NPB
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7010-20	CPAP MASK SM SOFT SERIES
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-133337-00	CPAP MASK SM WIDE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	133337	CPAP MASK SM/WIDE NPB
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7030-20	CPAP MASK SOFT SERIES LG RESP
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7020-20	CPAP MASK SOFT SERIES MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7022-20	CPAP MASK SOFT SERIES MED/WIDE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7035-20	CPAP MASK SOFT SERIES NARROW LG RESP
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	6-949	CPAP MASK SOFTWEAR 3 PT HEADSTRAP
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06941	CPAP MASK SOFTWEAR LG HIGH BRIDGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	6942	CPAP MASK SOFTWEAR LG HIGH BRIDGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06-937	CPAP MASK SOFTWEAR LG LOW BRIDGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06-933 DISC USE M127398	CPAP MASK SOFTWEAR MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06-933	CPAP MASK SOFTWEAR MED HIGH BRIDGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06929	CPAP MASK SOFTWEAR MED LOW BRIDGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06930	CPAP MASK SOFTWEAR MED LOW BRIDGE SEAL
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06925	CPAP MASK SOFTWEAR SM HIGH BRIDGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06-926	CPAP MASK SOFTWEAR SM HIGH BRIDGE SEAL
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	6-945	CPAP MASK SOFTWEAR W/ HEADSTRAP
252	A7034	NASAL INTERFACE MASK	RESMED INC	16004	CPAP MASK SULLIVAN CHILD BUBBLE SYSTEM
252	A7034	NASAL INTERFACE MASK	RESMED INC	60200	CPAP MASK SYSTEM PROTEGE STD REUSE SILCN
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	211008	CPAP MASK SZ MED HANS
252	A7034	NASAL INTERFACE MASK	RESMED INC	16577	CPAP MASK ULTRA MIRAGE SHALLOW /WIDE
252	A7034	NASAL INTERFACE MASK	RESMED INC	60622	CPAP MASK ULTRA MIRAGE STD N/HEADGEAR
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-233339-00	CPAP MASK ULTRA SOFTFIT MED WIDE
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-233337-00	CPAP MASK ULTRA SOFTFIT SM WIDE

Ops Class	HCPC	Category	Vendor Name	Model No	Product Description
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1025194	CPAP MASK W/O CUSH COMFORTLITE2
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-102622-00	CPAP MASK W/O DREAMSEAL
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	669133	CPAP MASK XSM 7600
252	A7044	ORAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	HC452A	CPAP KIT ORACLE 452
252	A7044	ORAL INTERFACE MASK	REDLINE HEALTHCARE	HC452A	CPAP KIT ORACLE 452 FISHER & PAYKEL
252	A7044	ORAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	HC451A	CPAP KIT ORACLE
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	S-133293-00B	CPAP KIT ADAMS CIRCUIT
252	A9999	CPAP KIT	REDLINE HEALTHCARE	S-133293-00B	CPAP KIT ADAMS CIRCUIT NPB
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-00	CPAP KIT BREEZE SM/MED/LG
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-101400-00	CPAP KIT BREEZE SM/MED/LG PILLOW
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1007963	CPAP KIT COMFORT CLASSIC W/ HEADGEAR SM
252	A9999	CPAP KIT	RESPIRONICS INC	1007964	CPAP KIT COMFORT CLASSIC W/HEADGEAR MED
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1007964	CPAP KIT COMFORT CLASSIC W/HEADGEAR MED
252	A9999	CPAP KIT	RESPIRONICS INC	1007963	CPAP KIT COMFORT CLASSIC W/HEADGEAR SM
252	A9999	CPAP KIT	RESPIRONICS INC	1004950	CPAP KIT COMFORT FULL W/HDGR LG
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1004950	CPAP KIT COMFORT FULL W/HDGR LG RES
252	A9999	CPAP KIT	RESPIRONICS INC	1004872	CPAP KIT COMFORT FULL W/HDGR MED
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1004872	CPAP KIT COMFORT FULL W/HDGR MED RES
252	A9999	CPAP KIT	RESPIRONICS INC	1004880	CPAP KIT COMFORT FULL W/HDGR SM
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1004880	CPAP KIT COMFORT FULL W/HDGR SM RES
252	A9999	CPAP KIT	RESPIRONICS INC	1014905	CPAP KIT COMFORT LITE S,M,4,5
252	A9999	CPAP KIT	RESPIRONICS INC	1007919	CPAP KIT COMFORT SELECT MED
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1007919	CPAP KIT COMFORT SELECT MED RES
252	A9999	CPAP KIT	RESPIRONICS INC	1007930	CPAP KIT COMFORT SELECT SM
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1007930	CPAP KIT COMFORT SELECT SM RES
252	A9999	CPAP KIT	RESPIRONICS INC	1007931	CPAP KIT COMFORT SELECT SM WIDE
252	A9999	CPAP KIT	RESPIRONICS INC	1014907	CPAP KIT COMFORTLITE W/HDGR & DRCT SEAL
252	A9999	CPAP KIT	FISHER & PAYKEL HEALTHCARE INC	HC407A	CPAP KIT FLEXFIT NASAL HC407
252	A9999	CPAP KIT	REDLINE HEALTHCARE	HC407A	CPAP KIT FLEXFIT NASAL HC407 FISHER&PAY
252	A9999	CPAP KIT	FISHER & PAYKEL HEALTHCARE INC	HC405A	CPAP KIT MASK FLEXIFIT
252	A9999	CPAP KIT	REDLINE HEALTHCARE	HC405A	CPAP KIT MASK FLEXIFIT FISHER PAYKEL
252	A9999	CPAP KIT	RESPIRONICS INC	1009043	CPAP KIT NASAL COMFORT GEL W/HDGR LG
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1009043	CPAP KIT NASAL COMFORT GEL W/HDGR LG RES
252	A9999	CPAP KIT	RESPIRONICS INC	1009042	CPAP KIT NASAL COMFORT GEL W/HDGR MED
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1009042	CPAP KIT NASAL COMFORT GEL W/HDGR MED RE
252	A9999	CPAP KIT	RESPIRONICS INC	1009040	CPAP KIT NASAL COMFORT GEL W/HDGR PET
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1009040	CPAP KIT NASAL COMFORT GEL W/HDGR PT RES
252	A9999	CPAP KIT	RESPIRONICS INC	1009041	CPAP KIT NASAL COMFORT GEL W/HDGR SM
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1009041	CPAP KIT NASAL COMFORT GEL W/HDGR SM RES
252	A9999	CPAP KIT	RESPIRONICS INC	1004087	CPAP KIT PROFILE LITE W/ HEADGEAR SM
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1004089	CPAP KIT PROFILE LITE W/HDGR MED RES
252	A9999	CPAP KIT	RESPIRONICS INC	1004111	CPAP KIT PROFILE LITE W/HEADGEAR LG
252	A9999	CPAP KIT	RESPIRONICS INC	1004112	CPAP KIT PROFILE LITE W/HEADGEAR LGNRW
252	A9999	CPAP KIT	RESPIRONICS INC	1004110	CPAP KIT PROFILE LITE W/HEADGEAR MDWIDE
252	A9999	CPAP KIT	RESPIRONICS INC	1004089	CPAP KIT PROFILE LITE W/HEADGEAR MED
252	A9999	CPAP KIT	RESPIRONICS INC	1004088	CPAP KIT PROFILE LITE W/HEADGEAR MED,SM
252	A9999	CPAP KIT	RESPIRONICS INC	1004086	CPAP KIT PROFILE LITE W/HEADGEAR PETITE
252	A9999	CPAP KIT	FISHER & PAYKEL HEALTHCARE INC	HC401A	CPAP KIT W/HEADGEAR ACLAIM
252	A9999	CPAP KIT	REDLINE HEALTHCARE	HC401A	CPAP KIT W/HEADGEAR ACLAIM F&P
252	A9999	CPAP MASK	RESPIRONICS INC	1014906	CPAP MASK NASAL CMFRT LITE SZ5,6,M,L,COM
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-100874-00	CPAP KIT ADAM CIRCUIT W/HEADGEAR LG
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	S-133294-00B	CPAP KIT ADAMS CIRCUIT
252	A9999	CPAP KIT	REDLINE HEALTHCARE	S-133293-00	CPAP KIT ADAMS CIRCUIT NPB
252	A9999	CPAP KIT	RESMED INC	16534	CPAP KIT ASSY F/FOREHEAD
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-102616-00	CPAP KIT BREEZE DREAMSEAL
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-103059-00A	CPAP KIT BREEZE DREAMSEAL LG
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-102616-00	CPAP KIT BREEZE DREAMSEAL MAL
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-102616-00	CPAP KIT BREEZE DREAMSEAL NPB
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-103074-00A	CPAP KIT BREEZE DREAMSEAL SHALLOW
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-101400-L	CPAP KIT BREEZE LG
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-L	CPAP KIT BREEZE LG NPB
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-L	CPAP KIT BREEZE LG NPB
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-L	CPAP KIT BREEZE LG NPB 2/PR
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-101400-	CPAP KIT BREEZE MED
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-101400-M	CPAP KIT BREEZE MED
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-00	CPAP KIT BREEZE MED & LG PILLOW
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-M	CPAP KIT BREEZE MED NPB
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-00	CPAP KIT BREEZE MED/LG PILLOW MAL
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-101400-S	CPAP KIT BREEZE SM
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-S	CPAP KIT BREEZE SM NPB
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400.00	CPAP KIT BREEZE SM/MED/LG
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-101400-XL	CPAP KIT BREEZE XLG
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1007964	CPAP KIT COMFORT CLASIC W/HEADGEAR MED
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1007963	CPAP KIT COMFORT CLASIC W/HEADGEAR SM
252	A9999	CPAP KIT	RESPIRONICS INC	1001652	CPAP KIT CONTOUR DELUXE LARGE
252	A9999	CPAP KIT	RESPIRONICS INC	1002146	CPAP KIT CONTOUR DELUXE SM
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1001652	CPAP KIT CONTOUR DLX LG
252	A9999	CPAP KIT	RESPIRONICS INC	1002148	CPAP KIT CONTOUR DLX MED

Ops Class	HCPC	Category	Vendor Name	Model No	Product Description
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1002148	CPAP KIT CONTOUR DLX MED RES
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1002146	CPAP KIT CONTOUR DLX SM RES
252	A9999	CPAP KIT	REDLINE HEALTHCARE	HC406A	CPAP KIT FLEXIFIT NASAL PETITE FPH
252	A9999	CPAP KIT	FISHER & PAYKEL HEALTHCARE INC	HC406A	CPAP KIT FLEXIFIT NASAL PETITE HC406A
252	A9999	CPAP KIT	SUNRISE MEDICAL HHG INC	9354G	CPAP KIT FLEXSET W/HEADGEAR GEL
252	A9999	CPAP KIT	SUNRISE MEDICAL HHG INC	9354GS	CPAP KIT FLEXSET W/HEADGEAR GEL SHALLOW
252	A9999	CPAP KIT	SUNRISE MEDICAL HHG INC	9354S	CPAP KIT FLEXSET W/HEADGEAR SHALLOW
252	A9999	CPAP KIT	SUNRISE MEDICAL HHG INC	9354D	CPAP KIT FLEXSET W/HEADGEAR STD
252	A9999	CPAP KIT	RESMED INC	60928	CPAP KIT FRAME ONLY VISTA
252	A9999	CPAP KIT	HUDSON RESPIRATORY CARE INC	NPXS100	CPAP KIT FREESTYLE NASAL PAP XS
252	A9999	CPAP KIT	SUNRISE MEDICAL HHG INC	113241	CPAP KIT MASK FULL FACE PETITE
252	A9999	CPAP KIT	SUNRISE MEDICAL HHG INC	113239	CPAP KIT MASK FULL FACE SM
252	A9999	CPAP KIT	SUNRISE MEDICAL HHG INC	113240	CPAP KIT MASK FULL FACE XSM 7600
252	A9999	CPAP KIT	RESMED INC	16530	CPAP KIT MIRAGE AUTOSET
252	A9999	CPAP KIT	SLEEPNET	50410	CPAP KIT NASAL PHANTOM W/HEAD GEAR
252	A9999	CPAP KIT	TIARA MEDICAL SYSTEMS INC	TMS-30345KIT	CPAP KIT NASAL SNAPP MED, LG
252	A9999	CPAP KIT	ROSCOE MEDICAL INC	CPAP-PRO	CPAP KIT PRO SYSTEM
252	A9999	CPAP KIT	RESPIRONICS INC	7010	CPAP KIT SM W/HEADGEAR
252	A9999	CPAP KIT	RESPIRONICS INC	7020	CPAP KIT SOFT SERIES MED
252	A9999	CPAP KIT	CAREFORE MEDICAL	SR-001LG-E	CPAP KIT SPIRITUS ELITE INTERFACE LG
252	A9999	CPAP KIT	CAREFORE MEDICAL	SR-001MD-E	CPAP KIT SPIRITUS ELITE INTERFACE MED
252	A9999	CPAP KIT	CAREFORE MEDICAL	SR-001SM-E	CPAP KIT SPIRITUS ELITE INTERFACE SM
252	A9999	CPAP KIT	CAREFORE MEDICAL	SR-001ST-E	CPAP KIT SPIRITUS ELITE INTRFCE MED PLUS
252	A9999	CPAP KIT	RESMED INC	16924	CPAP KIT STD LARGE DEEP
252	A9999	CPAP KIT	RESMED INC	16923	CPAP KIT STD MED SHALLOW
252	A9999	CPAP KIT	SLEEPNET	50725	CPAP KIT W/ HEADGEAR IQ
252	A9999	CPAP KIT	SLEEPNET	50777	CPAP KIT W/HEADGEAR & HOLEY CAP
252	A9999	CPAP KIT	VITAL SIGNS INC	9000	CPAP KIT W/HEADSTRAP
252	A9999	CPAP MASK	TIARA MEDICAL SYSTEMS INC	TMS-254077	CPAP MASK ADVANTAGE HUSH LG W/HEADGEAR
252	A9999	CPAP MASK	TIARA MEDICAL SYSTEMS INC	TMS-253077	CPAP MASK ADVANTAGE HUSH MED W/HEADGEAR
252	A9999	CPAP MASK	TIARA MEDICAL SYSTEMS INC	TMS-252077	CPAP MASK ADVANTAGE HUSH SM W/HEADGEAR
252	A9999	CPAP MASK	TIARA MEDICAL SYSTEMS INC	TMS-889	CPAP MASK IQ GEL W/HEADGEAR
252	A9999	CPAP MASK	SUNRISE MEDICAL HHG INC	9351D-670	CPAP MASK LG W/SILCN RING & CUSH
252	A9999	CPAP MASK	SUNRISE MEDICAL HHG INC	9351D-669	CPAP MASK MED W/SILCN RING & CUSH
252	A9999	CPAP MASK	RESPIRONICS INC	302219 M126317	CPAP MASK PETITE SOFT
252	A9999	CPAP MASK	TIARA MEDICAL SYSTEMS INC	TMS-770	CPAP MASK PHANTOM GEL MED W/HEADGEAR
252	A9999	CPAP MASK	RESPIRONICS INC	7030	CPAP MASK W/HEADGEAR LG
252	A9999	CPAP MASK	TIARA MEDICAL SYSTEMS INC	TMS-885	CPAP MASK W/HEADGEAR SLEEPNET IQ MED

APPENDIX

Deficit Reduction Act of 2005 Provisions on
Medicare Reimbursement for Oxygen and Durable Medical Equipment

Implementation Questions

I. Medical Necessity and Documentation

1. Will current regulations defining "continuous use" for capped rental DME remain unchanged?

2. How will CMS define "continuous use" for oxygen equipment? What will constitute a break in service so that a new period of continuous use commences for beneficiaries on oxygen?

3. When a beneficiary owns his or her oxygen equipment, will Medicare pay for new equipment on the basis of a change in condition? Does the change in equipment begin a new period of continuous use?

4. Will CMS issue regulations to address the issues raised in questions 1 and 2 above? If so, what is the projected timeline for a proposed rule?

5. If new technology becomes available that is medically appropriate and has the potential to improve health outcomes, will the beneficiary be responsible for paying for the new equipment (assuming there has been no change in condition)?

6. How will CMS define "oxygen" after the 36-month period of continuous use ends? How will the medical necessity documentation for oxygen change? Will lifetime CMNs be valid for beneficiaries who own their own equipment?

II. Reimbursement Questions

7. Will beneficiaries who have both a concentrator and stationary liquid or a concentrator and a portable concentrator be responsible for purchasing one of the two systems after 36 months?

8. How will CMS pay for refills on an oxygen cylinder? Will the payment amount differ between patients who require more refills because they have a greater need for mobility or a higher prescribed liter flow?

9. How will CMS take into consideration those patients who have a concentrator and a liquid system, where the liquid system is being primarily used for ambulatory/portable requirements? Will the Medicare program pay for additional portable cylinders after the 36-month rental period, or will it be the beneficiary's responsibility to purchase these items?

10. Will the beneficiary be responsible for purchasing supplies such as cannulas and tubing for their oxygen equipment or other items such as humidifiers?

11. May providers charge beneficiaries a rental or purchase for a back-up emergency cylinder that is not used to meet the patient's portable oxygen needs? These units would be used solely in the event of an emergency such as a power outage, a natural disaster, or a malfunction of the beneficiary's primary equipment. Will Medicare pay for the contents once these cylinders are used?

12. Will the payment amount differ based on different oxygen technologies that may be more or less costly for the provider to furnish?

13. Providers may be unable to service a patient-owned portable oxygen cylinder that they did not furnish. Will the beneficiary be responsible for purchasing a new oxygen cylinder under these circumstances?

14. Will rental months at a beneficiary's second residence apply towards the 36 months of continuous use? If so, which provider is responsible for transferring title to the beneficiary (i.e., the primary provider, or the provider at the second residence)? Similarly, if a beneficiary moves during the period of continuous use, which provider is responsible for transferring title (the new provider or the original provider)?

15. For short-term travel, the beneficiary pays for the oxygen out-of-pocket and the primary provider may reimburse all or a part of those costs. AAHomecare anticipates that this rule will not change for beneficiaries who own their oxygen equipment. That is, the beneficiary will continue to be responsible for arranging and paying for travel oxygen. With respect to the period of continuous use, please confirm that our understanding is correct. After title to the equipment transfers, will Medicare pay the beneficiary directly for short-term travel oxygen?

16. Will the beneficiary be responsible to pay charges for pick up and delivery of oxygen refills after title to oxygen equipment transfers to the

beneficiary? If not, what data does CMS propose to use to arrive at an appropriate payment amount for pick up and delivery charges?

17. For beneficiary-owned equipment that requires servicing, will Medicare pay pick up and delivery charges? If so, what data will CMS use to arrive at an appropriate payment amount for pick up and delivery charges?

18. Does CMS intend to apply any of the billing rules that applied to capped rental equipment to rent-to-purchase DME? A purchase option letter is unnecessary inasmuch as the beneficiary no longer has the "option" to purchase the equipment. Consequently, we see no need to use the BP, BR, or BU modifiers in the 11th, 12th, and 13th rental months.

III. Service and Maintenance

19. How will CMS define the useful of life of oxygen equipment?

20. If oxygen equipment is "irreparably damaged" after title has transferred to the beneficiary, but before the end of the equipment's "useful life," will Medicare pay for new equipment? If so, will this commence a new period of "continuous use," or will CMS pay a lump sum amount for the new equipment?

21. Does CMS have a timeline for issuing regulations that address questions 17 and 18 above?

22. Oxygen cylinders must undergo hydrostatic testing and other checks periodically. Though technically these tests are not "repairs," will they be reimbursed as repairs to account for the more extensive service they involve?

23. Will the Medicare program pay for emergency service calls for beneficiary-owned equipment that is still under warranty? If not, can providers contract with beneficiaries to provide on-call services for patient owned equipment?

24. If the manufacturer of equipment that is under warranty is no longer in business, will the beneficiary be responsible for paying for replacement parts? If the provider who furnished the equipment to the beneficiary is no longer in business, who is responsible for the repairs?

25. How will providers document that the maintenance and service they performed on oxygen equipment were reasonable and necessary? Will CMS require different documentation depending on whether the provider repairs the equipment it furnished or equipment furnished by another provider?

26. Will CMS issue temporary HCPCS codes to identify the service, maintenance and repairs for oxygen equipment, or will providers have to apply for the codes?

27. How will providers be reimbursed for service or maintenance to non-covered oxygen equipment such as conserving devices or oxygen titrating devices? Will providers bill the beneficiary for these services?

28. Will CMS issue temporary HCPCS codes to identify service and maintenance repairs and parts for equipment in the capped rental category, such as motor and hand controls for a bed, or will providers have to apply for the codes?

IV. Other Questions

29. Will the requirements of the DRA apply retroactively to January 1, 2006, regardless of whether the need for systems changes result in administrative delays in implementation?

30. Will CMS require providers to transfer title to beneficiaries who have unpaid deductible and coinsurance balances?

31. After title to the oxygen equipment transfers to the beneficiary, will beneficiaries be responsible for paying for clinical assessments required under state law? Will the beneficiary be responsible for paying for respiratory assessment ordered by the physician?

32. Please confirm that parenteral and enteral pumps are not subject to the rent-to-purchase methodology established under the DRA.

33. How will providers be reimbursed if beneficiaries begin to use oxygen or capped rental equipment under a Medicare Advantage plan? Will CMS begin a new period of continuous use each time the beneficiary has a payer change in or out of traditional Medicare?

Via E-Mail and Federal Express

April 20, 2006

Mr. Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **Implementation of the Deficit Reduction Act of 2005 to Medicare Reimbursement to Oxygen and Durable Medical Equipment**

Dear Mr. Kuhn:

As you are aware on February 8, 2006, the President signed into law the Deficit Reduction Act (DRA) of 2005, P. L. 109-171. Section 5101 of the DRA amends the provisions of the Social Security Act (SSA) that govern Medicare payment for home oxygen therapy and rental of certain items of durable medical equipment (DME). Beneficiaries who use home oxygen or rent DME now have a higher burden to manage their care and coordinate service and maintenance for their medical equipment. The DRA provisions also significantly impact the operations of suppliers who furnish oxygen and DME to beneficiaries. The American Association for Homecare (AAHomecare) is writing to request clarification on how the Centers for Medicare and Medicaid Services (CMS) intends to implement these new requirements, especially with respect to the specific questions we raise below. For your easy reference, we have also included the questions in an appendix attached to this letter.

By way of background, prior to February 8, 2006, Medicare reimbursed oxygen and oxygen equipment on the basis of a continuous rental. In other words, Medicare would pay for home oxygen therapy as long as a beneficiary met Medicare's coverage criteria. The monthly rental payment for oxygen is a modality neutral bundled payment that covers ongoing service and maintenance for the equipment. In contrast, under §5101, Medicare will pay for the rental of oxygen equipment over a period of "continuous use" of 36 months, after which title to the equipment transfers to the beneficiary. Medicare will pay only for "oxygen" after 36 months. Further, after the statutory period of continuous use, Medicare will pay only for service and maintenance of oxygen equipment that the Secretary deems "reasonable and necessary." This payment methodology became effective January 1, 2006 for all Medicare beneficiaries on home oxygen as of December 31, 2005.

Prior to the DRA, Medicare paid for certain DME items under a "capped" rental payment methodology. This means that beneficiaries could elect to own or rent the medical equipment after a rental period of 10 months. If the beneficiary chose to continue the rental, Medicare payments for the equipment would "cap" after 15 months, and the supplier would receive a maintenance and service fee every six months. Otherwise, title to the equipment transferred to the beneficiary after 13 months.

Section 5101 eliminates the capped rental payment methodology. Instead, Medicare will rent most items of DME for 13 months of continuous use, after which title to the equipment will transfer to the beneficiary. Medicare will pay only for service and maintenance the Secretary determines to be reasonable and necessary after the 13 month rental period. This new "rent-to-purchase" payment methodology is effective for rental periods beginning on or after January 1, 2006.

I. Questions on the Application of the DRA Provisions

The DRA fundamentally revises the payment structure for oxygen and capped rental DME. As a result, existing billing, payment, and documentation rules for oxygen and DME are inadequate to address the changes imposed under the DRA. CMS will need to revise the current rules and establish new HCPCS codes to capture the services and products that are no longer bundled into the monthly fee schedule amount for oxygen and DME. AAHomecare's questions pertain to CMS' plans for making these changes and the timeline for their implementation.

A. Medical Necessity and Documentation

How will CMS apply "break-in-service" rules to oxygen and DME under the new payment provisions? For capped rental DME, Medicare rules allow for temporary interruptions in the period of "continuous use." An interruption of no more than 60 days plus the days remaining in the rental month in which the use ceases is a temporary interruption, regardless of the reason for the interruption. When there is a temporary interruption in continuous use, medical necessity for the rented equipment is presumed to continue.[1] If the interruption is not temporary, then a new rental period begins, subject to the requirements specified in the rule.[2]

We expect these rules to remain in effect for DME and request that you confirm whether that is correct. For example, if a beneficiary using a support surface is "healed" within the meaning of the medical policy, but "breaks down" again after 60 days, will a new period of continuous use begin?

Importantly, §5101 (b) authorizes the Secretary to determine how he will define "continuous use" for oxygen and oxygen equipment. We believe CMS must issue regulations to define "continuous use" and what constitutes a "break in service" for

[1] 42 C. F. R. §414.230 (c) (3) (2006).

[2] The provider must submit a new prescription, new medical necessity documentation and a statement explaining the reason for the interruption and demonstrating that the medical necessity for the prior episode ended.

beneficiaries on oxygen. Specifically, when will a break in service for an oxygen patient commence a new period of "continuous use"?

In the past, if a beneficiary experienced a change in condition that resulted in the need to change his or her oxygen equipment (such as a change from stationary oxygen only to both stationary and portable oxygen), the provider would simply switch the beneficiary's existing equipment to other equipment consistent with the doctor's prescription. For example, a beneficiary on liquid oxygen during the first 30 rental months requires a medically necessary change in equipment in the 31st rental month, and the physician orders a stationary concentrator or a portable concentrator for the beneficiary. In this example, will the beneficiary's change in condition start a new 36 month period of continuous use?

Moreover, after a beneficiary owns the equipment, will Medicare pay for new equipment on the basis of a change in condition? Medicare program rules for capped rental DME contemplate that a new period of continuous use begins when the beneficiary has a new prescription or requires additional equipment;[3] these rules were not intended to apply to oxygen because oxygen was reimbursed as a continuous rental under the original fee schedules. Consequently, CMS must issue new regulations to address these questions. What is CMS' projected timeline for a proposed rule?

If new technology becomes available that is medically appropriate and has the potential to improve health outcomes, is the beneficiary responsible for paying for the new equipment (assuming there has been no change in condition)?

The DRA contemplates that Medicare will continue to pay for medically necessary oxygen after title to the equipment transfers to the beneficiary. How will the medical necessity documentation for oxygen change? Currently, the Medicare program requires a "lifetime" certificate of medical necessity (CMN). Will lifetime CMNs be valid for beneficiaries who own their own equipment?

B. Reimbursement Questions

Some beneficiaries have dual systems. That is, they have both a concentrator and a stationary liquid system or a stationary concentrator and a portable concentrator. Under Medicare's modality neutral payment methodology, providers only bill the Medicare program for one system. At the end of the period of continuous use, what equipment will these beneficiaries own? Will the beneficiary be responsible for purchasing one of the two systems?

We interpret §5101 (b) to require the transfer of title to oxygen equipment, including portable equipment, after 36 months of continuous use. As you are aware, portable equipment may include an oxygen cylinder equipped with a flow meter and a cannula. The DRA requires Medicare to pay for medically necessary oxygen after title to oxygen equipment transfers to the beneficiary. How will CMS pay for refills on oxygen

[3] 42 C. F. R. §414.230 (f) (2006).

cylinders? Will the payment amount differ between patients who require more refills because they have a greater need for mobility or a higher prescribed liter flow? How will CMS address payment for patients who have both a concentrator and a liquid system where the liquid system is being used primarily for ambulatory portable requirements? Will Medicare pay for additional portable cylinders after the 36 months, or will the patient be responsible for purchasing these items? Will beneficiaries be responsible for purchasing supplies such as cannulas and tubing for their oxygen equipment or items such as humidifiers?

May providers charge beneficiaries a rental or purchase for a back-up emergency cylinder that is not used to meet the beneficiary's portable oxygen needs? These units would be used solely in the event of an emergency such as a power outage, natural disaster, or a malfunction of the beneficiary's primary equipment. Will Medicare pay for contents once these cylinders are used? Finally, will the payment amount differ based on different oxygen technologies that may be more or less costly for the provider to furnish?

As you are aware, oxygen is a prescription drug, and oxygen equipment, including oxygen cylinders, is highly regulated by several Federal agencies including the United States Department of Transportation (DOT) and the United States Food and Drug Administration (FDA). An important safety concern for the FDA is the provider's ability to test oxygen cylinders and to verify their chain of custody. This will be very difficult to do for patient-owned equipment, especially if the beneficiary changes supplier after he or she owns the equipment (e.g., the beneficiary moves out of the provider's service area). This also raises significant liability issues for patient-owned equipment, especially if the beneficiary changes supplier after he or she owns the equipment (e.g., the beneficiary moves out of the provider's service area). There may be instances where beneficiaries purchase cylinders second-hand from non-providers (eBay®, for example). As a consequence, there may be instances where providers may be unable to service a patient-owned portable oxygen cylinder that they did not furnish. Will the beneficiary be responsible for purchasing new oxygen cylinders under these circumstances?

The local coverage determination (LCD) for oxygen states that the beneficiary is responsible for coordinating travel oxygen needs. The beneficiary's existing oxygen provider may service the beneficiary's travel oxygen needs, but is not required to do so. For short-term travel, the beneficiary pays for the oxygen out-of-pocket, and the primary provider may reimburse all or a part of those costs.[4] We anticipate that this rule will not change. That is, the beneficiary will continue to be responsible for arranging and paying for short-term travel oxygen. Please confirm that our understanding is correct with respect to the 36-month period of continuous use. After title to the equipment transfers to the beneficiary, will Medicare pay the beneficiary directly for short-term travel oxygen?

Beneficiaries who spend the winter or summer months away from their primary residence may have more than one supplier. Similarly, beneficiaries who move out of a provider's service area will have more than one provider. How will CMS determine the period of continuous use in these scenarios? Will rental months at the second residence apply

[4] See DMERC Region B Bulletin, Spring (1999).

towards the 36 months of continuous use? If so, which provider is responsible for transferring title to the beneficiary? We foresee significant access issues for beneficiaries if providers are forced to transfer title to equipment that they have rented for only a few months. Beneficiaries who move or change providers "midstream" may have difficulty finding a new provider for the same reason.

The Medicare Claims Processing Manual states that Medicare will not make a separate payment for pick-up and delivery of oxygen equipment because these charges are included in the monthly fee schedule payment for oxygen.[5] After title to oxygen equipment transfers to the beneficiary, will the beneficiary be responsible to pay charges for pick up and delivery of oxygen refills? If not, what data does CMS propose to use to arrive at an appropriate payment amount? The Medicare Claims Processing Manual also states that pick up and delivery charges are included in the Medicare fee schedule payment amount for capped rental DME. For beneficiary-owned equipment that requires servicing, will Medicare pay pick up and delivery charges? If so, what data will CMS use to arrive at an appropriate payment amount?

Finally, does CMS intend to apply any of the billing rules that applied to capped rental equipment to rent to purchase DME? A purchase option letter is unnecessary inasmuch as the beneficiary no longer has the "option" to purchase the equipment. Consequently, we see no need to use the BP, BR, or BU modifiers in the 11th, 12th, and 13th rental months.

C. Service and Maintenance

Section 1834 (a) (7) of the SSA states that the reasonable useful lifetime for capped rental DME is five (5) years, unless the Secretary specifies otherwise.[6] This statutory provision does not apply to oxygen and oxygen equipment. How will CMS define the useful life of oxygen equipment? If oxygen equipment is "irreparably damaged" after title has transferred to the beneficiary, but before the end of the equipment's "useful life," will Medicare pay for new equipment? If so, will this commence a new period of "continuous use," or will CMS pay a lump sum amount for the new equipment? Importantly, does CMS have a timeline for issuing regulations that address these questions? Finally we anticipate that the useful life for capped rental DME will remain 5 years consistent with §1834 (a) (7). Please confirm that our understanding is correct.

Providers are required to perform extensive maintenance checks on liquid oxygen equipment furnished to beneficiaries. These checks include testing for purity of content, performing a visual inspection for dents, performing a pressure check and checking for appropriate labels. Until now, these checks have been reimbursed under the monthly fee schedule payment for oxygen and oxygen equipment. Similarly, oxygen cylinders must undergo hydrostatic testing. Though technically these tests are not "repairs," will they be reimbursed as repairs to account for the more extensive service they involve?

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[5] Chapter 20 §60, Medicare Claims Processing Manual, 100-4.
[6] 42 U. S. C. 1395 (m) (7).

Section 5101 requires Medicare to pay for maintenance and service not covered under warranty. Will the Medicare program pay for emergency service calls for beneficiary-owned equipment that is still under warranty? If not, can providers contract with beneficiaries to provide on-call services for patient-owned equipment? When maintenance and service on oxygen equipment is reasonable and necessary, what documentation will providers be required to submit? Will CMS require different documentation depending on whether the provider repairs the equipment it furnished or repairs equipment furnished by another provider? Importantly, after title to equipment transfers to the beneficiary, what will be the impact on the beneficiary if the manufacturer is no longer in business and replacement parts are needed? If the original provider is no longer in business, who will provide service and maintenance on the equipment?

In order to facilitate payment for repairs, we recommend that CMS issue specific HCPCS codes to account for the need to have skilled technicians perform extensive maintenance with specialized tools. Will CMS issue temporary HCPCS codes for this purpose, or will providers have to apply for the codes?

Finally, how will providers be reimbursed for service or maintenance to non-covered oxygen equipment such as conserving devices, oxygen titrating devices, or technology that allows beneficiaries to fill their own cylinders? Will providers bill the beneficiary for these services?

D. Other Questions

Leased Equipment and Outstanding Patient Balances

The DRA provisions for oxygen and oxygen equipment impact provider's business operations in other ways. For example, leasing is a common means of financing medical equipment. It's likely that in many cases providers will need to reconcile lease terms with the statutory period of continuous use. Under this scenario, understanding the implementation date is very important for providers. Does CMS intend to apply these new payment rules as of January 1, 2006 even though their actual implementation is delayed for administrative reasons such as the need to issue carrier instructions and make system changes? In addition, we are concerned about any requirement to transfer title to oxygen equipment to a beneficiary with unpaid balances for co-pays and deductibles. Title to oxygen equipment should remain with the provider until the beneficiary has paid any outstanding deductible and co-payment amounts.

Clinical Assessments for Respiratory Patients

The change in reimbursement for oxygen and oxygen equipment also raises questions about the provider's obligation to furnish continuing care and monitoring. Although ongoing care, monitoring, and assessment of the beneficiary are not explicitly covered by Medicare, most private sector payers and national accrediting bodies expect providers of oxygen to furnish these services. Moreover, providers are required in several states to perform respiratory assessments for patients who receive conserving devices. Other states require the oxygen provider to furnish the patient with a clinical visit shortly after the oxygen is set-up. For Medicare beneficiaries, providers have included these services within the monthly fee schedule payment for oxygen. Will payment for these services

now become the beneficiary's responsibility? Will beneficiaries be required to pay for the services of respiratory therapists and other services that CMS considers non-covered?

Parenteral and Enteral Equipment

Finally, AAHomecare interprets the DRA to apply only to medical equipment in the capped rental Medicare payment category. As you know, parenteral and enteral (PEN) pumps are reimbursed under the prosthetic device benefit, and the payment rules that apply to them differ from the rules that apply to capped rental DME. Consequently, this new rent-to-purchase payment methodology does not apply to PEN pumps. Specifically, PEN pumps fall under the fee schedule category for "parenteral and enteral." PEN pumps can be purchased or rented whereas capped rental items can only be rented. Although rental payments for PEN pumps "cap" after 15 months, subsequent payment for service and maintenance on PEN pumps do not follow the capped rental billing rules. To avoid confusion among the carriers, we request that CMS confirm that PEN pumps are not subject to the DRA's new rent to purchase payment methodology.

Medicare Advantage Plans

As you know, beneficiaries may choose from a number of Medicare Advantage plans, some of which do not follow the payment and coverage policies of traditional Medicare. How will providers be reimbursed if beneficiaries begin to use oxygen or capped rental equipment under a Medicare Advantage plan? Will CMS begin a new period of continuous use each time the beneficiary has a payer change in or out of traditional Medicare?

II. Conclusion

AAHomecare understands that these new payment methodologies do not take effect immediately. However, their impact on our member's operations is immediate because they must begin to structure their operations to respond to the changes. Moreover, providers must plan now for their implementation in order to ensure a smooth transition for Medicare beneficiaries. AAHomecare and its members are prepared to work closely with CMS to address these issues, and we would like an opportunity to meet with you and your staff to discuss these issues further. We will contact you next week to arrange for a mutually convenient time for us to meet.

Sincerely,

Thomas Ryan
Chairman

Michael Reinemer
Vice President, Communications & Policy

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APTA
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June 30, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201-1850

RE: Proposed Rule on Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues (71 FedReg. 25654, May 1, 2006)

Dear Administrator McClellan:

On behalf of our 66,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) appreciates the opportunity to comment regarding the proposed rule on competitive acquisition of certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

Physical therapists provide orthotics, ambulatory aids, and mobility assistance devices to the patients they serve to help them improve their function. These items become an integral part of the treatment plan for the patients who need them. Thus, physical therapists have a significant interest in this rule.

As the Center for Medicare and Medicaid Services (CMS) proceeds with implementation of competitive acquisition, APTA strongly urges you to ensure that this program does not obstruct or diminish beneficiary access to medically necessary items or disrupt the delivery of care to Medicare beneficiaries.

Background Information Regarding Provision of DMEPOS by Physical Therapists

Physical therapists practice in a wide variety of settings including acute care hospitals, inpatient rehabilitation facilities, skilled nursing facilities (SNFs), rehabilitation agencies, home health, physical therapist private practice offices, and comprehensive outpatient rehabilitation facilities (CORFs). Physical therapists in private practice (PTPPs) enroll in the Medicare program, obtain individual provider numbers, and bill Medicare directly for the outpatient therapy services they furnish. Currently, if a physical therapist in private practice bills for DMEPOS items, the therapist must obtain a National Supplier Clearinghouse (NSC) supplier number in addition to their PTPP number. In contrast, physical therapists working in CORFs, rehab agencies, home health, and hospitals do not obtain their own Medicare provider numbers. Rather, their therapy services are billed through the facility. If the facility bills for DMEPOS, the facility must obtain the NSC number or obtain the DMEPOS items from a NSC supplier that bills the Medicare program for the item.

DMEPOS items are provided by physical therapists as an integral part of their physical therapy plan of care. The clinical judgment and expertise of the physical therapist is critical in selecting a particular DMEPOS item for the patient and is based on the therapist's evaluation of the individual patient. The physical therapist ensures that the item is appropriate to achieve the patient's functional goals, is properly sized and fitted for the patient, and that the patient and/or caregiver is educated in the proper use of the item. In many cases, it is essential that the patient have timely access to these items because the DMEPOS item may be necessary to immobilize and support an injured body part or to facilitate safe mobility or post-surgical recovery.

Providers and Practitioners Furnishing DMEPOS Integral to Their Plan of Care Should be Exempt or be Given Special Consideration

Under the proposed rule, providers (rehabilitation agencies, hospitals, CORFs, SNFs, physical therapists in private practice, and other practitioners who choose to bill for DMEPOS items) would be forced to competitively bid in order to continue to provide and bill Medicare for those items. CMS data shows that there are currently 40,000 practitioners and providers enrolled as NSC suppliers, including approximately 1,078 physical therapists in private practice that also have NSC supplier numbers.

APTA strongly urges CMS to exempt or give special consideration under the competitive bidding program to physical therapists in private practice, providers, and other practitioners enrolled in the Medicare program that provide DMEPOS integral to their plan of care. This exemption or special consideration should not apply if they are solely in the business of furnishing items, not providing patient care.

Special consideration should include: phasing in the program for providers and practitioners over at least 4 years; allowing them to provide items only to their patients rather than the entire competitive bidding area; exempting them from the requirement to provide all items identified in a product category; allowing them to participate even if they do not submit exactly the same type of bid required of much larger suppliers; and establishing a different standard for accreditation than that which would apply to a DMEPOS commercial supplier.

The private practice setting for physical therapists provides a clear example of why an exemption or special consideration is necessary. Physical therapists in private practice typically are small businesses providing DMEPOS only to their own patients as an integral part of their service. It does not make sense to apply the same standards to PTPPs as those applied to large commercial suppliers who are exclusively in the business of providing items.

Physical therapists in private practice typically provide services only to their own patients. Yet, under the proposed competitive bidding program, these therapists would be required to serve the entire competitive bidding area in which they practice and therefore provide items to beneficiaries who are not their patients. Physical therapists in private practice often specialize in treating certain conditions and provide a limited range of DMEPOS items for those particular conditions, such as specializing in lower extremity care or upper extremity care. It would be overly burdensome to require these physical therapists to provide all items in a product category when they do not treat patients with conditions that would require a particular type of item. Given the small size of physical therapy practices and the scope of services they furnish, most PTPPs will be unable to participate as contract suppliers under the competitive bidding program as currently proposed.

Medicare beneficiaries will be adversely impacted if physical therapists in private practice can no longer provide items to their patients in their offices. DMEPOS items such as prefabricated and custom orthotics and ambulatory assistance devices are commonly furnished by physical therapists in their office as part of an ongoing plan of care. Physical therapists must be integrally involved in providing DMEPOS items to their patients to ensure that the item is appropriate for the patient's condition or functional limitations, properly sized and fitted for the patient and the patient and or caregiver is instructed in the proper use of the item. In many instances, it is necessary for the physical therapist to provide the item before the patient leaves their practice. For example, physical therapists often provide patients with orthotics to immobilize a body part, such as fracture braces for humeral fractures, air casts for ankle sprains, or static wrist orthotics for carpal tunnel syndrome. When a physical therapist is treating a patient with a fracture or a sprain, it is necessary to immediately provide the patient with the orthotic to immobilize the injury. It would be unsafe and clinically inappropriate to delay the patient's access to items such as orthotics or ambulatory support devices.

Physical therapists also use orthotics to facilitate or augment a patient's movement. It is common for a patient who has had a stroke to develop weakness in his or her ankle dorsiflexors, resulting in a foot drop during the swing phase of gait. Physical therapists provide the patient with an ankle-foot orthosis (AFO) to facilitate movement at the ankle so the patient will not risk tripping or stumbling during ambulation. Patient falls frequently result in further injury and a cascade of other adverse events. By fitting the patient with the appropriate orthosis in the office, the physical therapist can proceed with gait training to assess whether there are sensory or skin problems and determine whether the orthosis allows the patient to ambulate properly. In contrast, a vendor would provide the orthosis but would not instruct the patient or caregiver in functional activities or be able to determine whether the particular orthosis appropriately facilitates gait and allows the patient to safely perform functional activities.

DMEPOS products are frequently needed as part of an ongoing plan of care for patients with musculoskeletal, neurological and pulmonary related conditions. Ambulation aids including canes, walkers and crutches are required for patients with progressively deteriorating ambulation status to facilitate balance, unload painful joints and minimize unnecessary energy expenditure associated with ambulation. It would be unsafe for a physical therapist to send a patient out of his or her office without a walker, crutches, or cane if the patient needs such an ambulation aid.

One of the goals of the competitive acquisition program is to achieve cost-savings. If Medicare beneficiaries are not furnished with the appropriate item at the appropriate time, the result will ultimately be a higher cost to the Medicare program due to injury, skin breakdown, or delayed healing. Therefore, **CMS should either exempt providers and practitioners such as physical therapists in private practice from the competitive bidding program or give them special consideration.** Another option, described in more detail below, would be to exclude from competitive bidding DMEPOS products that are commonly dispensed from the offices of health care practitioners who also serve as suppliers.

Criteria for Item Selection

Under the program, CMS has authority to determine which items should be subject to competitive bidding. **We urge CMS to limit the items and product categories subject to competitive bidding as the program is largely untested.** By minimizing the number of items subject to competitive bidding, adverse impacts on beneficiaries may be avoided or reduced. **We urge CMS to provide a list of the items that they plan to include in the competitive bidding program prior to implementation and allow sufficient opportunity to provide public comment on that list to ensure that patient care is not negatively impacted.**

CMS should amend the proposed definition of off-the-shelf orthotics

Section 1847(a)(2)of the Social Security Act describes the items subject to competitive bidding as including off-the shelf (OTS) orthotics. It further defines OTS as orthotics which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual. CMS proposes that minimal self-adjustment would mean adjustments that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform without the assistance of a certified orthotist (that is, an individual certified by either the American Board of Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification").

APTA strongly urges CMS to revise the definition of off-the-shelf orthotics to reflect the fact that physical therapists are qualified to make adjustments that require trimming bending, molding, assembling, or customizing to fit the individual. In other words, the definition of off-the-shelf orthotics should be modified to exclude products where trimming, bending, molding, assembling, or customizing to fit the individual requires the expert assistance of a physical therapist, occupational therapist or a certified orthotist. If CMS does not change the definition, many custom items would be included in the competitive bidding program, which was not the intent of Congress.

The Medicare statute clearly identifies physical therapists as qualified practitioners who furnish custom fabricated orthotics. Section 1834(h)(1)(F) of the Social Security Act, which was added by section 427 of the Medicare, Medicaid, and SCHIP Benefits Improvement Act of 2000 (BIPA) provides, in part, that no payment shall be made for prosthetics and certain custom-fabricated orthotics unless such items are furnished by a "qualified practitioner." Section 1834(h)(1)(F)(iii), in turn, defines "qualified practitioner" to include "a qualified physical therapist or a qualified occupational therapist." CMS has a well-established long-standing and consistent definition of "qualified physical therapist" within the Medicare program, which is included in the Medicare regulations at 42 CFR section 484.4 and the Medicare Manuals (Medicare Benefit Policy Manual, Chapter 15 Covered Medical and Other Services, Section 230.1B). **The statutory language clearly distinguishes physical therapists from orthotists and prosthetists and does not require that a physical therapist (who is licensed in all states) be ABC or BOC certified.**

CMS should exempt items commonly furnished in physician and physical therapist private practices

In the rule, CMS references section 1847(a)(1)(B)(ii) of the Social Security Act, which gives CMS the authority to phase in competitive bidding "first among the highest cost and highest volume items or those items that the Secretary determines have the largest savings potential." In addition, section 1847(a)(3)(B) of the Act grants CMS the authority to exempt items for which application of competitive bidding is not likely to result in significant savings.

We urge CMS to use this exemption authority to exclude from the competitive bidding program the types of items that are provided the offices of physicians, physical therapists or other practitioners that are integral to the provision of their services or necessary for the patient to safely depart from the physical therapist's or physician's office. These should include, but not be limited to: wrist, ankle, and finger orthotics; ankle foot orthotics; air casts; orthotic inserts' spine stabilization braces; cervical collars; canes; crutches; and walkers. These items are commonly furnished by physical therapists in their office as part of an ongoing plan of care. Physical therapists must be integrally involved in providing DMEPOS to select the appropriate item for the patient to achieve his or her functional goals and to make sure it is properly sized and fitted for the patient to ensure maximum benefit from the item and also prevent skin breakdown or increased risk of falling. If the patient is not initially given the proper item in a timely manner, the Medicare program will incur greater costs. Thus, these items should be excluded from the competitive bidding program because they will not result in significant savings, but rather could result in increased expenditures.

CMS has indicated there is a high likelihood that wheelchairs will be included in the competitive bidding program. **If a product category is established for wheelchairs, we strongly urge CMS to use its exemption authority to exclude the K5 ultralightweight wheelchairs, which are highly customized and unlikely to result in cost-savings.** The defining characteristic of a K5 ultralightweight wheelchair is an adjustable axle plate which allows the physical therapist to determine the patient's proper center of gravity during both static and dynamic activities to promote maximum balance in the wheelchair while still allowing for the necessary seat to floor height for transfers. The axle also adjusts up, down, forward, backward, which is important in the proper positioning of the upper extremities in relation to the pushrim. This feature assists with the prevention of repetitive stress injuries, which is particularly important for people who have weakened shoulders or hands. Because these wheelchairs are highly customized, the competitive bidding process would not result in significant savings to the program.

Quality Standards and Accreditation

APTA is very concerned that CMS has yet to finalize the proposed quality and accreditation standards for DMEPOS suppliers. The standards as previously proposed may be appropriate for large national DMEPOS suppliers, but they would be extremely burdensome for clinicians such as physical therapists and physicians. Compliance with the standards could prevent clinicians and providers from participation in the bidding process and therefore the program. CMS should consider a less burdensome process that would apply to physical therapists in private practice, physicians, and other practitioners and providers. **We recommend that physical therapists in private practice that are licensed**

by their state board to practice should be "deemed" as qualified to provide patients with DMEPOS.

Without knowing the true cost of compliance with the quality and accreditation standards, suppliers will not be able to calculate accurate bids that produce the pricing that the Medicare program is hoping for and that will also ensure they can continue to stay in business. A lack of understanding of the true costs associated with compliance could eventually have a negative impact on the timely supply of DMEPOS to beneficiaries including driving some suppliers out of business. **We strongly urge CMS to delay the release of the final rule for the competitive acquisition of DMEPOS until after the quality and accreditation standards have been finalized. In addition, we urge CMS to give suppliers an adequate period of time to learn about and understand the implications of the quality standards, the associated accreditation process, and the various elements of the final rule before they are required to submit any kind of bid or other expression of interest in participating in the competitive acquisition program.**

Physician Authorization/Treating Practitioner
Under the current proposal, physicians can request a specific brand of DMEPOS for patients if the physician or treating practitioner determines that use of the particular item would avoid an adverse medical outcome for that patient. If the physician or treating practitioner requests a specific item, brand, or mode of delivery, contract suppliers would be required to furnish that item or assist the beneficiary in finding another contract supplier to provide that item. We believe that this provision is extremely important as we are deeply concerned that under the new competitive bidding program, suppliers will have strong incentives to offer lower quality brands and less selection due to cost pressures.

We strongly urge CMS to add language to the rule acknowledging that physical therapists play a key role in specifying the need for a particular brand item and the adverse outcome that will occur if the patient does not receive that item. In most cases a physical therapist assesses a patient and makes recommendations to the patient's physician concerning the best item for that particular patient's condition. The physician ultimately orders the item based on the therapist's recommendation. It is important to ensure that the patient is assessed by the appropriate practitioner in order to ensure that the appropriate brand item is selected.

Within each HCPCS code there are a number of different brands or products. Not all the brands described by the HCPCS code will address the patient's needs. For example, although wheelchair cushions may share the same code they do not share the same characteristics. Some wheelchair cushions use air to offer pressure relief but may not be as good for positioning the patient correctly in their wheelchair. Cushions that are filled with gel can provide good positioning but may not protect skin integrity adequately for patients who are very thin.

Many factors are taken into consideration in making these recommendations for patients, and selection of the correct wheelchair cushion is critical in preventing skin breakdown and pressure ulcers. The proper wheelchair cushion can also assist patients with activities of daily living such as transfers. Physical therapists that specialize in seating and mobility are familiar with the products currently available and are experts in selecting the proper item for a given patient, taking all of these factors into account.

Although CMS is proposing that specific brands may be requested to avoid an adverse medical outcome, APTA remains concerned that there will be significant delays in receiving these items. When a request is made for a specific brand item that is not in the contract supplier's regular inventory, the contract supplier will need to go elsewhere to obtain the item. This could result in significant delays in access to these items, thereby limiting the ability of the therapist to proceed with the therapy plan of care and progress the patient to recovery. If they cannot proceed, the patient may lose functional gains they have previously made or remain in costly settings instead of being discharged to their home. The potential delays could have disastrous results to patients and could ultimately be more costly to the Medicare program.

We urge CMS to aggressively monitor contract suppliers to ensure that they are not providing a different item than that prescribed by the physician or treating practitioner, pressuring the physician to revise their order, or delaying delivery of the item. Such actions could result in delays in patient care and subject to the patient to risk of injury.

Submission of Bids

In the proposed rule, physicians and skilled nursing facilities are exempt from the requirement to furnish items to an entire competitive bidding area and can choose to furnish DMEPOS items to only those patients that they serve. **APTA strongly urges CMS to extend this exemption to other clinicians in private practice, such as physical therapists.** Given that clinicians are primarily focused on treating patients and provide DMEPOS items only to their own patients, physical therapists in private practice would be unduly burdened by having to furnish DMEPOS to an entire competitive bidding area. If they are required to provide services to the entire area, it is unlikely that many would reorganize their business to do so. Consequently, they will be unable to provide items to patients that are integral to their patient's plan of care. This is likely to disrupt the delivery of services and adversely affect the quality of care.

Payment Basis: Obligation to Furnish DMEPOS Items at Same Cost of Patient's Resident MSA

In the proposed rule, patients who live in competitively bid metropolitan statistical areas (MSAs) must be provided items of DMEPOS at the price of their resident MSA, and not where the DMEPOS is being furnished to them. Due to geographic differences in the pricing of items, it could be that a supplier may not

wish to furnish items of DMEPOS at a lower cost than they would receive from an entity with their own MSA. This could result in potential access problems for individuals who travel to warmer climates during the winter months. In addition, non-contract suppliers may not be willing to furnish items to Medicare beneficiaries at a lower cost, which could result in the same difficulty accessing items. It will also be difficult for suppliers to find out what the competitively bid price is at a beneficiary's resident MSA, or at the minimum, add another administrative step in order to find this information.

We urge CMS to consider allowing Medicare beneficiaries to receive DMEPOS at the Medicare fee schedule amount in effect where they are physically located at the time the item is furnished to them, and not their resident MSA. At the very least, such a policy must be adopted in cases where the beneficiary maintains a permanent residence in one of the competitive bidding areas. It would be unfair to hold suppliers in areas being visited by a beneficiary to the contract price obtained by selected suppliers under a competitive bidding process (through which winning suppliers presumably obtain some advantages such as increases in market share) and where local costs may be far different.

Opportunity for Participation by Small Suppliers

Section 1847(b)(6)(D) of the Social Security Act requires CMS to take steps to ensure that small suppliers of items have an opportunity to be considered for participation in the competitive bidding program. Although CMS includes a reference to steps it has taken to allow small suppliers to participate, these steps are not sufficient to enable a small provider such as a physical therapist in private practice to participate in the program. This may be due to the fact that CMS is proposing to use a definition of "small supplier" that would include nearly all suppliers, rather than one recognizing the great diversity of such "small suppliers" in terms of size, number of products offered, the size of market currently being served, the integral nature of DMEPOS products to other professional services provided to Medicare beneficiaries, and other important factors. Clearly, the suppliers with the largest product offering that can obtain economies of scale benefit from the proposed competitive bidding program.

CMS mentions that it considered allowing suppliers with fewer than 10 full-time equivalent employees to designate a service area that is smaller than the entire competitive bidding area. We believe such a policy would be helpful to small suppliers. **To allow small suppliers a greater opportunity for participation, CMS should also allow any qualified supplier to provide DMEPOS if the provider is willing to accept the single payment amount determined under the competitive bidding process.** We believe this could be deemed to satisfy the requirement that a bid include "a particular price" at least for certain categories of small suppliers, such as physical therapists or other health care practitioners who provide DMEPOS products as an integral part of other professional services they provide to their own patients. **Additionally, these**

small suppliers should be allowed to submit a level of bid-related information more in keeping with the amount of DMEPOS products they typically provide to Medicare beneficiaries. In other words, they should not be expected to go through the costly and time-consuming bidding process of preparing the same type of bid that CMS would require from large DMEPOS suppliers who provide millions of dollars of DMEPOS products and serve an entire community.

In order to allow small suppliers to participate, CMS proposes that suppliers form networks for DMEPOS bidding consisting of several companies joined together through a legal contractual relationship to submit bids. APTA believes this is not a realistic option for most small suppliers. Setting up a network would involve considerable legal resources to ensure that the network is not violating the antitrust laws, as well as significant administrative resources.

We are deeply concerned that if small suppliers are unable to participate, there will be a significant negative impact on patients. Often, small suppliers specialize in providing items for a specific condition, such as wound care products, orthotics, or a specific type of wheelchair. These suppliers offer considerable expertise in evaluating both the patient and the item in order to provide the patient with the best possible outcome. Many suppliers also use their expertise to provide adjustments and repairs of the items over an extended time frame.

Rebate Program

CMS proposes to allow contract suppliers that submitted bids below the single payment amount to provide the beneficiary with a rebate. We recommend CMS not proceed with implementation of such a program as offering such rebates would most likely be considered a violation of the federal anti-kickback statutes. The Department of Health and Human Services Office of Inspector General has issued numerous fraud alerts, bulletins, and advisory opinions in which it emphasizes that providing things of value to beneficiaries violates the anti-kickback laws. If one contract supplier offers a rebate to a Medicare beneficiary and another does not, the beneficiary clearly has an incentive to select the supplier that offers the rebate. The purpose of the anti-kickback laws is to prohibit financial incentives from driving the delivery of care.

Conclusion

In conclusion, among its key recommendations, the APTA urges CMS to take the following actions:

- Exempt or give special consideration under the competitive bidding program to physical therapists in private practice, providers, and other practitioners enrolled in the Medicare program who provide DMEPOS as integral to their plan of care. Special consideration should include: phasing in the program for providers and practitioners; allowing them to provide

items only to their patients rather than the entire competitive bidding area; exempting them from the requirement to provide all items identified in a product category; allowing them to participate even if they do not submit exactly the same type of bid required of much larger suppliers.

- If CMS chooses not to exempt practitioners, the Agency should use its authority to exclude from the competitive bidding program the types of items that are commonly provided in a physician, physical therapist or other practitioner's office that are integral to the provision of their service or necessary for a patient to depart from the physical therapist's or physician's office.

- Revise the proposed definition of off-the-shelf orthotics to reflect the fact that physical therapists also make adjustments that require expertise in trimming bending, molding, assembling, or customizing to fit the individual.

- Delay the release of the final rule for the competitive acquisition of DMEPOS until after the quality and accreditation standards have been finalized.

- Add language to the rule acknowledging that physical therapists play a key role in specifying the need for a particular brand item and the adverse outcome that will occur if the patient does not receive that item.

Thank you for your consideration of these comments. We look forward to working with CMS as you proceed with implementation of these rules. If you have any questions regarding the issues raised, please contact Gayle Lee at 703-706-8549 or Karen Stavenjord at 703-706-8508.

Sincerely,

G. David Mason
Vice President, Government Affairs

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The Alliance For Quality Nursing Home Care

ahca American Health Care Association

June 28, 2006

Mark B. McClellan, MD, PhD
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Washington D.C.
Attention: CMS-1270-P

Re: Proposed Rule on Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues

Dear Dr. McClellan,

On behalf of the American Health Care Association (AHCA) and the Alliance for Quality Nursing Home Care (the Alliance), we appreciate the opportunity to provide comments to the proposed rule on *Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues,* 71 Fed. Reg. 25654 (May 1, 2006) (the Proposed Rule).

AHCA, the Alliance and their respective members are committed to performance excellence and Quality First, a covenant for healthy, affordable and ethical long term care. AHCA represents more than 10,000 non-profit and proprietary facilities dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation's frail, elderly and disabled citizens who live in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities. The Alliance includes sixteen of the largest long term care providers in America, operating 1800 skilled nursing facilities, employing 300,000 people and caring for 300,000 patients each year.

The Proposed Rule would govern the delivery and price of certain covered durable medical equipment, prothetics, orthotics and supplies (DMEPOS) provided to certain patients in a long-term care facility. However, when the Centers for Medicare and Medicaid Services (CMS) sought to implement the new part D prescription drug benefit, it correctly recognized that patients in long term care facilities have special needs that

cannot adequately be met through a distribution process designed for beneficiaries who are mobile and not institutionalized.

As recognized in the implementation of Medicare Part D, CMS must balance its proposed policy changes with the existing federal requirements mandating that long term care facilities assume responsibilities that "each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care (42 CRF 483). Altering the acquisition of DMEPOS services could affect the ability of facilities to meet their regulatory obligations. The same types of concerns that led the agency to adopt special rules for pharmacy procurement to beneficiaries in long term care facilities should apply here. Accordingly, we urge CMS to exclude long term care facilities from the scope of the competitive bidding process.

At a minimum, CMS should study the affects that competitive acquisition will likely have on patients and institutions before extending the demonstration to include long term care facilities. It is our understanding that earlier demonstrations do not support the Proposed Rule. We believe that there is a burden on CMS to document the potential impact on the resident population and to set specific performance standards for safeguarding access to medically necessary DMEPOS items. CMS must affirm that competitive acquisition will not adversely affect the health and welfare of institutionalized beneficiaries. Until this is done, the implementation of these regulations to include long term care facilities is premature.

The following are the key points discussed in our comments:

- We believe the Secretary of Health and Human Services has both the express and implied authority to except patients who are in long term care facilities from inclusion in this new effort to limit the availability of DMEPOS through a competitive bidding process.
- Quality and accreditation standards of suppliers for long term care facility patients should be exempt from the new accreditation requirement if certain conditions are met.
- Reimbursement rates for covered DMEPOS for Medicare beneficiaries in long term care facilities should be based on the current fee schedules until such time as competitive bidding is implemented nationwide.
- All current suppliers of covered DMEPOS to Medicare beneficiaries in long term care facilities should be grandfathered and exempt from competitive bidding requirements for such facilities and their patients.
- We believe that the time for comment on the proposed rule should be extended.
- We urge the Secretary to conduct a complete and thorough Regulatory Flexibility Act analysis that examines the impact of the Proposed Rule on the long term care sector and those who reside in long term care facilities.

COMMENTS

A. The Rule Should Exempt DMEPOS that are Provided to Medicare Beneficiaries Who are in Long term Care Facilities

As this proposed rule implements a competitive acquisition scheme for certain Part B products and supplies, we believe such a system is untested, unwarranted and unworkable for Medicare beneficiaries who are in long term care facilities. We believe the Secretary has sufficient legal authority to exempt certain Medicare beneficiaries and should do so until evidence demonstrates that there will not be hardship imposed by implementing such the Proposed Rule.

Long term care facilities should be able to select the supplier of services for patients within the long term care facility. Under Federal rules, facilities are responsible for meeting the medical requirements of residents. This obligation cannot be ignored, nor should it be undermined. Most long term care facilities have established relationships with suppliers of covered products and supplies that are built on trust, service and responsiveness. Some long term care facilities obtain a supplier number and bill for the services directly. Other long term care facilities obtain a supplier number and employ a third-party to bill for the services. These are complex business relationships that may span multiple Metropolitan Statistical Areas (MSAs) if a long term care company has multiple facilities. Long term care facilities have an obligation to be responsive to clinical needs in a very timely manner. Absent the ability to leverage contracts and use suppliers that offer the type of services and performance necessary for patients within long term care facilities, the facility will be at risk without market choices.

As noted in the Proposed Rule, CMS has conducted the DMEPOS Competitive Bidding Demonstration to test the feasibility and program impacts of using competitive bidding to set prices for durable medical equipment and prosthetics, orthotics, and supplies. **In these sites, there was no conclusive evidence that there were any benefits for residents of nursing homes, yet there were administrative costs imposed upon the facilities.** We believe CMS should exempt long term care facilities from application of this new program at least until such time as there is a determination that there is no impact on the care of each patient and on the ability of the long term care facility to select a supplier that meets performance and service criteria necessary for the needs of their long term care facility patients.

For the following reasons, we strongly believe that the Secretary has sufficient legal authority to exempt long term care patients from the application of the Proposed Rule.

1. The Secretary Has Authority to Exempt those Items and Services Where Savings are Small

The Social Security Act (the Act, SSA) expressly authorizes the Secretary to exempt those items or services for which the savings through competitive acquisition would be minimal. SSA § 1847(a)(3)(B). At issue is whether the sale of a normally fungible item

or service can be viewed otherwise when purchased by a nursing facility, especially where that facility already realizes significant savings by purchasing through a GPO. In other words, can a single item be viewed as two items depending on the circumstances under which it is purchased, the special handling needs of the purchaser, and the special access requirements of the purchaser (*i.e.*, 24/7 access).

There is nothing in the legislative history or plain language of the Medicare Modernization Act (MMA) that would preclude the Secretary from interpreting the phrase "items and services for which the application of competitive acquisition is not likely to result in significant savings," to mean items or services purchased by an institution on behalf of beneficiaries from a group purchasing organization. SSA § 1847(a)(3)(B). The purpose of the competitive acquisition program is to ensure low competitive pricing; it would be inconsistent with this purpose if the acquisition program resulted in higher pricing which could be the case if current institutional purchasing patterns were to be distorted. This distortion would likely have profound negative effects by forcing nursing homes to purchase their own supplies (*i.e.*, for Part A residents) from one source (*e.g.*, GPO) and those on behalf of residents (*i.e.*, for Part B residents) from another source (*i.e.*, competitive acquisition supplier). This will reduce the volume of Part A purchases, decrease the discount, and increase the net cost to nursing facilities. In short, if section 1847 were applied to nursing facilities, it would likely drive-up overall costs. The exemption provision, if applied to purchases by nursing facilities on behalf of their residents, would preclude this from occurring.

2. *Section 1847 Distinguishes Between Purchases by Individuals and Purchases by Institutions on Behalf of Individuals*

It appears that section 1847 was never intended to apply to institutional purchasers and that the phrase "items or services" means those that are purchased directly by individuals and not by institutions on behalf of individuals. Institutions already purchase through competitive bidding albeit private. There is nothing to suggest that Congress intended to undermine institutional purchasing power when it enacted section 1847 or replace the current system or private competitive bidding with a public system. The language makes clear that section 1847 was designed to give individual beneficiaries similar, although not identical, purchasing leverage as enjoyed by institutional purchasers. The section's goal is to bring down the price of items purchased by individuals rather than raising the price of items purchased by institutions, whether on their own behalf or on behalf of beneficiaries.

The "individual" rather than the institutional focus of the section is highlighted by a provision which requires "access of <u>individuals</u> to a choice of multiple suppliers in the area." SSA § 1847(b)(2)(A)(iv) (emphasis supplied). The law further states that the "Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of <u>individuals for such items or services in the geographic area covered under the contract on a timely basis</u>." SSA § 1847(b)(4)(A) (emphasis supplied). The fact that the section contemplates only purchases directly made by individuals is further underscored by the fact the "Secretary

may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program." SSA § 1847(b)(8).[1] Such a provision makes no sense in the context of purchases by nursing homes on behalf of beneficiaries. In short, we believe that the Secretary could reasonably interpret the section so that institutional purchasing on behalf of in-patients or residents is outside the scope of the section altogether. Indeed, one could argue that MMA, with its emphasis on the "individual," precludes the Secretary from extending competitive bidding to institutional providers.

3. Implied Authority

The Secretary has broad rulemaking authority under the Social Security Act. *See* SSA §§ 1102(a) and 1871; *Hennepin County v. Sullivan.*, 883 F.2d 85, 87 (D.C. Cir. 1989). In exercising that authority, the Secretary normally attempts to harmonize programs to accommodate beneficiaries and to avoid rules that create artificial and counterproductive classifications. The Part D drug program expressly provides that the implementing rules "may include standards with respect to access for enrollees who are residing in long term care facilities." SSA § 1860D-4(b)(1)(C)(iv). The Part D provisions recognize the special needs of nursing facility residents. Although the competitive acquisition provisions do not explicitly distinguish between nursing home residents and ordinary beneficiaries, to ignore the distinction is to condone two levels of access—a heightened level for nursing home residents when it comes to purchasing drugs under Part D and a lower level for nursing home residents when it comes to purchasing items or services covered under Part B. This distinction, of course, makes no sense and therefore to avoid this irrational result, one must conclude that the Secretary has the authority under section 1847 to tailor his rules to accommodate the unique needs of nursing home residents.

4. Sound Public Policy Warrants Excluding from Competitive Bidding Items Delivered to Long Term Care Facilities

There is precedent for treating the coverage and payment of items and services provided to patients in long term care facilities differently than those provided to other beneficiaries. Under the MMA, the law creates a new Part D prescription drug benefit. The implementing rules and guidelines artfully distinguish between providing drugs to the Medicare population and providing those same drugs to Medicare beneficiaries in a long term care facility. For Medicare beneficiaries in a long term care facility, the implementing regulations require that there be standards "to ensure convenient access to prescription drugs for institutionalized beneficiaries." *See* 70 Fed. Reg. 4193, 4251 (Jan. 28, 2005) (*Final Regulation Implementing Prescription Drug Benefit Provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*). In addition, the pharmacies that serve long term care facilities will be subject to different quality and

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[1] *See* section 1847(c)(3)(A)(iv) noting that the "development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d)), and individuals." *See also* section 1847(d).

performance criteria than other pharmacies. Those criteria have been outlined in guidances. Finally, the pharmacies serving long term care residents under Part D receive two distinct payments: (i) payment for the drug that is prescribed and (ii) a payment for specific dispensing services that include comprehensive inventory and capacity, special packaging, on-call services, delivery service and miscellaneous reports, forms, and prescription ordering supplies. *See Long Term Care Guidance* <*http://www.cms.hhs.gov/pdps/LTC_guidance.pdf*> (March 16, 2005).

Providing drugs to long term care residents, according to CMS, requires "special attention to ensure the unique needs of the vulnerable population are met without compromising the quality of pharmaceutical care delivered to LTC residents." *See Issue Paper #26, High-Quality Access to Long term Care Pharmacies, http://www.cms.hhs.gov/medicarereform/issuepapers/title1and2/files/issue_paper_13_-_quality_improvements.pdf*> (Jan. 21, 2005). Until now, CMS has consistently recognized the unique needs of nursing facility patients in receiving covered benefits under the Medicare law.

In implementing the Part D benefit, CMS has also recognized that quality and price requirements for covered benefits must be different for those patients who are institutionalized in a nursing facility. The same considerations ought to apply for Part B covered products and supplies offered to patients within nursing facilities. The competitive bidding law requires competition regarding the price and quality of the services provided. However, with respect to nursing facility patients, the supplier of the item or service must travel to the patients; this is generally not the case for patients outside of the nursing facility setting. Therefore, transporting and maintaining the safety and quality of the product or supply must be assured. In the competitive bidding scenario, these types of costs and qualifications are not necessary for the broader population. There are other issues that must be addressed that are unique to the nursing facility population that can not be addressed through a competitive bidding process geared toward the general population.

Therefore, we believe that to ensure the unique needs of the vulnerable patients who are receiving care in a nursing facility, the residents should receive covered supplies and products with appropriate quality and access criteria and that cannot be done within the competitive bidding structure.

B. Quality and Accreditation Standards for Suppliers for Long Term Care Facility Patients Should Be Exempt from the New Accreditation Requirements if Certain Conditions are Met

While the quality and accreditation standards for suppliers have not yet been finalized, we are very concerned that the input on the draft standards did not reflect the current clinical or qualitative requirements necessary to supply DMEPOS to Medicare beneficiaries within a long term care facility. We believe that the standards are simultaneously over-and under-inclusive. On the one hand, standards that might work for

the intermittent interventions for a patient residing in the community will not meet the more rigorous requirements needed for the continuous application in a long term care setting. Furthermore, in evaluating the quality standards, it appears there was no consultation from the long term care community on appropriate standards for patients who are institutionalized.

On the other hand, an additional accreditation process, as proposed, makes little sense and may prove counter-productive. Very few long term care facilities are accredited by JCAHCO. Yet, long term care facilities are bound by strict federal and state quality oversight that is enforced through conditions of participation with the Medicare and Medicaid programs and through survey and certification requirements. To add an additional overlay of regulatory oversight appears to be costly and an administrative burden that would not result in improved quality. Moreover, a single set of accreditation standards is impractical. As a result of the varied types of relationships that long term care facilities have in providing supplies either directly or by a third party, it may be difficult to ensure that a separate accreditation requirement be met as required under the proposed quality standards. Therefore, we believe that quality and accreditation standards for suppliers should be exempt if the suppliers meet the current standards and the long term care facility is in compliance with the Medicare conditions of participation.

C. Reimbursement Rates for Covered DMEPOS for Medicare Beneficiaries in Long Term Care Facilities Should be based on the Current Fee Schedules Until Such Time as Competitive Bidding is Implemented Nationwide

By pre-selecting "winning" suppliers in selected MSAs, CMS is foreclosing long term care facilities from selecting the most appropriate suppliers of services in surrounding areas or in multi-regional selection. As a result, prices to long term care facilities may in fact increase or vary dramatically with no consistency among a local and outlying area. Currently, many facilities are leveraging their purchasing power to secure the best price and assure the necessary support. For Medicare beneficiaries in a long term care facility, competitive bidding to reduce rates is not necessary.

D. All Current Suppliers of Covered DMEPOS Services to Long term Care Facility Patients should be grandfathered and exempt from Competitive Bidding Requirements for Such Facilities and their Patients

The rule establishes a definition of "grandfathered suppliers" as those suppliers who have contracts for the provision of products that are generally "rented" products. We believe that all current suppliers with a contract with a long term care facility should be grandfathered and exempt from the competitive bidding requirements. At a minimum, DMEPOS suppliers that are affiliated with long term care facilities should be a "winning supplier" under an "any willing provider" exception so as to not undercut the provision of services to Medicare beneficiaries within such facilities and ensure quality and continuum of care until this program is demonstrated as a success in ensuring mechanisms are in place to protect such beneficiaries in receiving of covered products and supplies.

E. The Time For Comment on the Proposed Rule Should be Extended Until the Quality Standards are Finalized

The implementation of competitive acquisition should be delayed as there is not a complete record to provide comments. The delays in the development of the DMEPOS Supplier Quality Standards and the development of the Proposed Rule show that the issues involved are complex and their resolutions difficult. The quality standards set out the requirements to be a qualified supplier for purposes of bidding and supplying DMEPOS products in an area. Yet, these supplier quality standards have not been finalized. Many of the concerns raised when they were proposed **directly** relate to the fact that the rules do not reflect the types of requirements necessary for services provided in a long term care facility. The standards were more focused on homebound and home health care patients.

We believe it is difficult to comment on these rules absent a complete understanding of who can be a qualified supplier under the Supplier Quality Standards. We respectfully request that CMS delay the close of the comment period for this Proposed Rule until these quality standards are completed.

F. The Regulatory Flexibility Act Analysis Failed to Address the Effects of the Proposed Rule on Any Aspect of the Provision of Supplies to Those in Long term Care Facilities

Under the Regulatory Flexibility Act, 5 U.S.C. § 601 *et seq.* the Secretary is required to conduct a thorough analysis of the impact of a proposed major rule on small businesses, individuals, and non-profit entities. *See Nat'l Ass'n of Pyschiatric Health Sys. v. Shalala*, 120 F.Supp.2d 33 (2000) (ordering the Secretary to conduct an adequate RFA analysis). As noted above, the Proposed Rule will likely perverse effects on smooth and economic supply of DME to Medicare beneficiaries in long term care facilities. It may, in many cases, dramatically increase the cost of the item or service while reducing the quality or dependability of the service. The RFA analysis presented in the Proposed Rule makes not attempt to address any effect of the Proposed Rule on long term care facilities and those who reside in those facilities. As such, the RFA in our view is incomplete and inadequate.

G. Use of Terms. Grandfathered Supplier and Grandfathered Item. (§ 414.402)

The definition of the term "grandfathered supplier and grandfathered item" is proposed to be limited to only certain products and supplies where a supplier has a contract to furnish the products. We believe that grandfathered items and grandfathered supplier should be extended to those products and supplies that are provided to Medicare beneficiaries within a long term care facility where a supplier has an agreement, either verbal or written, to provide the products or that the long term care facility is providing the products or supplies directly.

H. Payment for Items Furnished by or Under Arrangements with Long Term Care Facilities. (§ 414.408(f) and (k))

The rule should be revised to expressly exempt products that are furnished by or under arrangement with long term care facilities until such time as the competitive bidding process for all DMEPOS is implemented on a nationwide basis. This is necessary to ensure there is no disruption or variation in the quality of supplies and suppliers that serve Medicare beneficiaries in long term care facilities who may be residing within a selected MSA versus those who are nearby in a similar setting. Furthermore, all items furnished by or under arrangement with long term care facilities should be excepted from the exclusivity requirements to the extent such items are competitively bid.

We appreciate the opportunity to provide these comments and suggestions on this proposed rule. The American Health Care Association and the Alliance appreciate CMS' efforts to ensure Medicare beneficiaries within the long term care facility get high quality products and supplies. We look forward to working with you to evaluate and reconcile the difficult issues raised in these comments.

Sincerely yours,

Bruce Yarwood
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AHCA

Alan G. Rosenbloom
President
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NASL Insight • Advocacy • Action

June 30, 2006

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RE: Proposed Rule on Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues

Dear Dr. McClellan:

The National Association for the Support of Long Term Care (NASL) submits the following comments in response to the proposed rule on *Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues*, 71 F.R. 25654 (May 1, 2006) (the "Proposed Rule").

NASL is a trade association representing providers of ancillary products and services to the long-term care and home care industries. Our member companies provide therapy services, diagnostic services, software systems, medical equipment and supplies, and other ancillary services to those care settings.

The Proposed Rule directly impacts NASL members and their customers. Therefore, NASL is a stakeholder in this matter.

We have divided our comments into a section setting forth general concerns regarding the implementation of competitive acquisition for DMEPOS, and a section setting forth our comments on specific provisions of the Proposed Rule. Our general concerns will be discussed in further detail and focus on the following six issues:

1. **Stakeholders cannot adequately comment on a proposed rule they have not seen. In the absence of final DMEPOS Quality Standards that expressly define who is qualified to be a bidder and therefore interrelate with many of the most important provisions of the Proposed Rule, it is impossible to comment effectively.**

2. **The Proposed Rule should exempt products provided to patients of long-term care facilities. The Secretary has both the express and implied authority to grant this exemption, and the exemption will benefit the program.**

3. **CMS should delay implementation of the Proposed Rule to allow sufficient time for a well-conceived and appropriate plan for competitive bidding to ensure that quality and access are not compromised.**

4. **Product categories and items subject to competitive acquisition in 2007 should be minimized because of the program is untested and experimental.**

5. **Program costs to CMS and suppliers should be considered when evaluating the savings potential of competitive bidding.**

6. **The Proposed Rule does not adequately protect small suppliers.**

GENERAL CONCERNS

1. Comment Period Should be Extended Until After the Release of Quality Standards

Recommendation: ***We urge that the comment period on the proposed rule be extended until at least 90 days after the publication of the final DMEPOS Quality Standards, as there is not a complete record to provide comments.***

Rationale: It is simply not possible to comment fully on elements of the Proposed Rule that have a substantial impact on suppliers in the absence of final Quality Standards.

The Quality Standards set out the requirements to be a qualified supplier for purposes of bidding and supplying DMEPOS products. The Quality Standards interrelate with key elements of the Proposed Rule because, for example, the Quality Standards will have an impact on the type and number of suppliers that may be able to submit bids, the size of the suppliers, the construction of product categories, and the appropriateness of the approach of the Proposed Rule's method for determining a single payment amount.

The exclusive use of the home care model reflected in the draft Quality Standards, if followed in the final quality standards, dramatically affects the application of the Proposed Rule to suppliers that are not home care providers and may dictate whether, among other things, a distinct bid process should be conducted for alternative methods of delivering DMEPOS to Medicare beneficiaries who are institutionalized.

Without having the final Quality Standards, it is not possible to even anticipate all of the interactions between the Proposed Rule and the Quality Standards that may be important and may need to be considered by CMS in the interest of Medicare beneficiaries and the Medicare program.

It was originally contemplated that the DMEPOS Supplier Quality Standards would be finalized prior to the comment period of the Proposed Rule. Since this did not happen, and because of the significance of the Quality Standards to competitive acquisition, **we submit that the comment period should be extended to not less than 90 days after the publication of the final DMEPOS Supplier Quality Standards.**

We have attached to these comments our prior request for extension of the comment period for the Proposed Rule as Appendix A to this letter, and incorporate it by reference.

2. The Rule Should Exempt Products Provided to Medicare Beneficiaries in Long-Term Care Facilities

Recommendation: ***Items furnished to long-term care facility residents should be exempted from competitive acquisition. In order to meet the unique needs of the high acuity and vulnerable patients who are receiving care in long-term care facilities, they should receive covered supplies and products with appropriate quality and access criteria. This cannot be done within the competitive bidding structure. We believe the Secretary should exercise the statutory authority within section 1847 to exempt items purchased by and delivered to Medicare beneficiaries residing in long-term care facilities from the competitive acquisition requirements.***

Rationale: Long-term care facility patients are of higher acuity than mobile, non-institutionalized patients, and they have special needs that cannot adequately be met by a distribution system designed for non-institutionalized patients. Institutionalized patients are often older and frailer than the typical beneficiary receiving DMEPOS.

Items furnished to long-term care facility patients typically are furnished by either the facility itself or by highly specialized suppliers. Arrangements for enteral nutrition, for example, involve high acuity patients in comparison to the typical beneficiary receiving DMEPOS. Either the facility directly administers the therapy or the supplier, working in a close clinical relationship with the facility's nursing personnel, furnishes the supplies for the therapy and is significantly involved in the patient's nutritional therapy. The level of clinical management and services related to the furnishing of DMEPOS to patients in institutionalized settings is substantially higher than that for non-institutionalized patients.

It is not in the best interest of beneficiaries for the facility to be forced into accepting a supplier that has prevailed in the bid process by bidding low margins, while betting on high volume and low service. Such a supplier may have little experience in the care of patients in long-term care facilities. Further, such a supplier will have little incentive to provide appropriate services and interaction with the facility's clinical staff, because this will adversely impact already low margins, and could cost more than the single payment amount established through competitive bidding. These considerations are precisely the same as those that led CMS to recognize the unique needs of patients in long-term care facilities covered under Part D of Medicare.

When CMS sought to implement the new Part D prescription drug benefit, it recognized correctly that patients in long-term care facilities have special needs that cannot adequately be met through a distribution process designed for beneficiaries who are mobile and not institutionalized.

As recognized in the implementation of Medicare Part D, CMS must balance its proposed policy changes with the existing federal requirements mandating that long-term care facilities assume responsibilities that "each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." 42 C.F.R. Part 483. Altering the acquisition of DMEPOS services could affect the ability of facilities to meet their regulatory obligations. The administrative and regulatory difficulties created for a facility by interference with the control over what suppliers have access to their patients are wholly unaddressed by the proposed rule. The same types of concerns that led the agency to adopt special rules for pharmacy procurement to beneficiaries in long-term care facilities should apply here.

Moreover, as discussed below, competitive bidding for institutionalized patients would result in, at best, minimal savings. The anticipated cost savings, therefore, do not justify the adverse impact that competitive acquisition, as reflected in the Proposed Rule, would be likely to have on beneficiaries. Accordingly, we urge CMS to exclude long-term care facilities from the scope of the competitive bidding process.

At a minimum, CMS should study the affects that competitive acquisition will have on patients and institutions before extending competitive bidding to include long-term care facilities. It is our understanding that results from earlier demonstrations did not support the Proposed Rule. We believe that there is a burden on CMS to document the potential impact on the resident population and to set specific performance standards for safeguarding access to medically necessary DMEPOS items. CMS must affirm that competitive acquisition will not adversely affect the health and welfare of institutionalized beneficiaries. Until this is done, the implementation of these regulations to include long-term care facilities is premature.

We believe that section 1847 of the Social Security Act ("SSA") provides ample statutory authority to exempt items purchased by, and delivered to, Medicare beneficiaries residing in long-term care facilities from the competitive acquisition requirements.

a. The Secretary Has Authority to Exempt those Items and Services Where Savings are Small

The SSA expressly authorizes the Secretary to exempt those items or services for which the savings through competitive acquisition would be minimal. SSA § 1847(a)(3)(B). Where beneficiary acuity and the necessary services associated with the furnishing of DMEPOS is substantially different in an institutional treatment setting, items within the same HCPCS code

are appropriately treated as different. This is particularly justified where the facility already realizes significant savings by purchasing through a GPO. In other words, a single item can be viewed as two items depending on the circumstances under which it is purchased, the special handling needs of the purchaser, and the special access requirements of the purchaser (i.e., 24/7 access).

There is nothing in the legislative history or plain language of the Medicare Modernization Act (MMA) that would preclude the Secretary from interpreting the phrase "items and services for which the application of competitive acquisition is not likely to result in significant savings," to mean items or services purchased by an institution on behalf of beneficiaries from a group purchasing organization. SSA § 1847(a)(3)(B).

The purpose of the competitive acquisition program is to ensure low competitive pricing; it would be inconsistent with this purpose if the acquisition program resulted in higher pricing which could be the case if current institutional purchasing patterns were to be distorted. This distortion would likely have profound negative effect by forcing nursing homes to purchase their own supplies (i.e., for Part A residents) from one source (e.g., GPO) and those on behalf of residents (i.e., for Part B residents) from another source (i.e., competitive acquisition supplier). This will reduce the volume of Part A purchases, decrease the discount, and increase the net cost to nursing facilities.

If long-term care facilities are not exempted, bidders will have to take the cost of serving long-term care facility patients into account in their bids, which is likely to increase their bids over what they otherwise would be. In short, **if section 1847 were applied to nursing facilities, it would likely drive-up overall costs.** The exemption provision, if applied to purchases by nursing facilities on behalf of their residents, would preclude this from occurring.

b. Section 1847 Distinguishes Between Purchases by Individuals and Purchases by Institutions on Behalf of Individuals

It appears that section 1847 was never intended to apply to institutional purchasers and that the phrase "items or services" means those that are purchased directly by individuals and not by institutions on behalf of individuals. Institutions already purchase through competitive bidding albeit private. There is nothing to suggest that Congress intended to undermine institutional purchasing power when it enacted section 1847 or replace the current system of private competitive bidding with a public system. The language makes clear that section 1847 was designed to give individual beneficiaries similar, although not identical, purchasing leverage as enjoyed by institutional purchasers. **The section's goal is to bring down the price of items purchased by individuals rather than raising the price of items purchased by institutions, whether on their own behalf or on behalf of beneficiaries.**

The "individual" rather than the institutional focus of this section is highlighted by a provision that requires *"access of individuals to a choice of multiple suppliers in the area."* SSA § 1847(b)(2)(A)(iv). The law further states that the *"Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis."* SSA § 1847(b)(4)(A).

The fact that the section contemplates only purchases directly made by individuals is further underscored by the fact the *"Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program."* SSA § 1847(b)(8). Such a provision makes no sense in the context of purchases by nursing homes on behalf of beneficiaries.

We believe that the Secretary could reasonably interpret the section so that institutional purchasing on behalf of in-patients or residents is outside the scope of the section altogether. Indeed, one could argue that MMA, with its emphasis on the "individual," precludes the Secretary from extending competitive bidding to institutional providers.

*c. **Implied Authority***

The Secretary has broad rulemaking authority under the Social Security Act. See SSA §§ 1102(a) and 1871; Hennepin County v. Sullivan., 883 F.2d 85, 87 (D.C. Cir. 1989). In exercising that authority, the Secretary normally attempts to harmonize programs to accommodate beneficiaries and to avoid rules that create artificial and counterproductive classifications. The Part D drug program expressly provides that the implementing rules "may include standards with respect to access for enrollees who are residing in long-term care facilities." SSA § 1860D-4(b)(1)(C)(iv). The Part D provisions recognize the special needs of nursing facility residents.

Although the competitive acquisition provisions do not explicitly distinguish between nursing home residents and other beneficiaries, to ignore the distinction is to condone two levels of access—a heightened level for nursing home residents when it comes to purchasing drugs under Part D and a lower level for nursing home residents when it comes to purchasing items or services covered under Part B. This distinction, of course, makes no sense and therefore to avoid this irrational result, one must conclude that the Secretary has the authority under section 1847 to tailor his rules to accommodate the unique needs of nursing home residents.

3. The Implementation Timeframe for Competitive Acquisition Should Be Modified

Recommendation: ***In addition to extending the comment period until after the publication of the final DMEPOS Quality Standards, the implementation of competitive acquisition should be delayed as much as permitted by § 1847(a)(1) of the SSA.***

Rationale: The agency's original timeline projected publication of the Proposed Rule in Spring 2005. The timeline also set forth a comment period of Summer 2005, with the final rule to be published in Spring 2006. This original timetable would have allowed for more thoughtful consideration of the many complex issues raised by the Proposed Rule, both by stakeholders and by CMS.
The original timetable would have allowed CMS and the supplier community from Spring 2006 through the end of 2006 to do all of the following: (i) make arrangements for the implementation contract, (ii) process supplier accreditation, (iii) conduct beneficiary and supplier education, (iv) initiate and complete necessary system changes, (v) request, submit and evaluate bids, (vi) award contracts, and (vii) review any outstanding issues with POAC.

The delays in the development of the DMEPOS Supplier Quality Standards, and in the development of the Proposed Rule, show that the issues involved are complex and their resolutions difficult. The original timetable contemplated implementation for items and MSAs on January 1, 2007. That the development of Quality Standards and the Proposed Rule has taken far more time than originally envisioned by CMS demonstrates that it is unrealistic to expect the final rule to be published and all of the implementation steps to be completed by early 2007.

In addition, we have identified a number of significant issues that will be difficult to adequately resolve by early 2007. We expect that other comments will also address significant issues of concern that will be difficult to resolve by early 2007.

It is essential that the implementation of competitive acquisition be successful in achieving savings without compromising the quality of care or disrupting access and the delivery of care to Medicare beneficiaries. After the significant delays in development of the Quality Standards and Proposed Rule, a subsequent rush to implement competitive acquisition by an arbitrary deadline that is not required by Title XVIII of the SSA, will ensure failure and harm beneficiaries.

The SSA's requirements are satisfied if competitive bidding is implemented in 2007. SSA § 1847(a)(1)(B)(i)(I). Implementation toward the end of 2007 would be more consistent with the original timetable in terms of time allocated to tasks, and would afford a much greater opportunity for the program to achieve its objectives without adversely impacting beneficiaries.

4. The Number of Product Categories and Items Subject to Competitive Acquisition in 2007 Should be Minimized

Recommendation: ***The product groups initially subject to competitive bidding should be sharply limited until CMS, beneficiaries and suppliers gain experience with the program.***

Rationale: Section 1847(a)(1)(B) of the SSA permits a phase-in with respect to the items subject to competitive bidding, as CMS has acknowledged in the proposed rule. *See, e.g.,* 71 Fed. Reg. 25670. As discussed in more detail below, competitive bidding by HCPCS codes (at least by the current codes) is inappropriate for many items. In many cases a single code includes a wide variety of items that (i) are not clinical equivalents, and (ii) have widely varying costs. This is not a new issue and, in fact, it was identified by the Government Accountability Office in its September 2004 report on competitive acquisition in Medicare. GAO, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies,* GAO-04-765 (September 2004). A critical analysis of codes that may be appropriate for competitive bidding is necessary before items can be competitively bid.

An analysis of the items included in HCPCS codes for the purposes of the competitive acquisition program is in the interest of both the Medicare program and Medicare beneficiaries. If items with widely varying costs are included in a single code, suppliers bidding on the product category will need to include an amount related to the risk that the mix of items dispensed in that code will shift toward the more expensive items, particularly as physicians are able to prescribe particular brands and modes of delivery with a code under section 1847(a)(5)(A).

The over-inclusiveness of some codes will result in no program savings. At the same time, once bids are awarded, the winning suppliers will have incentives to shift the mix of items dispensed in that code toward the least expensive items without regard to durability or efficacy. Such shifts would not be in the best interest of beneficiaries where they are driven by supplier economics. Examples of such over inclusiveness include wheel chairs, wheel chair seat and back cushions, support surfaces, and negative pressure wound therapy pumps.

Until a critical analysis of the items included in certain HCPCS codes is completed, **competitive bidding should be limited to a product group or groups that include only codes or items that are truly generic and clinically equivalent.**

The fact that the program is new and experimental provides a compelling additional reason for CMS to limit the number of product categories initially subject to competitive bidding. Serious problems have been identified in the Proposed Rule. If these issues are not addressed, there is no data or experience to show that the program will accomplish its goals of saving money, while maintaining access and quality.

It is not enough to point to the demonstrations in Polk County, Florida and the San Antonio, Texas MSA. These demonstration projects were materially different from what is contemplated by the Proposed Rule.

One of the most striking differences is the use of the median of bids below the pivotal bid to establish single payment amounts for items included in the product group. This is substantially different from pricing in the demonstration projects. It also is likely that there will be far fewer contracted suppliers in each competitive bid area than there were in the demonstrations. **These significant differences, as well as others, show that the competitive bid program may adversely impact access and quality in varying ways.** CMS acknowledged this by eliminating New York, Chicago and Los Angeles from competitive bidding in 2007.

5. **Program costs should be considered when evaluating the savings potential of competitive acquisition of specific items and product categories to ensure that the savings estimate reflects actual net savings**

Recommendation*: CMS, contractor and user costs must be taken into account in calculating a true cost analysis.*

Rationale: The Proposed Rule does not indicate that CMS and contractor costs will be taken into account in evaluating the savings potential for competitively bid items or product categories. Assuming that supplier costs will be absorbed and reflected in the bids, CMS and contractor costs that should be taken into account include the following: (i) the cost of administering the implementation of the bidding program for particular items and product categories, (ii) the cost of modifying systems and software, (iii) the cost of reviewing, selecting and managing accreditation organizations, (iv) the cost of ongoing administration of competitive acquisition once contract suppliers are chosen, (v) the cost of managing dual systems for competitive bid payments and fee for service payments. **We submit that an appropriate evaluation of savings potential must reflect the net of these costs. Only by doing this can we be sure that the total cost of competitive bidding for certain items or product groups does not exceed the gross savings.**

6. **Proposed Rule Should Allow Small Suppliers to Compete**

Recommendation: ***CMS should consider allowing any willing and qualified supplier to provide DMEPOS so long as payment is subject to the single payment amount determined through the competitive bidding process.***

Rationale: The Medicare Modernization Act requires some balancing of program savings through the competitive acquisition of DMEPOS with the protection of small suppliers. Although CMS references its concern for protecting small suppliers, the Proposed Rule offers no effective method of leveling the competitive playing field so that small suppliers are not disproportionately disadvantaged.

CMS states in the Proposed Rule that the law requires small supplies to be given an "opportunity to bid," but little regard is given toward enabling small suppliers to actually "win a bid." Further, the Proposed Rule's "Opportunity for Networks" (an attempt by CMS to aid small suppliers) would actually create an additional challenge for small suppliers who will already be hard-pressed to shoulder the inherent burdens of competitive bidding (especially during the first round of bidding).

The building of a network is no easy feat and it must be done with great caution and with even greater legal oversight. Assuming that a network can be constructed to meet the scrutiny of the Department of Justice (DOJ) and the Federal Trade Commission (FTC), the majority of small businesses will not be able to bear the additional expense of network-building, and will face the risk that disappointed suppliers will sue regardless of the DOJ and FTC views.

The network opportunity outlined in the Proposed Rule would require small suppliers to create the legal structure of any network prior to bidding. The investment of time and capital necessary to accomplish this task would likely discourage many small providers from undertaking the task. The antitrust litigation risk would further deter other small suppliers, who are ill equipped to fund antitrust litigation, from forming networks. In short, the proposal to allow small suppliers to form networks is unrealistic and unworkable, particularly under the abbreviated time frame proposed by CMS. As this proposal is the only attempt to assure the participation of small suppliers, it is respectfully suggested that the proposed rule has wholly failed to meet the requirements of the statute.

To address this inadequacy within the Proposed Rule, we recommend that CMS consider allowing any willing and qualified supplier to provide DMEPOS at the single payment amount determined through the competitive bidding process. **This program is intended to save money, not to put legitimate suppliers out of business, or to restrict patient access to quality goods and services.**

COMMENTS ON SPECIFIC PROVISIONS OF THE PROPOSED RULE

A. Use of the Term "Off the Shelf Orthotics" § 414.402

Recommendation: *The definition of the term "off the shelf orthotics" should be clarified to prevent infringement on state practice acts. We suggest that the standards of the Board for Certification in Orthotics/Prosthetics be applied to achieve consistency in the items that are "off the shelf orthotics" for purposes of the rule.*

Rationale: The preamble in the Proposed Rule suggests that where the intervention of a certified orthotist is required the item is not off the shelf orthotics. However, it is not clear whether CMS intends this to preempt state practice acts and current definitions of scopes of practice. There are wide variations in state laws and regulations with respect to items or activities requiring the involvement of an orthotist. Therefore, different items could constitute off the shelf orthotics in different competitive bid areas if the standard is defined by reference to state law. We do not believe the intent of CMS was to have this inconsistency.

We further urge caution in making changes that might negatively affect already heavily regulated long-term care facilities. These facilities require orthotic devices in order to comply with federal regulations that have been in effect since passage of the Omnibus Budget Reconciliation Act of 1987. Many of these devices are supplied by Certified Fitters working under the direct supervision of licensed therapists.

B. Payment Basis

1) Payment for Inexpensive or Routinely Purchased DME Furnished on a Rental Basis § 414.408(i)(5)

Recommendation: ***Where inexpensive or routinely purchased DME is included in competitive bidding, there should not be an option to have the equipment provided on a rental basis.***

Rationale: Rental billing for inexpensive or routinely purchased items is cost prohibitive even under the current fee schedule. Suppliers that furnish such items generally do so on a purchase basis, but not a rental basis.

To require suppliers to include in their bids furnishing inexpensive or routinely purchased DME on a rental basis will simply increase the bid amounts without any corresponding benefit. Suppliers will be forced to take into account the costs of billing and collection for 26 bills for such items under the Proposed Rule rather than two (13 months of rental multiplied by primary and secondary payer billing vs. one primary and secondary bill for a sale).

For inexpensive and routinely purchased items, the cost of billing and collection, if it must be done 26 times, can comprise a substantial portion of the total cost of the item. This necessarily will increase the bid prices. It is not in the interest of the Medicare program to require suppliers to incur these costs, as they will increase bid prices for the applicable items and thereby increasing program expenditures.

Any adverse impact on beneficiaries could be eliminated in cases of financial hardship by allowing beneficiaries to pay the beneficiary amount in installments, as is permitted in documented cases of financial hardship under current law.

Finally, the rule offers no consideration regarding the affect on suppliers in the following circumstances:

- Being required to rent products that are defined as "single patient use only" by the manufacturer.
- Being required to rent products that have very limited manufacturer's warranties.
- Having a patient expire during the rental period on a single patient use item.

Rental of inexpensive or routinely purchased items is not feasible from a practical or financial perspective and should be eliminated from the final rule.

2) Adjustment of Payment Amounts in Other Areas § 414.408(e)

Recommendation: ***It is not appropriate to use payment amounts determined in competitive bidding to make inherent reasonableness adjustments to payment amounts in other geographic areas, particularly in any formulaic manner as suggested in the Proposed Regulation.***

Rationale: There is no reason to suppose that competitive bid payment amounts will be reflective of the costs of providing the items in areas outside of the competitive bid areas. Competitive bid areas generally are more densely populated than other areas. In addition, winning bidders in competitive bid areas, in all probability, will pay less for the involved items than suppliers in other areas because of volume discounts.

The Proposed Rule also tacitly assumes that there will be some sort of uniformity or consistency in the payment amounts for items in the competitive bid areas. At best, this assumption is highly suspect. The costs of living in Northeast and Pacific Coast MSAs are dramatically different from those in Midwestern or plains MSAs. In the absence of uniformity or consistency in competitive bid payment amounts, there is even less basis for assuming that the single payment amounts have any relationship at all to "reasonable" payment outside of competitive bid areas, and it is not fair to use these amounts to make inherent "reasonableness" adjustments to payment amounts outside of the competitively bid MSAs. **Single payment amounts established for large MSAs on the basis of competitive bidding will have little relationship to appropriate payment amounts in areas outside of those MSAs.**

3) Payment Amount for Grandfathered Items § 414.408(k)

Recommendation: ***CMS should not change the payment amounts for Grandfathered items described in § 1847(a)(4) of the Act.***

Rationale: The section provides that CMS *"shall establish a process by which rental agreements for the covered items ... may be continued notwithstanding this section."* The price term of an agreement is not a peripheral detail, but a central term of the agreement.

The SSA plainly requires that the agreements be *continued* notwithstanding competitive acquisition. It does not state that the agreements may be continued as adjusted by competitive acquisition. CMS contends that Congress' direction to establish a "process" for continuing the agreements authorizes CMS to unilaterally change the contractual payment amounts for grandfathered items. This interpretation stretches the plain language of the law to the breaking point and beyond. A "process" is an administrative mechanism or methodology for continuation of the agreements, not an authorization to unilaterally modify agreements.

In addition, as a policy matter, it is not necessary to unilaterally reduce the price of grandfathered items. The higher co-payment associated with the unadjusted price will incentivize the suppliers to adjust the price, and if they do not, the lower single payment amount will provide an incentive for beneficiaries to change to the contract supplier. CMS should adhere to the plain language and meaning of the Act and provide for the continuation of agreements under § 1847(a)(4) without modification of the price.

Finally, CMS should apply grandfathering on an item basis at least for capped rental items. Under the SSA, CMS has the authority to establish a date of applicability of competitive bidding in a competitive bid area, and provide for implementation with respect to capped rental items after the expiration of the capped rental period. This alternative will save costs of administration related to DMERCs having to process claims with differing payment amounts.

C. Competitive Bidding Areas

1) Designation of Areas § 414.410

Recommendation: ***An area selection methodology should be used that initially results in a limited number of small competitive bid areas, consistent with the Act.***

Rationale: Since the competitive acquisition program is new and experimental, the method for selecting competitive bid areas should be modified. As CMS recognizes, the Act requires 10 of the largest MSAs, not the 10 largest. Due to the experimental nature of the program, and the challenges that will be encountered in its implementation, CMS has excluded New York, Chicago and Los Angeles.

In addition to the factors recognized by CMS, there are serious issues with the item selection and pricing methodologies of the Proposed Rule. All of these reasons demonstrate that an area selection methodology should be used that initially results in a limited number of small competitive bid areas, consistent with the SSA. This can reasonably be accomplished in several ways.

Under the methodology of the Proposed Rule, there is little geographic diversity in the competitive bid areas. They are disproportionately concentrated in DMERC Region C. The geographic diversity can and should be expanded to provide more useful information to be used in implementing the program in more areas in the future, as well as to minimize the consequences to Medicare beneficiaries of implementation challenges. The maximum number of competitive bid areas in a State should be limited to one instead of two.

The methodology should be changed to distribute the competitive bid areas to among the DMERC regions as evenly as possible, so that there are 3 areas in each of two of the DMERC regions, and 2 in each of the remaining two DMERC regions. This methodology would result in 10 of the largest MSAs for purposes of the Act.

In this way, better experience and less adverse impact on beneficiaries will result. The areas can be expanded as CMS, suppliers and beneficiaries develop more experience with the program, and can determine the features of the program that work best, and those that should be modified.

2) Nationwide or Regional Mail Order Competitive Bidding Program § 414.410(d)(2)

Recommendation: ***Different methods of delivery should <u>not</u> be treated differently.***

Rationale: As we have noted, the proposed rule does not include the DMEPOS Quality Standards. However, in describing the mail order competitive bidding program, the Proposed Rule refers to using mail order for the replacement of supplies. We strongly urge the final rule not treat different methods of delivery differently. Treating different methods of delivery differently, where this is not clinically necessary or appropriate, will only reduce the effectiveness of the competitive acquisition program in lowering costs and maximizing beneficiary choice.

Under this principle, mail order suppliers would bid in the same process as non-mail order suppliers both for initial and replacement DMEPOS. The methods of delivery would not be distinguished in the bid process or pricing. To the extent medically necessary, for example where professional services are required in initial fitting, the DMEPOS Quality Standards or Local Coverage Determinations could set forth appropriate requirements. This approach would most effectively achieve CMS' objectives of maximizing savings and beneficiary choice.

D. Criteria for Item Selection

1) Use of Medical Policies to Determine Product Categories

Recommendation: ***Product categories should be defined with reference to medical policies and clinical conditions.***

Rationale: Medical policies are created as much to categorize medical conditions and coverage, as they are to categorize products and codes. For example, if competitive bidding were considered from the standpoint of managing specific conditions, it would be unreasonable to consider combining a wound care patient group together with a patient group requiring a hospital bed or a wheelchair. From a simplistic approach it may seem appropriate to combine the medical policy for "wheelchair seating" with "wheelchairs" and "support surfaces" with "hospital beds" in forming a competitive bidding product category. However, there are stark contrasts in the medical necessity requirements between these medical policies and the beneficiaries that qualify for them.

In order to insure quality and access in a competitive bidding environment, CMS must ensure that the best providers have an opportunity to bid. Many providers structure their business around addressing specific disease states and conditions. It cannot be assumed that providers with a wound care expertise and focus are also wheelchair or hospital bed providers, nor can the reverse be assumed. The goal of competitive acquisition must be to reasonably reduce program and beneficiary costs while maintaining or enhancing quality and access.

Any combination of HCPCS codes from multiple medical policies lumped together into one competitive bidding product category will reduce the number of providers capable of bidding for specific goods and services. Those providers that carry the broadest product offering will benefit to the detriment of the specialty providers, and the level of competition will be reduced. Ultimately, the very providers most adept at providing quality goods and services for a specific medical policy may be prohibited from bidding due to combined medical policies that extend beyond their expertise and product offering.

The system may lose out on actual savings by inappropriately reducing the number of suppliers capable of bidding. Less competition will result in a seller's market and costs will increase. We understand CMS' goal that beneficiaries not be required to obtain related items from different suppliers. We submit that the use medical policies as described will achieve this goal.

The Proposed Rule lacks clarity regarding how product categories will be defined. Unless CMS adopts our recommendation that product categories be defined based on medical policies, we urge that the method of defining product categories be published for comment prior to the effective date of a final rule. As it stands, stakeholders are left in the dark. They can only make recommendations on how best to define product categories, and cannot provide comments to a method proposed by CMS.

2) The Sufficiency of Current HCPCS Codes for Competitive Bidding

Recommendation: ***Higher and lower priced items currently in a single HCPCS code should be separated into different HCPCS codes.***

Rationale: Certain current HCPCS codes are not sufficiently detailed and homogenous in order to be effectively bid. Clearly, bidding codes that include multiple items with widely varying costs, a variety of technologies and different clinical applications and efficacy would have a detrimental affect on patient care and access. Examples of these codes include support surfaces and wheelchair seating, which include within a single HCPCS code items of varying cost, configuration and complexity that are prescribed based on the patient's specific clinical condition. An example cited by the GAO is power wheelchairs, where different models represented by a single HCPCS code, range from $1,600 to nearly $17,000.

Competitive bidding of items in such codes will fail to maximize program savings because suppliers will have to include in their bids an amount reflecting the anticipated cost of the higher priced items in the code. The mix of higher and lower cost items within the code will be difficult for suppliers to accurately estimate because they do not have access to data regarding the mix in the competitive bid area; instead they only have their own mix data. In addition, the mix may be affected in amounts that are not possible to predict due to the SSA's provision that physicians may prescribe a specific brand or mode of delivery of product within a competitively bid code. *See* SSA § 1847(a)(5)(a).

Suppliers necessarily will be forced to add some amount of risk premium over the amounts that they would be able to bid for only the lower cost items, or for a known mix of lower and higher priced items. Program savings will be greater if higher and lower priced items currently in a single HCPCS code are separated into different HCPCS codes because these uncertainties and unknowns will be eliminated and suppliers will be able to bid their best prices for each of the lower and higher priced items.

In addition, **the use of HCPCS codes that include items of widely varying cost and clinical application will adversely affect the quality of care for the beneficiaries.** The use of such codes will result in a race to the bottom by suppliers, and diminish beneficiary access to medically necessary, higher cost or higher technology items that are included in HCPCS codes together with inexpensive items that may not be appropriate for some beneficiaries. This adverse impact on the quality of care was *specifically* cited by the GAO, and was the basis for its recommendation that CMS evaluate and "subdivide" codes where the characteristics and price range of items in the code "is too broad."

Once contracts are awarded to suppliers, the suppliers will have a significant incentive to furnish the lowest cost item within the code, unless the physician specifically prescribes a different item. This is particularly to be anticipated where highly competitive bidding results in a low single payment amount in comparison to the fee schedule amount. Suppliers may need to skew the mix of items toward the least expensive items in the code in order to be able to supply the items without suffering financial losses. Unlike prescription drugs, many items of DME included within the same HCPCS code are not directly interchangeable. The unique needs of the patient need to be addressed by the use of the correct product within any given HCPCS code. The Proposed Rule fails to address this issue.

Both of these effects can be avoided if competitive bidding is initially limited to codes that contain only homogenous, generic and clinically equivalent items. Many such codes offer significant opportunity for savings precisely because the included items are similar to each other in cost and technology. While competitive acquisition in product categories including such codes is implemented, a critical review of other codes should be conducted so that more appropriate codes can be established that do not include items of widely differing costs, technologies and clinical applications.

With some of the current codes, any supplier wishing to win a competitive bid may be forced into a situation where it disregards quality and efficacy for price. Historically, ethical providers have strived to differentiate themselves by their level of quality and service. If an under-defined HCPCS code, which includes a wide variety of technologies, is bid, then such a provider will either have to reduce its standards or lose business.

By more finely dividing the items selected for bidding, and increasing the number of HCPCS codes, CMS may achieve the benefit of competitive bidding without jeopardizing access to higher cost, higher technology items.

E. Conditions for Awarding Contracts

1) Quality Standards and Accreditation § 414.414(c)

Recommendation: ***CMS should re-evaluate the implementation of its accreditation approach.***

Rationale: An accreditation mandate has been proposed although the capacity of accreditation organizations to enable suppliers to comply with this mandate is clearly inadequate. Under the most optimistic view, there is not nearly enough time for suppliers to have a reasonable opportunity to become accredited.

Not only will the capacity gap impair the agency's ability to achieve a robust and effective bid process, it will have a disproportionately adverse impact on small suppliers. Accreditation organizations are incentivized by the accreditation fee structure to first satisfy the accreditation needs of large suppliers. The negative impact on small suppliers is not consistent with the requirements of SSA § 1847(b)(6)(D).

2) **Financial Standards § 414.414(d)**

Recommendation: ***CMS should clarify, revise and reissue its proposed financial standards for comment as a separate rulemaking.***

Rationale: The financial standards are not detailed, so it is not possible to provide detailed comments. However, we wish to emphasize the importance of recognizing that many suppliers are small businesses, and that the Act specifically requires CMS to protect small suppliers. SSA § 1847(b)(6)(D). Therefore, small suppliers that are not financially troubled must be reasonably able to comply with the financial standards implemented by CMS without having to incur undue cost.

Moreover, the absence of any transparency with respect to the financial standards is not at all appropriate in view of the centrality of the standards in the bid process. Satisfaction of the standards is a precondition to bidding. If the standards are too restrictive, fewer suppliers will be able to participate in the bid process, diminishing beneficiary choice and potentially adversely affecting the single payment amount. If the standards are not restrictive enough, unsound suppliers may be awarded contracts. These suppliers may not be able to supply beneficiaries at the single payment amount, resulting in impaired access.

The method of assessing the financial capability of suppliers planning to meet demand through expansion should be known so that suppliers can assess their ability, and that of their competitors, to meet demand through expansion. The failure to specify financial standards leaves both beneficiaries and suppliers vulnerable, and CMS should specify standards in time for comment prior to the effective date of the Proposed Rule.

3) **Market Demand, Supplier Capacity and Opportunity for Participation by Small Suppliers §§ 414.414(d), 414.414(g), 414.418**

Recommendation: ***The proposed rule should provide adequate protections for small suppliers.***

Rationale: Despite the Act's requirement for protection of small suppliers, the Proposed Rule is likely to have a serious adverse impact on small suppliers, and it is questionable whether small suppliers will be successful bidders in any of the competitive bid areas. It appears that the Proposed Rule attempts to limit any requirement for small business participation to "the opportunity to bid," rather than offering meaningful participation and an opportunity to be a contract supplier.

We contend that the Act requires some balancing of program savings with the protection of small suppliers. This is missing from the Proposed Rule. Under the Proposed Rule, only a sufficient number of suppliers need be selected to meet demand, and CMS states that in some cases this could mean only two suppliers. The Act requires that awards be made in each competitive bid area for each product category to "multiple" suppliers, and "multiple" does not mean two. SSA § 1847(b)(4)(B).

Under the Proposed Rule, it is quite likely that two large suppliers could satisfy the demand for any product category in any competitive bid area. Moreover, large suppliers obtain DMEPOS items at lower unit cost than small suppliers, and enjoy economies of scale. Large suppliers not only will have capacity, but also they will be able to consistently underbid small suppliers. CMS may view this as a desirable result, but it is not the result required or intended by the Act.

The proposal that small suppliers be permitted to form partnerships to bid does not adequately address the small supplier issue. It does not solve the inventory cost issue although it arguably addresses the capacity issue. More importantly, however, it raises serious antitrust issues. Regardless of CMS' market share limitation, what the Proposed Rule contemplates may be a horizontal market allocation agreement, which is illegal *per se* under antitrust law. *See* 15 U.S.C. § 1 *et seq.*

Even if the DOJ and the FTC were to defer to CMS as a matter of policy, there is nothing to stop a competitor from suing and alleging a violation. This significant exposure should give any supplier substantial reservations regarding entering into the joint ventures contemplated by the Proposed Rule.

F. Determining Single Payment Amounts for Individual Items

1) Single Payment Amount §414.416(b)

Recommendation: ***To assure beneficiary access, the pivotal bid should be the payment amount. Furthermore, the proposed rule should contain standards for rejecting bids that are below cost.***

Rationale: The Proposed Rule's method for determining the single payment amount is fatally flawed. The use of the median amount below the pivotal bid will assure that some contract suppliers will drop out and will impair beneficiary access. In a competitive environment, suppliers will bid the lowest amounts at which they are able to provide the items. The pivotal bid is the bid of the supplier at which the demand is just met. The single payment amount for items in a product category therefore should be the amounts bid in the pivotal bid (or should be the highest amounts bid by suppliers bidding the product category at equal to or less than the pivotal bid).

The single payment amount, however, is not set at the pivotal bid, but instead is set at the median between the pivotal bid and the low bid. If the suppliers that bid between the median and the pivotal bid submitted the best bids they could make, which again is the only reasonable assumption in a competitive environment, then they will not be able to furnish the supplies at the median, which is lower than the amounts they bid. This is a fundamental inconsistency in the pricing method. **At the very least, it is highly doubtful that suppliers bidding between the median and the pivotal bid will be able to furnish the involved items at a payment amount equal to the median.** If a supplier bidding between the pivotal bid and the median is not able to provide the items at the median, the demand will not be met and access will be impaired.

The Proposed Rule's provision for selecting additional suppliers does not resolve this fundamental flaw. Under the Proposed Rule, suppliers added after the bid process must accept the single payment amount, which is not changed. **For the same reasons as set forth above, it is not likely that suppliers bidding over the pivotal bid will be able to accept the median between the pivotal bid and the low bid as the payment amount.**

Demonstration project experience cannot be used as a guide because the Proposed Rule's single payment amount method is different from the payment method used in the demonstration projects. **To assure beneficiary access, we propose that the pivotal bid be the payment amount.** This amount is likely to result in substantial savings to the Medicare program, while avoiding access and quality issues likely to arise from using the lower median amount.

In addition, predatory bidding should not be allowed. We urge that the Proposed Rule contain standards for rejecting bids that are below cost. In the absence of such standards, it would be possible for one or more large suppliers to bid below cost in order to become one of the few, perhaps two, contract suppliers in a competitive bid area. In the next bid cycle, after competing suppliers have been driven out of business, ologopolistic behavior could result in higher bid prices than would have occurred in a competitive environment. **A provider that bids below marginal cost should be rejected. This will protect the program from predatory bidding and will result in a lower aggregate cost to the program.**

Similarly, as noted above, the Proposed Rule should contain standards requiring credible third party capital and financing commitments to the extent that suppliers' project capacity based on expansion. The absence of such standards will distort the bid process and artificially lower the single payment amount. To the extent such suppliers are not able to meet projected demand, it is not reasonable to expect that more responsible suppliers will be able to provide the items at the artificially depressed single payment amount. For these reasons, it is common for governmental competitive acquisition programs to contain rules excluding bids that are not responsible, and CMS should include rules as described above in the DMEPOS competitive acquisition program.

2) **Rebate §414.416(c)**

Recommendation: ***The proposed rebate plan conflicts with anti-kickback requirements and must be eliminated.***

Rationale: There is no place in Medicare for inducements that distort utilization patterns and encourage overutilization. The rebate proposal raises significant inducement and anti-kickback issues. We do not believe the provisions of the Federal health care program anti-kickback statute or the Medicare anti-inducement statute can be repealed by a CMS regulation. The HHS Office of Inspector General has on numerous occasions expressed the view that the provision of things of value to beneficiaries violates these laws.

Assuming, however, that the OIG would approve the rebate proposal as an exception under these laws, we submit that the same policies underlying these laws militate against the rebate provision. The policies underlying the laws include that the rebate will have an adverse impact on the quality of care. The OIG has specifically cited a concern that such inducements lead to a "race to the bottom" which creates strong "incentives to cheat on the quality" of the involved items or services. HHS OIG Advisory Opinion 02-14 (September 30, 2002).

These incentives would be particularly pronounced in a competitive bidding environment with reduced payment amounts. The rebate provision also violates the single payment amount provision of the Act, by permitting different payment amounts for different contract suppliers. **Finally, we submit that suppliers will have more than adequate incentive to bid aggressively in the competitive acquisition program without the rebate provision, and that it therefore should be eliminated.**

G. <u>Establishing Payment Amounts for New DMEPOS (Gap-filling) § 414.210(g)</u>

Recommendation: ***References to the technology assessment as a part of gap-filling should be removed from the final rule and published for comment as a separate proposed rule.***

Rationale: CMS proposes to amend its current gap-filling methodology for establishing fee schedule amounts for certain items of new DMEPOS and for readjusting fee schedules for some items of DMEPOS which had been previously established using gap filling. This new initiative is not required as part of the implementation for competitive bidding and is not mandated by either the MMA or the DRA.

While we agree that it is important to coordinate communication of technology information among different sections of CMS and between the agency and its contractors, the administration and review of a comparative technology assessment is a comprehensive effort that raises many important procedural questions.

Due to the complexity, comprehensive nature and serious implication for this type of initiative, CMS's use of the comparative technology assessment should be held to at least the same level of procedural predictability and transparency as the process for development of a National Coverage Determination, which has recently been defined in a guidance document published by the CMS Coverage and Analysis Group.

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Thank you for your time in considering these comments and suggestions. NASL appreciates the agency's efforts to expand access to the regulatory process to providers and suppliers for the improvement of delivery of quality healthcare to the beneficiaries of the Medicare Program. We welcome the opportunity to work with CMS in resolving the issues contained in this document. Please feel free to contact me directly at the following phone number (703) 549-8500 with any questions that you may have.

Sincerely,

Peter C. Clendenin
Executive Vice President

NASL Insight • Advocacy • Action

Appendix A

May 8, 2006

Mr. Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
Mail Stop C5-01-14
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Request for extension on Proposed Rulemaking for Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues (May 1, 2006).

Dear Mr. Kuhn:

The National Association for the Support of Long Term Care (NASL) hereby requests an extension to the comment period for the "Proposed Rulemaking on Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues," published in the Federal Register on May 1, 2006 (71 F.R. 25653-25704). NASL is a trade association comprised of more than 120 companies engaged in legislative and regulatory matters affecting the provision of ancillary services, products supply components, diagnostic testing and information systems to the post-acute care industry. NASL requests a 90-day extension of the Competitive Acquisition comment period, beginning upon release of finalized quality standards.

The proposed rule would implement competitive bidding programs for certain covered items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) throughout the United States in accordance with sections 1847(a) and (b) of the Social Security Act. Comments to the proposed rule are due no later than June 30, 2006.

A key component of the proposal involves the application of "quality standards" for all DMEPOS suppliers, including suppliers that participate in the DMEPOS competitive bidding program. The proposed rule would also detail requirements for CMS approved accreditation organizations that will be applying quality standards for all DMEPOS suppliers, including DMEPOS suppliers that participate in the DMEPOS competitive bidding program. Quality standards are a significant part of the proposal. **Indeed, "quality standards" are mentioned no less than sixty-three times in the proposed rule.**

Section 302(a)(1) of the Medicare Modernization Act of 2003 added section 1834(a)(20) to the Social Security Act, which requires the Health and Human Services Secretary to establish and implement quality standards for suppliers of certain items, including consumer service standards, to be applied by recognized independent accreditation organizations. Suppliers of DMEPOS must comply with the quality standards in order to furnish any item for which payment is made under Part B, and to receive and retain a provider or supplier billing number used to submit claims for reimbursement for any such item for which payment may be made under Medicare. CMS believes Section 1834(a)(20)(D) of the Social Security Act requires it to apply these quality standards to suppliers of items for which it deems the standards to be appropriate.

However, CMS has not finalized its quality standards. On September 26, 2005, CMS released its Draft Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), developed with Abt Associates. CMS provided a sixty-day public comment beginning September 23, 2005, and ending November 28, 2005.

As such, CMS has placed stakeholders in the unusual position of analyzing and commenting on a fundamentally incomplete proposal. The proposed quality standards in September 2005 are exhaustive. The quality standards may include performance management requirements to ensure the development, implementation, monitoring, and evaluation of policies, procedures, and products so that suppliers can maintain compliance with regulatory requirements and CMS policy instructions. The quality standards may also include language from current CMS standards and industry best practice standards for the following areas:

- Administration
- Financial management
- Human resource management
- Beneficiary services
- Performance management
- Environment and safety
- Beneficiary rights/ethics
- Information management

Finally, the supplier quality standards may include requirements for monitoring beneficiary satisfaction with products and suppliers' responses to beneficiary complaints.

Without finalized quality standards, NASL and its members are unable to ascertain the true and complete impacts of the May 1 Competitive Acquisition proposal. In addition, NASL is concerned with Administrative Procedure Act compliance. Administrative rulemaking must be sufficiently descriptive of subjects and issues involved so that interested parties may offer informed criticism and comments. Ethyl Corp. v. EPA, 541 F.2d 1, 35-37 (D.C. Cir. 1976). Agency notices must describe the range of alternatives being considered with reasonable specificity; otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decision-making. Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506 (D.C. Cir 1983). Finally, an agency commits a serious procedural error when it fails to reveal portions of technical basis for a proposed rule in time to allow for meaningful commentary. Connecticut Light and Power v. NRC, 673 F.2d 525 (D. C. Cir. 1982).

NASL is committed to working with CMS on this rulemaking. We plan on submitting detailed comments in response to the Proposed Rulemaking which we trust will assist CMS change the way that Medicare pays for items under Part B of the Medicare program. However, an extension of the comment period is warranted due to the pending quality standards. An extension would allow the regulated community the time it requires to appropriately respond to the proposed rulemaking.

Thank you for consideration of our request.

Sincerely,

Peter Clendenin
Executive Vice President

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APRIA HEALTHCARE

June 30, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

VIA Hand Delivery in Washington, DC Office

DMEPOS Competitive Bidding Team
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Room 445-G
Hubert M. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Reference: File Code CMS-1270-P - Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan and DMEPOS Competitive Bidding Team:

On behalf of Apria Healthcare, thank you for the opportunity to provide written comments in response to the Notice of Proposed Rule Making (NPRM or Proposed Rule) for the competitive acquisition (competitive bidding) program for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) covered by Medicare Part B.

Development of the competitive bidding program is an incredibly complex undertaking and the Centers for Medicare & Medicaid Services (CMS) competitive bidding team certainly has invested significant time and thought in drafting the NPRM. We appreciate the opportunity to comment on its content.

We believe we offer a unique perspective on the DMEPOS industry that your team will find useful when preparing the final rule. As you may know, Apria Healthcare is the nation's largest provider of DME, respiratory care services and home enteral nutrition. We are the third largest home infusion therapy provider in the country.

In addition, as an active member of the Professional Advisory Oversight Committee (PAOC) that was formed to advise CMS on the competitive bidding program, I personally have a direct interest in ensuring that the program is implemented in the most appropriate, fair manner possible. Therefore, we believe that

Apria's comments reflect current competitive contracting experience and will be helpful to you as you finalize the plans for competitive bidding this summer.

ORGANIZATION OF OUR COMMENTS

We have organized our comments as follows:

1) An Executive Summary to highlight our most significant comments and general concerns about the Proposed Rule.

2) Background on Apria Healthcare.

3) Detailed comments and questions on each applicable section of the NPRM for which the Agency seeks comment, as well as many concrete suggestions and recommendations.

Per CMS' request, each major section starts on its own page with a boxed-in header that clearly identifies it.

CONTACT INFORMATION FOR QUESTIONS ABOUT COMMENTS

Due to the extensive nature of these comments, questions may arise about them as the bidding team undertakes its review. Please feel free to contact the following Apria Healthcare employees who are leading our efforts on competitive bidding:

Lisa M. Getson
Executive Vice President
Government Relations, Clinical Services,
Investor Services & Corporate Compliance Officer
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APRIA HEALTHCARE
COMMENTS ON COMPETITIVE BIDDING

EXECUTIVE SUMMARY

I. Background on Apria Healthcare

Apria Healthcare is the nation's largest provider of home respiratory, infusion and medical equipment services. With over 500 wholly-owned respiratory/medical equipment branch locations nationwide, Apria serves patients in all 50 states, including those covered by Medicare, Medicaid and managed care plans. We own and operate 32 home infusion pharmacies that provide extensive clinical and patient support services to patients who require intravenous therapies to treat a wide range of chronic and acute conditions.

Apria also owns and operates three centralized clinical respiratory pharmacies that serve patients who require inhalation drug therapies and support services necessary to treat Chronic Obstructive Pulmonary Disease (COPD), the fourth leading cause of death in the United States. The Company also provides custom rehabilitation equipment and services and diabetic supplies to patients covered by Medicare, Medicaid and certain managed care insurers.

All facilities are licensed by all of the states where we operate, and we fill orders and prescriptions written by physicians who are licensed in those states. We provide direct care to hundreds of thousands of Medicare beneficiaries each year, and are contracted with over 2500 managed care plans as well.

As part of our overall commitment to compliance, Apria operates a robust corporate compliance program that includes an employee hotline, disclosure methods, checks against debarment databases and other features. Our Board of Directors has been recognized nationally for its corporate governance measures and, recently, we were informed that Apria has won the Ethics in America Award in the category of "National Public Company." The awards are sponsored by the Passkeys Foundation, an Orange County-based organization that is dedicated to "building a nation of character."

II. Apria Healthcare Has the Most Managed Care Contracting Experience of Any Provider

Apria Healthcare has the most extensive managed care contracting experience in the RT/HME/IV industry, with over 2500 managed care contracts nationwide. As such, we believe strongly in the merits of our general comment that the Medicare program's planned implementation of "competitive bidding" is not analogous at all to what private sector health plans implement. In the managed care negotiation processes, health plans are willing to narrow the number of providers participating in their "panel" in exchange for guaranteed patient volume. The various panel participants may have different payment levels depending on their original bid rates and the potential patient volume from the health plan.

By contrast, the Medicare program would like to achieve "savings" through a bidding process that simply results in a lower, fixed fee schedule without directing any correlation to potential patient volume, and without consideration of what an individual supplier believes its own cost structures can withstand. This approach is inconsistent with standard competitive contracting practices.

III. General Comments

We support the five stated objectives for competitive bidding in the NPRM and believe that, if done correctly, the program can contribute to improved service quality. If implemented incorrectly, however, the program could result in an immense administrative structure imposed upon an already-complex Medicare Part B system without any associated savings.

A. Timeline of Implementation Needs to be Refined and Published

The general timeline that CMS has set for competitive bidding is aggressive. When one considers the body of work that must be completed before even the first phase of the program begins (that of issuing the Request for Bids (RFBs)), one realizes that the timeline may be too aggressive. Consider that the following steps must be completed in the next few months alone:

- The final quality standards must be published, including product-specific ones that may be fraught with problems;
- The accreditation organizations must be selected and they must undergo the application and review process with CMS;
- CMS must finalize its plans for actually implementing the accreditation requirement of the program;
- The stabilization of the new DMEMACs such as National Heritage Insurance Company (NHIC) and Noridian Administrative Services, which does not even take effect until October 2006. Neither one has ever processed DME claims;
- CMS must publish the interim final and final regulations;
- CMS must complete the proposed rule for the Deficit Reduction Act and project how it will interface with competitive bidding, and vice versa;
- The first 10 MSAs and product categories must be selected;
- The RFB package must be finalized and issued for the first 10 MSAs;
- CMS will need 72 FTEs to review the first round of bidding packages; and
- A major beneficiary and supplier education process must ensue.

B. Positive Aspects of the NPRM

In terms of positive attributes, we were pleased that the rule includes guidance on mandatory accreditation, reference to the quality, financial and compliance standards, and reasonable formulas for selecting geographic markets in which to institute the program and for calculating suppliers' composite bids.

C. Proposed Rule Lacked Detailed Plans on Which to Comment

In general, however, we are concerned about the lack of details surrounding the implementation of this critical program. We found that the NPRM raised more questions than it answered, and that there are several sections on which we cannot provide specific and detailed comments until further information is released by CMS.

Examples of sections that lacked sufficient detail include:

- Handling of MSP (Medicare as a Secondary Payor) claims – this was not addressed anywhere in the Proposed Rule;
- Final product-specific quality standards;
- Final list of DMEPOS products that will be included;

- Final list of Metropolitan Statistical Areas (MSAs) for 2007;
- Contract terms and conditions;
- Grandfathering Medicare Advantage patients and how to handle patients that transition between other payors and Medicare;
- Repair and Maintenance expectations in light of the Deficit Reduction Act of 2005 (DRA);
- Network development and implementation;
- Administration of the accreditation requirement;
- Satisfying the requirement to furnish brand-specific products; and
- The anticipated interface between the Competitive Bidding Implementation Contractor (CBIC) and the Durable Medical Equipment Medicare Administrative Contractors (DMEMACs).

We are also concerned that the Proposed Rule does not include any type of transition plan that describes how the impacted MSAs would shift from the existing method of reimbursement and payment to the new one under competitive bidding.

As a member of the PAOC, I am also personally concerned that a number of sections, ideas or proposed methodologies contained in the Proposed Rule were never discussed at prior PAOC meetings. While the recent May 22-23 meeting was the most productive one so far, such a surprise element should be avoided in the future. I know that my fellow PAOC members welcome the opportunity for more frequent dialogue with the agency on the development and implementation of the competitive bidding program, and we recommend that it take the form of more frequent conference calls or in-person meetings.

Since it is already late June, it appears that the PAOC will not have an opportunity to review the quality standards again before CMS issues its final formulation. This is really unacceptable given the likelihood of significant changes due to the 5600-plus comments CMS received. Moreover, the quality standards will have a direct impact on any provider's ability to comment on this rule in appropriate detail, especially as the comments relate to the critical issues of the bidding process itself and the establishment of a single payment rate. We hope that CMS will schedule another in-person PAOC meeting prior to the publication of the Final Rule for competitive bidding. We also strongly urge CMS to provide the public with the opportunity for additional written comments on the competitive bidding program, since we expect CMS to receive a large response to this NPRM.

IV. Primary Areas of Concern

Our primary areas of concern, which will be detailed further in the applicable sections of this letter, are as follows:

1. Proposed Calculation of Single Payment for a Competitively Bid Item Differs Significantly from Method Used in Two Demonstration Projects

CMS proposes to set the single payment rate for any competitively bid item at the median of the array of bids of the "winning suppliers." This means that some of the winning bidders will have to accept less than their bids in order to participate in the program, even if those winning bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. The result is simply a new fee schedule, and is contrary to basic principles of contracting and competitive bidding. It is also significantly different than the method used in the Polk County, FL and San Antonio, TX demonstration projects and therefore it probably is not what Congress intended in approving competitive bidding as part of the Medicare Modernization Act of 2003 (MMA).

The far better course would be to set the payment rate at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This is the method used in the two demonstration projects.

2. *CMS is Exceeding its Authority by Extending the Competitive Bidding Program Beyond the MSAs Authorized by Congress*

CMS states in the Proposed Rule that it has the authority to extend the scope of the competitive bidding program in 2007 to counties, zip codes or parishes that are contiguous to the metropolitan statistical areas (MSAs) that are selected for participation in the first phase of the competitive bidding program. This appears to be directly contrary to the MMA, which clearly limits the first phase of the program to 10 of the largest MSAs in 2007. In fact, the second phase of the program also is limited to MSAs - 80 of the largest MSAs in 2009. Areas outside of MSAs are not eligible for participation in the program until after 2009.

As discussed in our comments about the definition of MSA, we believe that section 1847(a)(1)(B) of the Social Security Act prohibits CMS from extending individual competition areas beyond the MSA boundaries in 2007 or 2009. Not only is the proposal beyond the statutory language, but supplier compliance will be impractical due to systems and other operational limitations. Since DMEPOS suppliers' physical locations often serve multiple counties, it would be logistically impossible to administer additional competitive bidding pricing, quality standards and other requirements in selective zip codes or areas. Neither the computer systems nor operations of suppliers, even sophisticated organizations like Apria, can support such selective add-ons. The hard boundary should be the MSA as defined by the Office of Management and Budget (OMB) and as described in the statute.

3. *CMS Has Not Clearly Defined or Differentiated Between "Supplier Coverage Area" and "Capacity"*

In numerous sections of the Proposed Rule, CMS refers to supplier coverage area and supplier capacity but has neither defined nor clarified those terms. The Proposed Rule requires a contract supplier to be able to service the entire competitive bidding area but does not specify any minimal capacity that it must have in order to participate and accept additional volume. These terms must be clarified before the Final Rule is issued.

4. *The Proposed Rule Exceeds the MMA's Directive Concerning Physician Authorization/Treating Practitioner – the Ability of the Physician to Order Brand Specific Items*

We understand that the MMA includes authority for the Secretary to establish a process for certain items under which a physician may prescribe a particular brand or mode of delivery of an item. We understand the intent was likely to prevent substandard products from being provided to beneficiaries under competitive bidding. However, we believe that CMS has overinterpreted the provision and proposed a process that is much too complicated and costly to both the program and providers.

CMS proposes that all participating suppliers must provide brand-specific items and equipment as designated by the prescribing physician. If a supplier substitutes another item or equipment, the claim will be denied, despite the fact that the same item would be covered in a non-competitive bidding area. This is counter to how all suppliers operate not only under the Medicare program, but with all payors. Never in the history of the Medicare Part B DMEPOS program has Medicare required brand-specificity. Suppliers often carry items and equipment that the FDA deems to be functionally equivalent to other products. Physicians are often not the most well-informed about the features and benefits of new

technologies; the homecare supplier is responsible for matching the patient's needs to the equipment or supplies. Having to carry all possible items and equipment is extremely costly and burdensome and will only drive up suppliers' costs and therefore reduce potential savings from competitive bidding. It is not a business model used today by any supplier.

In addition, the HCPCS process must be revamped in order to facilitate this provision's success. Today, single HCPCS codes exist for numerous products that have a wide range of clinical benefits, product differentiation and provider acquisition costs. One example is the over 400 CPAP mask interfaces available on the market, all tied to a single HCPCS code. Until the HCPCS process reflects the full array of products available on the market today, the brand-specific requirement will be very difficult to implement.

At Apria, all products provided to patients have been screened, evaluated, proven, approved and/ or accepted clinically, technically, and commercially. Physicians, for the most part, do not verify or validate the clinical, technical or commercial merits of scripted items or equipment. CMS should permit the substitution of items and equipment that meet or exceed specifications or requirements and are functionally equivalent or superior to the designated items and equipment. The FDA has clear guidelines on functional equivalence.

If CMS insists on pursuing the provision as planned, it should delay implementation until the 2008 round of competitive bidding, which would allow time for it to be further studied and possibly piloted before expanding to all CBAs. In addition, an exception process would be needed, as well as simplified documentation requirements. (Please refer to section "O" of our comments for more details on this issue.)

5. CMS' Plans to Revise the Parenteral and Enteral nutrition (PEN) Schedule Without Formal Comments from the Industry are Inappropriate

As an intravenous medication, parenteral nutrition was never intended to be included in competitive bidding. So, we are unclear as to why the agency feels the need to revise this reimbursement methodology at this time. In addition, with the advent of Medicare Part D, some patients are attempting to coordinate their intravenous therapy needs between Medicare Part B and Part D. The significant challenges some patients are already experiencing will be exacerbated by the Proposed Rule.

6. The Beneficiary Rebate Proposal May be Illegal and Is Certainly Contrary to Existing Anti-Fraud and Abuse Initiatives by the Homecare Industry and the OIG

CMS proposes to permit suppliers whose bids are lower than the median bid to rebate a portion of the difference to beneficiaries. CMS would publish a list of suppliers that provide rebates, although suppliers themselves would not be permitted to promote or advertise such rebates.

This proposal is completely contrary to federal law, OIG guidance, comments of government prosecutors, and the general compliance efforts of the DMEPOS industry. For years, providers have not been allowed to waive even a $5 co-pay. The industry has worked too hard to eliminate fraud and abuse and CMS will in no way be able to monitor appropriate rebating practices. CMS should be more concerned about tracking quality and services and encouraging beneficiary supplier selection on these bases. CMS resources should be targeted with auditing quality services from providers and not trying to police rebate programs, which have no savings to the government.

Rebates represent an open invitation for fraudulent and abusive practices, and CMS should withdraw this provision. Medicare, OIG, state and other policies exist today that prohibit such rebates from being provided to patients covered by government insurance. The industry is working hard to improve its

image and practices, and this provision would be a significant step backwards in that regard. CMS could not possibly monitor compliance. A system that encourages suppliers to provide monetary inducements as a way to influence patient choice is contrary to the fundamental principles of governance for the industry.

In addition, the rebate concept was never discussed at prior meetings of the Professional Advisory Oversight Committee (PAOC), which was formed to advise CMS on DMEPOS competitive bidding. The PAOC was surprised by its inclusion in the NPRM and, as evidenced by the discussion on this subject at the May meeting, the entire PAOC is opposed to this provision, not just Apria Healthcare.

CMS should focus its efforts and resources on supporting quality service and encouraging beneficiary supplier selection on that basis.

7. CMS Proposes New Gap-Filling Procedures that Will Enable the Agency to Modify Payment Levels Without Due Process Protections for Homecare Providers

Despite the length of this section, too many definitions remain unclear and details unknown about how CMS would move forward with this new methodology. It appears that CMS plans to grant itself authority, without any Congressional or other agency review, to revise the existing gap-filling methodology to apply to existing products. Again, this is an inopportune time when so many different reimbursement cuts are occurring concurrently, many of which have several outstanding regulatory questions. Their effects are not only unknown at this time, but also have not yet been quantified in terms of dollars saved.

The outmoded HCPCS system is directly linked to the challenges associated with gap-filling. Advanced, more costly technology used to treat homecare patients has been approved by the FDA in recent years. Yet CMS and the HCPCS coding panel have routinely denied the creation of new codes and different payment levels to recognize the higher research and development costs that manufacturers pass along to suppliers in the form of acquisition prices.

Using a technology assessment alone to adjust payment amounts would amount to CMS' circumvention of the requirements under section 1842b. Under the "inherent reasonableness" (IR) authority, Congress specifically included requirements for notice and comment so that valid and reliable data would be used. CMS must develop a method that reviews providers' <u>total</u> cost of providing certain technology to patients and not one that is based solely on product acquisition costs.

Gap-filling was another subject of much discussion at the PAOC, and none of the members endorsed CMS' plan as described in the Proposed Rule.

8. The Overall Implementation Schedule for the Program Seems Overly Aggressive and the Estimated CMS Costs to Administer the Program Seem Understated

CMS' own estimates for the amount of time it will take to review 16,000 bids for the 2007 program equates to 72 full-time equivalents (FTEs) working full-time, at an estimated cost of $3.6 million. The numbers for the 2008 program escalate significantly. Given the major milestones that have to be reached between now and when the Request For Bids (RFBs) are issued, we do not believe that the implementation timeline is realistic or can be achieved.

9. *Projected Savings Associated with Competitive Bidding are Overstated*

We believe that the savings projected for competitive bidding have been significantly overstated because the reimbursement cuts mandated by a different section of the MMA and the recently-passed Deficit Reduction Act of 2005 (DRA) have not been adequately studied or integrated into the financial model for competitive bidding. At the recent PAOC meeting, CMS staff admitted that the DRA was passed very late in the development of the competitive bidding NPRM. Therefore, they did not have time to adequately address its impact – from a patient care, service, quality standards or financial savings perspective – prior to the publication of the NPRM or PAOC meeting.

Indeed, the DRA received only cursory references in a few sections of the NPRM. Yet, the policy and reimbursement changes mandated by the DRA represent the most dramatic, and most draconian, changes associated with oxygen and other home medical equipment that have been implemented since the advent of Medicare Part B coverage for DMEPOS. The policy changes will shift burdens that are currently shouldered by DMEPOS suppliers onto Medicare beneficiaries. No impact studies have been performed to assess the increased burden on patients, potential increased out-of-pocket costs or how the suppliers will be paid to provide certain non-equipment services that continue beyond the capped rental/ownership period.

The American Association for Homecare (AAHomecare) sent a formal letter to Herb Kuhn of CMS on April 20, 2006, outlining a list of questions for the agency to answer about the DRA's implementation. We urge the agency to respond to those questions as soon as possible, and the competitive bidding team to fully account for the already-legislated savings that will accrue from the DRA in its Regulatory Impact Analysis (RIA) regarding competitive bidding. The entire makeup of the industry has changed with the new capped rental guidelines, yet no corresponding financial analysis has been performed by any government agency or independent consulting firm. It is quite concerning to us that CMS would move forward without a complete financial analysis considering the industry has gone through reimbursement cuts that were not part of the initial financial review when determining that competitive bidding should be implemented, *i.e.*, DRA and FEHBP. Please note that the list of questions sent to Mr. Kuhn is attached as Appendix A.

We strongly believe that the original savings estimates for competitive bidding will have been largely realized through the implementation of the MMA and the DRA by the time the competitive bidding program is initiated. Thus, after considering the significant costs of implementation, competitive bidding will result in no additional savings to the Medicare program.

10. *Additional Comment Period Needed and Justified*

In light of the complexity of the new system the Proposed Rule attempts to implement, and the lack of enough detail in the Proposed Rule, we strongly urge the Office of General Counsel to require CMS to exercise its discretion and offer interested parties the opportunity to provide additional comments on key elements of the DMEPOS competitive bidding program before a final regulation is published. Not only is competitive bidding a new approach for the furnishing of DMEPOS to Medicare beneficiaries, it is a complex model whose operations and consequences remain relatively unfamiliar to CMS, suppliers, contractors and beneficiaries. It seems to raise more questions than it answers about the operations of competitive bidding, both this year and over the long-term lifespan of the program.

This lack of experience is reflected in the numerous critical topics discussed within the Proposed Rule that are proposed with minimal operational detail. These items include the criteria used to establish product categories and specific products, identification of the specific product categories and products that will be subject to competitive bidding in the first year, and identification of the geographic

competitive bidding areas, among others. While the public can comment generally on the proposal CMS has put forth, without the details of these important topics it is difficult for the public and the providers to meaningfully and substantively evaluate the proposal.

The lack of existing detail is not the only reason that the public should have an additional opportunity for comment before the rule is finalized. The trade press has vocally noted the absence of any CMS guidance on critical non-competitive bidding topics that will have a direct impact on the ability of suppliers to successfully participate in the program. Until this information is available, it is difficult for a supplier to meaningfully evaluate the Proposed Rule. For example, the Proposed Rule requires a contract supplier to service beneficiary-owned items for any beneficiary who resides in the competitive bidding areas. The Deficit Reduction Act of 2005 permits CMS to make numerous and dramatic changes to what repair and maintenance services Medicare might cover. The Proposed Rule is silent about the application of these new statutory provisions, and fails to recognize or acknowledge in any manner that CMS has issued no guidance on these significant topics.

Due to the monumental changes the competitive bidding program is initiating, we expect the interim rule will be very different than the Proposed Rule on many topics. Thus, CMS should exercise its discretion and publish its initial responses to the public comments as a new proposed rule or, alternatively, an interim rule with an additional opportunity for comment. The parameters of the Administrative Procedure Act permit CMS to offer additional opportunity for public comment on proposed regulations. In fact, CMS recently exercised this discretion in the proposed regulations for the competitive acquisition program for Medicare Part B drugs ("CAP"). The DMEPOS competitive bidding program is far more complex than CAP and deserves a similar opportunity for a robust and thorough public discussion of actual CMS proposals. Implementing the final regulation in stages would provide further opportunity for meaningful public comment and facilitate successful implementation of the competitive bidding program.

This would be more than good and fair policy. It also would be consistent with applicable law. Section 1871(a)(4) of the Social Security Act provides that a final rule will be treated as a proposed rule if it includes provisions that are not "logical outgrowth(s) of a previously published notice of proposed rulemaking." Congress clearly was concerned about the type of situation where a proposed rule does not flesh out CMS' intent with enough specificity so that the final rule's provisions surprise the public that commented on the proposed rule. On several points, this proposed rule approaches this line.

An additional comment period will not significantly impact the overall implementation timeline. It is more important to implement the program correctly, given its magnitude and the facts that only two demonstrations were conducted and that the current Proposed Rule departs significantly from the approach tested in those demonstrations. Any rush to implement any aspect of the program will only result in beneficiary and referral agent dissatisfaction, not to mention an unknown disruption factor on suppliers themselves.

V. Summary

Competitive bidding for DMEPOS on a large-scale basis is a brand-new initiative for CMS. We believe that both the timeframe for implementation and the projected cost savings are overly aggressive and urge CMS to proceed with caution, using a phased-in approach to the program overall and certain elements contained therein. These include, for example, the brand-specific requirement, repair and maintenance of equipment that the contract supplier did not supply in the first place, and other elements that have never been studied or implemented before. These specific sections should be piloted in one MSA before expanding to the others in either 2007 or beyond.

Although two demonstration projects were performed, much has changed since the early part of this decade in terms of providers' total cost of caring for Medicare beneficiaries, policy changes implemented by CMS since the conclusion of the demonstrations, and new legislation that was passed since that time.

The negative impact on patients caused by this legislation – the Medicare Modernization Act of 2003's reduced fee schedules for oxygen, nebulizers, wheelchairs, patient lifts, hospital beds and diabetic supplies, and the Deficit Reduction Act of 2005 – cannot be emphasized enough. CMS has already realized a significant amount of savings from the MMA's reduced fee schedule and therefore little savings remain to be had from competitive bidding. Too much remains unknown about how CMS plans to address the major gaps in service coverage that will be caused by the DRA's forced equipment ownership provisions. Fuel, labor, insurance, health benefits, licensure and other non-equipment costs have risen dramatically since the demonstration projects were implemented. These costs will have to be reflected in providers' bids for the program in 2007 and every subsequent bidding cycle.

Finally, one of the other aspects of the demonstration projects that was never studied was that of Medicare patient rehospitalization and/or emergency room visit rates. This is a key outcome measure that CMS should have evaluated to determine if savings created through Part B were actually resulting in expenditures under Part A. It's possible that a price-oriented DMEPOS model actually led to higher levels of institutional care. It would be prudent for CMS to study this in the 2007 round of bidding.

Apria Healthcare has contracted with managed care organizations to provide a comprehensive array of DMEPOS products and services for over 20 years. If conducted correctly and in a truly competitive fashion, competitive bidding can indeed improve quality and consistency of service across a large patient population and geography, while delivering savings to the payor. We applaud CMS and Congress for adopting mandatory accreditation for DMEPOS suppliers, quality standards and other noble goals for the program. CMS' proposed plans for competitive bidding, however, do not reflect standard contracting procedures in this industry and unfortunately, the end result will simply be a reduced fee schedule not unlike what exists today. This is an extensive amount of work directed toward less than further reducing 3% of the total Medicare budget. The Inherent Reasonableness (IR) authority already provides CMS with a much less costly method by which to study and reduce fee schedules and we therefore believe that the planned infrastructure for competitive bidding is essentially unnecessary.

We appreciate the opportunity to provide you with these comments and recommendations and welcome any additional questions you may have in the coming months as you review what will likely be a significant number of comments from individual stakeholders. I look forward to seeing the Medicare DMEPOS Competitive Bidding Team at the next PAOC meeting.

Our more detailed comments, by section, begin on the next page.

So, in reviewing the bids, we urge CMS to recognize that the bid prices offered by suppliers must and do include the full range of services necessary to not only deliver the equipment to the home, but also to ensure that the patient has access to 24/7 on-call assistance, clinical professionals as necessary, emergency assistance on weekend, evenings and holidays, equipment exchanges, billing and collections on the patient's behalf, and an interface with the patient's physician.

II. Definition of Metropolitan Statistical Area (MSA)

We agree that the definition of Metropolitan Statistical Area (MSA) should be consistent with the meaning given by the Office of Management and Budget (OMB). Using this definition, the boundaries of MSAs are quite clear.

We do not support CMS' proposal to selectively add zip codes, parishes, counties or other areas outside of a given MSA. Not only does this proposal present difficulties for internal operational systems of suppliers, but it also will cause confusion and complexity with respect to employee education, referrals, and patients.

Congress' intent in approving DMEPOS competitive bidding as part of the MMA was quite clear in the language it used regarding MSAs. The statute specifically states that competitive bidding is to be implemented in 10 of the largest MSAs in 2007 and 80 additional MSAs in 2008. There is no exception language giving CMS the authority or discretion to add zip codes. We believe that CMS has incorrectly interpreted the statutory language on this matter and has exceeded its authority in this area.

C. Implementation Contractor
Proposed 414.406
71 Fed. Reg. 25654, 25661-25662

Section 414.406 of the Proposed Rule states that CMS plans to designate one or more Competitive Bidding Implementation Contractors ("CBICs") to implement the competitive bidding program. These CBICs would prepare the bid requests and participate in design function, oversight, access and quality monitoring among other administrative tasks. In addition, CMS has proposed that the CBICs will interact with the four DME regional carriers ("DMERCs"), now referred to as DME MACs, that currently process most of the Medicare DME claims. Apria strongly suggests that the criteria for the selection of CBICs include a provision that disallows DME market participants who could abuse their position from serving as CBICs as further described below. Ideally, CBICs should have no presence in the commercial managed care industry. In addition, CMS should take specific contractual and regulatory measures to ensure the independence of the contractors and strictly limit the use of any bidding data for any purposes beyond the competitive bidding program.

I. Clarification of CBIC Entities

Apria is concerned that the Proposed Rule does not state who these CBICs will be. The Proposed Rule only makes vague reference to the fact that "appropriate entities" will be used, without providing any explanation as to what types of entities will qualify or what criteria will be employed to establish that an entity is appropriate. Apria requests that CMS further specify the criteria that will be used to designate a CBIC.

II. Potential Conflicts of Interest with CBICs

CMS should carefully consider the potential conflicts of interests that may arise if entities that have existing relationships with suppliers are chosen to become CBICs, and CMS should implement certain protections through regulations and CBIC contract terms. Once an entity is selected as a CBIC, it will become privy to proprietary pricing information as well as other confidential financial information about the supplier. This type of data may be very useful to the CBIC in the context of other negotiations and commercial relationships the CBIC entity has with the supplier outside of the Medicare program. For example, a CBIC that also operates a commercial health insurance plan would be very interested in comparing supplier Medicare bids with the rates a supplier has proposed in a commercial context. This would provide the CBIC with a highly inappropriate and unfair commercial advantage over the supplier.

CMS already has recognized some of these potential conflicts through its decision to separate the functions of competitive bidding claims processing and bid evaluation. Though the Proposed Rule states that the confidentiality of information provisions in the Federal Acquisition Regulation ("FAR") will be enforced, this only prevents CBICs from giving or selling the information to other entities. It does not address the internal use of confidential information by CBICs, gained while serving in their capacity as CBICs, outside of the competitive bidding program and to the disadvantage of the bidding companies.

Consequently, we request CMS go even further than FAR to ensure that proprietary supplier information is not used inappropriately in other contexts. These efforts could include: preferential selection of an entity with no commercial relationships with suppliers, such as a healthplan or similar organization; specific regulations prohibiting CBIC use of proprietary data for any other purpose and requiring internal firewalls to prevent data sharing; and inclusion of similar protections and certifications in the final CBIC

contracts. These measures will minimize the conflicts of interest that may arise and ensure the overall success of the competitive bidding program and adequate protection of suppliers.

D. Payment Basis
Proposed 414.408
71 Fed. Reg. 25654, 25662-25664

I. Overview of Comments

Our overarching comment for this section is that the method that CMS has proposed for establishing the single payment rate is not the same as was used in the demonstration projects. We believe that the proposed methodology for establishing the single payment amount, for example, in no way matches what Congress intended for the DMEPOS competitive bidding program when it included the provision in the MMA.

It is clear that the CMS competitive bidding team has dedicated significant thought and time into the development of the "Payment Basis" section (Section 414.408(a)) of the NPRM. There are several subsections of this section that Apria supports. However, we also have serious concerns about CMS' intent to use a methodology or formula that differs greatly from those used in the two demonstration markets.

Our comments on this major section follow the same sub-headings used by CMS in the NPRM.

II. Payment Basis (Section 414.408(a))

In the private managed care sector, health plans contract with multiple DMEPOS suppliers at different payment levels based on their rates negotiated with each supplier. These rates reflect the following criteria:

- The amount of potential patient volume from the payor due to the payor's limitation on the number of contracted or preferred suppliers,
- The bundle of services expected from the supplier which does not allow for providers to selectively opt "in" or "out" of various products,
- The geographic area the health plan expects each supplier to cover,
- The service standards the health plan expects each supplier to meet,
- Any health plan-specific requirements, such as a drug or DME product formulary,
- Any customized reports the health plan expects of each supplier,
- Any incremental overhead, information systems, web site, telecommunications, billing/collections or other business support costs the suppliers incur that are specifically attributable to that health plans' unique needs or patient population.

The proposed competitive bidding program for DMEPOS – especially the establishment of a single payment amount for all contract suppliers regardless of their original bid amounts – is not competitive bidding at all. Rather, it represents arbitrary competitive fee-schedule-fixing. It is a model that is inconsistent with general free market principles that are the basis of competition and, in fact, it will not alter the existing model of using a single payment rate in any appreciable way. Moreover, we are doubtful that this approach will provide Medicare beneficiaries to access to high quality suppliers while also lowering Medicare program costs.

III. Beneficiary's Permanent Residence

We agree with CMS' proposal to base the payment to the contract supplier on the single payment amount for the item in the CBA where the beneficiary maintains a permanent residence. This is similar to how we handle snowbirds or temporary residents today.

However, it will be very difficult for the information systems of most suppliers to maintain two or three different sets of pricing terms for the same Medicare item. Consequently, we expect to incur a higher level of revenue adjustments, such as write-offs to the gross revenue line, due to this process. Such write-offs occur when the payment levels are not clear upon admission of the patient or when the guidelines/rules are confusing. (This is true for all payors, not just Medicare.) Such revenue adjustments are a cost of doing business and will be reflected in our bid if Apria chooses to participate in one or more CBAs.

IV. Grandfathering Methodology

A. Ownership and Rental Time Period Under DRA

We generally support the proposed grandfathering methodology, although we are concerned about the impact of the new DRA-mandated equipment ownership and capped rental change for oxygen. The AAHomecare submitted the aforementioned long list of questions to Mr. Kuhn on April 20, 2006 to seek clarification to important issues that arose after the passage of the DRA. Until CMS addresses those questions, and clearly communicates with the industry as to how it plans to fill the gaps in HCPCS codes, repair, maintenance, service, and in-home clinical visits that patients need past the 13-month and 36-month marks for HME and oxygen, respectively, we do not have sufficient information to offer informed comments.

If CMS expects a supplier to include in its bid the cost of providing 24/7 service to capped rental patients that were set up by another supplier, or to patients the contract supplier was forced to accept a few months prior to the end of the capped rental period, the following must and will occur:

1) A provider must have access to information through the Common Working File (CWF) or direct access to the information through the customer service lines to know whether or not the patient has had similar equipment. CMS cannot expect a provider to accept a patient in the eleventh month of rental, only to discover the Medicare claim is going to be denied because of same or similar equipment used in the past. How will a provider recover its equipment or obtain any reimbursement from Medicare? Additionally, it is critical that the DME MACs be current on recoupment activity, particularly when patients go in and out of the hospital or a skilled facility. In today's environment, suppliers sometimes receive refund requests up to two years after the equipment and services have been provided. With equipment capping at 13 months and the ownership transferring to the patient, this type of continuing backlog with the DME MACs will be unacceptable and will require suppliers to build these costs into their bids.

   In addition, in the Request for Bid (RFB) process, CMS must provide suppliers with the raw number of beneficiaries that are in each of the rental months for the equipment subject to bidding and provide contract suppliers with updated information 90 days before the "go live" date. This is needed particularly in light of the nine-month period that will elapse between the time the supplier bids on the MSA and the contracts are actually initiated.

   Using hospital beds as a product example and Orlando, FL as an MSA example, CMS must inform interested suppliers, during the bid process, that the Orlando MSA has 1,000 Medicare

beneficiaries using hospital beds in the market, and that 100 are in their first month, 200 are in their second month, 300 are in their third month, etc.

2) We anticipate that suppliers' bids will increase if they are expected to budget for the costs associated with accepting patients of non-contract suppliers who have "capped out" and therefore will need to be serviced with no corresponding monthly revenue;

3) As a result of the above, the savings associated with competitive bidding will be lower than what CMS has estimated.

B. Grandfathering Patients Who Transition Between Fee-for-Service and Medicare Part C (Medicare Advantage)

As the nation's largest managed care contractor, we process thousands of "payor changes" every single week. A payor change results when a patient's insurance plan changes in any way. It is very common for Medicare Advantage patients to elect to leave their Medicare Part C plan and re-elect fee-for-service coverage. The opposite occurs too, of course. Another unpredictable factor is the health plan's individual decision-making process for whether it will even continue to offer a Medicare Advantage plan at all; several years ago there was an almost wholesale exit from that market.

The rule is silent on how CMS expects these patients to be incorporated into the competitive bidding program. In a given MSA, the patients may be served by a provider who is not a contract supplier for competitive bidding. How does CMS propose that these patients obtain service? Will patients have the choice to continue using their existing provider or will they be forced to switch to another one? What rules will apply to this patient population under competitive bidding?

For purposes of avoiding patient abandonment and additional stress placed on patients, we recommend that patients who reenter the traditional Medicare program be allowed to remain with their existing provider under the grandfathering provisions outlined in the rule.

To minimize some of these unfair consequences, we suggest CMS consider specifying a firm transition period by which time a beneficiary must choose a contract supplier or a non-contract supplier chooses to grandfather. The option to make this decision cannot be an open-ended proposition. We see the potential for a non-contract supplier to elect to grandfather its patients as long as they are in the early months of a 13- or 36-month capped rental period. When the patients approach the end of that period, the supplier could inform the patient that they must transfer to a contract supplier, and that the equipment will be picked up. Then, in accordance with the Proposed Rule, the contract suppliers will be forced to (i) accept the patient on service and (ii) provide the patient with its owned equipment even though there may be only one or a few rental months left in the capped rental period.

Unless CMS establishes a firm deadline by which a decision to transfer is made, it will penalize the contract suppliers and reward the non-contract suppliers in a manner that surely was unintended.

We believe this deadline approach mirrors CMS' approach with Medicare Part D. Under Medicare Part D, CMS established a deadline by which beneficiaries were required to sign up for a Part D plan or face penalties.

In addition to establishing a deadline for electing whether or not to continue with a grandfathered supplier, we urge CMS to consider re-starting the rental counter when a contract supplier accepts a transfer patient, particularly one who is leaving a non-contract supplier. Even for a transfer patient, the receiving supplier must process the patient as a new patient, incurring all of the expenses associated with

new patient admissions such as administrative paperwork, patient and caregiver education, the procurement, provision and delivery of new equipment, and establishing billing and collection protocols. Even if CMS requires the previous supplier to furnish certain material information, such as the CMN, the processing costs for a new supplier may be significant. While this certainly is the cost of doing business, it may be disproportionately burdensome when the patient only has a very short rental period remaining for which the supplier may recover any funds. Thus, re-starting the rental period is a reasonable and fair approach to protect contracted suppliers.

CMS states that "the grandfathered supplier be paid the single payment amounts determined for those items under the competitive bidding program since beneficiaries rent these items for extended time periods ***as long as the items remain medically necessary***." *See* 71 Fed. Reg. at 25663 (emphasis added).

We take issue with the above section for three reasons:

1) The reference to "extended time periods" is outdated language thanks to the DRA.

2) The reference to "as long as the items remain medically necessary" is inaccurate. Patients have a medical need for HME today that extends beyond Medicare's capped rental period of 13-months as defined by the DRA. The DRA's unprecedented change to how oxygen treated, by capping it at 36 months, is going to leave over 250,000 Medicare beneficiaries per year who continue to have a medical need for the drug oxygen without any monthly reimbursement levels.

3) CMS does not recognize nor reimburse for the related services and support required and provided to patients when items remain medically necessary after the capped rental period.

The DRA includes provisions that now work in opposition to this language and still leaves many unanswered questions about how "rental agreement and supplier arrangements may be continued." The capped rental counter should begin at month one when a contract supplier accepts a patient after the noncontract supplier chooses not to accept CMS' single payment rate through the grandfathering provisions.

As Appendix A, we are providing a copy of the list of questions that AAHomecare sent to Herb Kuhn in April.

C. Suppliers That Lose Their Contract Status in a Subsequent Competitive Bidding Program

Comments, concerns, issues and exceptions to 1847(a)(4) of the Act as they apply to Grandfathering of Suppliers should follow suit when applying 1847(a)(4) of the Act to Suppliers that Lose their Contract status. *See* 71 Fed. Reg. at 25663.

D. Payment for Accessories for Items Subject to Grandfathering

This section generally makes sense except that it does not adequately reflect the unknown implementation aspects of the Deficit Reduction Act of 2005. For example, oxygen cannulas and tubing which must be changed frequently, as well as backup oxygen tanks, are currently supplied and reimbursed under the monthly bundled reimbursement rate for oxygen. Although there are HCPCS codes for these supplier (A4615 and A4616), there are no corresponding Medicare allowables. Unless CMS addresses the shortcomings of the DRA between now and the time when the 2007 competitive bidding RFBs are issued, providers will not know how to incorporate this unknown factor into their bids.

It is unrealistic to expect either a contract supplier or a grandfathering supplier to continue supplying oxygen tubing, cannulas or other accessories/supplies for free to beneficiaries after the capped rental period commences and patients own their equipment.

By that time, warranty coverage, service and support from the manufacturer will have expired. It is imperative that CMS issue the answers to the questions posed by AAHomecare in its letter to the Agency so that providers may incorporate that information into their bids later this year.

The only major item now left in the frequent and substantial servicing category is a ventilator, which provides life support in the home. Almost every other item is now in the capped rental category or inexpensive and routinely purchased category.

However, if a supplier is forced to pick up another patient base that has already capped out, that is not a fair proposal. While it would have made sense under the historical payment mechanism for oxygen and durable medical equipment where the equipment either rented as long as the patient had a medical need or in the 15-month capped rental plus every-six-month service and maintenance fee scenario, it no longer makes sense in light of the Deficit Reduction Act of 2005.

E. Payment Adjustment to Account for Inflation (proposed section 414.408(b))

The rule states that the fee schedule payment amounts for DMEPOS items are updated by annual update factors related to the percentage change in the CPI-U for the 12-month period ending June of each year.

However, it is important to note that oxygen and DME fee schedules have been frozen since 2004. Looking closely at even earlier years, a freeze has applied for most of the past 15 years. So, it is misleading to state that the DMEPOS fee schedule is updated annually by a CPI-U factor.

Nevertheless, the rule states that an annual inflation update to the single payment amount would be applied to the single payment amount each year of the three-year contract associated with competitive bidding. We agree with this plan since operating costs such as labor, fuel, vehicle lease, rent, utilities and insurance continue to increase with each passing year.

F. Authority to Adjust Payments in Other Areas (section 414.408(e))

In the Rule, CMS argues that it has the discretion to apply the payment information determined under the competitive bidding program to adjust the payment amounts for the same DMEPOS in areas not included in a competitive bidding program. The Proposed Rule asserts the same proposal for enteral nutrition but that the detailed methodology for doing so has not yet been developed by CMS.

We are vehemently opposed to this approach. We believe it is beyond CMS' authority until at least 2009, and even then, the methodology for competitive bidding does not support application in very different markets.

The general theme of our comments in this section centers around four main facts:

1) Providers' TOTAL costs of caring for patients who need a particular DMEPOS item may vary considerably in different parts of the country.

2) Although we believe the competitive bidding payment methodology is somewhat flawed, the program seeks price concessions from suppliers in exchange for some, perhaps very small reduction, in the number of competitors. This exchange does not exist in the non-competitive bidding areas, thus, it is inappropriate to apply the pricing beyond the CBA.

3) Instead of using competitive bidding pricing in these other areas, CMS should apply the existing processes of Inherent Reasonableness and the related notice process for changing prices.

4) It is entirely too premature for CMS to even contemplate this approach. Too much remains unknown with the DRA and competitive bidding in terms of the scale that CMS is embarking on in 2007.

CMS proposes to incorporate a threshold or amount or level of savings that the Medicare program must realize for an item or group of items before it would use payment information from a competitive bidding program to adjust payment amounts for those items in other areas. This is essentially government price-fixing and not competitive bidding at all.

In addition, providers' total costs of providing certain DMEPOS products and services in different geographic areas may differ greatly from the original competitive bidding area where a certain single payment rate applied. Examples of variable costs in different states include fuel, utilities, rent, labor, overtime, regulatory compliance, and licensure.

Finally, the single payment rate that a supplier agreed to in a given competitive bidding area may have been notably less than the supplier's original bid in that market.

CMS would determine whether adjustments of payment amounts in these areas would be on a local, regional or national basis, depending on the extent to which the single payment amounts and price indexes for an item or group varied across different areas of the country.

Again, the single payment amount that bidders use reflects their TOTAL costs for providing that item of DMEPOS and its related support services in a specific MSA. These can vary dramatically in different areas of the country and it would be unfair and unrealistic to apply rates from one area to another for this reason.

CMS would also consider whether adjustments of payment amounts in other areas would be based on a certain percentage of the single payment amount(s) from the competitive bidding area(s). This is anti-competitive and simply wrong. CMS proposes no studies, no methodology, and no process for arriving at a certain percentage.

G. Requirement to Obtain Competitively Bid Items from a Contract Supplier (section 414.408(f))

Most of our payors have a difficult time enforcing this same requirement for open-choice managed care products such as Preferred Provider Organizations (PPOs) and Point of Service plans (POS). Many noncontracted suppliers eventually pay a claim related to a noncontract supplier through a process usually described as "contract leakage." In this situation, when a patient has already visited a noncontracted provider, the claim is usually billed at retail and then the payor reimburses the noncontracted provider a non-par amount (usually 50-60% of billed charges). Unless CMS is going to build a system that has strict exclusion provisions, providers could still get paid even if they are noncontracted. (However, we do not support CMS' plan, stated elsewhere, to "flag" Medicare supplier numbers, since a single location could serve both CBA- and non-CBA Medicare patients. See below.)

H. Limitation on Beneficiary Liability for Items Furnished by Noncontract Suppliers (section 414.408(f))

We are very concerned about the long-term effectiveness of the proposed supplier flagging process at the NSC. This process is flawed because we anticipate that many contract suppliers may serve broad geographic areas that include both competitive and non-competitive bidding areas. Apria operates branches, each with its own supplier number, that currently service beneficiaries in geographic areas that include the proposed competitive bidding areas.

Another example where this process would be problematic is that of a centralized (*i.e.*, "mail order") pharmacy from which diabetic supplies are provided to patients in numerous states. While the pharmacy requires applicable state licenses to serve patients in those states, it usually requires only one Medicare supplier number. Therefore, Medicare could not flag its supplier number as a non-contracted supplier in one market if it serves hundreds of other markets nationwide.

Instead, we suggest that flagging occur at the patient level based on his/her permanent residence. This is a preferable approach because it addresses the challenges associated with suppliers' geographic coverage beyond a given MSA and the issues associated with patients who reside temporarily in another part of the country or travel frequently.

Suppliers would need to be given access to this patient-level flag through some electronic means that could be verified during the routine Medicare insurance/secondary insurance verification process that all suppliers implement upon the referral of a patient from a referral agent.

E. Competitive Bidding Areas
Proposed 414.410
71 Fed. Reg. 25654, 25665-25669

I. Phase-In Approach

We agree with CMS' planned approach to phase-in competitive bidding. However, we are concerned about the aggressive nature of the plans, especially for 2008, when CMS is proposing to expand the competitive bidding program to eight times as many markets as in 2007. This is a huge undertaking and we strongly suggest that CMS consider a more moderate approach. In our experience, it takes a supplier approximately ninety days to appropriately coordinate implementation for a brand new contract. In addition, this program involves new Medicare carriers. CBICs have yet to be selected or identified, and an entirely new mindset for both beneficiaries, suppliers, and referral agents is required. It remains unclear how CMS itself, and its internal support systems such as the ombudsman, will fare under the new program. Consequently, we recommend CMS consider no more than 50 MSAs in 2008. If the first markets are not implemented until late 2007, CMS should consider further reducing the 2008 projection.

II. Proposed Methodology for MSA Selection for 2007 and 2009 Competitive Bidding Programs

A. The Scope of a Competitive Bidding Area Should Remain Consistent with the MSA Boundaries

The MMA states that competitive bidding will be implemented in a gradual fashion. CMS adopted this approach in the Proposed Rule and we support that decision. We disagree with how CMS intends to define the proposed competitive bidding areas and believe CMS has exceeded its statutory authority.

Until at least 2009, the scope of a competitive bidding area should be concurrent with a metropolitan statistical area ("MSA"). CMS is incorrect in its presumption that it has the discretion to define a competitive bidding area as being anything other than concurrent with an MSA. Even if CMS were correct, it would be administratively very burdensome for suppliers to implement competitive bidding in geographic regions that meander outside of the clearly-defined MSA borders.

From 2007 through 2009, the Social Security Act authorizes CMS to implement competitive bidding in some of the largest MSAs in the country. Specifically, section 18471(B) of the Social Security Act states that competitive bidding shall be phased in:

> among competitive acquisition areas in a manner so that the competition under the programs *occurs in—*
> (I) 10 of the largest metropolitan statistical areas in 2007;
> (II) 80 of the largest metropolitan statistical areas in 2009; and
> (III) additional areas after 2009; (emphasis added).

The statutory language clearly contemplated that the competitive activities would occur in an MSA. There is no discussion about the bidding areas occurring around an MSA or including an MSA. Based upon the clear statutory language, there is no authority for CMS to expand the program beyond the boundaries of an MSA until 2009. Only at that time, and not until then, may additional areas be included. It would be inappropriate and outside of CMS' statutory authority to design a competitive bidding area that exceeded the applicable MSA boundaries.

Even if CMS had the discretion to be creative with the boundaries of each competitive bidding area, it should not exercise that authority. In order for contract suppliers to efficiently furnish services in accordance with the program parameters, it is essential that the bidding area boundaries be clearly defined.

All parties agree that competitive bidding will add an additional layer of operational complexity for suppliers. This will be particularly true for those suppliers who service from one location Medicare beneficiaries in both traditional and competitive bidding programs because of the different reimbursement rates and scope of brand product that must be supplied. The business systems of most suppliers will not easily permit implementation of gerrymandering geographic boundaries. To avoid legal challenges, minimize unnecessary administrative burden and reduce the likelihood of confusion, CMS should establish competitive bidding areas with clearly defined borders. Adhering to the defined MSAs is the easiest approach.

B. Selection of MSAs for 2007

CMS proposes to use a multiple step process in selecting the MSAs for 2007. We generally support the approach CMS has suggested. For example, we agree that the three largest MSAs in the U.S. should be exempt from the competitive bidding program in 2007, until CMS gains more experience with the program. However, we are very disappointed that CMS did not publish the July 1, 2005 U.S. Census Bureau population data for each MSA and therefore publish the first 10 markets for competitive bidding. CMS has had a significant amount of time to analyze market data and DMEPOS expenditures.

Regarding the weighting methodology proposed, we agree that each factor should be weighted 50 percent.

We do not agree with CMS' assertion that "areas having more suppliers per beneficiary are more likely to be "competitive." CMS' use of the term "competitive" in this context implies that competition is solely based on price, when in fact research suggests that the home DMEPOS market is already very competitive based on several other non-price factors, *i.e.* clinical reputation, after hour/on-call service, product availability, and professional staff.

We are unclear how CMS plans to handle suppliers that were established in 2004-2006 since two different sections of the Proposed Rule define "new suppliers" differently and provide different information as to how they will be considered for participation in the program.

This section describes eligibility applying only to those suppliers that had a Medicare supplier number in 2003 or that generated at least $10,000 in Medicare claims. This conflicts with language later in the document. CMS must allow a new location or supplier number that was established in 2004-2006 to apply as long as all other eligibility criteria are met for that location. When a supplier buys a new business and the new location does not roll into an existing location for the supplier, the acquirer must obtain a new provider number along with all applicable licenses for that new location. For the NSC to issue a new provider number, it often takes up to 90 days. Therefore, it could appear that revenue is low for a given supplier when in fact an acquisition or other issue could be impacting it.

Regarding specific markets, we believe that San Juan, Puerto Rico should be included in the first 10 markets in 2007 since the business connection to the Miami market is strong. In addition, San Juan has a history of issues with compliance and fraud and abuse. To try and overcome these adverse influences, this market represents a strong candidate for inclusion in the first round.

We recommend that any market that crosses over two or more states be exempt from the first 2007 round of bidding. For example, the Kansas City MSA is a complicated one due to the fact that Missouri and

Kansas have very different clinical practice acts, state licensure requirements, etc. Implementing competitive bidding across state lines represents more complexity than should be addressed in the first round.

Any market dominated by integrated healthcare systems or large teaching hospitals should also be exempt from the first round in 2007. Chicago is already exempt, but Pittsburgh, St. Louis, Washington, DC, Boston and Seattle also should be exempt for the same reason. In these markets, patients may travel long distances from outside the MSA for care and therefore their permanent residence may be located several hundred miles or even multiple states away from the market in which the hospital is located. The integrated healthcare system may also dominate the local market, which would result in an anti-competitive situation if its homecare company were to win as contract supplier.

C. DMEPOS Expenditures in Rule Do Not Reflect MMA Savings That Began in 2004

It is important to note that their 2003 DMEPOS expenditure data does not reflect the 10%+ oxygen savings and DME savings associated with the Federal Employee Health Benefit Programs (FEHBP) fee schedule. Nebulizers, for example, experienced an 18% reduction. Nor does the DMEPOS expenditure data include any savings that will accrue from the 2007 implementation of the DRA and then again in 2009 when the DRA's provisions for oxygen first take effect. Therefore, it will be critical for CMS to publish the 2005 DMEPOS expenditures and, if applicable, re-rank the MSAs since dramatic changes could have occurred since 2003.

D. Only Clearly-Defined MSAs Should Be Used as "CBAs"

We vehemently disagree with this interpretation of the act. CMS must use a "clean" MSA with clean boundaries.

We agree that the 2007 round of bidding should include no more than two MSAs per state and at least one CBA in each DMERC region. For the government, this distributes the responsibility and implementation across various DMERCs. For multi-site providers, this also alleviates operational burden associated with starting up and implementing competitive bidding in more than one region.

E. Program is Designed to Achieve Savings, Not Specific Profit Targets for Suppliers

CMS states that age distribution is not uniform across MSAs. *See* 71 Fed. Reg. at 25667. MSAs located in states that have either large immigrant populations or have experienced rapid recent growth often have younger than average age profiles. Another reason is that DMEPOS utilization and potential profits are not uniform across MSAs.

While the general theme of competitive bidding is "savings," we were disturbed to read that CMS is attempting to use the program to determine profit levels for the DMEPOS industry. *See id.* America's free market and governing laws prevent price-fixing or pre-determined profit levels and we are alarmed by CMS' explicit reference to the same.

CMS proposes to "adopt other criteria regarding issues described above or other criteria and options brought to our attention through the comment process." *See* 71 Fed. Reg. at 25668. If other criteria are added that even impact providers only slightly, the PAOC should review the information before the criteria are finalized.

F. 2007 Program Should be Fully Evaluated Before Proceeding to 2009 Round of Bidding

Regarding the selection of markets for 2009, we generally agree with the selection methodology. Since 2005 data will be more current, projected savings levels could change (downward). However, we believe that the 2007 round of bidding should be thoroughly evaluated, with official reports generated for Congress, the Administration and the DMEPOS community before CMS proceeds with the 2009 round.

We do have concerns about CMS' idea to modify the ranking of MSAs for 2009 based on allowed DMEPOS charges per beneficiary so that it focuses on items that experienced the largest payment reductions or savings under the initial round of competitive bidding in 2007. They include:

- Suppliers' overall costs will change over time. For example, for Apria alone, fuel rose over 30% in the fourth quarter of 2005 alone, and 19% year-over-year. So, CMS should not assume that savings levels would be the same from year to year or contract to contract.

- Other policy, regulatory or statutory changes could occur during the 2007 contract period, such as capped rental, coverage criteria, local coverage determinations (LCDs), etc. could greatly impact savings.

- CMS stated that they "do not propose limiting the number of MSAs that can be selected from any one state." We disagree since it would be too burdensome for suppliers to have different prices and policies in the same state, not to mention the amount of resources required to bid on and participate in numerous markets with different cost structures in the same state.

- We anticipate that the dramatic changes impacting patients and the industry in 2007-2008 in conjunction with the DRA will further impact the perceived success of competitive bidding.

III. Establishing the Competitive Bidding Areas for 2007 and 2009 (414.410(b))

As discussed in our comments about the definition of MSA, we believe that section 1847(a)(1)(B) of the Social Security Act prohibits CMS from extending individual competition areas beyond the MSA boundaries in 2007 or 2009. Not only is the proposal beyond the statutory language, but supplier compliance will be impractical due to systems and other operational limitations. No "adjoining" area (which CMS did not define), parish, county, or zip code should be added to an existing MSA. *See* 71 Fed. Reg. at 25669.

We request that CMS refrain from using the term "competitive" interchangeably with "price savings." The two concepts are different and should be applied accordingly.

The bullet point that says "the area is part of the normal service area or market for suppliers who also serve the MSA market or areas within the boundaries of an MSA in which a competitive bidding program will be operating in 2007 or 2009" describes another mistaken assumption. Service areas vary by each individual company and can change at any given time, such as when a provider decides to close or relocate a branch operation. Such a closure or relocation may be unrelated to the Medicare beneficiaries it serves and be based on other reasons.

IV. Nationwide or Regional Mail Order Competitive Bidding Program (section 414.410(d)(2))

One general aspect of this section is that it does not define "mail order." Most suppliers that provide centralized pharmacies STILL have to employ a large clinical and administrative staff to support the non-

supply needs of patients, such as Medicare and secondary insurance billing, pharmacist and pharmacy technician oversight, accreditation and licensing.

Although CMS' data shows that a significant percentage of certain items such as diabetic testing supplies are furnished to beneficiaries by national mail order suppliers, the other competitive bidding programs should be launched first. We urge CMS to refrain from including mail order items until the mechanics of the competitive bidding program have been tested and work smoothly. This is likely to be after all the parties have had at least two to three years experience with the proposed program.

Products that could be suitable for competitive bidding via a centralized distribution model in the future include:

- Diabetic supplies and testing strips
- Incontinent and ostomy supplies
- Nebulizer compressors and supplies
- Cannulas, tracheostomy tubing and supplies
- Suction catheters
- Pulse oximeters and sensors
- Certain ambulatory aids that do not require a two- or four-hour delivery after initial referral

The following would be inappropriate for drop-ship:

- Oxygen
- CPAP
- Ventilators, BiPAPs, Respiratory Assist Devices
- Hospital beds

We were pleased to see that CMS again referred to supporting services in conjunction with the discussion in this section. CMS needs to ensure that the supplier can offer access to a diabetic educator, respiratory therapist, pharmacist or other clinician if a patient receives drop-ship supplies, depending on the nature of the supplies. CMS also needs to define "timely basis" and "brand specificity" for glucose monitors and strips. There are numerous "functionally equivalent" monitors that should be allowed to be provided as long as the manufacturers have deemed them to be compatible with the accessories or supplies.

V. Additional Competitive Bidding Areas After 2009 (section 414.410(d))

It is unacceptable that beginning in 2010, CMS would designate additional competitive bidding areas through mere program instructions. This critical element of the program should be routed back through the PAOC for formal consideration as well as a public comment period. Things change in MSAs -- new technology and products are introduced by manufacturers that may have higher costs, clinician shortages ebb and flow, natural disasters occur, and all of these factors impact DMEPOS expenditures and market dynamics.

F. Criteria for Item Selection
71 Fed. Reg. 25654, 25669-72

Competitive bidding is generally suitable for certain products and services included under the DMEPOS benefit. However, others are not. In fact, services such as intravenous therapy and enteral nutrition (tube feeding) are usually categorized under either the Major Medical or Prescription Drug Benefit of managed care plans, including senior risk plans.

I. CMS' Authority to Exclude Items from Competitive Bidding is Clear

The MMA gives CMS the discretion under the MMA to exclude:

1) Products and product categories from the 2007 phase of the competitive bidding program, which CMS acknowledges in the preamble to the proposed rule,

2) Products and product categories in particular settings, such as nursing homes, from the 2007 phase of the competitive bidding program.

Section 302 of the MMA expressly distinguishes between where Congress intended the Secretary to exercise significant discretion and those where it did not. The statute provides that the Secretary "**shall** establish and implement programs under which competitive acquisition areas are established" and that the programs "**shall**" be phased in so that competition occurs in a certain number of the largest MSAs by certain times. However, the statute also provides that the program "**may**" be phased in first among the highest cost and highest volume items and services or those with the greatest savings potential, and that the Secretary "**may**" exempt certain rural and low population density areas and items and services for which competitive acquisition is not likely to achieve significant savings. The statutory language specifically directs the Secretary to establish competitive acquisition areas on a certain schedule, but permits flexibility in design and implementation to encourage efficient operation. By stipulating that the competitive acquisition areas "**may** differ for different items and services," Congress gave the Secretary wide discretion to choose those products and services that are most amenable to competitive bidding (and to exclude products and product categories that are not) and to first implement the program in the metropolitan statistical areas of his choosing.

These grants of discretion gave the Secretary sufficient flexibility to implement the program in the most effective way possible. It also is clear, then, that if there is evidence that it would be in the interests of a successful competitive bidding program to exclude nursing homes from the first implementation phase, the Secretary has the discretion to do so.

CMS alluded to reports and studies as providing evidence and guidance as to product categories that are over-reimbursed under current fee schedules and where competitive bidding could bring needed changes to payment levels. As a principle, this is a sensible criterion. Our issue with this approach, however, rests with the caliber of the studies CMS is likely to rely upon in its analysis.

II. Government Studies Are Usually Narrow in Scope

The Office of Inspector General ("OIG") has issued many reports over the years about a wide array of product categories. A number of these studies were not written, or designed, to reflect all of the issues faced by policymakers on a particular subject. Instead, they were focused largely on a narrow issue or a small subset of issues, and as a result the reports often reflect a skewed perspective of (1) the

particular problem and (2) the suggested solution to that problem. In addition, OIG reports generally collects information from across the United States, while competitive bidding is market-specific. Finally, none of the historical OIG studies could not have reflected the costs associated with accreditation, either in terms of the administrative costs of seeking and maintaining accreditation or the costs of complying with the quality standards that are the bases of accreditation. In light of this clear discrepancy, we urge CMS not to rely heavily on OIG reports in determining product selection for the competitive bidding program. It would be inappropriate for CMS to use OIG data or recommendations for payment adjustments at the local MSA level.

If CMS wishes to use outside sources to gather information about various homecare services and costs, we urge CMS to consult with the American Society for Parenteral and Enteral Nutrition (ASPEN), the American Association for Respiratory Care (AARC), the American Nurses Association (ANA), the American Dietitians Association (ADA), the National Home Oxygen Patients Association (NHOPA), the American Lung Association (ALA), the American Diabetes Association (ADA) the Joint Commission on the Accreditation of Healthcare Organizations and other accrediting organizations as to their perspective on what is involved in the provision of homecare products and services.

The rule refers generally to "reports and studies" that might be used to determine which DMEPOS items would be included in competitive bidding. CMS should specify which ones and which types will be considered.

A number of OIG reports about homecare products and services contain estimates about supplier acquisition costs for supplies and equipment, and compares those acquisition costs with Medicare payment rates. The OIG often describes the gap between the acquisition costs and payment rates as "waste" or "abuse," despite the fact that the OIG has never conducted studies that focus on:

- The services and functions required of suppliers to provide good quality care,
- The costs associated with these services and functions, or
- If payment rates are limited to the acquisition costs of items and equipment, then no supplier will be able to remain in business to provide products and services to Medicare beneficiaries.

Recent examples that support this assertion are the studies on inhalation therapy services and the soon-to-be-released on concerning the cost of oxygen concentrators. The latter study collected information about a limited number of activities performed, but did not collect information about the full array of services required to support a Medicare oxygen patient at home, and it did not collect any provider labor or cost data. Therefore, it is likely to result in a very one-sided presentation of the subject of oxygen concentrator costs, repair and maintenance activities.

Also, we would like to know who will review the studies to determine their validity? Will on-site visits to homecare providers be conducted by CMS team leaders to further explore assertions contained in the reports and studies, or will a desktop-only analysis be conducted? We obviously disagree with a superficial desktop review of such studies and welcome the CMS team and Congressional staffers to visit our offices at any time.

III. Infusion Therapy Services and Enteral Nutrition Should be Excluded

Infusion therapy and enteral nutrition are much more complex than traditional DMEPOS. Home infusion involves the administration of medication or nutrients directly into the bloodstream, administered through a needle or catheter. Other routes of administration include intramuscular and epidural routes. Enteral

nutrition involves liquid nutrients delivered directly into the gastrointestinal tract through either a surgically-implanted feeding tube or a nasal feeding tube.

Patients who require infusion therapy and/or enteral nutrition typically suffer from a chronic, acute or terminal illness such as Crohn's Disease, Ulcerative Colitis, Motility Disorders, Multiple Sclerosis, Lupus, Rheumatoid Arthritis, Bacteremia, Septicemia, Endocarditis, Osteomyelitis, Lyme Disease, all kinds of cancers, leukemias and lymphomas.

Infusion therapies generally fall into major categories such as total parenteral nutrition (TPN), antibiotic/antifungal/antiviral therapy, chemotherapy, pain management, intravenous immune globulin (IVIG), hydration, colony stimulating factors, hemophilia therapies and others. Therapy may be needed continuously (daily) over a long period of time, or it may be intermittent in nature, as in the case of chemotherapy treatments. Such therapies are almost always prescribed after an oral or other course of treatment fails.

Examples of the complexity involved are frequent prescription changes in either dosage, drug or frequency; intensive patient admission and monitoring processes, intensive patient/caregiver education and 24/7 service supporter, coordination of care between a physician's office, an outpatient setting and the homecare setting for care and other unique aspects of care.

Therefore, we strongly oppose the inclusion of these two product categories in any round of competitive bidding.

IV. Infusion Therapy is Too Complex for Medicare Competitive Bidding to Be Successful

Only specialized home infusion pharmacies that are licensed and/or accredited by the Joint Commission or another accrediting body may provide home infusion to patients in any given state. Only high-tech nurses may administer IV therapies to patients at home; these nurses usually have advanced education, training or certification in their area of expertise, such as cancer, pediatrics, nutrition or pain management.

All medications must be prepared in a sterile environment, where clinical pharmacists who again have specialized training and education prepare each medication according to the individual patient's prescription. The clinical team routinely consults with the patient's physician to serve as his/her "eyes and ears" at home.

There are also policy reasons why infusion drugs and pumps should not be considered for competitive bidding. In some ways, infusion drugs have been "shoehorned" into the Medicare DMEPOS benefit simply due to the way that the benefit is structured for "pure" DMEPOS products or the infusion pumps used in conjunction with IV therapies. Managed care plans, on the other hand, usually include home infusion therapy coverage under either their major Medical benefit or their prescription drug benefit.

The matter is made more complicated by Medicare Part D. While 23 drugs may be covered in the home under Part B, hundreds of home IV drugs are now coverable under Part D (although it is important to note that only the drugs are covered; unlike the private sector that appropriately recognizes the full range of services and supplies needed to safely administer these drugs at home, the Part D program only covers the drugs.) Medicare Part D plans and home infusion providers alike are still working through operational and implementation issues and shortcomings associated with the Part D program and IV drugs. There are already patients who require both Part B and Part D drugs and experience tremendous confusion. To add competitive bidding to the mix would only serve to confuse both patients and referral agents further.

V. Level of Infusion Expenditures Does Not Warrant Competitive Bidding

Since CMS proposes to consider the level of expenditures of each product category as one factor to determine whether a product should be included in competitive bidding, it is important to note that infusion drugs, supplies and pumps comprise a very small part of the Part B expenditures (especially when only the homecare portion is considered and the physician's office-based chemotherapy and other expenditures are stripped out).

After deleting other expenditures that are not truly "infusion" in nature (e.g. insulin pumps and supplies and limited distribution products), Medicare's allowed charges for home infusion therapy are estimated to slightly exceed $87 million, making it the 14th highest ranking product category.

VI. Rate of Growth for True Infusion Spending Actually Decreased from 2003 to 2004

After accounting for increased expenditures in sub-categories that are not considered "traditional infusion" in nature (e.g. insulin and insulin pumps and limited distribution drugs such as Flolan), it appears that the rate of increase for infusion pumps and drugs actually decreased significantly from 2003 to 2004. (Data source: Physician Supplier Procedure Summary Master File, DMERC advisories from 2002-2004 and DMERC data).

Since Flolan and other single-source or limited distribution drugs comprise the majority of growth in expenditures, competitive bidding does not apply since the drugs are only available from a narrow list of infusion pharmacies.

We recommend that CMS direct its energies toward those product categories that stand to yield the greatest savings and that make the most sense in terms of a "fit" with competitive bidding. Neither infusion therapy nor enteral nutrition meet that criteria.

VII. Enteral Nutrition's Inclusion in Demonstration Project Did Not Work

Enteral nutrition was not tested successfully during the two demonstration projects and was categorized as not well suited for competitive acquisition by CMS. Enteral nutrition originally was included in CMS' Polk County, Florida demonstration project that tested competitive bidding for certain Part B items. However, enteral nutrition was removed from that demonstration after the first phase of the project. We believe it was removed primarily because most enteral patients reside in long term care facilities, where the application of the competitive bidding regimen would be difficult and confusing. Thus, use of competitive acquisition to set prices and pay for enteral nutrition in Medicare has not been tested sufficiently or successfully.

In addition, based on its own analysis of the data from the DMEPOS competitive bidding demonstration projects, CMS concluded in its final report to Congress that enteral nutrition was not well suited for competitive acquisition. Recently, CMS staff echoed this perspective, indicating that certain products may not be suitable for competitive acquisition because Medicare will not realize sufficient savings to justify the administrative expense of the competitive acquisition program.

VIII. Rate of Growth

Our analysis of enteral claims data from the years 2002-2004 indicates that Medicare payments for enteral nutrition are not growing at an abnormally high growth rate. The rate of growth of Medicare allowed charges increased by 1.7% from 2002 to 2003, and actually decreased by approximately 5% from 2003 to 2004. Thus, Medicare allowed charges for enteral nutrition in 2004 were $20,624,897 less than

they were in 2002. Clearly, this is not an area that requires immediate action and attention from CMS to restrain inexplicable increases in the rates of Medicare expenditures. If this factor truly is an important criterion in CMS' product selection, then enteral nutrition is a poor choice for inclusion in the 2007 phase of competitive bidding on that basis.

IX. Potential for Savings

Throughout the rule, CMS refers to "significant" or "large savings" potential associated with the program. Yet, it does not define these terms. We request that CMS explain what specific measure will be used to identify an item's true potential savings, after accounting for any recent policy changes and rate cuts.

Our questions include the following:

Is there a minimum threshold of savings or expenditure level that will trigger a particular item's inclusion in competitive bidding?

When CMS reviews annual growth in product expenditures, is there a threshold growth percentage and does it vary by any measure?

Regarding supplier capacity, CMS has not provided enough detail needed to calculate reliable supplier capacity numbers. Is CMS using a supplier capacity threshold to determine the final number of suppliers in a particular MSA?

Since only a limited number of product categories were included in the two demonstration markets and the number of categories for future rounds is likely to be larger, what savings threshold will CMS use to determine whether other categories should be included or not?

X. New Product Categories Are Not Needed

We are greatly concerned that CMS is proposing to create new product categories subject to competitive bidding, especially if the plan is to increase the number of categories. The existing product categories have guided coverage and reimbursement for many years; CMS' own web site is organized by product category and suppliers access the site frequently for information. It would be far too confusing for the categories to be modified, especially when a provider operates multiple sites. Such providers usually operate a single information systems platform and keeping track of old categories and new categories in a single market or state would be next to impossible. Much more information is needed about CMS' plans before we can comment further.

Policy changes made in recent months or years will further reduce potential savings that can be attributed to competitive bidding. A new 2006 policy will significantly bring down the $131.1 million in 2003 allowed charges for the following three HCPCS codes:

- E0470 (Respiratory assist device (RAD), bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device);

- E0471 (Respiratory assist device, bi-level pressure capability, with backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device), and,

- E0472 (Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device).

CMS uses nebulizers as an example, but again, FEHB brought those expenditures down substantially. CMS should republish allowed 2004 and 2005 charges post-FEHB.

CMS has proposed a number of variables it would consider when making determinations about an item's potential savings as a result of the application of competitive bidding. Our comments on each are noted below:

- Annual Medicare DMEPOS Allowed Charges – We agree

- Annual Growth in Expenditures – It is important to note that certain products may show a negative growth rate from 2004 to 2005 based on the FEHB cuts. In addition, growth could be attributed to other factors unrelated to "inappropriate" supplier behavior, such as an increase in the number of new beneficiaries or elimination of Part C in various markets.

- Number of Suppliers – We do not agree that savings should be measured using the available number of suppliers. Rather, savings should be based on capacity.

- Savings in the DMEPOS Demonstrations – Any savings should be adjusted for after FEHB and DRA methodology before the impact of it is calculated.

- Reports and Studies -- We are concerned that CMS does not always use reports and studies that are comparable to the industry or specific situations being evaluated. It appears that at least 7 of the 10 proposed markets are significantly more complex than Polk County, based upon total (all payors) revenues, not just Medicare.

We disagree with the CMS presumption and corresponding language that "Medicare overpays for specific items" at 71 Fed. Reg. at 25671. The studies that OIG and GAO conduct often collect data on only a portion of a supplier's total costs. (See comparison data from Muse & Associates in 2004 and 2005 vs. OIG on inhalation drugs.) Government studies from GAO and OIG are important data sources, but CMS should not rely upon them exclusively and without critical assessment. CMS should ensure that OIG conducts robust studies that capture what we believe is a complete and accurate reflection of a supplier's TOTAL costs, not just equipment costs. We are also concerned that some of the studies upon which CMS seems to rely are outdated and do not reflect changing markets and realistic price pressures.

Pending or future changes to likely competitively bid products include:

- The revision to the power wheelchair product category– currently underway and includes major changes to HCPCS codes, product descriptions and mobility assist equipment as well

- The proposed LCD that would effectively eliminate patient and physician access to the inhalation drugs DuoNeb and Xopenex could also impact nebulizers

- CPAP was impacted by a National Coverage Determination (NCD) in 2006

- Respiratory Assist Devices (RADs) were moved to the capped rental category

G. Submission of Bids Under the Competitive Bidding Program
Proposed 414.412
71 Fed. Reg. 25654, 25672-25674

I. Physicians (proposed section 414.404, 414.422)

In this section, CMS requires that "[p]hysicians that do not become contract suppliers must use a contract supplier to furnish competitively bid items to their Medicare patients."

We recommend that the Office of Inspector General (OIG) eliminate one of the last remaining loopholes of physician self-referral by preventing their ability to own sleep laboratories and provide Part B DMEPOS items in their offices. By studying the impact of physician ownership on overnight sleep study expenditures incurred by Medicare Part A and the growth rates of the past few years, the OIG will likely conclude that such ownership needs to be eliminated just as it was for clinical laboratories and traditional home medical equipment (HME) operations.

A. Physicians as DMEPOS Suppliers

Regarding specific language in this section, CMS should replace the phrase "must use" with the phrase "must refer to." Use the term "refer" because it is illegal and against our compliance program to enter into certain non-safe harbored relationships with physicians. In most cases, physicians cannot own businesses that provide DMEPOS to government-insured patients.

Apria strongly believes that any contracted supplier should satisfy the standards CMS has established, including accreditation, quality standards, Medicare supplier standards, financial and compliance standards, and other requirements associated with being a DMEPOS supplier under Medicare Part B competitive bidding. This obligation should apply to any physician or physician's practice that wants to participate in competitive bidding. There should be no exceptions.

B. Financial Information Required of Large Suppliers

We also agree with CMS' plan to require suppliers to submit a minimum of financial information with their bids. We ask CMS to consider the logistical difficulties and practicalities for large or publicly-traded organizations. As a publicly-traded organization, Apria already has supplied a significant amount of financial information to public markets and the Securities and Exchange Commission (SEC). This includes consolidated information for our multiple locations, since balance sheet, debt, interest and other financial data are not typically available at the branch or supplier number level. This type of public, consolidated information should be sufficient for the CMS bidding process. Organizations like Apria should not be required to prepare unique reports for CMS, and we request that this be made clear in the final rule.

C. Physical Location Within the MSA

CMS has proposed that a supplier must be physically located within a competitive bidding area in order to submit a bid to furnish items in that area. We agree with and strongly support this approach, even for items and services that could be furnished from another company-owned centralized location or via the mail. We do believe that even if a supplier has a centralized pharmacy for providing, for example, diabetic supplies and testing strips, the corporate parent should also operate a physical location within the

MSA. The purpose of this site would be to ensure that beneficiaries have access to contact employees who work for the same corporate entity in the event of a time zone or other limitation.

Without such a requirement, CMS runs the risk of contracting with suppliers that simply drop-ship into the MSA's zip codes without any additional local support whatsoever. They could "cherry-pick" certain product categories without having to make any investment in the MSA. While certain products lend themselves to centralized pharmacy or operations management, others do not and if CMS does not provide some guidance in this area, all kinds of medical equipment may be shipped interstate with or without an appropriate level of patient and caregiver education. This may seriously jeopardize patient safety or violate state licensing and shipping laws and regulations.

II. Product Categories for Billing Purposes (proposed section 414.412)

A. Use of Same 55 Product Categories or Policy Groups

In the Proposed Rule, CMS suggests that it may establish all new "product categories" solely for the purpose of competitive bidding. Although much more detail is needed before we can comment more comprehensively, this proposal is unwieldy and unnecessary given the fact that the existing product categories have been in existence for decades and are commonly-referenced by the industry and DMERC employees alike. We are uncertain why CMS would like to develop alternative categories, and CMS offered no reasonable explanation in the Proposed Rule.

Although the competitive bidding program will launch in 10 markets in 2007 and more in 2008, many markets will continue to operate under the existing product categories. Parallel systems will add unnecessary confusion for suppliers, DMERC claims processing employees and patients. A branch operation may find itself serving patients with the same exact DMEPOS item, but the item could fall into two different categories depending on the zip code of the patient's permanent residence. Few information systems would be able to accommodate such bifurcation.

Before we can make extensive comments on this section, we need to understand how CMS plans to create separate product categories specifically for competitive bidding purposes. CMS was not clear as to the rationale behind the creation of all-new product categories. The 55 categories work for most other reasons, such as how coverage criteria is currently organized, so we need more information on CMS' detailed plans.

B. Submitted Bids: What Do They Include?

CMS states that the submitted bid must "include all costs related to the furnishing of each item such as delivery, set-up, training and proper maintenance for rental items." *See* 71 Fed. Reg. at 25672. This list does not reflect the full range of services or associated costs of the services, such as 24/7 on-call/emergency availability and responsiveness, new patient admission/insurance verification costs, coordination of traveling patients' needs between locations, billing/collections, rent, utilities and regulatory compliance. Most importantly, it does not reflect what might or might not be contained in the proposed quality standards for competitively bid items.

Thus, we ask CMS to clearly specify that these additional costs should be factored into a supplier's bid. While CMS has defined "bid" to recognize these costs, we believe reemphasizing the point here will eliminate future confusion and increase the likelihood of bids that reflect a similar bundle of products and services.

C. Requiring Suppliers to Submit a Bid for All Items in Every Defined Product Category

We are unpersuaded by at least one rationale CMS has offered for the use of new product categories. CMS asserted at 71 Fed. Reg. at 25673 that it believes that "the use of product categories will allow Medicare beneficiaries to receive all of their related products (for example, hospital beds and accessories) from one supplier, which will minimize disruption to the beneficiary."

This is not necessarily true. It is only true if a supplier who is capable of providing all or most of the items being included in that MSA's product list bids on and wins the contract with CMS for the MSA. If not, a patient who requires oxygen, a hospital bed, a wheelchair, a walker, nebulizer and commode chair could, theoretically, have to interact with six different suppliers. This means they would receive six separate monthly bills or statements, six different sets of patient education materials and possibly policies to follow, and other examples of mass confusion. So, any patient who requires multiple DMEPOS products – and many do – will still have to coordinate care with multiple suppliers. This inherently adds additional costs to the entire healthcare system. Referral agents will also be very confused by this process. This seems to be an extremely inefficient and confusing approach and in no way mirrors how private sector managed care organizations handle this.

On the other hand, CMS also stated that in regard to design options, it considered requiring suppliers to submit a bid for all items in every defined product category. *See* 71 Fed. Reg. at 25672. CMS asserted that it would like to "accommodate DMEPOS suppliers who want to specialize in one or a few product categories." *See* 71 Fed. Reg. at 25683.

While there are certainly suppliers that currently specialize in one or a few product lines (diabetic supplies and power wheelchairs are two good examples), we believe that certain suppliers who offer a broader range of DMEPOS may elect to "cherry-pick" the system and directly or indirectly manipulate the CBA's referral patterns. If suppliers focus on one or two product lines and leave other products out of their bids, even though they provide them in that market, it could cause problems when the referral agents apply their "rotation system" in the hospitals. It is well-understood that different product categories have different cost structures and service requirements, accreditation standards, labor and other operating expenses. Therefore, the profit margins for each may vary and some providers may "cherry-pick" if this policy is not thoroughly reviewed. We provide the following scenario for your consideration:

- Supplier A COULD bid on oxygen, standard wheelchairs and walkers, but elects to only bid on oxygen. Supplier A wins the bid on oxygen.

- Supplier B bids on oxygen, standard wheelchairs and walkers, and wins on all three. However, once the discharge planner in the local hospital learns which suppliers they have to choose from for the different products and applies the "rotation system" under which the employee goes down the list in either alphabetical or chronological order, Supplier A could receive a disproportionate share of the hospital's oxygen referrals, while Supplier B could receive a disproportionate share of wheelchairs and walkers. Depending on the final single payment rate for these products, and the associated quality standards, a provider could find itself upside down financially and have to either withdraw from the competitive bidding program or request an increase in the single payment rate.

CMS states that the Act grants the authority to exempt "items for which competitive bidding is unlikely to result in significant savings. We would propose not to include items in a product category if they are rarely used or billed to the program." CMS builds on its earlier plan to create separate product categories specifically for competitive bidding by going on to say that it "may establish different product categories from one CBA to another, as well as in different rounds of competitive bidding in the same CBA." *See* 71 Fed. Reg. at 25673.

We urge CMS to define "significant" when used in reference to potential savings. It is used throughout the document but is never defined.

We agree that items that have low utilization should be excluded from consideration for competitive bidding.

We also provided extensive comments on why infusion therapy and enteral nutrition should be excluded from competitive bidding.

D. Small and Large Suppliers' Ability to Furnish All Product Categories

CMS asserts that "a supplier may be able to furnish a bundle of items at a lower cost than it can product each individual item. This approach is also more favorable to small suppliers because they can choose to specialize in only one product category. It would be more difficult for a small supplier rather than a large supplier to furnish all product categories. This approach is also more convenient for Medicare beneficiaries, as they can choose to receive all their related supplies from one supplier and would not have to deal with multiple suppliers to obtain the proper items for their condition." *See* 71 Fed. Reg. at 25673.

We also disagree with your assertion that it would be more difficult for a small supplier to furnish all product categories. Apria Healthcare purchased 42 independent, private home DMEPOS companies in 2004-2005. Many offered a broader array of DMEPOS products than what Apria offers. While large suppliers may have greater access to capital, everything is scalable and relative to individual financial structures. Some small suppliers' cash flow is at a higher rate than for large suppliers; others may have incurred too much debt to be able to expand rapidly.

This section was not clear to us, but we refer to you to our comments from the immediate section above regarding the need for CMS to guard against "cherry-picking."

Regarding convenience for beneficiaries, again we reiterate that allowing suppliers to selectively participate in competitive bidding by product line could create havoc for beneficiaries who require multiple DMEPOS products to support their health condition. It is not uncommon for a patient with COPD to require, either upon hospital discharge or admission to our service, or as his/her condition worsens due to the natural progression of the disease, oxygen, nebulizer, inhalation therapies, a hospital bed, wheelchair and walker or other assistive device. If the patient also has obstructive sleep apnea (OSA) or diabetes, he/she may need a CPAP and diabetic supplies. In this case, the patient could find the need to use up to six separate suppliers. No patient or referral agent is going to be able to coordinate this easily.

If CMS is truly interested in adopting time-proven methods of contracting for home healthcare services as in the private sector, it should mandate that a supplier bid on all products that they typically supply in an MSA.

E. Relationship Between the DMEPOS Supplier and the Medicare Beneficiary

We appreciate that CMS recognizes the importance of the relationship between the patient and the supplier. However, we believe that CMS oversimplified that relationship by describing the services involved as "...deliver[ing] the item to the beneficiary, set[ting] up the equipment and also educat[ing] the beneficiary on the proper use of the equipment."

This oversimplification was further reinforced at the recent PAOC meeting when Linda Smith shared the results of the very small sample-sized focus groups by indicating that beneficiaries primarily view their supplier as a "delivery person."

1. Comments

Several industry studies have documented a much broader range of services. A June 2006 study conducted by Morrison Informatics, Inc., of Mechanicsburg, Pennsylvania, documents that for oxygen alone, the following services are provided in conjunction with the "furnishing" of the equipment.

Moreover, private managed care payors have been relying on homecare provider patient satisfaction survey results for decades. These surveys have been time-tested for statistical significance and the dimensions that are measured are commonly accepted as the primary services associated with the provision of DMEPOS to all patients, regardless of their insurance source. These dimensions include:

- ***Customer Service***, including the admission process, overall customer service, telephone interactions, the insurance benefits verification process, scheduling the in-home care, responsiveness to the patient after hours or on weekends, issue resolution, coordination of travel, etc.
- ***Clinical respiratory therapists*** – access to this care at home, timeliness, courtesy and professionalism of the therapist involved in educating the patient and/or caregiver
- ***Patient/caregiver education*** – in both printed and verbal form, and in regard to both the equipment's operation, trouble-shooting, patient safety instructions, emergency preparedness, how to reach the DMEPOS supplier with questions, etc.
- ***In-Home Delivery*** – timeliness, courtesy, professionalism, appearance, quality of instruction, etc.
- ***Billing/Collection*** – the extent to which the patient was informed of his/her financial responsibilities in terms of co-pays or deductibles, the accuracy of the billing, the responsiveness of the billing department if the patient had questions, etc.
- ***24/7 Emergency Service and Availability*** – Accrediting bodies require that suppliers offer around-the-clock service. Patients frequently access homecare providers on weekends and during natural disasters.
- ***Overall value of homecare*** – the patient assesses the overall value to his/her life, the degree to which homecare aids in the performance of activities of daily living, etc.

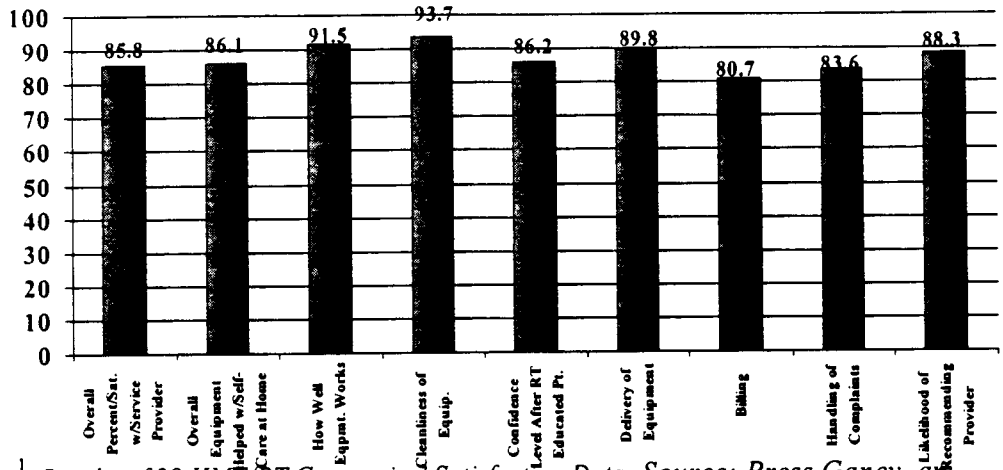
The above list only includes the services most obvious to the patient and does not, of course, account for numerous behind-the-scenes services that are required to ensure a smooth interaction between the company and the patient. Examples of the latter include accreditation, licensure, repair/maintenance and equipment cleaning/disinfecting functions, employee training and certification, telecommunications, regulatory compliance, management information systems, HIPAA compliance, SOX compliance, and more.

Below is a chart that shows the major service dimensions that are involved in measuring patient satisfaction with HME providers:

Patients Are Very Satisfied with HME Providers' Services

(75 Points is Considered "Satisfied")

Very Good	Good	Fair	Poor	Very Poor
5	4	3	2	1
100 points	75 points	50 points	25 points	0 points



[1] *Results of 29 HME/RT Companies' Satisfaction Data. Source: Press Ganey, an independent satisfaction measurement firm. Data represents approximately 580 physical locations. Data also represents multiple product lines and all payor sources.*

We do not see how the use of product categories will "facilitate the transition for those beneficiaries who have to change suppliers." CMS needs to provide much more background on how and why this is needed before we could change our views on this matter.

III. Bidding Requirements (section 414.408)

A. Inexpensive or other routinely purchased DME items

CMS states that "the current fee schedule amounts for these items are based on average reasonable charges for the purchase of new items, purchase of used items, and rental of items from July 1, 1986 through June 30, 1987. *See* 71 Fed. Reg. at 25673. In those cases where reasonable charge data from 1986/87 is not available, the fee schedule amounts for the purchase of new items are generally based on retail purchase prices deflated to the 1986/1987 base period by the percentage change in the CPI-U..."

1. Comments/Recommendations

Using data from 20 years ago or applying a deflation factor associated with the same surely must represent one of the most archaic fee schedule systems in the entire Medicare/Medicaid program. The home DMEPOS industry is remarkably different today than it was 20 years ago – the sheer number of new products and technologies introduced since 1986 could not possibly be reflected in a 20-year-ago fee structure.

Moreover, a CPI-U freeze has been in effect for the majority of the years since 1986, so the rates do not reflect either the cost of inflation or large increases in certain operating costs that providers must incur, such as fuel, vehicle expense, liability insurance or costs associated with state or federal legislation that has occurred since then. These examples include COBRA expenses, Sarbanes-Oxley compliance, HIPAA compliance, compliance with requirements of the Department of Homeland Security, the Department of Transportation, the Food and Drug Administration, the Occupational Safety and Health Administration, state pharmacy and licensure boards.

B. DME items requiring frequent and substantial servicing

We have no comment on continuous passive motion exercise devices as the plan appears acceptable.

C. Oxygen and oxygen equipment

CMS states:

> If included under a competitive bidding program, we would propose that the single payment amounts for oxygen and oxygen equipment be calculated based on separate bids submitted and accepted for furnishing on a monthly basis of each of the oxygen and oxygen equipment categories of services described in section 414.226(b)(1)(I) through 9b)(1)(iv).

1. Comment

It is important to state here that oxygen and oxygen equipment are facing the most dramatic policy and reimbursement changes in the history of coverage for this life-sustaining drug therapy and equipment. The Deficit Reduction Act of 2005 will limit reimbursement for oxygen to 36 months regardless of a patient's ongoing medical need, which flies in the face of how every other drug is covered and paid for in America.

The DRA's negative consequences on patients include:

- It forces patients to take ownership of their equipment and be responsible for identifying when preventive maintenance or repairs are needed.
- It will prevent patients from exercising their right to switch providers due to a move or dissatisfaction, since a provider will be unlikely to accept a patient who has reached the 36-month cap and for which there is no associated monthly reimbursement to care for that patient.
- It represents significant patient safety risks in the form of forcing them to own, maintain and dispose of FDA-regulated medical devices that are subject to manufacturer recalls and intensive regulatory scrutiny by the FDA, DOT and accrediting bodies.
- When patients might benefit from a different oxygen technology due to a change in their condition or their physician's preference, they will not have access to such technology because they will own the one they had during the 36-month period.
- Despite a reduction in benefits, there is no corresponding decrease in the patients' Part B premiums. In fact, the premiums will likely rise due to physician fees.

The NPRM in general is very "light" on how the DRA will interrelate to the competitive bidding program. Since over 23% of Medicare beneficiaries who require home oxygen therapy exceed the 36th

month, it is imperative that CMS address the numerous open questions about how the agency plans to address the gaps caused by the DRA.

The American Association for Homecare submitted a list of questions to the agency on April 20, 2006 . As an active member of AAH, Apria respectfully requests the agency to respond to that list of questions as soon as possible as the patients impacted by the Act's changes will feel that effect in just six short months when providers are required to inform them of the change in ownership and their associated responsibilities, effective February 2007. (*See Appendix A – "AAHomecare List of Questions About the Implementation of the Deficit Reduction Act of 2005)*

IV. Capped rental items

A. The Deficit Reduction Act of 2005 Dramatically Changes the Landscape for HME and Competitive Bidding's "Success" Will be Negatively Impacted by Its Provisions

This section marks the first reference to the DRA. We hope CMS understands that despite the fact that homecare providers are required to inform patients of their right to take ownership of their equipment at the current policy of month 15 of their rental period, less than 10% elect to do so. Patients were not asking for more ownership or "control" over their equipment; they need it just to get through the day, sleep through the night or walk to the mailbox.

Therefore, CMS needs to prepare for another 90% of patients who will take ownership of their equipment and all that it entails.

B. Payment for Maintenance and Servicing

CMS has proposed that suppliers submit a separate bid for all items in a particular product category. The bid must include all costs related to the furnishing of the item, including proper maintenance for rental items. The Proposed Rule suggests that a supplier's bid need not cover the costs for maintenance of an item once a beneficiary purchases it. 42 C.F.R. §§ 414.408(g), (i). On the other hand, CMS has proposed that a supplier must agree to service, repair, and replace all beneficiary owned items. 42 C.F.R. § 414.422(c).

These conflicting directives are confusing and make it difficult for suppliers to accurately determine their responsibilities under competitive bidding. While CMS might refer suppliers for guidance to the historic repair and replacement obligations of DME suppliers, enactment of the DRA has significantly modified the coverage terms. Under the DRA, Medicare will cover service and maintenance only if the Secretary had determined the payment is reasonable and necessary, and appropriate for the equipment. The Secretary has issued no guidance on this topic, and, with respect to certain items, such as oxygen equipment and supplies, this is an area of potentially significant supplier liability. Until suppliers know what service and maintenance activities Medicare expects suppliers to furnish, it is almost impossible for suppliers to accurately project costs of participation in the competitive bidding program. CMS should clarify the maintenance and repair obligations for suppliers in the final rule. CMS also should initially exclude those products from competitive bidding where the impact of this uncertainty is most troubling, such as oxygen equipment and supplies.

CMS states that "under the Medicare DMEPOS Competitive Bidding Program, we propose that separate payment for reasonable and necessary maintenance and servicing only be made for beneficiary-owned DME. Payment for maintenance and servicing of rented equipment would be included in the single payment amount for rental of the item." *See* 71 Fed. Reg. at 25674.

1. Question

Is CMS proposing to establish codes tied to product categories down to the labor and parts level or expecting providers to bid on a lump-sum basis for repair and maintenance?

We are unclear on CMS' intent for this area.

2. Comment

The current fee schedule and HCPCS codes for maintenance and repair is woefully inadequate. It has not been updated in years and in no way reflects the full range of maintenance, repair and "servicing" that providers currently perform for patients, largely under the monthly bundled payment rate. The fee schedules for labor and parts have not kept pace with the actual cost of providing such services.

Because the payment rate for HME and oxygen has been bundled, and because suppliers retained ownership to the equipment for all the years leading up to 2007 (re: HME), most providers merely exchanged the patient's equipment when it was broken, damaged or otherwise in need of repair. They took the patient's existing equipment back to their facility where it was then repaired and returned to inventory, or, if unsalvageable, they have to write the equipment off as an inventory loss. In other words, most providers have not billed the Medicare program for all of the repair and maintenance that the equipment actually would need under an ownership situation.

The DRA also eliminated the semi-annual payments for service and maintenance that Medicare paid if the patient with a capped rental item was still using the equipment after the monthly payments ended. This service and maintenance fee essentially covered providers' costs of providing patients with telephonic support, troubleshooting, additional patient or caregiver education in the home, an equipment exchange involving an in-home delivery, ongoing infrastructure costs and 24/7 emergency availability.

We are very concerned that CMS and certain members of Congress believe that a "seamless web of services" will continue to be available to patients once they own their equipment and are 100% responsible for it. Due to the elimination of the semi-annual payments – which were very nominal in the big picture of Medicare expenditures – as well as the inadequacy of the current HCPCS codes available concerning repair, maintenance and servicing, many providers will have no choice but to eliminate or dramatically scale back their repair functions. Moreover, if CMS does not create new HCPCS codes and reasonable payment allowables to address the other services that patients require after they own their equipment, providers will have to charge patients for such services and request payment up-front since the service will essentially be a non-covered item.

Examples are:

1) Emergency assistance on a weekend when their equipment malfunctions,
2) Coordination of travel needs between company-owned locations or between providers that are not legally related,
3) In-home reinforcement of patient education/instruction on how to use the equipment,
4) Safe pickup and disposal if the patient or family cannot handle this on their own (currently this is a service we provide because we own the asset),
5) An in-home clinical assessment performed by a licensed respiratory therapist per an order from the patient's physician. Who is going to pay for a clinical visit or telephonic counseling sessions?

3. Recommendation

There are several steps that CMS must take immediately to fix the problems associated with the DRA's provisions related to equipment ownership. The Act provides the Secretary with a broad level of authority to create appropriate methods to ensure that patients continue to have access to necessary service above and beyond repair/maintenance:

1) Convene a panel of industry experts to work with CMS to create a list of new HCPCS codes that address the myriad "a la carte" service needs of a patient beyond the capped rental period.
2) Create a fair fee schedule associated with the current and new HCPCS codes which fairly reflects providers' fully-loaded costs of providing those specific services. Such allowables should be subject to an annual CPI-U.
3) Establish a monthly service and maintenance fee and associated HCPCS codes for oxygen patients who continue to have a medical need beyond the 36th month. Such codes and fees could reflect the type of oxygen system they have at home since the service intensity of each may vary, e.g., liquid oxygen requires more frequent in-home deliveries.
4) Clarify that the portable oxygen tanks themselves, or those that are used as backup systems in the event of power failures, are not to be owned by the patients. There are significant FDA and DOT medical gas policy concerns, chain of custody and drug adulteration concerns that cannot be ignored. In addition, there exists no separate payment mechanism for the back-up oxygen tanks that patients require for daily safety measures and in the event of a power outage. Congress clearly did not consider the regulatory constraints surrounding this issue when it passed the legislation quickly in late 2005/early 2006.
5) Establish a clear process for how CMS expects to handle patients who move or desire to switch providers after the capped rental period. We recommend that the "rental counter" start over if the patient either switches providers after the capped rental period begins, or in the case of a patient obtaining new equipment in the home prior to the onset of the capped rental period.
6) Any patient who moves his/her permanent residence from one home to another (not to a skilled nursing facility (SNF) or other institution where this would not apply) and, as a result, switches homecare suppliers, should also represent the restart of the rental counter. This is due to the fact that the new supplier must admit that patient to service using all-new paperwork, patient education, etc. and thus incurs a significant amount of costs associated with the transfer. In the case of a patient who moves before the capped rental period, the patient would have to return the equipment to the original supplier and obtain new equipment from the new supplier. In the event where there were only a few months left on the "rental counter," there would be no motivation for the new supplier to accept that patient on service.

C. "Purchase Bids and "New Items"

CMS states that it proposed "purchase" bids be submitted for the furnishing of new items in this category. Based on these bids, a single payment amount for purchase of a new item will be calculated for each item in this category for the purpose of determining both the single payment amount for the lump sum purchase of a new power wheelchair, and for calculating the single payment amounts for the rental of all items in this category." *See* 71 Fed. Reg. at 25674.

1. Question

What is CMS' definition of "new" in this context? Does it mean a never-used item or new technology that may include different or better features/benefits for the patient? Since both definitions could apply to DMEPOS, we ask for clarification before we can comment effectively.

D. Enteral nutrition equipment and supplies

1. Comments

Apria Healthcare opposes the inclusion of enteral nutrition equipment, nutrients and supplies in competitive bidding for the following reasons:

1) The demonstration projects for competitive bidding proved that enteral was not a suitable product for competitive bidding because the majority of patients who require it reside in skilled nursing facilities. We outlined our reasons why enteral should be excluded from competitive bidding in the applicable section.
2) Enteral nutrients cannot be "rented;" they represent life-sustaining nutritional products that are prescribed much like a drug by a licensed physician; caloric requirements can fluctuate and therefore dosing can vary much like pharmaceuticals.
3) Patients' condition may change over time, requiring them to move between the four enteral product categories and payment levels, thus making it very difficult for providers to project their total costs and therefore bids.

The current HCPCS codes and allowables for certain enteral supplies are outdated and inadequate. They do not reflect the more modern supplies that are on the market today, such as low-profile or "Mic-Key" buttons which cost providers significantly more than the older products covered by the existing HCPCS codes.

Several years ago when the HIPAA standardized coding rules went into effect, Apria Healthcare, the Coalition of Wound Care Manufacturers and several manufacturers applied for a separate HCPCS code and allowable for "Mic-Key" buttons. Despite proof sources that showed the extent to which the products are prescribed and used in the U.S. market, and the fact that private managed care payors were willing to pay a differential amount for that product when it was ordered by a physician, the HCPCS coding panel denied the request.

If the HCPCS coding process is not modernized to reflect the changing nature of products available in the U.S. market, providers will have no choice but to reflect the higher costs associated with them in their bids for competitive bidding, and savings will be further eroded.

Finally, we oppose the gap-filling methodology that CMS proposes to grant itself for existing products such as enteral and parenteral nutrition. Our detailed comments on this can be found in the gap-filling section.

E. Maintenance and servicing of enteral nutrition equipment

CMS describes its current authority to pay for maintenance and servicing of enteral nutrition equipment after monthly rental payments have been made. It goes on to say that "maintenance and servicing payments are to be made in amounts that we determine are reasonable and necessary to ensure the proper operation of the equipment." *See* 71 Fed. Reg. at 25674.

1. Question/Comment

What methodology does CMS use to determine what is "reasonable and necessary" in terms of ensuring the proper operation of equipment? CMS should not be in the equipment maintenance business when all pump manufacturers have issued service, repair and preventive maintenance guidelines based on years of product testing, quality control programs, FDA inspections, etc.

The whole section at 71 Fed. Reg. at 25674 where CMS describes how specialized testing equipment should be available for enteral nutrition illustrates how CMS is overextending its reach into equipment maintenance rather than focusing on medical coverage and payment policies.

Please provide the methodology that CMS plans to use to determine "reasonable and necessary."

F. Supplies used in conjunction with DME

CMS states briefly that "We propose that bids be submitted for the purchase of supplies necessary for the effective use of DME, including drugs (other than inhalation drugs)." 71 Fed. Reg. at 25673. Based on the bids submitted and accepted for these items, we would calculate payment amounts for the furnishing of these items on a purchase basis.

1. Question/Comment

Again referencing the impact of the Deficit Reduction Act, we ask CMS to clarify how oxygen supplies such as tubing and cannulas, both of which must be changed frequently for patient hygiene and efficacy reasons, will be reimbursed once the patient reaches the 36-month cap. Today, these supplies have HCPCS codes but do not have a corresponding Medicare allowable and are not reimbursed separately as they are included in the monthly bundled rate.

Separate HCPCS codes with an appropriate reimbursement allowable should be established for these supplies using current industry data (not data deflated back to 1986).

In addition, certain oxygen patients receive their oxygen through a trans-tracheal catheter directly into their airway as opposed to through their nose via a cannula. Despite the fact that there is a separate HCPCS code for the catheters, there is no separate allowable that appropriately reflects the higher acquisition cost of the catheters. Therefore, Medicare's current policy effectively limits patient access to this important technology.

Trans-tracheal catheters are not for everyone, but since a small portion of the oxygen patient population does benefit from this modality versus the cannulas, CMS should modernize the HCPCS schedule to reflect their use in the Medicare patient population and providers' actual acquisition costs. Today, the Medicare allowable for A4608 is $58.15, while providers costs simply to procure the catheters are at least 30% greater than the allowable, and that is before any accompanying service is provided to the patient. Unless the system is modernized, again, providers will be reluctant to refill the patients' catheters or accept those patients on to service in the first place if they are going to be reimbursed below the acquisition cost of the necessary supplies.

Finally, oxygen conserving devices (OCDs) are another integral part of an overall oxygen patient's care. These devices conserve oxygen, thus enabling a patient to be out of the house or ambulatory within the house for longer periods of time. For payors that pay for oxygen contents, they also appreciate the value of OCDs.

However, Medicare currently does not reimburse providers separately for OCDs. The monthly bundled payment rate is considered to cover the devices, which can sometimes cost 50% or more of the total acquisition cost of the primary oxygen system in the home. After the DRA takes effect, providers will be unable to provide such expensive devices free on a stand-alone basis, so again a HCPCS code and allowable is needed.

G. OTS Orthotics

Apria has no comments on this section.

H. Conditions for Awarding Contracts
Proposed 414.414
71 Fed. Reg. 25654, 25674-79

I. Quality Standards and Accreditation (proposed section 414.414 (c))

Pages 82-83 of the NPRM outline the Act's requirement that a contract may not be awarded to any entity unless the entity meets applicable quality standards and that this requirement is applicable to all DMEPOS suppliers in all geographic areas, not just CBAs. The section goes on to describe a possible grace period that may be granted for suppliers that have not had sufficient time to obtain accreditation before submitting a bid and requests comments on such a grace period.

A. Apria Was The First HME Provider to Seek and Obtain Accreditation 18 Years Ago

Apria Healthcare has been a long-term advocate for mandatory accreditation in the home medical equipment industry. In fact, Apria was the first HME provider to seek and obtain accreditation from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) 18 years ago.

From the ten-year period from 1996 through May 31, 2006 Apria has paid $4.9 million in application fees for JCAHO accreditation. Prior to the 1995 merger that formed Apria, we estimate that the two constituent companies invested another $3.1 million, for a total of $8 million over those 18 years. When one adds the costs of policy implementation to meet JCAHO accreditation standards, conducting internal pre-survey audits and other preparatory costs, we estimate that the company invests well over $750,000 per year in accreditation-related costs.

We have expanded the number of JCAHO-accredited sites to over 500 since then. In the ensuing years, we have competed with independently-owned HME providers that have never been accredited, never complied with any independent accrediting bodies' standards and, in some cases, never followed certain laws and regulations. Therefore, we strongly support the development of quality standards and the requirement that all DMEPOS providers obtain accreditation as a condition for supplying and billing the Medicare program on behalf of Medicare beneficiaries.

Another reason we support mandatory accreditation is that private sector managed care organizations with whom we contract have insisted that HME providers be accredited for over 15 years. Although the Medicare beneficiaries cared for by Apria and other accredited providers have essentially been receiving the same quality-oriented benefits as managed care patients, the same cannot be said for those beneficiaries cared for by a non-accredited organization. We believe Medicare beneficiaries deserve the same level of quality-oriented care as all others.

B. No Grace Period

Regarding a grace period, we oppose it for the following reasons:

1) The Medicare Modernization Act was passed in December 2003, thus giving all suppliers at least three years' notice of the need for accreditation prior to the initiation of the competitive bidding application process.

2) For suppliers outside of the first 10 CBAs slated for 2007, they will actually have four years' notice.

3) Thus, there has been plenty of advance notice for suppliers to select an accrediting body, apply and complete the accreditation process.

4) Since accreditation fees are on a sliding scale based on the provider's total patient census and number of physical locations, the smaller the provider, the lower the accreditation fees. In addition, the smaller providers will have lower internal costs to audit, prepare and undergo the accreditation itself.

5) Unless a supplier has undergone the accreditation process, it cannot properly estimate its costs associated with seeking and maintaining accreditation and therefore it cannot submit an accurate bid to CMS to participate in competitive bidding. Examples of incremental costs that might be incurred include: improved warehouse operations management, increased levels of tracking patient satisfaction and complaints; increased reporting to the accrediting body; increased internal audit and travel costs; increased medication and incident reporting; increased performance improvement documentation and management; and state or federally mandated licenses.

C. CMS Should Select up to Three Well-Established National Accreditors to Which to "Deem" Authority

There are three national accrediting bodies that have a track record of experience in accrediting home medical equipment/respiratory/infusion suppliers. They are:

- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- Accreditation Commission for Health Care (ACHC)
- Community Health Accreditation Program (CHAP)

We do not believe that CMS should experiment with such a new and important program by including any Internet-based or other relatively new accreditation organization. It is very important for the accrediting body to have a level of experience with the industry and be able to prove to CMS that it has a rigorous process that does not automatically "rubber-stamp" accreditation. For example, JCAHO's rate of non-accreditation for its homecare division is a documentable 6 percent.

D. Grandfathering Already-Accredited Providers

We agree with CMS' plan to recognize that a provider that already holds a valid accreditation with a CMS-approved accreditation organization should be "grandfathered" to participate in the application and bid process.

E. Multi-Site Providers Must Conform to Medicare Supplier Number Requirements

We want to emphasize that CMS should ensure that multi-site providers conform to National Supplier Clearinghouse (NSC) requirements by applying for and obtaining a Medicare supplier number for any and all locations that will physically provide DMEPOS to beneficiaries through competitive bidding. It is possible that there are still providers that hold one Medicare supplier number to bill on behalf of several different but still company-owned branch locations. This may be true for smaller, not larger, suppliers. While this is not directly related to accreditation in terms of quality standards, it is something CMS should incorporate into its application and audit process.

However, a physical site visit by the accrediter is not needed for every single location. The NSC already has a process in place to ensure that the Medicare supplier standards are met before a supplier number is issued. This site inspection is designed to ensure that the supplier actually has a physical location. That

is not the function of an accreditation organization. All three of the major accrediting organizations have a process in place that statistically samples sites, patients, records and other documentation associated with the provider. The statistical sampling process, coupled with the fact that the branches that may not receive an on-site visit do not know it in advance and therefore must be prepared for such a visit, has been proven as an effective method and should be adopted by CMS.

F. Quality Standards: General Comments

We were very concerned about the nature of the draft standards that were published by CMS in the Fall of 2005. Those standards appeared to be lifted from some provider's operational policy and procedure manual as opposed to reflecting commonly-accepted standards of care in the home respiratory and HME industry. We filed formal comments critiquing the standards and hope that the revised standards reflect the input of the over 5600 organizations that filed comments on the quality standards.

The standards even go so far as to prohibit certain methods of delivery, which is outside of the purview of this process; the standards should not dictate operational decisions of homecare providers who elect to participate in competitive acquisition. The direct-to-home delivery of CPAP/Bi-Level replenishment supplies, for example, is a well-established standard in the industry and has never been a concern of private managed care organizations, including those that serve Medicare Advantage patients. If CMS insists on dictating certain operational standards, providers' costs will INCREASE compared to today's levels and the direct result of that will be a lower level of savings than what has been ascribed to the competitive acquisition process for HME starting in 2007.

It was very disappointing that most recommendations that were made by the true homecare industry experts in the area of quality standards were not included in the report issued to the PAOC and CMS by the consulting organization. We are not clear on why the consulting organization completely disregarded the input of the homecare industry, when it has shown a significant level of commitment to cooperate with CMS by providing draft standards that conform to the current HME industry professional practice standards and the requirements of private sector managed care payors nationwide.

Quality standards need to be the standard measurement of overall quality of a provider; they should not describe how a provider should handle each piece of equipment (that is considered one of the most basic aspects of any homecare operation and no payor in America specifies such things). As a reminder, Medicare does not "officially" reimburse providers for service and policymakers have repeatedly gone on the record to say that it pays for equipment only under the Part B DMEPOS benefit. If CMS' intent is to increase the breadth of service requirements, providers should be compensated for this service separately from and in addition to the monthly rental or purchase amount for the equipment.

G. Independent Accrediting Bodies Already Mandate and Monitor Quality Standards That Meet and Often Exceed the HME Industry and Professional Standards; CMS Should Simply Add Financial and Compliance Standards to Existing Accreditation Standards to Consider a Homecare Provider to Have Met CMS Standards

Frankly, as a company that has literally spent millions of dollars in both accreditation fees and the higher operating costs associated with preparing for and maintaining accreditation by the JCAHO since 1987, Apria Healthcare questions why CMS cannot simply deem between one and three already-existing accrediting organizations to meet its expectations and then require any provider that desires to participate in competitive acquisition to become accredited by one of those three organizations. It is much simpler to administer, will save American taxpayers the cost of redundant and unnecessary standards development at CMS and is the way that private sector managed care organizations have operated for years.

As one example, JCAHO currently has over 400 standards that we must comply with to obtain accreditation. Non-compliance could result in the suspension of the accreditation.

Standards should establish the benchmark that a provider must meet, but should not be so specific that they dictate specific operating policies, care or service. Moreover, standards this specific become obsolete when technology or clinical standards of practice change. CMS would never be able to keep up with changing standards as specific as they are currently written, while the accrediting bodies whose very history, mission and livelihood depends on monitoring and amending such standards already incorporate such an update process into their accreditation models.

Because the current draft standards do not reflect industry input and will create additional administrative or labor burdens on DMEPOS suppliers, the program is going to be very difficult to operationalize and such an extra burden would simply have to be reflected in suppliers' bid prices. Therefore, the projected savings could be less. Who at CMS is going to keep the quality standards up-to-date and who will be auditing these standards? What type of financial analysis has been done?

Because the current draft standards do not reflect industry input and will create additional administrative or labor burdens on DMEPOS suppliers, the program is going to be very difficult to operationalize and such an extra burden would simply have to be reflected in suppliers' bid prices. Therefore, the projected savings could be less.

Based on the above concerns, we strongly recommend that CMS approve two or three of the long standing accrediting bodies and request that these CMS approved accrediting bodies add CMS' draft standards for Financial Management and the requirement for a Corporate Compliance Program. We believe that more than 95% of the draft standards in the balance of Section 1 are addressed by the established accrediting bodies. We believe that CMS should delete the "Appendices for Supplier Product Specific Service Requirements" from the quality standards as JCAHO, CHAP and ACHC have rigorous standards that address this section of the proposed draft standards. In addition, all three organizations have industry clinical experts that review both the standards and the emerging technology as part of their continuous review process.

II. Eligibility

CMS proposes that "all bidders must meet eligibility rules to be considered for selection under the...program. Also, each bidder must be enrolled with Medicare and be a current supplier, in good standing with the Medicare program, and not under any current Medicare sanctions. Again we ask CMS to more clearly define "sanctions." 71 Fed. Reg. at 25675. Each bidding supplier must certify in its bid that it, its high level employees, chief corporate officers, members of board of directors, affiliated companies and subcontractors are not now and have not been sanctioned by any governmental agency or accreditation or licensing organization. In the alternative, the bidding supplier must disclose information about any prior or current legal actions, sanctions, or debarments by any Federal, State or local program, including actions against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, and subcontractors."

A. Question Regarding Definition of "Current" Supplier

In the above section, CMS references "current" supplier. How does CMS define "current" and how will it handle a situation where a contract supplier decides to add a physical location in a part of the MSA that might improve overall Medicare patient access and responsiveness in that area?

Our recommendation is that CMS allow any winning contract supplier to add a physical location to its competitive bidding contract as long as 1) the physical location obtains its own Medicare supplier number and meets all eligibility requirements, 2) the location is considered accredited by that organization's accrediting body, and 3) the location is linked to the same tax ID # as the location(s) listed on the original application.

This approach should apply even to acquisitions pending at time of the contract application or award process, or acquisitions after a contract is awarded.

We definitely support CMS' goal of eliminating "fly-by-night" suppliers that enter and exit markets, but the Agency also needs to allow for expansions in a given MSA.

B. Corporate Compliance Program

Apria Healthcare strongly agrees with CMS' direction regarding eligibility. We have incorporated a multi-faceted Corporate Compliance Program into our daily business operations since the 1990s. We were recently notified that we will receive an award for ethical business practices in the "National Public Company" category, sponsored by the Passkeys Foundation.

Our Compliance Program includes several different vehicles for stakeholders to express concerns about the company's practices, policies, operations, etc. These disclosure mechanisms include the following:

Toll-Free Hotline –For employees that is untraceable and unrecordable. Employees have the right to remain anonymous and many do exercise that right, despite the company's explicit written policy regarding retaliation, for which the company has zero tolerance.

Exit Interviews – All employees who separate from the company are sent an Exit Interview and asked to complete it.

Annual Regulatory Compliance Certification by Middle and Senior Management – The Compliance Officer issues an annual mailing to all mid-level and senior managers requesting an attestation of the company's compliance with all applicable regulations and laws to the best of their knowledge.

Website, Letters and Other Correspondence – Employees, patients and other stakeholders have been known contact Apria via the Contact_Us@apria.com email address, direct correspondence via letters or other methods.

Regardless of the disclosure mechanism, all communicated concerns are reviewed closely by either the Compliance Officer or the Legal Department and, if applicable, added to the Company's corporate compliance process for further follow-up.

C. Compliance with Medicare Rules and Licensing Rules

Medicare regulations require suppliers with multiple locations to obtain separate supplier numbers for each location. The Proposed Rule requires each bidder to be properly enrolled with Medicare and to be a supplier in good standing. In the Proposed Rule, CMS states that the bidder must have all State and local licenses required to furnish the items that are being bid. *See* 71 Fed. Reg. at 25675.

Compliance with Medicare regulations and licensing requirement adds administrative and operational costs to a supplier's operations. CMS should make every effort to ensure that bidders with multiple locations that are seeking a contract as a single bidder comply with all existing regulations, including

appropriate enrollment of each location. This will ensure a level playing field for all suppliers and lead to more accurate bids.

We urge CMS to review the FDA's medical gas registration requirements for those providers who supply compressed gas and liquid oxygen. Our acquisition experience has shown that there are small providers who may not fully understand all of the federal registration requirements and may not have the appropriate medical gas registrations on-hand. Part of the application process should review this.

D. "Good Standing" Needs to be Defined as It Relates to CMS' Authority to Terminate a Contract

CMS states "we would suspend or terminate a contract if a supplier loses its good standing with us or any other government agency." *See* 71 Fed. Reg. at 25675.

While we agree with this concept of terminating or suspending contract suppliers who have lost their standing, it would help if CMS would define "good standing" as it relates to other government agencies. A provider could be involved in a tax dispute with the Internal Revenue Service (IRS) or something else that has nothing to do with their Medicare program participation. Such a dispute does not constitute "bad standing" and therefore we request that CMS issue clarifying language.

III. Financial Standards

CMS outlines the financial standards for the program. *See* 71 Fed. Reg. at 25675. We applaud CMS' efforts to establish financial standards as part of the competitive bidding program. Again using Apria's acquisition experience as an example, we have seen the occasional situation where a bankrupt or near-bankrupt provider does not have the capital or cash flow necessary to procure new medical equipment or comply with the basic preventive maintenance and repair that it requires. We have seen situations where payroll was held or delayed.

A. Allowing Existing Reports to Suffice

The basic financial information that CMS described is certainly applicable to small businesses that use independent accountants, law firms, third party billing services, etc.

However, in terms of public companies that already file extensive financial reports with the Securities and Exchange Commission, comply with Sarbanes-Oxley requirements and conform to Generally Accepted Accounting Principles (GAAP), we recommend that CMS allow existing reports to suffice when a public company submits its competitive bidding application. Examples include:

- 10-K Annual Report
- 10-Q Quarterly reports for the quarters since the last annual report
- 8-K reports for current developments

In addition, we recommend that in the case of any company – public or private – that has more than one physical location attached to a competitive bidding application, the financial information should only have to be provided once as long as the applicant attests that it applies to all locations. Most national and regional providers cannot produce a balance sheet , for example, at the individual location level. On the other hand, the parent corporation's strong financial position will help each individual location in the event of a natural disaster, emergency or other problem where access to capital and assets are critical to continuing to service patients (e.g. Hurricane Katrina).

B. Formula to Determine "Business Capacity" Needs to Be Defined More Clearly

This is one area that needs much more definition and clarity by CMS.

We are very concerned that the rule is too vague on the subject of business capacity. Contrasted with the very detailed formulas that CMS provided for calculating DMEPOS suppliers per Medicare beneficiary, prioritization of the MSAs, etc., business capacity was left too vague. In addition, we are concerned that if a provider is permitted to commit to almost any increase in capacity without have some assessment mechanism on CMS' part, an access-to-care problem could arise when the patients are unable to obtain that service or product from the supplier.

Apria Healthcare has extensive experience in business capacity planning. In late 2005, we were awarded the national contract to serve one of America's largest managed care plans. The contract was set to "go live" on February 1. In the intervening months, Apria embarked on an extensive capacity planning process that accounted not only for the medical equipment needed (or "units," as CMS described in one section of the rule), but also the incremental labor, telecommunications equipment, facilities, vehicles, supplies, etc. that would be needed to meet the expected demand.

A better capacity planning process to enable providers to meet the demand in any given MSA would be as follows:

BID PROCESS:

1) During the bid process, CMS provides total number of beneficiaries likely to require service

2) CMS provides data on the number of patients in each rental month for any capped rental item (e.g. 120 patients with hospital beds are in rental month one, 100 are in month two). One key is that providers must know how many patients (not a percentage) have already or will reach the cap period and therefore own their equipment per the DRA.

3) This data must be updated again 90 days before the contract goes "live," especially since CMS states that a nine-month period could elapse between the time when bids are submitted and when the contract goes live.

4) CMS would assess the standard financial information that suppliers provide on the RFB application.

5) The RFB application must require that the supplier provide a detailed business expansion plan that addresses how it will increase its capacity not only in terms of additional equipment it can procure, but more importantly, how it will attract additional staff, telecommunications and computer equipment, facilities, vehicles and other support services needed to support the increased volume.

AFTER CONTRACT SUPPLIERS ARE SELECTED:

1) Since nine months may have elapsed, provider should have to affirm that nothing has changed financially since the application date.

2) CMS must provide updated data on which suppliers are electing to grandfather their patients and inform the contract suppliers of the number of patients for each product category. CMS must also provide the names of the other winning suppliers and their capacity. This will help contract

suppliers understand what the "adjusted" increase in volume is likely to be, if any, and plan accordingly.

Because there is a downstream effect of this program, in terms of increased demand that could be placed on manufacturers of medical equipment, vehicles, etc., and because leases can take up to a year to negotiate, we recommend that CMS build in the 90-day transition period that was described earlier. Most managed care payors allow such a period to facilitate joint planning between the contracted supplier(s), the noncontracted suppliers and the plan itself.

C. Days Sales Outstanding/Accounts Receivable Performance

CMS lists certain financial indicators that are important for evaluating financial stability. *See* 71 Fed. Reg. at 25675. We recommend using Days Sales Outstanding (DSO), which is a measure of the company's performance in accounts receivable and can impact cash flow that otherwise would be used to purchase equipment, hire staff, etc. There is no need to ask for Medicare DSO – a blended rate will suffice for your purposes.

D. Expertise of Staff to Evaluate Financial Standards Conformance

The rule is reasonably clear about the financial data that will be requested of suppliers who wish to participate in competitive bidding. Such financial data is "cut-and-dry" when it comes to what the indicators suggest about a business.

However, the financial standards are not "standards" at all since they do not specify a minimum threshold, range of acceptable performance or other criteria that is defined as "acceptable. Moreover, at the May PAOC meeting, we grew concerned when certain CMS staff members described a less objective, more subjective review process in which they might decide to select one supplier over another based on financial performance in one area or another. This concerns us because CMS has not stated what the financial standards or range of performance need to be, such as Cash Flow of X, DSO of Y, what defines a "positive credit history," etc.

The ability for CMS to subjectively discard one supplier's application over another, especially if the bid prices vary significantly, could be fraught with problems and lead to allegations of unfair business practices and single payment rate ("price") manipulation against CMS.

We urge CMS to either hire or consult with financial experts who may assist in determining an acceptable range for each of the indicators and then publish them so that all suppliers will understand the exact financial standards they have to meet.

IV. Evaluation of Bids

We refer you to the comments already supplied in another section, in which we urge you to consider how best to avoid situations where providers could "cherry-pick" a market. And we reiterate the fact that a patient who needs oxygen, a CPAP, a hospital bed and wheelchair could STILL find themselves receiving service from four different suppliers. This is neither efficient nor how it is done in the private managed care sector.

A. Market Demand and Supplier Capacity (proposed section 414.414 (e))

CMS describes, in more detail, how it plans to address market demand and supplier capacity. *See* 71 Fed. Reg. at 25675-76. Regarding the calculation of expected demand, CMS proposes to:

1) Examine claims data to determine the number of units of each item supplied...during the past two years;

2) Determine the number of new beneficiaries that have entered the market during the last two years;

3) Gather data on the number of new fee-for-service Medicare enrollees coming into a competitive bidding area and use this number to project the number of new enrollees;

4) Calculate two years worth of claims on a monthly basis to determine beneficiary demand;

5) Take into consideration the expected demand over the total duration of the contract and the seasonal effects;

6) Use two years of data to identify any time trends.

1. *Comments on Market Demand Calculations*

Again we agree in principle with all of the above criteria, but we do have some concerns and guidance for the Agency to consider.

- Historical claims data is one criteria for projecting future volume

- Although the number of new beneficiaries is important, CMS should also look at disease prevalence and age-related data, since there could be a higher ratio of new beneficiaries with, for example, COPD, and therefore the utilization would be higher

- The effect of seasonality, especially on patients with chronic respiratory illnesses, cannot be emphasized enough. A provider could experience a substantial increase in demand solely due to a bad flu season, large fluctuations in temperature, etc. It is a proven fact that COPD patients utilize more oxygen in the summer and less in the winter and more nebulizer medications in the winter than in the summer. This variance is solely related to the specific disease and seasonal effects.

2. *Estimating Supplier Capacity*

CMS then states, on page 86-87, its proposed approach for estimating supplier capacity. The proposal is for CMS to:

1) Analyze Medicare claims to determine how many items a supplier is currently providing in the competitive bidding area, as well as in total.

2) Ask suppliers to say how many units they are willing and capable of supplying at the bid price in the CBA.

3) Compare this information to what the supplier has dispensed to Medicare beneficiaries in the past and what it specified in its response to the RFP as its projections.

B. Question

Will CMS provide the number of projected patients, by product category, that will be encompassed in the entire CBA? In addition, suppliers will need to know – prior to submitting their bid -- the number of patients, by product category, in each month or episode of care so that they will have visibility to the number of patients who have either "capped out" or are approaching their rental cap where they will then own their equipment and no monthly revenue will accrue.

It is important for this data to be issued to all suppliers at the time of the RFB. Otherwise, the supplier will not know what kind of capacity is expected from CMS and it will not be able to formulate an effective bid. In managed care contracting, the payor almost always issues the projected future volume during the bidding process.

C. Comments on Estimating Supplier Capacity

We refer to the comments made earlier in this section and add the following comments.

The method CMS proposed above is severely flawed for several reasons:

1) A supplier might have obtained a new supplier number within the two years prior, gained a significant amount of market share and have a lot of additional capacity. That would not show up if CMS were looking only at supplier numbers that have been in existence since 2004.

2) A supplier might be caring for a very large number of patients who are not covered by Medicare and have much larger capacity to double or triple the number of Medicare patients they care for. If CMS only reviews Medicare claims and Medicare "units," it will not capture the true picture of a supplier's capacity in any given market.

3) Managed care organizations switch suppliers without looking back to see if they billed the plan in the past – the key is to determine the future capacity correctly.

4) This process does not allow for the situation where a large provider might have covered the CBA from another location and then decided to put a new physical location in an area. Because Medicare's proposed method is at the supplier number level, it would cause the new site to show a very low Medicare utilization/expenditure level and could be very misleading if historical claims alone were used to assess capacity.

D. "New" Suppliers

CMS writes, "For new suppliers, we would ask them for their expected capacity, look at trend data for new suppliers in that area, and examine the capacity of other suppliers in that area. We would need to use this data to make estimates about capacity because suppliers may have more capacity potential than they are currently exhibiting. During the DMEPOS demonstration, demonstration suppliers were able to expand their output to meet market demand and replace market share previously provided by non-demonstration suppliers; indeed, some demonstration suppliers were disappointed that they did not gain more market share during the demonstration." *See* 71 Fed. Reg. at 25676.

1. *Comment*

CMS' use of the term "new supplier" in this section conflicts with its earlier statement from the section where it stated essentially that only those suppliers that had a Medicare supplier number in 2004 or billed the program a minimum of $10,000 may participate in the bidding process. If we are misinterpreting that section, it is because it is not clear and should be further detailed by CMS.

Any new supplier should also have to provide its ability to accept additional capacity. Other language also causes us to infer that once the contracts have been awarded, no "brand-new" supplier would be able to contract with CMS. "Brand-new," and "expansion or acquired "new" locations associated with existing contract suppliers" need to be clearly defined by CMS in order to avoid confusion and should be included.

In regard to demonstration suppliers who were disappointed that they did not gain more market share, this only reinforces the assertions we made earlier in the document:

1) Today, Medicare reimbursement is the same for every supplier.

2) Therefore, providers compete on many more dimensions other than price, such as ease of doing business, depth and breadth of payor contracts, product availability, geographic coverage and overall service.

3) Under the competitive bidding program, since a single payment rate will be established, reimbursement will again be fixed.

4) Unlike managed care organizations that guarantee providers certain volume in exchange for pricing discounts which enables providers to set up and plan their infrastructure investments, Medicare does not guarantee any volume. Capacity has nothing to do with the volume the provider will actually receive.

5) **Therefore, providers will continue to compete on the basis of service, not on price, and some will win more market share than others! Price is not the prevailing factor in Medicare market share growth.**

2. *Recommendations*

We recommend the following definitions and guidelines:

1) **"Brand-new" supplier/location** – Defined as a start-up business tied to a tax ID number/company that has never billed the Medicare program before. This type of provider should not be able to participate in a competitive bidding contract that is already underway but should be allowed to bid in any subsequent round in that market.

2) **"Expansion or acquired "new" locations associated with existing contracted suppliers"** – Defined as a new physical location and associated Medicare supplier number that came about due to an expansion of an existing contract supplier or the acquisition of an existing supplier in the market. As long as these two examples are tied to the same existing supplier's tax ID #, they should be allowed to participate in competitive bidding after the contract begins, as long as they meet all eligibility criteria and agree to accept the single payment rate in that CBA.

E. Composite Bids (proposed section 414.414 (e))

In this section, CMS describes the methods for computing:

- Composite bid
- Item weight

1. *Comments on Composite Bid*

Apria agrees with CMS' intent to compute a composite bid in the manner in which it has suggested: multiply a supplier's bid for each item in a product category by the item's weight and sum these numbers across items.

2. *Item Weight*

Apria also agrees that the weight of an item should be based on the utilization of the individual item compared to other items within that product category based on historic Medicare claims. However, we want to emphasize that the utilization used as the weight should be CBA-specific and not based on nationwide Medicare claims, since age, the patients' illnesses or conditions and a number of other demographic or clinical/community standards of care could cause variations in utilization among disparate MSAs.

We have grave concerns about the following sentence:

"We would select item weights that ensure that the composite bid is directly comparable to the costs that Medicare would pay if it bought the expected bundle of items in the product category from the supplier." *See* 71 Fed. Reg. at 25676.

This sentence, which follows the paragraphs that describe the weighting methodology that would be based on utilization of the individual item compared to other items, based on historic claim data, implies that CMS would not use that methodology but would manipulate the item weights in order to change the composite bids. If this is CMS' plan, this is an unacceptable and unfair variation on the plan.

We believe that the best method of weighting individual items within a product category is to set the weight for each item based on the volume of the individual item's share compared to the total utilization of the product category. This is how the managed care sector handles weighting.

We want to emphasize the following:

1) The weighting should be MSA-specific.

2) Individual suppliers have different contracting and pricing strategies. Some suppliers use "loss leader" strategies where they purposefully price certain items within a category lower and other items higher so that the blended rate in that category helps them win a bid for a larger-scale contract. We advise CMS not to read too much into prices that are submitted for individual items. There are several references in the NPRM where CMS implies that a low price means that the item requires less service and associated costs when in fact that may not be true. Every individual company has a different pricing philosophy and strategy.

3) If an item's utilization is increasing due to an increase in beneficiaries or a particular condition in a certain geographic area, but CMS uses utilization data based on 2003 claims, this could create an unfair outcome based on an inaccurate weighting methodology. For example, the incidence of obesity and obstructive sleep apnea (OSA) in America has led to a nationwide increase in prescriptions for CPAPs and related supplies. This is true for all payors across the United States; neither Medicare nor any other payor is alone in this experience.

We would like to bring several other concerns about the weighting methodology to CMS' attention for your consideration:

- The current HCPCS system is outdated, does not reflect the current broad range of products and technology that physicians and patients want/need and does not reflect the wide range of acquisition costs providers incur.

- The new brand-specific requirement described in that applicable section will cause providers' operating costs to rise and therefore those costs will have to be reflected in providers' composite bids. Or, an unsophisticated bidder who does not understand his/her cost of doing business could win a bid with an unrealistically low bid price.

- Both of the above factors will result in a lower level of savings associated with the competitive bidding program.

- There are geographic preferences for certain brands or type of equipment and supplies. In this case, composite bids will reflect the same and again, savings could vary greatly if providers incur higher operating costs than under the current program.

We use the following simplified example to illustrate the potential effect of brand specificity or unreasonable quality standards for a particular item. This data is illustrative only and does not represent either an actual allowable or actual provider costs.

Current Medicare Allowable for Item =	$100
Provider bids, brand specificity not required, achieves savings @ 12%	-12
New single payment rate in CBA	$ 88
Savings vs. current allowable	12%

But, now providers are forced to provide a brand-specific item that does not necessarily offer any incremental features, advantages or benefits to the patient. However, it costs the provider 10% more to provide that item to the beneficiary than it would today.

Current Medicare Allowable for Item =	$100
Provider bids, brand specificity is required, achieves savings @ 2%	-2
New single payment rate in CBA	$ 98
Actual savings vs. current allowable	2%

F. Determine the Pivotal Bid (proposed section 414.414 (e))

We also agree that prior to bid selection, CMS should first ensure that suppliers meet quality and financial standards prior to arraying the bids and selecting suppliers. In fact, CMS should look at suppliers' bids on the basis of meeting the accreditation, quality and financial standards first before wasting valuable time to review bids from suppliers who do not meet the eligibility criteria.

We also agree with CMS' final proposal to base the pivotal bid on the point where expected combined capacity of the bidders is sufficient to meet expected demands of beneficiaries. All of the alternative methods that CMS considered but did not propose, such as pre-determining a number of suppliers, allowing those providers whose bids are "close" and making the pivotal bid dependent on a summary statistic such as the mean, median or 45th percentile, are inappropriate. They do not reflect a true competitive bidding process such as what we see in the private sector, and they artificially manipulate the number of suppliers and the single payment rate.

If CMS were to base the pivotal bid on a target composite bid such as the 20 percent below the DMEPOS fee schedule that was described at 71 Fed. Reg. at 25678, we believe that would be tantamount to government price-fixing and thus quite undesirable for both the government and suppliers.

We are also very concerned about several aspects related to the pivotal bid:

1) "Supplier Capacity" is much too loosely defined and the formula that CMS briefly outlined is an inaccurate method for calculating and validating supplier capacity.

2) Since supplier capacity is one of the most critical variables in the entire competitive bidding process, we urge CMS to adopt a more formal process for calculating, assessing and validating supplier capacity.

3) When all the bids are received, the FIRST thing the CMS bid team should review is whether or not the provider meets eligibility criteria such as the quality, accreditation and financial standards. Only after the team has determined that the supplier meets the eligibility criteria should the team then move on to review the bid submitted.

4) What happens if the bidder refuses to supply the products at the lower price?

And, of most grave concern to us:

5) **CMS is proposing to use a different method to establish the single payment rate than what was used in the demonstration projects. This runs counter to what Congress intended when including competitive bidding in the MMA language.**

CMS' definition of the pivotal bid seems acceptable, but our careful scrutiny of this section causes us to restate our serious concerns about the formula itself and the validation method CMS plans to adopt for "Supplier Capacity." *See* 71 Fed. Reg. at 25678. Since "Supplier Capacity" is one of the three primary criteria to be used to determine the pivotal bid, we believe that CMS should adopt the capacity planning formula that we described in an earlier section.

Unless CMS tightens up the definition of supplier capacity, suppliers could underestimate the operational and financial resources required to meet a significant increase in volume. This could lead to an access-to-care problem for beneficiaries.

G. Homecare Providers Are Often "First-Responders" In A Disaster or Emergency

Another aspect of supplier capacity that CMS must validate is that of emergency preparedness or a local disaster plan. In the case of Hurricane Katrina, some suppliers lost their businesses, telecommunication or information systems and had no way to replace their displaced patients' equipment, communicate with them or assist them in the aftermath. A managed care plan in Florida called on Apria to assist by helping current and new patients because their contracted provider did not have the resources. During Katrina and all other natural disasters, Apria was able to transport extra equipment, supplies, bottled water, emergency generators and employees into the stricken areas so that operations could continue and patients could be served.

On September 11 and in the days that followed, New York and Washington, DC area hospitals called on Apria to donate a large volume of home medical and respiratory equipment. In rapid response, Apria's area teams were able to deploy the necessary equipment to the hospitals, police and fire rescue teams.

Other examples of emergencies or disasters where homecare providers have been among the first to respond and enable patients to remain at home or be evacuated safely are the great blackout of the Northeast/Midwest (Summer of 2005), deep freezes/ice storms in the Northeast, floods throughout the U.S. and Southern California wildfires.

Regarding other possible methods of determining the pivotal bid, CMS should not determine a competitive range for the composite bid. This would only be appropriate if CMS were going to allow each supplier within the competitive range to bill Medicare at that level, as in the case of private managed care contracting. However, since CMS plans to establish one single payment rate anyway, such a range would be arbitrary and inappropriate. It could lead to allegations of small business and other discrimination.

H. Review Supplier on Quality/Financial Standards FIRST, Then Look at Bids

CMS describes the demonstration process for evaluating quality and financial standards as "time-consuming for the bid evaluation panel and required bidders to provide extensive information on quality and finances." *See* 71 Fed. Reg. at 25677. Apria asserts that the evaluation of the quality and financial standards is more important than the evaluation of the prices submitted. Almost any supplier can bid a low price, but meeting the quality and financial standards will require a higher level of commitment on the part of any winning or contract supplier.

1. *Reviewing Adherence to Quality Standards*

CMS could minimize the time involved in reviewing suppliers' adherence to the quality standards if it would simply adopt or "deem" the accrediting bodies' standards of accreditation. CMS should simply accept JCAHO, ACHC and CHAP accreditation as a proxy for meeting quality standards. Then, it could focus the bid review team on the financial standards and bids themselves. This is how the private managed care sector works; payors do not try to reinvent quality standards or conduct time-wasting validation surveys.

2. *Accredited Multi-Site Providers Require Less Review Time*

Another way for CMS to minimize the amount of time spent reviewing the bids is to recognize that if a multi-site provider is accredited in a particular geographic area or state, it is likely that ALL owned locations in that state are accredited based on the same standards and accreditation cycle. For example, if an accreditation application includes all branches in Florida and two MSAs in Florida go through competitive bidding, CMS would only have to review that supplier's accreditation/quality standards for one MSA and not waste time doing so for the other MSA.

I. Assurance of Savings (proposed section 414.414 (f))

Throughout the document, CMS asserts that Section 1847(b)(2)(A)(iii) of the Act prohibits awarding contracts to any entity for furnishing items unless the total amounts to be paid to contractors in a competitive bidding area are expected to be less than the total amounts that would otherwise be paid. Therefore, CMS would not accept any bid for an item that is higher than the current fee schedule amount for that item.

While this makes sense conceptually, it is another form of price-fixing since it is quite possible that current Medicare allowables for certain DMEPOS items do not adequately cover providers' costs. Moreover, the CPI freeze put in place by the MMA for most DME has exacerbated the problem because fuel, insurance, labor and other operating costs continue to rise. Even the competitive bidding

demonstration projects illustrated the effect of requiring bidders to bid below the existing allowable. In regard to incontinence and ostomy supplies, the bidders bid too low, experienced financial challenges and the single payment rates had to be raised.

We believe that CMS will find that some suppliers will not choose to bid on certain product categories because they already represent unprofitable business once all of the non-product costs are factored in. Therefore, savings would again be reduced.

Net program savings should be viewed at the product category level by comparing the savings to a "snapshot picture" of expenditures, not at the HCPCS level. Again, some suppliers use certain items as loss leaders, while others have a "no loss leader" pricing philosophy.

Also, CMS needs to realize that individual HCPCS expenditures may decrease, but the overall spending in a particular category could still increase after accounting for the following factors that could ensue during the competitive bidding contracting period:

- An increase in beneficiary enrollment,
- An increase in the number of patients with particular conditions in the area, such as COPD,
- A severe flu season or other seasonal effect,
- Changes in community standards of care,
- Changes in physician prescribing patterns,
- The introduction of new technology to be used at home, such as portable oxygen concentrators, higher-featured CPAP devices, low profile enteral tubes and portable ventilators,
- CMS medical coverage policy changes, and/or,
- Changes with Medicare Part C/senior risk plan enrollment that could result in a situation where patients move from Part C back to traditional Medicare coverage.

J. Assurance of Multiple Contractors (proposed section 414.414 (g))

Apria agrees that the program must offer choices to beneficiaries, referral agents and treating practitioners that order DMEPOS for Medicare beneficiaries. We also agree that CMS would neither generate the "significant savings" it desires nor reduce its own administrative costs of claims processing, etc., if it selects too many suppliers to service a competitive bidding area.

Again we reinforce the importance of supplier capacity and the need for CMS to formalize a process for calculating and assessing supplier capacity. We suggest a method within this comment letter.

K. Selection of New Suppliers After Bidding (proposed section 414.414 (h))

CMS states that it could determine that the number of contract suppliers it selected to furnish a product category was insufficient to meet beneficiary demand for those items. *See* 71 Fed. Reg. at 25678. It then goes on to describe how it would handle situations where a contracted supplier's contract was terminated. CMS suggests that a new supplier that would be added to the process would have to agree to accept the already determined single payment amounts for the individual items within the product category in the CBA.

Section 414.414(h)(1) of the proposed rule provides that "Subsequent to the awarding of contracts under this subpart, CMS may award additional contracts if it determines that additional contract suppliers are needed to meet beneficiary demand for items under a competitive bidding program." (71 Fed. Reg. 25701.) To select additional contractors, CMS plans to use bids previously submitted by bidders in the specific product category for which additional contract suppliers are needed to make award. *Id.* CMS

plans to offer award first to the disappointed bidder whose composite bid is the first composite bid above the pivotal bid for that product category. *Id.*

This is an inappropriate method for the acquisition of additional contractors following award. First, by awarding contracts after award without competition, CMS would violate the clear language of the statute, which requires that CMS conduct a competition for the award of any contracts for the items specified by the statute. The statute states: "[t]he Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services." (Section 302(b)(1) of the Medicare Modernization Act of 2003; Sec. 1847(b)(1) of the Social Security Act.) A post-award contract award to the next-in-line disappointed bidder who participated in the initial competition is not a competitive acquisition. It is not a continuation of the original competition. It is a sole-source acquisition. (*See* 41 U.S.C.A. § 253(a),(c) (West 1987 and Supp. 2006); *see* 48 C.F.R. 2.101 for the definition of sole source acquisition.) Sole-source awards to contractors for items and services within competitive acquisition areas are not authorized by the statute.

1. *Question*

How will CMS determine that capacity is insufficient? This must be formalized because if CMS decides to add other suppliers to a given MSA after the competitive bidding program is already underway, it would essentially constitute a "bait and switch" practice for the suppliers that bid at the beginning and were awarded contracts. Managed care companies usually go to their existing contracted providers FIRST to gain a commitment that they can handle additional volume before electing to add any other suppliers to their network.

2. *Comment*

We do not agree with CMS' intent to require a new supplier to accept the already determined single payment amount. CMS should also not choose the option to conduct a new round of bidding to select additional suppliers as this is too administratively burdensome for everyone involved and again constitutes a "bait and switch" for the suppliers who bid initially and won.

In the event that CMS proceeds with adding other suppliers to the MSA after it has already been launched, the fairest method is for CMS to re-array all of the suppliers' bids from lowest to highest, recalculate the pivotal bid and recalculate the single payment rate accordingly.

Another option would be for CMS to split up the volume of the terminated supplier fairly among the remaining contract suppliers in order to expedite the transition process and avoid a major disruption in patient care.

If CMS does not follow these methods, it will likely find itself hard-pressed to persuade additional suppliers who obviously bid at a rate even higher than the original pivotal bid who are willing to accept the existing single payment rate. Suppliers' internal costs could have increased since the time the contract was initiated, as in the case of fuel, labor and other expenses. Or, the Medicare program might have implemented a policy change or required more paperwork that also drives providers' costs up. Therefore, they might bid differently 12 or 18 months later than they did initially. The gap between the single payment rate and what they bid might be too great for them to accept since they have to cover their costs.

The same comment applies if a contracted supplier's contract is terminated by CMS – the new supplier(s)' original bids should be re-arrayed and a new single payment rate re-calculated.

I. Determining Single Payment Amounts for Individual Items
Proposed 414.416
71 Fed. Reg. 25654, 25679-80

I. Setting Single Payment Amounts for Individual Items (proposed 414.416 (b))

Beginning on page 97, CMS describes the process for determining single payment amounts and the options it considered on this subject. On page 98, CMS describes its preferred approach to use the median of the supplier bids that are at or below the pivotal bid for each individual item within each product category.

A. We strongly disagree with CMS' preferred approach because it does not reflect the method used in the two demonstration projects, on which Congress based its legislative approval.

CMS proposes to set the single payment rate for any competitively bid item at the median of the array of bids of the "winning suppliers." This means that 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. The result is simply a new fee schedule, and is contrary to basic principles of contracting and competitive bidding. It is also significantly different than the method used in the Polk County, FL and San Antonio, TX demonstration projects and therefore it probably is not what Congress intended in approving competitive bidding as part of the MMA.

The far better course would be to set the payment rate at the pivotal bid level using the adjustment factor described on page 99-100 of the NPRM. This method defined the pivotal bid as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This is the method used in the two demonstration projects.

Using the pivotal bid in this manner still meets the statutory requirement that CMS should expect to pay less and that single payment amounts are to be based on bids submitted and accepted. It is also still consistent with the intent of competitive bidding.

Two additional flaws in the method that CMS has proposed are:

1) The single payment method and projected savings is highly dependent on whether there is an even or odd number of suppliers in the final array. This is a meaningless variable.

2) Individual supplier capacity, rather than quality or even bid prices, is one of the key variables in how the single payment method is calculated.

Another option that CMS considered was to take the minimum winning bid for each item. This does not make sense and does not reflect true competitive bidding processes. So, we agree that CMS should not pursue this option either.

B. CMS' Principles for Setting Single Payment Amount

Despite the fact that this entire method of setting single payment amounts and selecting contractors varies greatly from the time-tested, proven methods used by private managed care organizations, we agree on

the first principle used to determine the single payment amounts for individual items in a product category:

1) Bid amounts from all winning bids for an item in a CBA will be used to set the single payment amount for that item in the CBA.

2) We do not agree with principle #2 despite the reference in the statutory language:

3) [CMS] must expect to pay less for each individual item than we would have otherwise paid for that item under the current fee schedule. Single payment amounts cannot be higher than our current fee schedule amounts for individual items within a product category.

In the earlier section, we commented on the fact that there are many product categories or HCPCS codes today where providers are in an unprofitable situation after all of their costs are accounted for. The CPI for DMEPOS has been frozen for most years in the past decade-plus. Yet, providers' costs have risen in almost every cost category. The demonstration project proved that such a requirement could have a deleterious effect on the market, suppliers, patient and physician access to suppliers and products (incontinence and ostomy supplies).

C. HCPCS Process Flaws and Brand-Specific Requirements Will Negatively Impact Potential Savings

Again we reiterate earlier comments about the current HCPCS coding process flaws and concerns about the unprecedented requirement to fulfill brand-specific prescriptions. The current HCPCS codes for some of the most frequently-utilized DMEPOS are too limited in number and definition. The HCPCS codes, application process for the same and Medicare allowable-setting process have not kept pace with advances in technology and manufacturers' practice of constantly introducing new products to the market.

As an example, we reference the continuous positive airway pressure (CPAP) mask HCPCS code. There are over 100 masks manufactured today that tie to this single HCPCS code. Yet, the acquisition cost that providers incur for the masks varies by as much as 400% from the low end to the high end of the cost spectrum. Medicare's current allowable for the mask causes many instances where the provider is "upside down" from a cost perspective, even before other non-product costs are considered. *(See Appendix B, CPAP Masks).*

If CMS intends to implement the brand-specific requirement in the manner it described in another section, and a single HCPCS code exists for these several hundred masks, well-managed providers will have to incorporate the increased costs associated with the brand-specific requirement into the bids they submit for competitive bidding. That is, of course, if they CAN estimate what percentage of total masks will be for certain brands. Because there has never been a brand requirement under Medicare in the history of the program, this is an unknown factor and could cause suppliers to underestimate their costs of providing CPAP masks after the program launches and manufacturers begin detailing physicians about how to write brand-specific prescriptions.

D. Single Payment Amount Should be Set for Three-Year Contract Period Regardless of New OIG or GAO Reports or Any Subsequent Legislation, and CPI-U Applied

Since the competitive bidding program was mandated by the MMA and indirectly augmented by the DRA, we believe that those Acts' provisions are the ones that should take precedent. Because CMS and the competitive bidding contract suppliers will essentially enter into a three-year contract in good faith, it would be wrong for CMS to adjust the single payment amount downward based on any OIG, GAO, MedPAC or other report. In addition, regardless of any new legislation or Medicare coverage policy

changes that might ensue after a contract is initiated, the agreed-upon single payment rate should prevail through the entire contract period.

Of course, the CPI-U that CMS described in an earlier section would still apply to the single payment amount in each of the contract years.

II. Rebate Program (proposed section 414.416 (c))

CMS proposes permitting contract suppliers who submitted bids for an individual item below the single payment amount determined through the bidding process to provide beneficiaries with a rebate. CMS states that such rebate, if provided, must be equal to the difference between the supplier's actual bid amount and the single payment amount. CMS' proposal, however, is directly contrary to several laws. In particular, permitting the proposed rebates is contrary to the Anti-Kickback, the Beneficiary Inducement Statute, and the Medicare provisions governing the waiver of co-payments.

We have grave concerns about the proposed rebate program and its inherent risks for four primary reasons that we detail below:

1) We believe it violates existing laws and regulations,

2) It would be logistically impossible for a provider to implement in its information system, branch operation and accounts receivable processes,

3) The industry has worked hard to improve compliance and eliminate fraud and abuse. The rebate program would not only set the industry back in this area but would also be impossible for the agency to monitor. It would recreate the "uneven playing field" of years ago before the OIG issued strong guidelines in this area.

4) Patients will already realize savings from the program through the reduction in the fee schedules.

5) Discrimination Issues

A. Anti-Kickback Statute Implications

Permitting any rebates, no matter how determined, to lessen a beneficiary's co-pay obligations would violate the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (the "AKS"). The AKS prohibits knowingly and willfully soliciting, receiving, offering or paying anything of value to induce referrals of items or services payable by a federal health care program. The waiver of beneficiary co-payments, or the economic equivalent, rebates of the co-payment, has long been identified by government enforcers as a violation of the AKS.

Indeed, the OIG has highlighted the legal problems with routine waivers of beneficiary co-payments. See, e.g., OIG, Special Fraud Alert, 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994). There, the OIG identified waivers of Medicare deductibles and co-payments as abusive violations of the AKS that likely lead to excessive utilization of items and services paid for by Medicare. The OIG states in its Special Fraud Alert that when "suppliers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase items or services from them." See id. The OIG acknowledges that at first glance, "it may appear that routine waiver of copayments and deductibles helps Medicare beneficiaries." See id. However, the OIG cites studies that show that patients who are required to pay a portion of their care become "better health care

consumers, and select items or services because they are medically needed, rather than simply because they are free." See id.

Similarly, the OIG notes that the "routine waiver of all or a portion of the Medicare copayment is suspect under the anti-kickback statute," regardless of whether it is styled as a "discount" or a direct payment to a beneficiary. See OIG, Advisory Opinion No. 01-03 (May 3, 2001), at 5, available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2001/ao01-03.pdf. The OIG concluded that waiver of co-pays was abusive because the federal government would not receive the full benefit of the discount provided under such a waiver and the waiver likely would lead to overutilization of services. *See id.* at 5-6. Under the proposed rebate program, the federal government would not be receiving the benefit of the discount and the reduction in the beneficiary's out of pocket costs potentially would lead to overutilization of certain DME services.

The OIG Compliance Program Guidance for Durable Medical Equipment, Prosthetics, Orthotics, and Supply Industry ("DME Program Guidance") also highlights the OIG's "programmatic concerns when DMEPOS suppliers routinely waive deductibles and coinsurance." See 64 Fed. Reg. 36368, 36378 (Jul. 6, 1999). The DME Program Guidance states that DMEPOS suppliers are permitted to waive Medicare co-payment amounts only for cases of financial need. See id. Furthermore, the OIG recommends that a supplier's written policies and procedures should state that it will not routinely waive deductibles and coinsurance for Medicare beneficiaries. If a supplier plans to waive co-payment amounts, the OIG suggests that the supplier develop and maintain written criteria documenting its policy for determining financial need and attempting to collect this co-payment. See id.

For all of the reasons set forth in the OIG's prior guidance, both to the DMEPOS industry and in general to all Part B suppliers, CMS' proposal is contrary to law. Nothing in the statutory basis for the Competitive Bidding program authorizes CMS to authorize an action that would violate the AKS. Thus, we strongly urge CMS to reconsider this proposal.

B. Beneficiary Inducement Statute Implications

In addition to violating the AKS, any rebate or waiver of co-payments also is contrary to the Beneficiary Inducement Statute, 42 U.S.C. § 1320a-7a(a), contained under the Civil Monetary Penalties statute. The Beneficiary Inducement Statute states, in relevant part, that:

> Any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5) of this section) that:
>
> > (5) offers to or transfers remuneration to any individual eligible for benefits under subchapter XVII of this chapter, or under a State health care program (as defined in section 1320a-7(h) of this title) that such person knows or should know is likely to influence such individual in order to receive from a particular provider, practitioner, or supplier and item or service for which payment may be made, in whole or in part, under subchapter XVIII of this chapter, or a State health care program (as so defined);...
> >
> > shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $10,000 for each item or service.
>
> *See* 42 U.S.C. § 1320a-7a(a)(5).

For purposes of the Beneficiary Inducement Statute, the term "remuneration" includes the waiver of any partial coinsurance or deductible amounts. *See* 42 U.S.C. § 1320a-7a(i)(6); *see also* OIG, Advisory Opinion No. 00-5 (Jul. 7, 2000), at 4. The statute excludes waivers of co-payments from the definition of "remuneration" *only if* (i) the waiver is not offered as part of any advertisement or solicitation; (ii) the person does not routinely waive coinsurance or deductible amounts; and (iii) the provider waives after determining in good faith that the individual is in financial need or fails to collect the coinsurance or deductible amounts after making reasonable collection efforts. *See* 42 U.S.C. § 1320a-7a(i)(6). The rebates proposed by CMS cannot satisfy these requirements. In particular, the proposed rule would equate to routine waivers of all or a portion of the co-payment without regard to financial need. Indeed, CMS is requiring that once a supplier decides to provide rebates, rebates must be provided to all beneficiaries regardless of an individual's financial situation.

The OIG has consistently expressed its concerns over waivers of co-pays in the context of the Beneficiary Inducement Statute. In Advisory Opinion No. 99-7, the OIG stated that "the statutory proscription in section 1128A(a)(5) of the Act [Beneficiary Inducement Statute] reflects serious programmatic concerns with waivers of coinsurance." *See* OIG, Advisory Opinion No. 99-7 (Jun. 30, 1999), at 3, *available at* <http://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_7.htm; OIG, Advisory Opinion No. 97-4 (Sep. 25, 1997), at 3-4, *available at* < http://oig.hhs.gov/fraud/docs/advisoryopinions/1997/97_4.pdf>. When "providers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be inducing the patient to use items or services that are unnecessary, simply because they are free." *See id.* Thus, the proposed rebate program is contrary to the prohibitions in the Beneficiary Inducement Statute. Nothing in the statutory basis for the Competitive Bidding program authorizes CMS to authorize an action that would violate the Beneficiary Inducement Statute. Thus, we strongly urge CMS to reconsider this proposal.

C. Medicare Requirements for Collecting a Twenty-Percent Co-Payment from Beneficiaries

The plan design for Medicare Part B benefits has always included beneficiary co-payments. The purpose behind the twenty (20) percent co-payment is to discourage excessive or unnecessary utilization. See 42 C.F.R. § 419.41 (calculating national beneficiary co-payment amounts and national Medicare program payment amounts); 42 U.S.C. § 1395e (requiring Medicare payments for inpatient and outpatient hospital services to be reduced by co-payment amounts). The rebate proposal runs counter to a fundamental principle of the Medicare program that requires beneficiary coinsurance. Nothing in the statutory basis for the Competitive Bidding program permits CMS to authorize an action that would fundamentally change the Part B plan design by eliminating some co-payments. Thus, we strongly urge CMS to reconsider this proposal.

D. Harm to Quality and Disadvantaging Smaller Suppliers

The nature of the CMS competitive bidding proposal is that winning bidders, on average, will be able to recoup their costs from their bid proposal in supplying the full range of services. While some items might have competitive bidding pricing less than bid of some suppliers, other items will have prices higher than the bid. On average, the winning bidders should recoup at least their overall bid amount. Under the proposed rebate structure, however, there is a risk that rather than focusing on supplying all items for which the bidder has submitted a bid, the supplier will instead focus on those items where the reimbursement price is greater than the supplier's bid amount. For those items, the supplier can provide the inducement of a rebate, while still not falling below the bid price. By providing the rebates, the supplier will have less of a profit margin to support the provision of those items for which the supplier's bid was higher than the reimbursement amount. Suppliers paying rebates are likely to be less inclined to provide service in those areas where the supplier has bid above the contract price.

Moreover, the rebates will not benefit the Medicare program. By its terms, all of the rebate will go to beneficiaries, none to the Medicare program. It is hard to see how such a system will have any benefit at all to reducing the government's expenditures on Medicare, the key objective behind the competitive bidding program.

For all the reasons stated above, permitting any beneficiary rebates will be unwise and contrary to existing law.

E. Logistical Challenges with Implementation of Proposed Rebate

As it relates to rebates, CMS' proposal would create significant logistical and management information systems challenges for providers. These are sample factors that would make it almost impossible to implement such a program in a given branch operation:

1) Since CMS has indicated that it may implement competitive bidding in a portion of an MSA, that could mean that the beneficiaries within the CBA would be eligible for a rebate but beneficiaries who live one zip code or town away would not. Yet, they would be served by the same location under two different sets of rules.

2) Competitive bidding will only apply to certain DMEPOS items, not to all. Keeping rebates straight on certain items will be challenging. Patients who have a competitively-bid item in their home and a non-competitively bid item in their home (e.g. oxygen that might be in and a walker that might be out) would be confused by the process. We would still be required to make a good-faith effort to pursue a $5 co-pay on a non-competitively bid item but could rebate $2 on a competitively bid one in their home. The whole idea is impractical.

3) Physicians would have no way of keeping this information straight either. Research has shown they want a very easy referral process when working with homecare providers.

4) If only CMS may inform referral sources and patients about the suppliers that have chosen to provide rebates, how is the supplier's representative supposed to answer a direct question about this subject when posed by a referral source or patient? How would CMS inform POTENTIAL patients of the rebate offered by some suppliers, when the beneficiaries may not yet realize they will need DMEPOS in the future? The entire secrecy shroud is fraught with potential problems, not to mention the fact that CMS should not waste valuable taxpayer dollars on this program by advertising or marketing rebate-related information.

5) Certain beneficiaries may elect to "supplier-hop" between suppliers simply to obtain a $5 rebate. This adds additional cost to the healthcare system because the new supplier would have to invest all of the same up-front admission time and costs as had already been invested by the first supplier.

6) It often costs more to issue a rebate check than the value of the check itself. Most businesses cannot issue a check for less than $15 in labor and processing expenses, so again the concept only adds to suppliers' cost structure, regardless of whether it is voluntary or not.

7) A recent national industry study of 74 home respiratory providers showed that patient bad debt expense already runs 5% of total revenues on average for home respiratory care providers. That means for every $100 Medicare dollars a supplier bills in revenue, it writes off $5 to bad debt. CMS has not historically acknowledged bad debt for home respiratory providers, but it is a real cost of doing business, which cannot be ignored.

8) How would CMS expect a provider to integrate such a rebate with the patient's Part B supplemental insurance plan where the plan pays 100% of the 20% co-pay amount? Or integrate it with a "Financial Hardship" waiver policy where the patient has to attest to his/her financial situation before the provider could grant a full or partial waiver of the co-pay amounts due?

F. Competition Should be Based on Quality and Service, Not on Price. Rebate Concepts Represents "Backsliding" In Area of Compliance Expectations for Program.

The competitive bidding program should be one that advances competition among suppliers on the basis of quality and service, not on price in the form of either the single payment amounts or nominal rebate amounts. In future years, CMS should be able to publish comparative patient satisfaction or other outcome data. This would be much more meaningful data on which patients and referral sources could make a decision to use one supplier over another in any given CBA.

Given the strides that the homecare industry has made in recent years in terms of promoting Codes of Ethical Business Conduct, implementing formal compliance programs and adopting the guidelines, recommendations and rules issued by the Office of Inspector General (OIG), United States Sentencing Commission (USSC) and American Health Lawyers Association (AHLA), we are concerned that the rebate concept would set the industry back substantially.

For all of the reasons cited, we urge CMS to eliminate the rebate concept from either consideration or implementation.

J. Terms of Contract
Proposed 414.422
71 Fed. Reg. 25654, 25680-82

I. Termination of the Contract

The statute, 42 U.S.C. § 1395w-3(b)(3)(A), requires the Secretary to specify the "terms and conditions" to govern contracts between CMS and suppliers under the competitive bidding process. Under the Proposed Rule, CMS may terminate a contract with a supplier based on ill-defined, unduly subjective reasons, which include:

1) CMS' determination that Medicare is not realizing "significant savings;"

2) A change in the ownership of a supplier from merger or acquisition, even if the successor entity meets all the necessary qualifications and standards;

3) Breach of contract by a supplier, which includes failure to comply with "governmental agency or licensing organization requirements";

4) For the "convenience" of CMS. The Proposed Rule further states that suppliers are bound for the full length of the contract period, which CMS proposes to specify for each item when it requests bids.

The Proposed Rule's provision governing the terms of the contract raises several concerns. The Proposed Rule grants CMS the unilateral right to terminate the contract without cause merely if it is "convenient" for CMS to do so. There is no definition of "convenience" under the Proposed Rule. A contract supplier that has not breached its contract, has dutifully followed all applicable federal and state regulations and licensing requirements, and incurred significant cost to submit an accepted bid should not have its contract terminated without cause. Such a right to unilaterally terminate without grounding in any articulated economic contravenes CMS' goal of broad participation by suppliers in the competitive bidding program and reduction of cost for DMEPOS supplies. Permitting CMS to terminate without cause eliminates the principal advantage for winning bidders. Without modification of the Proposed Rule, bidders would be dissuaded from submitting the lowest bid possible because they would have to calculate the financial risk of termination and compensate for this uncertainty in their bid price.

A. Varying Length of Contracts for Different Product Categories Too Confusing to Administer

On page 103, CMS references the section of the Social Security Act that gives the Secretary the authority to recompete contracts at least every three (3) years and then indicates that it would award contracts for different lengths of time for different product categories. This is much too confusing and administratively burdensome for both CMS and suppliers to administer. The private sector generally locks in long-term contracts for two or more years. Private sector plans also have a much simpler bidding process up-front. Given the extremely burdensome method that CMS is pursuing to issue RFBs by individual product category, define all-new product categories specifically for competitive bidding (which we oppose), evaluate bids and arrive at a single payment rate for each individual CBA, and develop duplicative processes for accreditation, we believe that for every given MSA selected for competitive bidding, the length of the contract should be the same for each product category included in that market.

B. Supplier Must be Given Right to "Cure" the Alleged Breach of Contract

CMS should be permitted to terminate contracts on the basis of a "material breach," subject to a contract supplier's right to cure the breach within a specified time upon notification of such breach. This is consistent with CMS' right to terminate agreements with entities participating in other government-run programs. For example, under the Medicare Part D Final Rule, CMS may terminate its contract with a Part D sponsor if the Part D sponsor "[s]ubstantially fails" to carry out the terms of the contract or meet various Part D regulation requirements. See 42 C.F.R. § 423.509. All of the stated reasons for termination are limited to substantial failure to perform expected duties or comply with applicable law.

C. Contract Should Lock in Pricing for Entire Contract Term

One significant flaw in the Proposed Rule is that it does not explicitly prohibit the Secretary from unilaterally changing the price of an item in a competitive bid area during the term of the competitive bidding contract. If CMS holds such a right, the suppliers, who accepted their contracts based on the bids they submitted and not this new price, should be given the option of continuing their contract or terminating the contract without being subject to breach of contract remedies. If CMS believes that it has the right to re-price during the term of the contract, suppliers should have the opportunity to terminate the portion of their contract subject to re-pricing without any penalty or negative consequence.

The Proposed Rule states that contract suppliers are held to their contracts for the full length of the contact period or they are considered to be in breach. There are no provisions that allow suppliers to terminate their contracts for any reason no matter how meritorious it may be. There should be a provision that allows suppliers to terminate, without being in breach of contract, in cases of hardship or material change in circumstances that are not the fault of or within the control of the supplier. For example, the availability of new equipment that is frequently prescribed and significantly more expensive than that existing at the time of the bid submission may raise sufficient financial hardship to merit a contract termination. Certainly, CMS has proposed such a right for itself. The lack of parity in the ability of the contracting parties to terminate may serve as an impediment to many potential bidders' submission of the lowest possible bid.

D. Supplier Contract Termination Rights

Therefore, CMS should implement regulations that (1) eliminate any right of CMS to terminate a supplier's contract without cause or for convenience; (2) allow suppliers the choice of voluntary termination if the Secretary changes the price of an item outside of the bidding process; and (3) permits a supplier to terminate its contract without penalty if unexpected circumstances arise that hinder its ability to render performance.

E. Competitive Bidding Contract Review Process

CMS lists the minimum provisions that contracts will address, such as subcontracting rules and potential onsite inspections. *See* 71 Fed. Reg. at 25680-81. Two sections cause concern:

1) "Compliance with changes in Federal laws and regulations during the course of the agreement"

We assert that if such regulations or laws either change the then-current coverage guidelines and corresponding payment levels or cause the supplier to incur substantially higher costs to care for the beneficiary who requires a particular item, the supplier should have a right to renegotiate that line item of the contract since it would represent a material change to the information the supplier used to bid for the contract at the outset. A current example of such a regulatory change is related to the Respiratory Assist

Device (RAD) policy and local coverage determination (LCD). Other examples include the pending changes to Power Wheelchair codes, coverage guidelines and payment levels, and a proposed FDA requirement concerning how medical gases such as oxygen are handled in the home. These changes would significantly increase providers' costs over and above today's levels.

2) "Non-discrimination against beneficiaries in a competitive bidding area (so that all beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier would provide to other customers)."

This requirement is in direct contrast to CMS' proposed inclusion of selective rebates, since only certain beneficiaries would be eligible for such a rebate and others would not. In addition, it conflicts with the brand-specific product language found in the applicable section of the NPRM. As we commented in that section, the brand-specific requirement is fraught with problems. It could cause a supplier to provide the lowest quality product simply because a physician writes a prescription for that brand. And, since the Medicare program has never mandated brand specificity before and will continue to adhere to this guideline in the non-CBAs, it is possible that beneficiaries will receive different products than before CBA, and this would have nothing to do with whether or not the product is of the same level of "quality," however that term might be defined.

F. Preamble's Terms Not Found Within Regulation, Require A Separate NPRM

Finally, we note that the Preamble discussion contains a number of different proposed contract terms that are not found within the regulation itself. We presume the actual contract provisions will be subject to a separate Notice of Proposed Rule-Making in order to permit suppliers to offer more productive comments.

II. Furnishing of Items (proposed section 414.422(c))

CMS states that "a contract supplier must agree to furnish the items included in its contract to all beneficiaries who maintain a permanent residence or who visit the competitive bidding area and request those items from the contract supplier. *See* 71 Fed. Reg. at 25681. Later in the paragraph it states that "a physician that is also a contract supplier must only agree to furnish the items included in its contract to his or her patients." *See id.*

A. Question

If five or 20 bidders win a contract, does one have a choice not to accept the patient? An extreme example, but one that occurs occasionally, is when the patient is not a suitable candidate for homecare services according to the individual supplier's policies and procedures. For example, a patient may not have a caregiver at home, or there may be an insurmountable language barrier that would represent a patient safety risk if patient education could not be conducted adequately. Medical records may indicate that the patient is combative and non-compliant with the homecare regimen their physician has prescribed in the past. Each provider's policy and procedure manual differs slightly from the next; each has different "patient admission criteria" for certain respiratory, HME and infusion products/services.

In addition, most suppliers have trained their employees to provide, repair and maintain a certain list of products. It would be logistically impossible for a provider to train its employees to effectively provide the full range of products available on the market today. Therefore, the supplier should have the right to refer the patient to another contract supplier to provide a certain product if that other supplier is known to provide that particular brand.

B. Comments

Physicians that are also contract suppliers should also be required to furnish items to visiting or traveling patients, just as homecare suppliers do today. They should not be given the option to only provide the products to their own patients as this does not address the issue of a patient who winters in or travels to another area, and then finds himself/herself in need of a particular item from a physician. This is especially true in an emergency situation.

III. Repairs and Replacements of Patient Owned Items Subject to Competitive Bidding

This section, although short in length in the NPRM, represents a significant area of concern and unanswered questions. The section does not address how the repair and replacement of patient-owned items subject to competitive bidding will be addressed after the Deficit Reduction Act's forced ownership takes effect.

The NPRM states that "repair or replacement of patient-owned DME and enteral nutrition equipment...must be furnished by a contract supplier because only winning suppliers can provide these items in a competitive bidding area. The contract supplier cannot refuse to repair or replace patient-owned items subject to competitive bidding. This proposed policy...is consistent with the CB program in that it directs business to contract suppliers."

A. Question

We have numerous questions about repair and replacement after the DRA's provisions take effect. They were not answered in any section of the NPRM. AAHomecare submitted a long list of questions to Herb Kuhn on April 20, and we hope they will be answered very soon, since the first impact will be felt by patients in February 2007. This is the month in which the first Medicare beneficiaries will take forced ownership of their hospital beds, patient lifts, wheelchairs and other HME.

Sample questions already posed to CMS include:

- How will CMS pay for an in-home service visit that does not involve any repair or maintenance? Telephonic support requested by the patient? A patient assessment ordered by a physician and performed by a licensed clinical respiratory therapist? Coordination of services between several locations in the event of patient travel, a move or other need? These are everyday occurrences that have not been addressed by CMS and are not covered at all by existing HCPCS codes for repair and maintenance.

- Does the requirement for a contract supplier to not refuse to repair or replace patient-owned items apply to equipment that the contract supplier did not originally provide? This cannot be the case, since the contract supplier would essentially be required to use its own assets to replace equipment that was provided by another supplier.

- How does CMS plan to pay for a replacement item once it is owned by the patient under the new DRA rules? How does CMS expect a provider to explain to a patient that he/she cannot access new technology that has been launched since he/she took ownership of the original oxygen equipment? None of this has been specified in any rule issued thus far.

CMS' proposed requirement that a contract supplier must repair or replace patient-owned items solely because the supplier won a contract and therefore would be interested in that particular volume is flawed. To repair or replace such an item could represent a financial loss to the supplier and therefore risk the

supplier's overall financial viability if only repairs or replacements were directed its way by the Medicare program.

B. Recommendation

When a beneficiary switches to a contract supplier, CMS should allow a new period of continuous use to begin since beneficiary access is a key goal of CMS in implementing this program. Such a decision would also protect the contract supplier who may have to furnish equipment to the beneficiary without compensation.

In addition, rather than request a supplier to include the cost of repairing patient-owned equipment in an overall HCPCS bid category, CMS should treat this as a separately-bid line item on the RFB.

IV. Furnishing Items to Beneficiaries Whose Permanent Residence is Within a CBA

In this section, CMS proposes that "the contract supplier must agree to accept as a customer a beneficiary who began renting the item from a different supplier regardless of how many months the item has already been rented. This is particularly important in those cases where a supplier or noncontract supplier does not elect to continue furnishing the item in accordance with the grandfathering provisions...Suppliers must factor the cost of furnishing items in these situations into their bid submissions."

A. Comment

We vehemently oppose this requirement in light of the passage of the DRA. Under the prior reimbursement methodology, a supplier who "inherited" a patient from another supplier could at least attempt to cover his costs through the semi-annual service and maintenance fee that would ensue after the capped rental period.

The DRA's provisions for forced ownership makes dramatic changes that make CMS' proposal for competitive bidding a "non-starter." As an example of this problem, the following is a very real situation that occurs every day in the homecare community:

TODAY

- Patient starts on liquid oxygen with a portable stationary with supplier A and uses oxygen for 33 months.
- In that 33-month period, patient may have tried other oxygen systems, asked for more or less tanks, tanks of different sizes purely for convenience.
- At month 34, patient decides to move permanently from one state to another.
- In this case, patient returns oxygen system to supplier A and is admitted to supplier B's service in the new state. Supplier B provides patient with all-new oxygen system it has purchased and, because it is a separate business with a separate Medicare supplier number, must incur all of the expenses associated with admitting and servicing a brand-new patient. This is even true of multi-site providers. Supplier B continues providing oxygen system and support as long as patient has a medical need. If patient's condition changes or his/her physician orders a different system, supplier provides it or one that is functionally equivalent.

UNDER THE DRA

- Patient starts on liquid oxygen with a portable stationary with supplier A and uses oxygen for 33 months.

- At month 34, patient decides to move permanently from one state to another.
- Patient returns oxygen system to supplier A.
- CMS expects supplier B to provide an all-new oxygen system asset and supporting service in the new state and yet the supplier will receive only three (3) months of reimbursement.
- If patient's condition changes or his/her physician orders a different system, supplier provides it or one that is functionally equivalent.

It is unrealistic for CMS to expect a contract supplier to be forced to accept a patient if, thanks to the DRA, it cannot cover the cost of providing the equipment and associated service to the patient.

In addition, CMS favors the non-contract suppliers who elect to non-grandfather, and penalizes the contract suppliers! The supplier that decides to non-grandfather should not relinquish its responsibility and force a winning supplier to pick up all responsibility and liability for that patient at either no charge or only a limited number of rental months.

B. Recommendation

When a patient elects to change suppliers for any reason, the "rental counter" should start over at month one. That way, CMS can ensure that there is patient access and that a supplier will be able to cover the costs of admitting a new patient to service. Unless the oxygen section of the DRA is repealed, this is the only way to administer this section.

CMS needs to address the issue of how the contract supplier is essentially being penalized under this section, while the supplier that refuses to grandfather is "rewarded." Surely CMS did not intend these incentives to be so misaligned and the challenge is directly related to the DRA.

V. Furnishing Items to Beneficiaries Whose Permanent Residence is Outside a CBA

On page 106, CMS proposed that "...a beneficiary whose permanent residence is located outside of a CBA must use a contract supplier to obtain all items subject to competitive bidding in the competitive bidding area that he or she visits."

A. Comments

We are confused by this requirement in that it infers that certain products might be drop-shipped into the temporary geographic location where the beneficiary is visiting. Oxygen is one example of equipment and service that should not be drop-shipped from one area to another. There are many more. This section requires clarification by CMS.

VI. Information Collection from the Supplier

On page 107, CMS lists the terms, conditions and information it proposes a supplier must agree to provide to CMS for purposes of assessment prior to becoming a contract supplier. In general, we agree with the items on the list, but we are concerned that CMS has not defined certain terms which, if not defined properly in advance of the contracting process, allow too much room for interpretation. These include:

- Information on product integrity – Define "integrity" of products.
- Information on business integrity – Define "integrity" as it relates to business. Does CMS intend for all suppliers to have a corporate compliance program? A Mission Statement and Operating Principles? Other ethical aspects of their business? This must be clarified.

- Organizational conflicts of interest – Must be clearly defined.
- NSC number of any affiliated company – For public companies with multiple locations tied to a single tax ID #, the definition of "affiliate" must be simplified so that we do not have to provide the names or supplier numbers of all 500+ locations on an application form for a single CBA.
- Employee information – Specify the level of employee information you expect, e.g. highest ranking local manager, title, etc., or CEO, COO of public company.
- Customer service protocol – Needs to be defined since different companies define the customer service process differently.

In addition to the list CMS provided and the comments on the six listed above, we recommend that CMS also require suppliers to provide:

- A description of the provider's corporate compliance program;
- The company's procedure for checking to ensure that it does not knowingly employ any individuals who have been debarred from participating in government programs;
- The company's procedure for conducting background checks on employees who will have direct contact with patients;
- Awards, honors or other distinction issued to the company;
- A description of the provider's credentialing program if a subcontractor will be used to care for patients;
- A description of the provider's emergency preparedness plan;
- A description of the provider's process for selecting products and, if applicable, independently testing them through objective metrics.

VII. Change In Ownership (proposed section 414.422 (d))

The Proposed Rule requires contract suppliers to notify CMS sixty (60) days prior to any changes in ownership, mergers or acquisitions. There are no assurances that CMS will ultimately permit the successor entity to assume the contract, even if the successor entity meets all CMS bidder requirements. Or, if the transaction is structured as a sale of stock, CMS apparently may terminate the arrangement with the supplier even though the supplier has a contract with CMS and continues to meet all of the requirements. If CMS determines that there is no longer a need for the acquired entity to function as a contractor to ensure Medicare's capacity to meet, CMS may no longer recognize the acquired entity as a contract supplier. Unfortunately, CMS' proposal will act as a disincentive for companies to participate in the bidding program by dramatically reducing the marketability of such companies. Obviously, winning a CMS contract is an economic asset that should be recognized in a sale. If CMS will not recognize the buyer as a supplier, however, companies desiring or needing to sell for whatever reason will be penalized for having been a successful bidder. Limiting the ability of successful bidders to sell the company can hardly be in the best interests of the Medicare program. Indeed, penalizing successful bidders by making a portion of their business non-transferable in a sale will discourage competitive bidding.

A. <u>CMS Must Allow an Acquirer to Participate as Long as it Continues to Meet Eligibility Requirements After the Transaction</u>

Moreover, CMS' articulated concerns for denying contractor status to an acquired successful bidder are misplaced. CMS states that it does "not want to allow suppliers to adopt a strategy of circumventing the regular bidding process by gaining winning status through acquisitions of or mergers with contract suppliers or to violate any anticompetition prohibitions." CMS fails to recognize that companies are sold for varying reasons at varying times in their life cycle and that the competitive bidding process is a repetitive event, whereas a merger or acquisition is a one-time transaction wholly unrelated to the bidding

process. Sometimes a provider's founder retires, passes away or must liquidate its investment for personal financial reasons such as medical costs, a divorce or college education (all of which we have experienced when buying small providers in recent years). While a losing bidder might be able to stay in business in an area during the term of the contract by acquiring a winning bidder, in order to stay in business in the area, the acquirer will need to submit competitive bids in the future. Any company that acquires a winning bidder is likely to be committed to doing whatever it takes, including submitting competitive bids in the future, to retain the business. Clearly, the acquisition of a winning bidder should not adversely impact the initial bidding process, since by definition the bid process has been completed and the contract awarded to the winning bidders. Nor could the acquisition adversely impact any subsequent bids, since to retain the business, the acquired entity will need to continue submitting competitive bids.

It also is highly unlikely that a company would fail to submit an initial competitive bid with the expectation that if it did not get a contract, it could just acquire a company that did acquire a contract in the area. A company operating in the area of competitive bids cannot reasonably expect that it can stay in business by failing to submit a competitive bid and instead acquiring a winning bidder. There is no way to know post bidding whether any successful bidders will be for sale, or whether the price for a winning bidder will be reasonable. Thus, if a company wants to get the business in an area, the only practical strategy for doing so is to initially submit a competitive bid. We cannot think of a plausible scenario under which the ability subsequently to acquire a winning bidder to get the business would adversely impact the prior bidding process.

B. Sixty-Day Prior Notice Requirement is Unrealistic and Burdensome

A sixty-day prior notice requirement is a burdensome restraint on legitimate corporate transactions. Acquisitions and mergers frequently occur in a much more compressed time frame. But for the proposed requirement, there generally is no advance notice requirement prior to completing and acquisition and/or merger. Note Hart-Scott-Rodino requirements generally are not applicable in small DME company transactions.

C. Recommendation

We suggest CMS revise the proposed rule to require no more than thirty (30) days prior notice or, if the transaction is set to close within less than thirty days, then the parties should have an obligation to provide notice as soon as the parties sign a letter of intent to change ownership.

CMS should be able to assure itself that the acquired entity continues to meet all obligations and requirements for eligible suppliers. However, CMS' review should be limited to a consideration of whether post acquisition, the entity: (1) meets all the requirements of a contracting supplier; (2) is willing to assume all obligations under the contract; and (3) has executed a novation agreement. The only limited circumstances where CMS may have a legitimate concern over a transfer of ownership is in a case where the acquirer, through the acquired entity, does not satisfy one of the foregoing three requirements. Thus, the presumption should be that the entity post acquisition will be acceptable to CMS unless it fails to satisfy the requirements applied to all contract suppliers, refuses to assume the obligations and liabilities borne by the prior contract supplier, or declines to execute a novation agreement. Thus, there should be an explicit presumption that unless the entity post acquisition fails to meet these listed conditions, the entity will be able to continue acting as the contract supplier following the acquisition.

Winning a bid should not diminish the marketability of any supplier. Companies need to be able to preserve their marketability, and a key component of the marketability is that the acquisition not jeopardize the pre-sale business of the entity. CMS' proposed regulations actually punish the winning

bidders by making a potentially significant portion of the business unmarketable. If this aspect of the proposed regulations is not changed, companies that might need to contemplate a change in ownership (for family, tax, or economic reasons) will be discouraged from bidding. If CMS desires to encourage all companies to bid, the contract supplier's status as the winning bidder should be preserved as a valuable asset for consideration in any commercial transaction. Accordingly, CMS should change the prior notification requirement and modify the scope of its review of an acquisition.

VIII. Suspension or Termination of a Contract (proposed section 414.422 (f))

It is reasonable for CMS to expect that contract suppliers will be held to all the terms of their contracts for the full length of the contract period.

However, we are concerned about a few aspects of this section:

1) CMS states that it may include reprocurement costs if a supplier's contract is terminated for breach – this is not how the private sector handles it and is unreasonable since the supplier cannot know CMS' reprocurement cost structure.

2) CMS states that it could "preclud[e] the supplier from participating in the competitive bidding program," but it does not specify if that is only for that certain competitive bidding area or for the entire competitive bidding program.

3) CMS states that it would have the right to terminate the contract for "convenience." This is not defined anywhere in the document and must be so defined in the final rule. Otherwise, this is much too one-sided and again, patient care could be at risk if CMS were to simply terminate a supplier's contract after it invested a significant amount of time and money in preparing to participate in competitive bidding.

4) There must be a clear "cure" period, process and timeframe (this is how private managed care plans handle such contracts). This must include a written and/or verbal appeal process such as those that exist with the Joint Commission, the FDA, state licensing agencies, etc.

K. Administrative or Judicial Review
Section 414.424
71 Fed. Reg. 25654, 25682

I. Administrative or Judicial Review (Proposed § 414.424)

The statute restricts the bases for seeking administrative or judicial review within the competitive bidding program context. However, these limitations do not preclude the establishment of some process in which suppliers may communicate with CMS regarding grievances and seek redress. In addition to the recommendations previously made regarding the scope of CMS' termination rights and the need for a cure period for a supplier's breach, CMS should consider mechanisms that allow suppliers to provide feedback and seek redress for grievances. Consistent with Constitutional due process rights, this should include the opportunity for suppliers to have at least some administrative appeal mechanism with respect to CMS contract termination decisions.

L. Opportunity for Participation by Small Suppliers 71 Fed. Reg. 25654, 25682-83

In principle, we agree that small suppliers should be given every opportunity to participate in competitive bidding. Numerous small suppliers across America provide a consistently high level of quality service to over 50% of the Medicare DME/respiratory market and obviously play a key role in doing so.

We believe that CMS should make the results of the focus groups conducted with small suppliers public as the agency refers to them at 71 Fed. Reg. at 25683 but does not provide the summary in any appendix.

A. General Comments

We want to emphasize the following points related to small suppliers:

1) Accreditation fees and related internal operating costs to prepare for, undergo and maintain accreditation are on a sliding scale based on the size of the individual supplier. So, a small supplier incurs significantly lower out-of-pocket costs for accreditation than a large supplier and therefore the argument that mandatory accreditation is too costly for small providers is, in our opinion, unsupportable.

2) Two other accreditation options exist for small suppliers to access today, when compared to a decade ago when the Joint Commission "owned" the accreditation market. Therefore, we believe that if a small supplier made plans to become accredited by the 2007 competitive bidding timeframe, or the 2010 year in which it will be mandatory for all Part B suppliers, ample time and resources exist for these suppliers to seek and obtain accreditation prior to the 2007 competitive bidding launch in only 10 markets.

3) Regarding applicable financial standards, which again have not been clarified by CMS for providers of ANY size, we believe that the entities either meet the standards or they do not – there should not be any room for interpretation based solely on size. Operating cash flow, access to capital, and ability to expand capacity are factors that all suppliers should be able to address. Only the scale differs.

4) Regarding applicable quality standards, we believe that Medicare beneficiaries deserve no less than their managed care counterparts. Every managed care organization in America requires accreditation as a minimum condition of participation in serving its members. Again, the cost of conformance to the quality standards should be viewed on a sliding scale according to the supplier's size.

B. Small Business Definition

CMS' definition of a small DME supplier as an entity that is generating less than $6 million in revenue per year, ironically appears to include over 75% of Apria Healthcare's individual locations. *See* 71 Fed. Reg. at 25691-92. In addition, CMS notes that "at least 90 percent of DMEPOS suppliers had Medicare allowed charges of less than $1 million in 2003." Again, Apria would have a significant number of individual branch locations that fall under this definition. Surely this is not how CMS intended to define a "small business" in terms of participating in competitive bidding. We recommend that CMS view individual supplier size by the cumulative revenues they generate across all supplier numbers tied to the tax ID number to which they are commonly linked. In this manner, CMS and the Small Business

Administration (SBA) would be able to truly assess the size of various suppliers that participate in the program.

C. Requirement to Service an Entire CBA

We also agree that all contract suppliers should be expected to service the whole competitive bidding area. We do NOT agree that CMS should allow a supplier with fewer than 10 employees to carve out a geographic service area that is smaller than the entire CBA. The number of employees does not directly correlate to a supplier's ability to service an area. Beneficiaries WOULD be confused as CMS described, and the issue of "cherry-picking" certain geographic areas would once again be likely. We note that CMS considered and rejected that carve-out option and we fully support this decision.

D. Participation by Small Suppliers in the Demonstration Projects

CMS notes that some small suppliers were able to increase their market share substantially during the demonstration, while others experienced little change in market share. Again we want to emphasize that suppliers in any given market – today or in the future under competitive bidding – compete on SERVICE and not on price. A large national provider with a small local branch usually offers the same local flavor, community involvement and medical community knowledge as a truly small competitor. Therefore, the size of the supplier has little relevance; a small supplier can certainly out-service a large one, or vice versa, and frankly it is all dependent on the people, business processes, responsiveness and relationships at the local level – not only on the equipment itself.

E. Proposal to Conduct Separate Bidding Competitions for Product Categories

We understand CMS' intent behind its proposal to allow suppliers to decide how many product categories for which they want to submit bids, rather than conducting a single bidding competition for all DMEPOS items and other equipment. CMS seems to believe that this will also allow small supplier that specialize in one or a few product categories to participate more easily.

However, there are flaws with this proposal:

1) Conducting separate bidding processes for individual product categories is the most administratively burdensome method CMS could select. Private managed care plans – including senior risk plans – issue RFPs for a comprehensive list of products and services. The paperwork alone is going to add significantly to the cost burden of CMS and bidders.

2) CMS may find little bidding interest in certain product categories that already represent a financial loss to suppliers, regardless of their size. These are categories where suppliers' service or product costs have risen while the Medicare allowables have decreased or been frozen for many years. Examples are ventilators, CPAP devices and supplies and ambulatory aids such as walkers, canes, commode chairs, etc.

3) The assumption that large suppliers could expand their product offering easier or more quickly than small suppliers is oversimplified and overstated. Privately-owned, small providers may be able to move more quickly than large organizations that must seek approval from their Board or other stakeholders before certain business expansion occurs.

M. Opportunity for Networks
71 Fed. Reg. 25654, 25683

In general we agree that the network model would enable small providers to better cover an entire CBA and that the entity should be formalized through a legal contractual relationship. CMS noted that networks were an option in the demonstration projects, but none were submitted. *See* 71 Fed. Reg. at 25683. In Polk County, that could be due to the fact that the geographic area was small enough for a single provider or location to cover the entire county and therefore it had nothing to do with the competitive bidding program itself. Obviously, other markets will require some degree of networking due to their sheer geographic reach, population density or number of Medicare beneficiaries to be served.

I. Recommendations

A discrete legal entity – rather than an informal referral network – is needed in order to prevent the commingling of Medicare funds, unintentional or intentional violations of anti-kickback, self-referral rules and regulations, and allegations of unfair business practices among the participating providers.

II. Networks Must Satisfy Same Conditions as Individual Suppliers

CMS proposes to allow suppliers to form networks for bidding purposes. In the event that CMS permits networks of independent suppliers, it is crucial, as CMS recognizes, that each supplier in a network satisfy the same conditions that suppliers who are not participating in a network must satisfy. In particular, each member of a network should be independently eligible to bid and satisfy the applicable accreditation and quality standards.

III. CMS Needs to Address Open Questions About How Network Entity Will Obtain Medicare Supplier Number and Be As Accountable as a Single Supplier

The requirements proposed by CMS, however, may not be sufficient to prevent networks from being formed that do not provide beneficiaries with appropriate levels of service and quality of items. Where a network of unrelated suppliers serve an area, there is a real risk that beneficiaries will fall through the cracks. Where a single supplier is responsible for the entire area, there is a single entity that can be held accountable. There is a substantial risk that, absent appropriate safeguards, no single entity will have the same level of accountability as with a single supplier. CMS needs to both add requirements to ensure that contracting networks are as accountable and responsible in the aggregate as single bidders and scrutinize bids submitted by networks to ensure that each network has appropriate mechanisms to ensure accountability and that each beneficiary has a single point of contact that ensures satisfactory resolution of any performance problems or other issues across the stated geographic region.

In addition, the PAOC raised the question about how a network entity would obtain a Medicare supplier number. Since all 21 Medicare supplier standards must be met before an entity can obtain such a number from the National Supplier Clearinghouse (NSC), and the network entity, as proposed, would merely represent the individual members of the network, it is not clear how the network entity will obtain that number. There should be no exceptions in terms of requiring an entity to meet the 21 supplier standards that exist today.

IV. Contractor/Subcontractor Relationship as an Option

We agree that this should be an option in those cases where a beneficiary resides in an area that is simply un-serviceable by a contract supplier, but CMS should recognize that the contract supplier is likely to find itself in an unprofitable situation when it must subcontract. This is due to the fact that the service costs far outweigh the equipment costs and the subcontractor would therefore negotiate a high price in order to take care of that patient. With shrinking single payment levels and rising fuel/labor costs, this scenario may be even more untenable under competitive bidding.

If a subcontracting arrangement is used, CMS should require the contract supplier to describe its formal credentialing process in the RFB process before contracts are awarded. Such a process should clearly define the roles and responsibilities that is appropriate for employees and subcontractors, outline the training required, and require the adoption of certain policies and procedures to ensure consistency with our own service and liability limitations.

V. Calculating a Network's Collective Market Share

CMS states that a network cannot be anti-competitive, a principle with which we agree. *See* 71 Fed. Reg. at 25683. The Proposed Rule states that "the network members' market share for competitive bid item(s) when added together, cannot exceed 20 percent of the Medicare market within a CBA. See id.

We have questions for CMS' consideration:

1) How will CMS calculate the market share and monitor changes in it over the course of the contract?

2) What does CMS propose to do to the network or its members if the market share grows to, for example, 40 percent?

VI. Networks Should be Subjected to Pre- and Post-Payment Audits

Just as individual suppliers are subject to pre- and post-payment audits, the same process should apply to networks. The Program Integrity Unit should include networks in their sampling methodology to ensure that regardless of their size in terms of Medicare allowed charges, they are audited in exactly the same manner as those suppliers that generate higher levels of allowed charges.

N. Education and Outreach
71 Fed. Reg. 25654, 25683-84

In general, we agree that education and outreach are key components of the competitive bidding program. We are very concerned about the aggressive timeframe which CMS has outlined in order to implement the program in 2007 and beyond, and believe that the level of beneficiary, supplier and referral agent education required may actually surpass CMS' expectations and budgeted resources.

I. 90-Day Notice Period Needed from Contract Award to Implementation Date in Every CBA

Therefore, we request that the supplier community be given a minimum of 90 days notice prior to implementation of the CB program from the bid award process to the actual "go-live" implementation date. This 90-day period is common in the private managed care sector and benefits all stakeholders involved:

1) It will allow CMS to fine-tune its launch plans by CBA, reprogram its computer systems, communicate with DMEMACs, the NSC and other government agencies as applicable.

2) Providers will have time to re-program their computer systems, make changes to operating policies and procedures, attempt to sign new contracts or secure additional facilities to support the contract, notify patients and referral agents of the upcoming CB program and its implications for them;

3) Referral agents will have time to become acclimated to the new process in their market and will be more likely to support the program than if they are caught by surprise due to a short implementation phase;

4) Patients will experience less disruption if their supplier has time to analyze the applicability of the grandfathering provisions if it does not win a contract and to learn more about the competitive program in general before it becomes effective.

II. Supplier Education

We agree with CMS' overall plan to involve the CBIC, DMEMAC, customer service support and the claims processing system to notify and educate all parties regarding competitive bidding. We agree that bidders' conferences should be held to provide an open forum for suppliers to exchange information with CMS.

We request that CMS collaborate with industry groups, such as the American Association for Homecare ("AAH"), to develop appropriate communications to be sent to suppliers to minimize confusion in the supplier community. Organizations like the AAH have extensive collective knowledge about suppliers' day-to-day operations and can provide expertise that may help CMS streamline its communications with the supplier industry.

The PAOC should also review any materials that relate to DMEPOS competitive bidding to avoid mistakes and reflect the expertise of the industry.

III. Beneficiary Education

We also agree that beneficiary education will be critical to the success of the program. However, CMS mischaracterizes some of the patient-directed messages that would be associated with competitive bidding. *See* 71 Fed. Reg. at 25684. CMS states that the benefits of the Program include "lower out-of-pocket expenses and increased quality of products." *See id.* These two alleged benefits are not necessarily true. The Deficit Reduction Act's forced equipment ownership requirement may actually increase patients' out-of-pocket expenses for certain services that are currently included in the monthly bundled rental payment rate. Since CMS has not issued any rule or guideline regarding, for example, a Saturday evening emergency delivery to a home after the equipment has reached its capped amount and is owned by the patient, the supplier will likely need to charge the patient an after-hours in-home delivery rate – something that it does not do under the current system.

Regarding "increased quality products," we caution CMS about using such a statement since Medicare beneficiaries across America already receive quality products. Since it is illegal to discriminate against patients based on payor source in most U.S. states, most suppliers go through a formal product selection process and then provide those products to all patients, regardless of payor. This is also more logistically sensible than trying to maintain multiple separate sets of inventory, etc., and again goes to the point that providers will continue to compete on service, not price or equipment.

IV. Direct Mail and other Direct Marketing Should be Used, Not Mass Media

However, we do not believe that CMS should waste taxpayers' resources by investing in expensive direct-to-consumer televisions or media advertising on this subject. Rather, targeted direct mail or information dissemination through high-Medicare volume physicians' offices would be more effective. In addition, CMS should relay on the homecare supplier community itself to educate beneficiaries, since we visit patients' homes every single day of every year.

V. Suppliers Should Use Their Own Homecare Education Materials

In another section of the NPRM, CMS references the possibility that patient education materials for the homecare services and equipment itself would be developed and standardized in the competitive bidding markets. This is unnecessary and would be problematic for providers who serve multiple payors. At Apria, for example, our patient education materials have been reviewed thoroughly by the Joint Commission, our Legal Department, insurance carriers and certain manufacturers' Legal departments since some content relates to their equipment's safety, troubleshooting tips and maintenance schedules. They are all written at the sixth grade reading level and many have been translated into Spanish and other prevalent languages.

We certainly hope that CMS does not intend to impose a requirement on providers to create and print all-new patient education materials. This represents a waste of resources. Instead, CMS should simply require that providers give patients written and in-person education that is appropriate to their health condition and that meets the expectations of the supplier's accreditation organization.

O. Monitoring and Complaint Services for the Competitive Bidding Program 71 Fed. Reg. 25654, 25684

We agree that an effective complaint monitoring system is needed as part of the competitive bidding program. We believe this should be a simple process that incorporates existing channels for Medicare beneficiaries to voice complaints – such as the Ombudsman program – and should not attempt to either recreate what exists in another section of the program or overcomplicate the process.

CMS has cited examples of potential problems that CMS would consider to be serious, such as contract suppliers refusing to furnish items to beneficiaries in the CBA and contract suppliers furnishing items of inferior quality.

CMS concludes this short section by stating that "claims data will be monitored to identify trends, spikes or decreases in utilization and changes in utilization patterns within a product category." 71 Fed. Reg. at 25684.

I. Comments/Recommendations

1) Current Medicare supplier standards require that suppliers show the NSC the complaint resolution process through the site inspection required prior to the issuance of a provider number.

2) Patients should be directed to call their supplier FIRST regarding any alleged service issues before calling the Medicare Ombudsman or other contact, since the majority of issues are easily resolved at the local branch office location and do not require escalation.

3) CMS must define "items of inferior quality" and other terms used in this section, since our experience suggests that patients will complain if their oxygen tubing is clear instead of their preferred blue, even if the quality is exactly the same. They may not be familiar with all of the features and benefits of a certain product, or new technology that makes their old product obsolete, and therefore believe that the supplier is providing them with something other than their typical quality product. Typically we resolve these questions and concerns quickly and easily without the need for any outside involvement.

4) In determining whether a supplier is experiencing a high level of complaints, CMS must view complaints not in an isolated, numerical manner but expressed as a percentage of the total number of in-home deliveries made to Medicare patients in a given month. Otherwise, CMS could misconstrue the level of complaints if an individual supplier were to have, for example, the largest Medicare market share in a given CBA and thus the raw number of complaints were to appear large. Expressing the complaints as a ratio of total in-home deliveries is how the private sector now looks at complaint monitoring.

II. CMS Cannot Force a Supplier to Furnish an Item it Does Not Routinely Supply

In terms of furnishing items, again we ask CMS to address the quite-common situation where a supplier does not carry a particular item or know how it works, must be maintained, etc. It is not uncommon for a supplier to contract with a few quality manufacturers to provide the majority of the products patients need, making it difficult and more costly for that supplier to obtain a non-contracted items from another manufacturer, especially on short notice. Mandating that supplier to furnish that item could raise patient

safety, employee safety and other liability concerns. As long as SOME contract supplier in the CBA can supply that particular item, it should be acceptable to CMS; that is part of the reason why multiple suppliers are needed to service a given CBA.

III. Product Utilization May Have Nothing to Do with Competitive Bidding

While claims monitoring may be effective for some purposes, using it to suggest that a spike in certain items' utilization may be attributable to competitive bidding is narrow-minded. As we stated in an earlier section, certain areas of the country are experiencing rapid Medicare beneficiary population growth, the baby boomers are entering the program in disproportionately high numbers, the incidence of certain diseases is higher in some parts of the U.S. than others, and new products/technologies are introduced every year which enables a larger number of patients to remain independent at home.

P. Physician Authorization/Treating Practitioner and Consideration of Clinical Efficiency and Value of Items in Determining Categories for Bids (proposed 414.420) – Also known as "Brand-Specificity" 71 Fed. Reg. 25654, 25684

CMS describes its proposed plan for fulfilling the Act's authority granted to the Secretary as intending to "establish a process for certain items under which a physician may prescribe a particular brand or mode of delivery of an item within a particular HCPCS code if the physician determines that use of the particular item would avoid an adverse medical outcome on the individual." *See* 71 Fed. Reg. at 25684.

We have serious concerns about this entire requirement, as it is the first time in the history of Medicare DMEPOS coverage that the agency has ever concerned itself with brand-specific products, and it will add to both the administrative burden and cost of the entire program. Moreover, we believe that the way in which CMS has interpreted its authority is more prescriptive, onerous and punitive than Congress may have originally intended.

The phrase "avoid an adverse medical outcome on the individual" must be clearly and carefully defined. Currently, neither the CMN nor any other Medicare document contains a space for the physician to either prescribe by brand-name or document that the product is needed to "avoid an adverse medical outcome." Physicians cannot be expected to remain abreast of all new products on the market, warranties, commercial status, problems experienced with each, manufacturer product recalls, backorders, shortages, etc. Therefore, they could actually prescribe a product that would cause an adverse medical outcome if the homecare provider were to supply it to the patient! Finally, our experience shows that certain brands are prescribed purely due to manufacturers' sales efforts, market perception or features of the equipment that solely offer comfort and convenience to patients.

Based on historical experience, the Medicare program has not paid for "convenience" items and product features. Product aspects such as color, weight, portability, battery-operation, etc., have never been considered valuable by Medicare before, and we are concerned that Medicare will discriminate against beneficiaries in non-CBAs if it approves of products with these features in the CBAs but still does not approve of such products in the non-CBAs.

Three examples are (1) battery-operated, portable nebulizers, (2) ambulatory enteral nutrition pumps and (3) CPAP devices featuring C-FLEX technology. We also find this requirement interesting and in conflict with the recent Local Coverage Determination (LCD) issued by the three DMEMACs in regard to Medicare Part B inhalation drug therapies. In it, Medicare suggested that physicians' brand-specific prescriptions for Xopenex® and DuoNeb® would not be recognized or honored by the Medicare program. Yet, patients who are forced to switch to another drug in lieu of Xopenex or DuoNeb could actually experience a true "adverse medical outcome." The program cannot require that brand-specific prescriptions be honored in one part of the DMEPOS program and disregarded entirely by another. We provided extensive comments on this subject under separate cover to the three DMEMAC medical directors in May 2006. Also, keep in mind that a high percentage of patients receiving products under the competitive bidding program may be the same ones who use Xopenex and DuoNeb, so confusion would reign among physicians, patients and providers alike.

With Apria's extensive experience working with national and regional managed care plans, brand-specificity is very rarely, if ever, a requirement of the contract.

I. Current Proposed Rule

The Proposed Rule generally requires contract suppliers to provide brand-specific items and equipment as designated by the prescribing physician. Although a contract supplier may consult with the treating practitioner to find a suitable alternative product for the beneficiary, if the contract supplier is unable or unwilling to furnish the equipment the treating practitioner ultimately requests, the supplier must assist the beneficiary in finding another contract supplier in the competitive bidding area. CMS has proposed that the contract supplier still be required to support and service the item and the patient. If a supplier substitutes another item or equipment, the claim will be denied.

We believe that the way in which CMS has interpreted its authority is more prescriptive, onerous and punitive than Congress intended.

II. Difficulty in Providing Brand-Specific Items Within the Context of Competitive Bidding

The proposal implementing the specific brand mandate raises serious financial consequences for suppliers and creates unnecessary uncertainty in the bids to be submitted. The primary bases for this concern are the unpredictability of the application of this new right to make brand-specific requests and the wide range of costs among brands within a single HCPCS code. These issues are outside the control of the supplier who is going to be financially responsible for the outcome. Consequently, we strongly use the Office of General Counsel to support CMS' effort to implement the brand specific mandate in phases, requiring the designation of product categories and product codes that are distinct enough to allow suppliers to calculate realistic bids and product inventory assumptions. Alternatively, CMS should consider an exception process to fairly compensate suppliers for the provision of items that are very expensive in comparison to other products within the same HCPCS code.

III. High Level of Acquisition Cost Variance for DMEPOS Products Tied to Single HCPCS Codes

The right to brand specificity is a new concept within the Medicare program. We anticipate it will be very difficult for suppliers, even large, more sophisticated businesses, to accurately predict brand specific product utilization and fully incorporate these factors into their bids. The high level of price variance for certain types of products, such as oxygen concentrators, nebulizers, CPAP devices and masks, combined with an inability to predict prescribers' preferences and prescribing behavior, will make it difficult for suppliers to submit accurate bids. Extensive overbidding or extensive underbidding will not financially benefit the Medicare program, nor the level of care furnished to beneficiaries.

IV. HCPCS Coding Process Has Challenges and CMS Should Delay Implementation of Brand-Specific Requirements Until the HCPCS Process is Revamped

In the Proposed Rule CMS states that it believes that "the HCPCS process has worked well in the past, and we believe that it adequately separates items based on their function." We do not agree with this assessment.

The advent of the Health Insurance Portability and Accountability Act's (HIPAA) Transaction Code Set (TCS) requirements forced a change in the role and relative importance of the HCPCS Coding Panel and new HCPCS code application/approval process. Prior to the TCS requirement, the HCPCS coding panel primarily focused on products and codes that were used in the Medicare population, while managed care payors allowed a much more broad array of customized codes to reflect different products, acquisition costs and service level variances.

Since HIPAA mandates that code sets be standardized among all payors – regardless of whether they are government or private managed care in nature – the HCPCS coding panel is now in a position to create codes that are more likely to be used in the private sector.[1] New HCPCS codes have been routinely denied to manufacturers who complete the application process after introducing new technology to the market and outlining the product features that differentiate the products from existing ones. Despite clear differentiation and therapeutic benefits desired by both patients and physicians, the HCPCS coding panel has denied new codes and forced those new products into existing HCPCS categories with allowable reimbursement often far less than the acquisition cost.

The cost differences among brands within one HCPCS code can be significant and enforcing brand-specific delivery under the current proposal would almost certainly result in financial hardship for contract suppliers. For example, the more advanced, increasingly prescribed models of CPAP devices may cost five times as much as a standard CPAP that offers enough benefits to the patient to treat his/her condition less effectively. New technology, such as a portable oxygen concentrator, may cost as much as four times more than a traditional model. Yet, these products fall within the same HCPCS code and will be subject to the same single payment amount as their older generation predecessors. If a physician insists on prescribing the more expensive model, the supplier may face a dramatic financial shortfall if the single payment amount has not fully captured the anticipated volume and value of furnishing the much more expensive product. This may adversely impact the ability of the supplier to continue participating in the program or the level of patient care.

To address this concern, we have recommended that CMS consider delaying implementation of the brand-specific mandate until it ensures that the product categories and applicable HCPCS codes recognize the cost distinctions of these products. This could be accomplished through a phased-in approach to the brand mandate. For example, the entire product category of wheelchair coding already is being revised through new and revised codes and definitions. This phasing and more deliberate approach will minimize the onerous and unfair consequences to which suppliers otherwise will be subject and which we strongly believe was not Congress' intent when enacting the statutory language.

V. Exception Process Needed

Whether or not CMS implements a more refined product category and HCPCS classification, the Office of General Counsel should support CMS efforts to develop an exception process to protect suppliers when a physician orders a disproportionately more expensive brand. In other government program contexts such as the Medicare Part D program, CMS has recognized the importance of risk adjustments and risk corridors to decrease the exposure of Part D plans where the allowed cost exceeds the estimated plan payments for the Part D benefit. Similarly, CMS should take into consideration the potential exposure of suppliers who participate in the competitive bidding program and must handle unexpected requests (or an unpredicted request volume) for more costly items.

We anticipate there will be instances in which a physician refuses to modify a prescription and the contract supplier cannot provide the specifically requested item, or no contract supplier will furnish the specified item. Under the Proposed Rule, the contract supplier may furnish an alternative item within the same HCPCS code in an effort to meet a beneficiary's medical needs. Even though this item would be covered in a non-competitive bidding area and the item is considered equivalent to the ordered item

[1] Since 80% of the total Obstructive Sleep Apnea (OSA)/CPAP market is commercially insured, this is a good example of a product category for which HCPCS codes need to be modernized. Pediatric products used in Medicaid and commercial populations is another other example where the HCPCS codes available do not mirror current-day technology that is available and being used to treat children.

because it falls within the same HCPCS code, the supplier will not be able to bill Medicare. Instead, the item will be considered a "non-covered item." It is unclear why the contract supplier should be left with the cost of the item in these situations. This is an entirely inequitable result and, we believe, inconsistent with the Congressional intent.

In light of the grave concerns related to the implementation of this brand-specific provision, CMS should delay implementation of the brand-specific component of the competitive bidding program until CMS develops a system that can more adequately distinguish supplies by relative cost and features. This approach will permit suppliers to calculate and offer realistic bids and, ultimately, receive fair reimbursement as they continue to supply high-quality services and items to Medicare beneficiaries.

VI. Substitution Process and Documentation Requirements

If a physician or treating practitioner requests a specific brand, the contract supplier is allowed, under the current Proposed Rule, to consult with the prescriber concerning a suitable alternative. If the treating practitioner is willing to modify the original order, the Proposed Rule mandates the supplier receive a revised written prescription. Verbal orders are acceptable in most states. This proposal is well beyond the legal mandates of many states and imposes significant administrative burdens on suppliers and physicians.

First, many of the existing CMS documents, such as the CMN, have no place for a physician to specify a particular brand of equipment. Rather than requiring a supplier to obtain and store both a CMN and a separate prescription, CMS should modify its forms so that only one document is required. This approach is more efficient for physicians and suppliers, and is consistent with the general industry directive to reduce unnecessary paper.

Second, the proposed documentation requirements concerning order modification are not consistent with standard practice within the DME industry. Revised written prescriptions are not presently required for many DME items under state law. Thus, in appropriate circumstances, it is common for suppliers to furnish alternative products that physicians have orally approved without further physician documentation. Mandating a revised written prescription is an onerous and unnecessary burden on both the treating practitioner community and suppliers, and is likely to distract from the medical community's primary focus on patient care. The Proposed Rule should be modified so that a supplier is permitted to make appropriate notations in its internal documentation, such as system-generated prescriptions, in order to document a physician's oral consent to substitution of a particular product. A new physician prescription should not be required unless mandated under state law. Again, verbal orders are acceptable in most states. This suggested approach is consistent with industry practice and will improve the ability of suppliers to efficiently deliver necessary and proper items to beneficiaries.

Finally, the Proposed Rule should be clarified with respect to a contracted supplier's obligation to refer a beneficiary to an alternative supplier if the original supplier does not carry a requested item. The Proposed Rule suggests that in this situation the supplier is initially permitted to contact the treating physician and discuss an alternative product. Only if the supplier cannot fill the order must the supplier assist the beneficiary in locating an alternative source. The Proposed Rule Preamble, however, implies that the supplier must first contact other contract suppliers within the competitive bidding area ("CBA") before consulting with the physician. Since the language in the Proposed Rule is consistent with current industry practice and minimizes disruption for the beneficiary, this would appear to be the most appropriate approach. CMS's clarification on this topic will minimize confusion among suppliers regarding the proper course of action.

VII. Reasonable Effort Standard

The Proposed Rule states that if a supplier does not carry a requested item, the supplier may refer the beneficiary to another supplier in the CBA that does. CMS should specify the level of effort that a contract supplier must expend in locating another contract supplier. An appropriate standard would be to require contract suppliers that are unable to supply the requested item to use "commercially reasonable efforts" to locate an alternative supplier. CMS also should clarify a supplier's obligation to furnish a brand-specific item when no alternative suppliers can be located.

VIII. Perception of Discrimination and Unfairness

Implementation of the brand-specific provision of the Proposed Rule appears to be inconsistent with the Preamble discussion about the terms of a supplier contract. Specifically, the Preamble states that the supplier contract is likely to contain a requirement that the supplier not discriminate against beneficiaries in a CBA, so that "all beneficiaries inside and outside the CBA receive the same products that the contract supplier would furnish to other customers." 83 Fed. Reg. at 25681.

It is unclear how a contract supplier may comply with this directive while furnishing brand-specific items only to competitive bidding beneficiaries. It is also unclear how a supplier will be able to avoid potential beneficiary allegations of discrimination and unfairness when certain items will be covered in a non-competitive bidding area, but will be considered non-covered in the competitive bidding area if a physician insists on a specific brand, but the supplier is only able to furnish a different product. CMS should clarify these potential inconsistencies and ensure that suppliers will not be subject to inadvertent CMS and beneficiary liability.

In addition to these concerns, the current proposal will add administrative costs to those suppliers (including Apria) that have locations serving both competitive bidding and non-competitive bidding beneficiaries. These costs will include the need for additional training on the brand-specific issue, as well as the need to develop additional internal systems and protections to ensure appropriate implementation. It would be logistically impossible for every provider to train its employees on every single product available in the marketplace. Such training, if possible, would need to extend to our employees who must be able to set up, educate patients on and explain all brands of equipment. This is neither practical nor cost-effective for either the provider or the program.

IX. CMS Cannot Consider an Item Non-Covered if it Has a HCPCS Code and is Reimbursed by Medicare Outside of the CBAs

The proposal also calls for the contract supplier to not bill Medicare for a product it supplies if it does not match the prescription as CMS would consider this a "non-covered item." This also represents and unfair and discriminatory business practice, as the supplier's location might actually be providing that same product to beneficiaries who live outside of the CBA, and the supplier will have incurred the full expense burden associated with delivering that equipment to the patient's home within a very short period of time after the referral was received.

X. Brand-Specific Requirement Cuts Into Potential Program Savings

The competitive bidding program is designed to drive savings for the Medicare program. Homecare providers drive savings that they could pass on to the program by consolidating purchases among a few manufacturers. If this provision moves forward in its current form, it will undoubtedly result in reduced savings that may be attributed to the competitive bidding program. If a provider must account for higher product acquisition costs in the bids submitted during the application process, the savings levels will be

lower. This certainly is not the result Congress intended when authorizing the competitive bidding program.

Here is a very real and practical scenario that could occur:

1) The provider conducts a formal product reviews among various manufacturers of CPAP masks and selects three or four masks that fit the clinical, comfort and overall needs of 80% to 90% of all patients (regardless of payor source) likely to need them. The provider signs a contract with two manufacturers to secure product availability and pricing associated with those three or four masks.

2) In CBA A, a competitive manufacturer's sales representative persuades the local sleep management physicians and/or sleep laboratory technicians to write a brand-specific prescription for a mask that 1) does not offer any incremental benefits to those 80% to 90% of all patients, but 2) costs the provider three times more than the ones they've selected as standard.

3) The provider would need to make attempts to educate physicians and/or beneficiaries about availability and quality of masks that are contracted. If the physician does not write an all-new prescription, the provider would need to supply that more costly mask.

4) If the more costly masks were to constitute a significant percentage of total Medicare CPAP mask patients served, the provider would have to reflect the higher acquisition cost in its bid to Medicare.

XI. Section Summary and Recommendations

In summary, this entire requirement is fraught with many adverse consequences, presumably unintended. While Congress may have believed it was ensuring that patients continued to have access to "quality" products (again, not defined anywhere), the way in which CMS has interpreted this section will cause a significant increase in administrative burden, decreased cost savings associated with competitive bidding and possibly even low-quality products being provided to beneficiaries solely because a physician writes a prescription for them.

We urge CMS to delay the implementation of the brand-specific requirement until 2008 after the 2007 program is up and running in all 10 initial markets. In addition, CMS must:

1) Clearly define the phrase "to avoid an adverse medical outcome."

2) Adopt the FDA's definition of "functional equivalence" used to approve medical devices that are similar to already-approved ones and allow a provider to substitute such a device without extensive documentation;

3) Eliminate the financial penalty aspect of the proposal by allowing a supplier to bill Medicare for a substitute product that meets the functional equivalent standard;

4) Phase in the requirement by piloting it in one CBA in 2008 to study the ramifications of implementing it;

5) Allow enough time for the HCPCS system to be updated to reflect the broad range of products and associated provider acquisition costs within certain categories;

6) Further consult with the homecare community to develop the most streamlined, least punitive method for implementing such a provision;

7) Build safeguards into the process that are designed to prevent product manufacturers from taking advantage of this provision to drive up unnecessary costs associated with certain brand specificity;

8) Study the discrimination aspects of this rule, since Medicare patients in non-CBAs will not be subject to the same brand-specific requirements.

Q. Quality Standards and Accreditation for Suppliers of DMEPOS 71 Fed. Reg. 25654, 25684-87

As stated in our opening comments, Apria Healthcare is an ardent supporter of the need for quality standards and mandatory accreditation as part of the Medicare Part B DMEPOS program. Both requirements will "level the playing field" among all suppliers, regardless of whether they participate in the competitive bidding program or not.

However, we are concerned about several aspects of the proposed methods that CMS would use to implement these two very important components of the program:

1) The quality standards are not yet finalized and therefore we, along with every other supplier, are unable to adequately and comprehensively comment on their content or their impact on our operations and cost structure once competitive bidding is launched;

2) The proposed quality standards are too abstract and "policy and procedure" in nature, demonstrating a lack of understanding of the homecare industry from the consulting organization, and do not reflect actual quality standards that have long been used in the private sector;

3) Rather than "recreate the wheel" in terms of accreditation, CMS should simply designate the three large national DMEPOS accrediting bodies to have "deemed status" and, by virtue of a provider's successful accreditation from one of the three, CMS could assume that the provider essentially meets all standards associated with the program.

4) CMS' proposed "Validation Review" process is much too duplicative with the existing accreditation process and questions remain as to the background, experience and training of any CMS employees who would perform such validation surveys. No managed care plan in America conducts such a validation survey as the costs far outweigh the benefits.

5) No grace period should exist in which a supplier would obtain accreditation. The Medicare Modernization Act was passed in December 2003, so suppliers will have had three years to seek and obtain accreditation by the time the competitive bidding program is underway later this year.

6) Cost savings will be further eroded if CMS proceeds with its plan to implement a redundant Validation Review process of accreditation surveys.

I. Special Payment Rules for Items Furnished by DMEPOS Suppliers and Issuance of DMEPOS Supplier Billing Privileges (section 424.57)

We strongly urge CMS to select the three national, well-established accrediting organizations to implement and monitor the standards. These are the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Accreditation Commission for Health Care (ACHC) and Community Health Accreditation Program (CHAP). All three have a proven track record of developing standards in order to meet the changing realities of homecare services, surveying DMEPOS providers and developing a success/failure rate over time. Newer organizations do not have such a track record and we therefore recommend that they develop at least three years of data before being considered for inclusion in the Medicare Part B accreditation program.

In this section, CMS also states that proposed new paragraph (c) (22) would specify that all suppliers of DMEPOS and other items be accredited by a CMS approved accreditation organization before receiving a supplier billing number.

II. Questions

Regarding this latter point, CMS must clarify how acquisitions of existing suppliers would be handled. Currently, if an accredited supplier buys a non-accredited supplier and keeps that physical location open, the acquirer's accreditation status and process would ensue, meaning that the accrediting organization would likely conduct a survey of the acquired location(s) subsequent to the acquisition. The schedule of that survey hinges almost completely on the accrediting body's availability to conduct the survey. CMS should not delay either the issuance of a supplier number or payment for patients served through that location where the acquiring organization is fully accredited while the individual acquired location is pending a post-acquisition accreditation survey. Evidence of notification to the accrediting body should be adequate proof to move forward with issuance of the provider number.

CMS has also not accounted for the very real situation where an accredited supplier would open a new physical location providing like services as those provided by the accredited organization to better serve Medicare beneficiaries in a particular part of the CBA. Today, the accrediting body would consider the new location to be accredited since it is owned by the same parent organization, follows the exact same policies and procedures, uses the exact same information system, accounting procedures, compliance program, complaint monitoring program, etc. It would do so without necessarily conducting an on-site visit. We recommend that CMS make an allowance for this situation and consider any start-up location associated with an already-accredited organization to qualify for the immediate issuance of a Medicare supplier number, followed up by a subsequent accreditation survey. Since this situation occurs every single month in markets across America, it cannot be ignored, especially if the expansion helps to serve Medicare beneficiaries better.

III. Accreditation (section 424.58)

We generally with the plan that CMS describes to use existing procedures for the application, reapplication, selection and oversight of accreditation organizations and apply them to organizations accrediting suppliers of DMEPOS seems to make sense.

A. CMS Must Not "Force-Fit" Part A Processes On To Part B DMEPOS

However, CMS must not try to "force-fit" existing Part A home health procedures into the DMEPOS industry. It must recognize the differences between Part A and Part B. One section references the deemed status authority related to Part A and the state surveys that are performed on Part A agencies. This is inapplicable to Part B, since many states impose completely different state licensing requirements and the FDA, DOT and other state/federal agencies are involved in providing oversight to and audits of DMEPOS suppliers.

B. Adopt Existing Accrediting Bodies' Survey Procedures, Do Not Duplicate or Add Burden

Again, we urge CMS to rely on the Joint Commission and other accrediting bodies to seek their counsel on any standards, audit procedures, self-evaluations, etc., rather than recreate the wheel. The quality standards for competitive bidding should not differ very much from the 400-plus performance standards that the Joint Commission and others already have in place. The "crosswalk" that CMS references on page 122 should be brief since the standards should be the same.

Also, CMS must adopt the accreditation organizations' processes and procedures for notifying suppliers of compliance or noncompliance with accreditation requirements, monitoring the correction of deficiencies found during the survey, coordinating surveys with another accrediting organization and quality review processes for deficiencies. CMS must NOT create additional administrative burdens on either the accrediting bodies or the suppliers since again, this will have to be reflected in the cost structure of the program. If CMS adds significantly to the accrediting bodies' operating costs by, for example, requiring them to conduct a physical audit of each and every location of a national accredited provider that follows the exact same policies and procedures, the accrediting body will have to pass those increased costs on to suppliers. The suppliers, in turn, will have to reflect those increased costs in the bids they develop for competitive bidding, and savings will be eroded.

C. Other Information CMS Should Seek from Accreditors

In addition to the professional background information that CMS may request from the surveyors themselves, the agency should also ask the accrediting bodies for their conflict of interest disclosure policies, since some surveyors also have consulting businesses that may conflict with certain clients.

D. Notice Requirements for Accrediting Organizations

On page 123, CMS outlines some of the other data requests it may make of accreditation organizations. While most of the requests make sense, some of the reporting that CMS is referencing does not exist today. For example, accrediting bodies do not currently notify ombudsmen programs or the National Supplier Clearinghouse (NSC) of unfavorable accreditation decisions related to DMEPOS.

Any such notice process must be preceded by or include an appropriate appeal and "cure" process for providers to access prior to any punitive action being taken against the organization. The Joint Commission currently has a stair-step appeal and escalation process which is appropriate given the importance of accreditation to an individual supplier's ability to participate (today) with managed care organizations and (future) with the Medicare program.

E. Revocation of Supplier Number Should Not be Performed Wholesale Since Supplier May Serve Non-CBA Medicare Beneficiaries

CMS indicates that it would revoke the supplier's billing number and re-evaluate the accreditation organization's approved status.

These two plans need careful evaluation and a phased-in approach because any given supplier may be serving both competitively bid and non-competitively bid patients. While quality standards are going to be implemented for all suppliers, mandatory accreditation is not required until 2010. In addition, if competitive bidding only applies to certain products and quality standards are ascribed to only those products, CMS should not revoke the supplier number permitting a supplier to bill for non-competitive bid patients if compliance with the competitively-bid quality standards is in question.

Also, CMS needs to consider the situation where the supplier has another physical location in the CBA that is in full compliance with all applicable standards and could absorb the existing patient volume of the location that loses its supplier number without any interruption in patient care. In this case, CMS should allow the parent company/supplier to transfer the patients into another owned location that meets the applicable standards. Of course, that new location will bill under its own Medicare supplier number per standard operating procedures that exist today.

In sum, there are a number of issues associated with the application of some of the accreditation requirements. Accordingly, any requirements for CBA suppliers absolutely must be phased in and not implemented across the board upon the launch of competitive bidding.

IV. Ongoing Responsibilities of CMS Approved Accreditation Organizations

While we understand the deemed status process that applies to Part A or other areas may require certain documentation from independent accrediting bodies, we believe that with regard to DMEPOS, CMS should mirror the private sector, not other Medicare programs. For example, requiring the approved accreditation organizations to provide copies of all written surveys, corrective action plans and summaries represents a significant paperwork burden to the accrediting organization and CMS. CMS will be inundated with volumes of paper that it could not possibly review without adding a significant number of new staff members, thus further eroding potential program savings.

Moreover, the current format of the survey reports is not necessarily self-explanatory. Scoring methodologies differ among the three major accrediting organizations; slightly different standards and requirements may be assessed. The degree of narrative description to accompany the scores is often limited. Without an executive summary written by either the accrediting organization or the provider itself, CMS might find itself unable to accurately interpret the results of the survey.

The key information CMS needs is that the supplier has or has not achieved accreditation or renewal. Of course any significant change in accreditation status should be reported to CMS, but we urge CMS to forego the need for copies of the surveys themselves. No private payor in America requires copies of the actual survey results. The copy of the cover letter from the accreditation organization should suffice.

V. Notice of Beneficiary Complaints Should Be Limited to Clearly-Defined "Serious" Ones

CMS should not require the accrediting organization to provide notice of all complaints related to suppliers of DMEPOS since certain complaints may be minor in nature and easily resolved between the accrediting organization and the supplier. Examples of minor complaints might be a curt telephone manner used by a supplier's employee and the patient, delivery on Tuesday instead of Thursday, the color of their tubing changed, etc.

Only the most serious complaints should be reported to CMS. We would be pleased to work with CMS and JCAHO to define "serious complaint" and a method for sending CMS this information.

VI. Notice of Changes in Accreditation Standards, Requirements or Survey Process

While it is reasonable for CMS to expect the accrediting organizations to inform the agency of changes in standards, etc., it is unreasonable to penalize the organization by withdrawing its approval if it implemented the changes before or without CMS' approval.

Keep in mind that accreditation standards apply to all patients cared for by suppliers, regardless of their payor source. If CMS in any way delays review or approval of amended or new standards, it could impact a much larger number of patients and payors than those covered by Medicare competitive bidding.

Since most accreditation organizations update their standards annually, develop an appropriate annual calendar to ensure that appropriate notice is given to all parties.

In this section, CMS also alludes to the fact that it would be allowed to change the quality standards at any time during the contract period. This is another "bait and switch" proposal since such changes could

cause a substantial increase in providers' cost structure, which would impact the amount they bid if they had known the change would occur. Quality standards should remain intact for at least a calendar year before amending or changing them, unless of course patient safety is the crux of the issue.

VII. Continuing Federal Oversight of Approved Accreditation Organizations

A. Equivalency Review

CMS' plan to conduct an equivalency review seems reasonable as briefly described in this section. Again, however, we are concerned that CMS infers that it could impost new requirements at any time throughout the contract, causing additional burdens on suppliers that may not have been revealed by the agency during the RFB process. Annual updates would be acceptable.

B. Validation Review

The accreditation organizations' procedures are time-tested and have been in place for many years, if not decades. The Joint Commission's survey failure rate for DMEPOS is 6%, which proves that it is not a "rubber-stamp" process. Each accrediting body has its own performance improvement and evaluation process in which it consults with industry advisors to modify and add to its standards every year.

The 10% disparity guideline outlined on page 127 is irrelevant and unneeded. Accreditation organizations all have slightly different philosophies in their scoring methods, the standards they deem most or least important (weighting), etc. Because CMS has not outlined the background, experience level, survey experience or any other aspect of the team that would be assigned to perform the validation survey, we cannot endorse this process in any way. If there were no independent accreditation organizations or if DMEPOS represented an all-new product category for them to survey, our opinion might differ. We believe it is an unnecessary incremental burden on the government cost structure for this program.

1. *CMS' Plan to Conduct Validation Survey of Accredited Suppliers is Redundant*

It is a waste of time and taxpayer resources for CMS to perform validation surveys. No other payor in America – including senior risk plans – conducts such duplicative surveys. CMS is not in the business of conducting DMEPOS accreditation surveys, and the Rule did not specify the background or experience of the people it would rely on to conduct such critical surveys. By contrast, the accrediting bodies have comprehensive training, development and monitoring programs for their surveyor employees. These programs are updated regularly and CMS has not described any comparable process in the Rule or any other document.

We are especially concerned that CMS would conduct such surveys in response to allegations of supplier noncompliance with quality standards. Even before the competitive bidding program is launched with all of its new requirements that will surely evolve over time, Medicare rules and regulations are very complex; inexperienced employees, competitors and surveyors can often misconstrue them. This causes some allegations to be unsubstantiated and unsupportable once the facts are made clear.

Instead of conducting validation surveyors, CMS should do two things:

1) Direct the supplier's accrediting organization to conduct follow-up with the supplier on any allegation of supplier noncompliance with quality standards. The accrediting organization is best-equipped to conduct such follow-up and mechanisms exist today for them to follow-up on complaints that reach their office. Accrediting organizations such as the Joint Commission already have mechanisms in place that require providers to develop and implement corrective

action plans. We urge CMS to rely on the expertise of the private sector for all of these services, just as it relied on private sector specialists to implement the complex Medicare Part D program.

2) Take the resources that would be used to conduct validation surveys and direct them toward conducting unannounced billing audits of suppliers that have not had such an audit in the past year. The Program Integrity Unit's current plan of auditing only high-volume, claims-generating DMEPOS suppliers causes a situation where those suppliers are audited over and over again, with largely successful outcomes, while the suppliers that may not be following Medicare guidelines go unaudited for many years. Audits represent a large administrative burden for suppliers, and those that pass "successfully" should be moved on to some kind of representative sampling methodology to ensure ongoing compliance. If the PIU continues its current sampling methodology, it will continue to overlook those suppliers that are more likely to be violating rules and regulations than the ones that have high volume and pass audits successfully time after time.

If CMS insists on performing validation surveys, it should focus only on those accrediting organizations that have been performing DMEPOS surveys for two years or less. Again, a mediation or "cure" process must be included in the overall plan so that a provider or an accreditation organization would have a channel for appealing CMS' validation survey findings.

2. *Notice of Intent to Withdraw Approval for Deeming Authority*

Individual suppliers have too much at stake if CMS were to withdraw its approval of one or more accreditation organizations without an appropriate notice and transition period. Suppliers would need to contact another organization to discuss accreditation through that organization, and depending on the volume of displaced suppliers involved, a serious backlog could occur.

On page 127, an example of the lack of specificity of this entire rule exists when CMS states that "if an equivalency review...or our concerns with the ethical conduct of the accreditation organization suggest [it] is not meeting the requirements..." How does CMS define "ethical conduct of the accreditation organization"? This too-vague description provides too much risk to the supplier, since it could lose its right to participate in the Medicare program purely due to actions of the accrediting group and CMS' perceptions thereof.

3. *Withdrawal of Approval for Deeming Authority*

CMS states that it could essentially withdraw approval of an accreditation organization at any time. No grace period, transition period or other notice to the supplier was described by CMS in this section.

Individual suppliers should not lose their ability to participate in a competitive bidding program solely due to the fact that their accrediting body is sanctioned by CMS due to noncompliance with the administrative or paperwork requirements that CMS has outlined. The supplier has no control over the accrediting body's compliance in this area. It can only be responsible for its own performance in meeting the expectations of the accrediting body and CMS.

CMS needs to outline an appropriate transition period that would facilitate a supplier's ability to continue participating in the program. How does CMS propose to handle a situation where the accrediting body is sold to another group? Undergoes a merger? Goes bankrupt?

4. *Reconsideration*

The written reconsideration process described on page 128 appears to be reasonable. However, we are concerned that the accrediting organization would only be entitled to an "informal hearing conducted by a hearing officer appointed by the Administrator of CMS." The word "informal" is then used repeatedly throughout this section.

The hearing process needs to be formal and involve a more independent, objective mediator than one that is appointed by the CMS Administrator. It should allow testimony and other evidence to be accepted and admissible under the usual rules of court procedures. The process, as described, would afford all legal benefits to CMS and none to either the accrediting organization or the supplier. This one-sidedness represents unfair business practices.

Hundreds of thousands of Medicare beneficiaries' care could be disrupted by a negative outcome concerning the accrediting body, and we doubt that is CMS' intention by limiting the appeal process to such an informal process. A stair-step method of escalation is required for such an important aspect of the Medicare Part B program.

The current Joint Commission appeal process should be used as a model for escalating appeals in order to ensure a fair presentation of all of the facts involved in the situation. Its method is stair-step in nature and involves an objective review board composed of independent members when the appeal reaches a certain level.

R. Low Vision Aid Exclusion
(proposed section 414.15)
71 Fed. Reg. 25654, 25687.

Apria Healthcare has no comments on this section.

S. Establishing Payment Amounts for New DMEPOS Items (Gap-filling) (proposed section 414.210(g)) 71 Fed. Reg. 25654, 25687-89.

I. Gap-Filling Proposal

CMS proposes to modify its current gap-filling procedures and instead use far more subjective criteria in developing payment levels for new products and for new HCPCs. We agree that the current gap-filling practices should be revised – they are not well understood and often result in payment levels that are significantly lower than the payment levels found in the private sector.

CMS also states that "there is an inherent responsibility to pay enough for beneficial new technologies to ensure beneficiary access to care, while also being a prudent payor. To increase the Medicare program's ability to ensure fair treatment across technologies, we have focused on developing strategies that recognize those technologies that provide a demonstrated clinical benefit and clearly identify the additional benefits over existing technologies."

II. Medicare Part B Structure and Coding Process Has Not Kept Pace With Changing Technology

Frankly, our experience in recent years suggests that CMS does not follow the philosophy described immediately above. Numerous examples of advanced, more costly technology used to treat homecare patients have been approved by the FDA. Such technology has clear differential advantages over certain existing technology, offering demonstrated clinical benefits. Yet, CMS and the HCPCS coding panel have routinely denied the creation of new codes and different payment levels to recognize the higher research and development costs that the manufacturers pass along to suppliers in the form of acquisition prices. Examples include: The Pulmonetic® (now Viasys) portable ventilator, portable oxygen concentrators, portable liquid oxygen systems, ambulatory infusion pumps, ambulatory enteral pumps, transfilling oxygen concentrator systems, auto-titrating CPAP devices, non-traditional CPAP masks, low-profile enteral tubes and more.

In this section, CMS proposes to use three main areas to study new products. Our comment for each of the three is written in italics below:

1) **Functional assessment** – *Who were the healthcare providers interviewed? What was their background? Were they experienced in ordering the devices for use at home or solely in the hospital? What was the background of the people who evaluated device operations? No information about the contractor CMS hired was provided in the NPRM.*

2) **Price Comparison Analysis** – *What data source is used for cost? Medicare cannot solely look at the cost to acquire equipment. It must incorporate the total costs borne by suppliers to take care of patients who require that equipment. A recent industry study on oxygen, for example, shows that for every $1 providers spend on equipment, they spend $3 on support services and overhead. Did the group incorporate costs such as managing product recalls, complying with FDA and other government requirements, etc., in their cost analysis? No detail was provided in the NPRM.*

3) **Medical Benefit Assessment** – *Again, what was the background of the "health care providers" interviewed? Are they familiar with homecare or simply institutional or office-based care? We*

need to understand how CMS or its contractors defined "significantly improved clinical outcomes" before commenting further on the effectiveness of the Medical Benefit Assessment.

Using a technology assessment to adjust payment amounts would amount to CMS' circumvention of the requirements under section 1842b and the related regulations for implementation. Under the Inherent Reasonableness (IR) authority, Congress specifically included requirements for notice and comment so that valid and reliable data would be used. The goal was to protect the interest of beneficiaries and providers and prevent an access-to-care problem. The technology assessment that CMS has proposed appears to use a method that would look solely at the cost of acquiring a particular technology and not the total cost providers incur to take care of patients who require it.

III. Recommendation

If CMS proceeds with the use of a technology assessment to establish a payment amount or a new HCPCS code, we believe that an appropriate notice and comment period should proceed for all stakeholders to provide input into the process.

A. CMS Should Not Grant Itself Authority to Alter Gap-Filling in This Manner

We must strongly oppose the particular gap-filling modification proposed by CMS. CMS simply listed a number of general factors for determining gap-filling amounts, without any indication how they would be used. CMS is proposing to give itself what appears to be virtually unfettered authority to choose and apply payment criteria for any new product. Perhaps of greater concern is CMS' intention to apply this broad authority to new codes. It would appear that CMS could trigger this authority by simply modifying a HCPC for a product category, thus reorganizing and creating a new code. By doing so, CMS could set aside the existing fee schedule and substitute its own judgment as to what is a reasonable payment level based on the general factors listed in the proposed rule.

There is no reason to expect that the payment for new technologies under a competitive bidding proposal should be determined on the basis of bids for products that were specifically included in the competitive bidding proposal. In submitting a bid for existing products, a DMEPOS supplier knows what its costs are and can bid appropriately. Use of a gap-filing process to determine competitive bid reimbursement for new technologies is likely to establish prices for new technologies that do not cover the costs of the DMEPOS supplier in providing those new technologies. If new technologies are developed, it is more appropriate to not include the new technologies under the existing competitive bidding agreement, but rather to wait until the next bidding period to determine the competitive bidding level of reimbursement for the new technologies. Any attempt to impute a competitive bidding price for new technologies is likely to force DMEPOS suppliers to incur losses in supplying the new technologies.

B. CMS Already Has Authority to Modify Payment Amounts

Congress has provided CMS with the specific authority to modify payment amounts if CMS determines after a prescribed analysis that the payment levels are grossly excessive or grossly deficient. This so-called "inherent reasonableness" authority is set out at 42 CFR 405.502 and includes a number of procedural and substantive safeguards to ensure that CMS and its contractors do not act arbitrarily. None of those safeguards is present in the CMS proposal on gap-filling. The scope and limitations of CMS' inherent reasonableness authority will be meaningless if CMS can use its gap-filling authority to change payment levels for existing products merely by first changing the HCPC codes for those products.

Inherent reasonableness may only be used if payment levels are determined to be grossly excessive (or grossly deficient), which CMS has defined by regulation as being at least 15% more or less than a

reasonable level of payment. CMS must use valid and reliable data in its analysis and its calculation of new payment levels. Part B suppliers must have the opportunity to comment on the finding that payments are grossly excessive and on the new payment level determined by CMS or its carriers. In addition, if CMS seeks to make an adjustment that will have a significant effect on a substantial number of small suppliers, it must publish an analysis in the Federal Register pursuant to the Regulatory Flexibility Act.

Further, CMS has defined to some extent how it will interpret various factors in its application of inherent reasonableness. CMS and its carriers also must consider the effects on the Medicare program, including:

1) The effects on the Medicare program, including costs, savings, assignment rates, beneficiary liability, and quality of care;

2) What entities would be affected, such as classes of providers or suppliers and beneficiaries;

3) How significantly would these entities be affected; and

4) How would the adjustment affect beneficiary access to items or services.

In addition, the carriers must evaluate the comments received on the proposed notice. And, to ensure the use of valid and reliable data, CMS or the carrier must meet the following criteria to the extent applicable:

- Develop written guidelines for data collection and analysis.
- Ensure consistency in any survey to collect and analyze pricing data.
- Develop a consistent set of survey questions to use when requesting retail prices.
- Ensure that sampled prices fully represent the range of prices nationally.
- Consider the geographic distribution of Medicare beneficiaries.
- Consider relative prices in the various localities to ensure that an appropriate mix of areas with high, medium and low consumer prices was included.
- Consider criteria to define populous State, less populous State, urban area and rural area.
- Consider a consistent approach in selecting retail outlets within selected cities.
- Consider whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population.
- Consider the products generally used by beneficiaries and collect prices of these products.
- When using wholesale costs, consider the cost of the services necessary to furnish a product to beneficiaries.

C. Additional Factors Apply to Modify Payment Levels in a Given Year

Additional factors apply if CMS seeks to modify payment levels by more than 15% in a given year. Yet, none of these processes and criteria, which result directly from several statutes and recommendations of the Government Accountability Office, will have any applicability if CMS chooses to use its gap-filling authority instead of its inherent reasonableness authority to adjust payment rates. We do not believe CMS has the legal authority to modify payment levels for existing, covered products by manipulating the particular HCPCs for those products. Where Congress sought to provide CMS with the authority to modify payment levels, it did so in an explicit and structured manner. The proposed rule on this issue appears to be little more than a reach for additional authority to undertake actions that could be precluded under the inherent reasonableness authority or would be more time-consuming under that authority. Congress, by its actions on inherent reasonableness, effectively limited CMS to the scope of that authority.

D. Too Many Definitions Unknown in This Section

The entire gap-filling section of the NPRM is filled with terms that are not clearly identified. CMS must clarify them before moving ahead. Here is a list of terms that may be interpreted very differently by different readers:

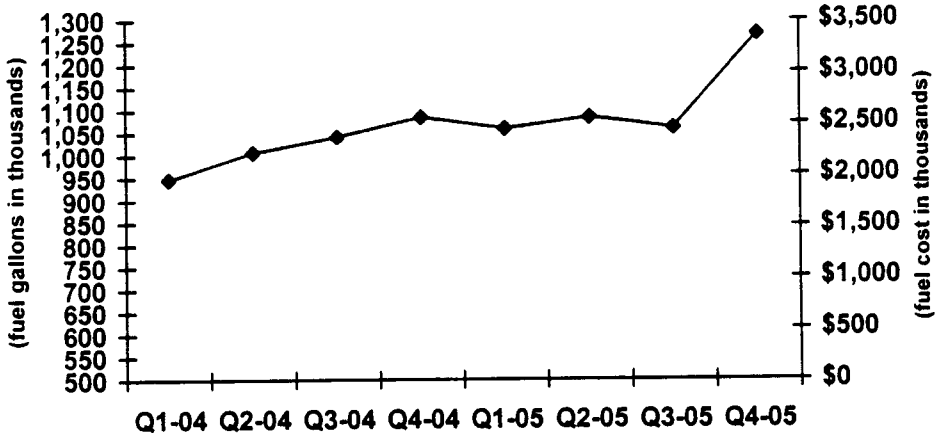
- Comparable item
- Prices in effect at the time that the fee schedule amounts are established
- Manufacturer pricing information
- Retail pricing
- Wholesale prices
- Appropriate mark-up
- Cost comparison analysis
- Middle of a bidding cycle
- New item
- Related or similar items

E. Renegotiation of Contract if Gap-Filling Results in Change of >2% in Single Payment Rate

If CMS moves ahead with this plan despite vocal opposition by the industry, suppliers must be offered certain protections that would ensure continuity of care for patients. While CMS appears to be studying acquisition costs of technology, the Rule is silent on how it plans to assess the non-equipment costs that providers incur in providing that technology to the patient.

In addition, CMS should adhere to a standard calendar for making changes to anything associated with the competitive bidding contract for the next calendar year. Providers may need to reprogram their information systems, train or retrain staff on anticipated changes, notify physicians or beneficiaries of the changes and implement other operational requirements. If CMS moves ahead, suppliers should be given notice of any contractual changes by October 1 of the year prior to a January implementation date.

To illustrate how non-product costs impact providers, below is a chart that shows how fuel costs at Apria escalated from 2004 to 2005, despite a significant improvement in overall productivity among our delivery personnel. Unless CMS accounts for providers' non-equipment costs, the system for assigning new codes and payment levels for each will continue to be flawed well into the future.


(fuel gallons in thousands)
1,300
1,250
1,200
1,150
1,100
1,050
1,000
950
900
850
800
750
700
650
600
550
500
$3,500
$3,000
$2,500
$2,000
$1,500
$1,000
$500
$0
(fuel cost in thousands)
Q1-04 Q2-04 Q3-04 Q4-04 Q1-05 Q2-05 Q3-05 Q4-05

T. Fee Schedules for Home Dialysis Supplies and Equipment (proposed section 414.107) 71 Fed. Reg. 25654, 25689.

Apria Healthcare has no comments on this section other than to observe that since these supplies are subject to a CPI-U, the products we provide should be eligible too, as the same inflationary cost factors impact our products as those supplied by home dialysis suppliers. We also find it interesting that CMS uses data for allowed services furnished in calendar year 2005 on which to base the CPI-U. This is certainly more reflective of dialysis suppliers' current costs than the archaic gap-filling methodology that CMS applies to DMEPOS products.

U. Fee Schedules for Therapeutic Shoes (proposed section 414.228 (c)) 71 Fed. Reg. 25654, 25689.

Apria Healthcare has no comments on this section.

V. COLLECTION OF INFORMATION REQUIREMENTS (COMMENTS ON PAPERWORK) 71 Fed. Reg. 25654, 25689-90.

ALSO COPY THIS SECTION TO:

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs,
Regulations Development and Issuances Group
Attn: William Parham
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

And

Office of Information and Regulatory Affairs
Office of Management and Budget
Room 10235, New Executive Office Building
Washington, DC 20503
Attn: Carolyn Lovett, CMS Desk Officer, carolyn_lovett@omb.eop.gov, Fax (202) 395-6974

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In this section, CMS solicits comments on each of four issues related to the information collection requirements associated with the competitive bidding program.

We will expound further on the regulatory impact of this program under Section V: Regulatory Impact Analysis, and submit a copy of those comments to the above-named CMS employees in addition to the comments on this particular section.

Our general comments on this section fall into five categories:

1) Due to the lack of specificity of the proposed rule, it is impossible for either Apria or CMS to accurately estimate the amount of incremental time required to complete the bid process and participate in the program. Only two demonstration projects were performed, and they did not include many of the requirements that CMS has proposed in the next round of implementation. This is true for both the application/bid review process as well as the quality and financial standards review, mandatory accreditation, etc.

2) Overall, competitive bidding is an administratively burdensome program for suppliers, CMS and its contractors. It represents an incremental administrative process that is layered on top of an already complex Medicare Part B system. The more manual processes, reports, documents, interviews and visits that CMS integrates into this program, the more administratively burdensome it will be for all parties.

3) In order to reduce both a paperwork and administrative burden, we have provided recommendations in other sections of this document that urge the agency to adopt existing

accreditation standards, existing patient satisfaction tools, existing patient complaint and resolution processes and existing financial reports rather than attempt to "recreate the wheel."

4) Competitive bidding will add costs to both suppliers and especially CMS, in the form of increased staff and reporting procedures.

5) The projected savings associated with competitive bidding are overstated and have not been adjusted to adequately reflect the savings that Medicare began realizing from another section of the MMA in 2004 and will realize from the DRA, beginning in 2007.

I. Section 414.412 Submission of Bids Under the Competitive Bidding Program

In this section CMS provides an estimate of 70 hours per bid on each supplier's part. CMS arrived at this number by using the median of the hours that suppliers estimated they required during the two less complicated demonstration projects. We assume this is per location, which for Apria could represent quite an arduous task. We are unclear as to whether this 70-hour estimate includes time spent attending bidders' conferences and preparing internal analyses or simply the amount of time needed to complete the application process.

However, if one includes the time spent reviewing, analyzing and responding to the NPRM, Apria has invested over 250 hours of executive and mid-level management time on this portion of the program alone. At the local branch level, if it indeed takes 70 hours to complete the application process, and Apria has an estimated 25 branches impacted by the first round of competitive bidding in 2007, our company would need to invest 1750 hours in preparing bids.

II. Competitive Bidding Layers on Over $4.1 Million to Provider Cost Structures in 2006-2007, Escalates to $178 Million in 2007-2008

In regard to the total number of hours that suppliers would invest in 2006 in regard to the 2007 round of bidding, CMS' own estimate on page 142 of the Rule is that 1,158,150 hours would be needed by the industry (16,545 bids). If a conservative, fully-loaded $35 per hour average salary rate is used, this amounts to an incremental $41 million attributable to the first 10 CBAs alone. In 2008, this escalates dramatically to an incremental 5,100,550 hours needed to prepare 72,865 bids, which in turn computes to $178.5 million in supplier labor!! These costs have to be accounted for in the bids suppliers submit to Medicare.

We agree that the cost associated with the requirements pertaining to the accreditation program should not formally be included as part of the cost or burden for the competitive bidding program. However, there are numerous other incremental costs that we have described in individual sections of this document.

III. Recommendation

The proposed application process and certain provisions described in the rule appear to be too paper-intensive. CMS could save a significant amount of paperwork for itself and suppliers (and thereby, time), if it adopted the following recommendations:

1) Automate the supplier application process by making it Web-based. Allow an attachment feature for the financial reports and other supplemental information specified.

2) Automate the accreditation organization application process by making it Web-based. Allow an attachment feature.

3) The bid review team should start reviewing those bids that meet the quality and financial standards first before proceeding on to review the bid prices. Any supplier's bid package that does not meet these two standards would be eliminated from further review. This will eliminate a significant amount of time and paper that CMS would have to review.

4) Any multi-site provider that is owned by the same corporate parent or tied to the same tax ID# should be allowed to provide certain standard information only one time. Examples include a financial summary filed with the Securities and Exchange Commission (SEC), JCAHO accreditation report for a specific geographic area, list and background of corporate officers, etc.

5) Adopt a standardized Medicare patient satisfaction questionnaire for DMEPOS, such as that developed by the independent firm Press-Ganey Associates, to assess patient satisfaction with DMEPOS suppliers.

6) Keep the beneficiary and supplier education simple and low-cost.

7) Eliminate the brand-specific requirement and associated paperwork that is described in section "O."

8) Rather than requiring a separate application for every competitively-bid product category in a given MSA, consolidate the application form itself into a check-box format where the supplier would check (a) the products it is bidding on, and (b) the MSA it is bidding on. See example below:

9) Rather than creating an all-new government infrastructure that essentially duplicates what exists in the private sector (including senior risk plan oversight and management), we recommend that CMS consider subcontracting with several large managed care organizations to administer this program for Medicare beneficiaries nationwide. This checkbox format is also how the National Supplier Clearinghouse (NSC) has customized Apria's application process in order to reduce administrative burdens for both parties.

SAMPLE APPLICATION FORM CONTENT

Please check the box(es) next to each product category on which you are bidding in this MSA.

☐ Oxygen and oxygen equipment
☐ CPAP and CPAP supplies
☐ Wheelchairs
☐ Walkers

Please check the MSA(s) on which you are bidding via this application.

☐ Miami
☐ San Juan, Puerto Rico
☐ Dallas
Etc.

Are you bidding on the same products in all of the MSAs you have checked above?

☐Yes ☐No EXPLAIN_____

10) After a supplier has successfully completed round one of competitive bidding, it should only have to provide an attestation statement regarding its compliance with quality standards, financial standards, etc. and report any major changes that would impact its ability to participate in round 2, such as a change in ownership or some other large event. It should not have to complete an all-new application simply to participate in the second round of bidding in the exact same MSA.

IV. RESPONSE TO COMMENTS

Apria Healthcare has complied with CMS' deadline for submitting these comments. If any reader has any questions, feel free to contact the Apria executives below:

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Investor Services & Corporate Compliance Officer
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SUMMARY

Competitive bidding for DMEPOS on a large-scale basis is a brand-new initiative for CMS. We believe that both the timeframe for implementation and the projected cost savings are overly aggressive and urge CMS to proceed with caution, using a phased-in approach to the program overall and certain elements contained therein. For example, the brand-specific requirement, as well as repair and maintenance of equipment that the contract supplier did not supply in the first place and other elements have never been studied or implemented before. These specific sections should be piloted in one MSA before expanding to the others in either 2007 or beyond.

Although two demonstration projects were performed, much has changed since the early part of this decade in terms of providers' total cost of caring for Medicare beneficiaries, policy changes implemented by CMS since the conclusion of the demonstrations and new legislation that has been passed since that time.

The negative impact caused by the MMA's reduced fee schedules for oxygen, nebulizers, wheelchairs, patient lifts, hospital beds and diabetic supplies, and the DRA of 2005, cannot be emphasized enough. The DRA in particular will have unintended, negative consequences on beneficiary access to care and new technology, which seem contrary to the goals publicly-stated by the Secretary. CMS has already harvested a significant amount of savings from the MMA's reduced fee schedule and more will accrue from the DRA. Therefore, the savings that remains to be gleaned from competitive bidding is not likely to be "significant" or "large" as the rule suggests. Too much remains unknown about how CMS plans to address the major gaps in service coverage that will be caused by the DRA's forced equipment ownership provisions. Fuel, labor, insurance, health benefits, licensure and other non-equipment costs have risen dramatically since the demonstration projects were implemented. These costs will have to be reflected in providers' bids for the program in 2007 and every subsequent bidding cycle.

Apria Healthcare has contracted with managed care organizations to provide a comprehensive array of DMEPOS products and services for over 20 years. If conducted correctly and in a truly competitive fashion, competitive bidding can indeed improve quality and consistency of service across a large patient population and geography, while delivering savings to the payor. We applaud CMS and Congress for adopting mandatory accreditation for DMEPOS suppliers, quality standards and other noble goals for the program. CMS' proposed plans for competitive bidding, however, do not reflect standard contracting procedures in this industry. This represents an unbelievable amount of work directed toward further reducing what amounts to less than 2% of the total Medicare budget.

We appreciate the opportunity to provide you with these comments and recommendations and welcome any additional questions you may have in the coming months as you review what will likely be a significant number of comments from individual stakeholders.

I look forward to seeing the Medicare DMEPOS Competitive Bidding Team at the next PAOC meeting and again want to reiterate that you and any member of the CMS team are invited to visit one of our branches in the greater Baltimore/Washington area or any part of the country.

Sincerely yours,

Lawrence M. Higby /T.C.S.
Lawrence M. Higby
Chief Executive Officer

Attachments (Electronically and by Mail)

Appendix A – Letter from AAHomecare to Mr. Herb Kuhn with questions about the Deficit Reduction Act
Appendix B – Master List of all CPAP Products, by Brand

Cc: Herb Kuhn, CMS (Executive Summary Only)
Leslie Norwalk, CMS (Executive Summary Only)

V. REGULATORY IMPACT ANALYSIS
71 Fed. Reg. 25690-96.

ALSO COPY THIS SECTION TO:

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs,
Regulations Development and Issuances Group
Attn: William Parham
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

And

Office of Information and Regulatory Affairs
Office of Management and Budget
Room 10235, New Executive Office Building
Washington, DC 20503
Attn: Carolyn Lovett, CMS Desk Officer, carolyn_lovett@omb.eop.gov, Fax (202) 395-6974

Dear Mr. Parham and Ms. Lovett:

Thank you for the opportunity to provide comments on the Regulatory Impact Analysis (RIA) associated with the Notice of Proposed Rule Making (NPRM) for the Medicare Part B DMEPOS Competitive Bidding Program. Apria Healthcare is the nation's largest provider of home respiratory services, medical equipment and home infusion, and our managed care contracting experience is extensive. We believe that experience provides us with expertise in the area of competitive bidding that is valuable as Medicare embarks on this program.

In addition, I am a member of the Professional Advisory Oversight Committee (PAOC) that was established by the Medicare Modernization Act of 2003 (MMA) in order to advise CMS on the implementation of the program. As such, I am very interested in providing you and your colleagues with concrete feedback, recommendations and suggestions for how this program should be implemented most efficiently and cost-effectively.

Under separate cover, we provided comprehensive comments on the entire NPRM and submitted them to the DMEPOS competitive bidding team as well as to Dr. McClellan. The purpose of this document is to provide our comments specifically as they relate to the RIA and the program's impact on numerous stakeholders.

We have organized our comments according to the order in which the applicable sections of the RIA were presented in the Proposed Rule. Due to the extensive nature of these comments, you may have questions about them as the bidding team reviews the document this summer. Feel free to contact the following Apria Healthcare employees who are leading our efforts on competitive bidding:

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A. Overall Impact

This section describes the intent of a Regulatory Impact Analysis (RIA) in terms of directing agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). It also references the fact that an RIA is required for any final rule that would have an annual effect on the economy of $100 million or more in any one year, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or communities.

CMS' own comments in this section indicate that until the product categories and markets are selected, potential savings, implementation costs, the number of affected suppliers and supplier bid costs all remain unknown. We again express our disappointment about the fact that after 18 months, CMS did not publish the product list or MSAs as part of the proposed rule.

COMMENTS

Timeline of Implementation Needs to be Refined and Published

The general timeline that CMS has set for competitive bidding is aggressive. When one considers the body of work that must be completed before even the first phase of the program begins (that of issuing the Request for Bids (RFBs)), one realizes that the timeline may be too aggressive. Consider that the following steps must be completed in the next few months alone:

- The final quality standards must be published, including product-specific ones that may be fraught with problems;
- The accreditation organizations must be selected and they must undergo the application and review process with CMS;
- CMS must finalize its plans for actually implementing the accreditation requirement of the program;

- The stabilization of the new DMEMACs such as National Heritage Insurance Company (NHIC) and Noridian Administrative Services, which as you may know, does not even take effect until October 2006. Neither one has ever processed DME claims.

- CMS must publish the interim final and final regulations;

- CMS must complete the proposed rule for the Deficit Reduction Act and project how it will interface with competitive bidding, and vice versa;

- The first 10 MSAs and product categories must be selected;

- The RFB package must be finalized and issued for the first 10 MSAs;

- CMS will need 72 FTEs to review the first round of bidding packages; and,

- A major beneficiary and supplier education process must ensue.

We Do Not Believe $100 Million in Savings Will Be Achieved in 2007/2008

The NPRM contained DMEPOS expenditures for 2003 and a list of the top MSAs' expenditures in that year. Since the data was for 2003, it did not reflect the reimbursement cuts (savings) that Medicare began realizing from the fee schedule reductions associated with the Federal Employee Health Benefits Program (FEHBP) in January 2005 for HME and April 2005 for oxygen. The oxygen reduction, for example, was over 10% and the reductions for individual HME line items ranged from 12% to 24%. Nebulizers, for example, were cut 18%.

Added to this, the Deficit Reduction Act will also deliver savings to the program. Apparently the Congressional Budget Office (CBO) scored the Act's provision at zero over five years, and we are unclear why, since oxygen savings begin to accrue in 2009. Meanwhile, the reimbursement structure for power wheelchairs and a few other product categories is undergoing a major change, which will result in savings to the program that cannot be attributed to competitive bidding.

Therefore, if one reviews the expenditures for the top 10 MSAs that will most likely be included in the 2007 round of bidding, the most likely product categories to be included and then accounts for the significant savings that have already been realized and applies a conservative rate of savings that might accrue from competitive bidding, the actual savings will not likely meet the defined goal of being "significant" or "large."

We urge the OMB and CMS actuaries to ensure that savings are not counted "twice." That is, savings which are generated from the DRA in 2007, 2008, 2009 and beyond should not be counted toward both the DRA and competitive bidding.

Negative Impact on Patients

We do believe that the competitive bidding program could have a negative impact on patient care, productivity, competition, jobs and public health, especially when it is viewed in conjunction with the Deficit Reduction Act's provisions related to oxygen and home medical equipment. While this document is likely requesting comment related solely to competitive bidding's impact on these areas, we have yet to see a proposed rule on how CMS plans to implement the DRA's requirements to force ownership of FDA-approved medical equipment on to patients who have not asked for such responsibility.

Patients will be impacted negatively in the following ways:

- Patient choice among providers in a community could be eliminated
- Patients who reach a rental cap and own their HME or oxygen equipment would have difficulty finding a provider to repair or service their equipment
- Due to the DRA, patients will not be able to access the non-equipment support services that are typically included in a monthly rental rate structure. They will own their equipment and therefore the fiduciary relationship between the supplier and the patient is severed.
- Patients will not be able to obtain new technology that might improve their condition once they own their medical equipment and oxygen equipment.
- Patients may have to obtain multiple DMEPOS products and services from multiple providers solely due to the convoluted bidding mechanism that has been proposed. This translates to multiple bills every month, multiple co-pays to be paid and more confusion.

CMS Already Has a Simpler Method Available to Reduce Fee Schedule Reductions

In addition, we believe that CMS has had the authority to effect fee schedule reductions in a much simpler, less paperwork-intensive and less administratively burdensome. It does not need to proceed with competitive bidding in order to achieve savings. This is an unbelievable amount of work directed toward less than 3% of the total Medicare budget. The Inherent Reasonableness (IR) authority already provides CMS with a much less costly method by which to study and reduce fee schedules and we therefore believe that the planned infrastructure for competitive bidding is essentially unnecessary. Although we generally disagreed with the MMA's provision to apply the median rate of FEHBP reimbursement levels to the very different Medicare program, such a process, if performed with an appropriate level of detailed research by an independent agency or research firm, could also provide CMS with a more simplified mechanism for adjusting payment levels.

It seems obvious that the Office of Management and Budget (OMB) and CMS' Office of Strategic Operations and Regulatory Affairs would want to see a side-by-side comparison of the cost/benefit analysis associated with Inherent Reasonableness versus competitive bidding. Has such a comparison been requested of CMS?

No Public Health and Safety Impact Analysis Yet Performed Re: DRA's Forced Equipment Ownership Provisions

Also, we have seen no public health and safety impact analysis associated with the DRA's forced equipment ownership provisions. Forced equipment ownership has never been piloted, studied or analyzed from any angle. No other payor in America has adopted such draconian measures as they relate to oxygen patients and those who require home medical equipment to remain at home instead of in an institution. We urge the Agency and the OMB to require that such a study be performed before proceeding with forced ownership, set to begin in February 2007 with certain HME items and then in 2009 for oxygen.

Flawed Assumption on DMEPOS Fee Schedule Inflation Rate Increases

CMS assumes that the Medicare DMEPOS fee schedule will increase at the rate of inflation for those years in which a statutory freeze has not been put in place by the MMA, and that total charges will increase at the same rate as Part A and Part B.

We do not agree with this assumption at all. The Medicare Part A increases are largely attributable to rate and utilization increases in inpatient hospitalization. Medicare Part B increases are almost exclusively attributable to physicians' rate increases and increased utilization of physicians' office services. Non-DME, non-home health nursing costs are the segments that are driving the huge increase in overall Medicare expenditures. Moreover, once CMS accounts for savings realized in 2004 and 2005, it will see that expenditures based on a base year of 2003 have resulted in flat to decreased spending in most of the key categories that are being considered for competitive bidding.

B. Anticipated Impacts

CMS Underestimates the Impact on Referral Agents

CMS indicates that although the workload of referral agents appeared to increase during implementation of the demonstration, it does not anticipate that competitive bidding will result in an appreciable, ongoing burden on referral agents.

We are unclear as to why CMS would draw this conclusion when the demonstration projects clearly showed that the burden on referral agents increased. Moreover, the Polk County MSA in particular is a relatively small market with clearly definable borders. Once competitive bidding takes place in larger markets, and if CMS proceeds with its plan to bid each product category individually, it will be very difficult for referral agents such as hospital discharge planners, physicians, physicians' office staff and case managers to keep the details of the program straight. For example, they may have to refer hospital beds to one of 20 suppliers, nebulizers to one of 15 different suppliers and oxygen to one of still 10 other suppliers. A patient who requires all three will pose an interesting challenge to the discharge planner who was used to calling one company to arrange for homecare services.

In addition, certain new provisions of competitive bidding that did not exist in the demonstration projects will also add to the administrative and cost burden of referral agents. The brand-specific product requirement that would require all-new paperwork from a physician's office rather than allowing the homecare provider to substitute another quality product of functional equivalence is one example. Another would be the confusion surrounding the philosophically-flawed rebate concept; referral agents could not possibly remember which suppliers offer the rebate, at what level and how to explain it to sick patients being discharged from the hospital.

In addition, CMS has suggested that it would selectively add zip codes, parishes and areas outside of the official MSA boundaries. Although we oppose such indiscriminate amendments to government-defined MSAs, if the plan were to proceed, it would result in massive confusion among referral agents who would be discharging patients.

We believe that OMB or another government agency, such as the Government Accountability Office (GAO) should perform a more concrete analysis of the increased burden on referral agents and assign a cost accordingly.

DMEPOS Suppliers to Be Impacted Most by Program

We agree with CMS' assertion that DMEPOS suppliers that provide at least one product category will be impacted most. However, CMS' data that suggests that approximately 90 percent of registered suppliers are considered small is flawed. Because this data was likely studied at the Medicare supplier number level and not at the tax ID # level, it implies that over 75% of Apria Healthcare's 500 locations meet the definition of a small business. The same would hold true for other large homecare providers, whether public or private.

Regardless of size, if an individual location were to lose its ability to participate in the Medicare program because of not winning a competitive bidding contract, that location would be impacted significantly. It would have to lay off employees, consider closing the facility in that community, consider selling to another provider, risk bankruptcy if Medicare is its primary source of revenue or make other difficult business decisions.

Therefore, we urge OMB to reassess the true impact on small businesses nationwide, since it appears that the number of businesses impacted may have been grossly, albeit inadvertently, overstated. OMB should utilize the tax ID # to determine the size of a given DMEPOS business.

Fixed Costs Required to Undergo the Bidding Process Also Are Relative to Size of Business

CMS asserts that the fixed costs required to undergo the bidding process may be a larger deterrent to small businesses than larger firms. Similar to accreditation survey fees and internal operating costs to prepare and maintain accreditation, we believe that the fixed costs associated with participating in competitive bidding are relative to the size of the business. Therefore, a $2 million provider with one location will spend substantially less money and time preparing for and participating in competitive bidding, while a $1 billion provider with multiple impacted locations will spend a higher amount that is still relative to the size of its business.

CMS' Own Estimates Suggest That by 2008, DMEPOS Suppliers Will Incur Direct Costs of $178 Million

The data that CMS provided in the sections related to paperwork requirements and the regulatory impact analysis regarding the amount of time it would take for the supplier industry to prepare bids for the 2008 round of bidding suggests that the total cost would be $178 million. This DOES exceed the $120 million per year that the Unfunded Mandates Reform Act (UMRA) addresses. CMS may believe that since suppliers can choose whether to submit a bid for the competitive bidding program and therefore collectively they may not cross the $120 million threshold of the UMRA, the reality is that the majority of small and medium suppliers of DMEPOS actually rely on Medicare revenues for a majority of their business. Even a few national providers rely heavily on Medicare, while Apria represents a more diversified payor base that includes managed care plans nationwide.

Accordingly, it is likely that few suppliers will sit on the sidelines and not participate in the program. Therefore, we urge the OMB to review the competitive bidding program's incremental and fixed costs placed on the industry in light of UMRA regulations.

CMS Offered No Detail on Resources Needed for Overseeing Program Operations

On p. 149 of the rule, CMS outlines the government contractors that would be impacted by the program. However, it offered only one cursory reference to a "...need to devote resources necessary for overseeing program operations."

This is very concerning to us because it is clear from the rule's provisions that CMS will need to incur a significant amount of expense attributable to program oversight. Examples of provisions that represent incremental costs to the program include:

- An estimated 72 full-time equivalents (FTEs) needed to review 16,500 bids in 2007 alone, escalating in 2008 when the number of impacted MSAs increases eightfold.

- The accreditation validation survey process – where CMS would employ a group of people to conduct redundant, random accreditation surveys that mirror what the professional accrediting organizations already know how to perform.

- Financial expertise/employees who have the right background to review bidding suppliers' adherence to the financial standards and who can make the right judgment call about financial performance

- Additional claims processors to handle the influx of questions, problems and issues associated with the brand-specific requirement

- CBICs layered on top of the DMERCs

- Additional Medicare ombudsmen to answer an increase in questions, complaints and problems associated with beneficiaries' confusion about the new program

- Resources to support beneficiary and supplier education, in the form of printed materials, direct mail and potentially other media

- Monitoring ongoing compliance with quality, financial and other standards throughout the life of the contract

- The additional staffing/auditors to ensure overall compliance with the contractual requirements of competitive bidding

None of these costs has been described by CMS to date, nor has CMS ever issued the costs associated with contracting with Research Triangle Institute (RTI), the Apt Group and other consultants; managing the Professional Advisory Oversight Committee (PAOC), and developing the operations framework, Request for Bids (RFBs) and administration of the CIBCs.

C. Implementation Costs

It is disappointing that CMS made no attempt to estimate bid solicitation and evaluation costs at this time. Using CMS' own data, we estimated that CMS will need 72 full-time equivalents (FTEs) to evaluate 16,500 bids in the 2007 bid cycle. At a conservative $50,000 per FTE (fully loaded, with fringe benefits included), this will cost CMS $3.6 million in incremental labor. The next round of bidding, in which 75,000 bids will be received, could cost CMS an incremental $16.2 million in labor.

Viewed in the context that competitive bidding may not generate $100 million in savings per year, that labor ratio, coupled with other operating costs of the program, will greatly erode the net savings that may be generated.

CMS also estimates the start-up costs to CMS and its contractors will include $1 million in immediate fixed costs for contractor startup and system changes for the initial phase. Again, we believe these costs are grossly understated and urge the OMB to require an update from CMS on the total costs of

implementing this program, an updated cost/benefit analysis and quarterly updates as program implementation continues.

CMS states that it will only incur bid solicitation and evaluation costs in the years in which competitive bidding is conducted. Even if one amortizes the almost $4 million in estimated bid costs for the first round and $16 for the next, that will cost between $1.3 and $5.5 million per year for CMS – numbers that do not correlate to the low estimates provided by CMS on page 149-150.

On page 150, CMS goes on to state that maintenance costs will include a "small staff to oversee the program," office costs for the staff, travel costs, three new Ombudsmen, education/outreach expenses, printed materials and overhead. CMS did not provide any detail on these costs and we respectfully ask that they be published in the final rule.

CMS believes that the time required to evaluate bids will be lower than in the demonstration, and ultimately depend on the number of suppliers that choose to submit bids. We believe that other factors will impact the amount of time needed, such as the number of counties served, the number of beneficiaries impacted, crossover into other states, etc.

Also, CMS plans to have the CBICs administer the bidding process. Since the CBICs have not yet been made public, we cannot comment on their individual experience in contracting for DMEPOS services. However, given their newness to the Medicare Part B program, it is likely that they will need to spend more time per bid than the reviewers did in the two demonstration, at least initially.

D. Program Savings

On page 151, CMS once again states that it "estimates large savings" from the competitive bidding program. Yet, it does not define "large" and it does not account for savings already "in the bank" due to the MMA and in the future due to the DRA. Quoting savings ranges from nine to 30% and an average of 20 percent is misguided since so many things have changed since the early part of the decade (Refer to comments found in the section entitled "Paperwork Requirements.") If the MMA had not contained the FEHBP fee schedule cuts and if the DRA had never been passed, such a starting point might be appropriate, even though meanwhile, providers' costs have risen as well. That is not the case – savings of well over 10% have already been realized and therefore the projected savings, especially netted against the same-sized fixed infrastructure needed for the program, will not be "large" despite CMS' assumption that they will still achieve the same net savings levels as though the FEHBP and other cuts had never taken place.

In addition, Medicare's own data, found in a table on page 151, shows that nebulizer drugs accounted for 22% of the total savings in the San Antonio demonstration market. As you may know, inhalation drugs were addressed through separate reimbursement cuts associated with the MMA and have experienced a reduction of well over 50% since 2004. They are also statutorily excluded from being included in competitive bidding, so again the potential savings associated with competitive bidding has been reduced.

CMS' chart on page 152 reinforces our assertion under an earlier section regarding the Unfunded Mandates Reform Act (UMRA) that this program must be reviewed in light of UMRA since it does not begin to achieve savings over that level until 2009.

"Spillover Effect" From Competitive Bidding Onto the Medicare Advantage Program

In its fiscal year presentation of savings data, CMS states that it expects lower prices for DME products in the fee-for-service (FFS) program will lead to lower prices in the Medicare Advantage market. It states that most managed care plan rates are linked to FFS expenditures

While historically this may have been true, in recent years, most managed care contracts have converted from a "Medicare-minus" pricing methodology to a fixed fee schedule methodology. This is due to the fact that private plans operate differently than Medicare in terms of guaranteed market share, different medical coverage policies (for example, private health plans cover a full range of home infusion therapy services, while Medicare does not) and because suppliers' costs increase for fuel, labor, etc., may fluctuate over time. We speak from extensive managed care contracting experience on this issue.

Frankly, we are shocked that CMS would attempt to credit savings in Medicare Advantage (Medicare Part C) toward the DMEPOS expenditures reimbursed by Medicare Part B. This is a new variable in the total cost/benefit analysis and we again urge OMB to evaluate the Part B competitive bidding infrastructure costs and potential savings in their own "silo." When the home infusion industry conducted an independent study that proved that significant savings would be realized under Medicare Part A if only the home infusion benefit were structured correctly under Medicare Part B, it was advised that the agency does not look at savings in that manner. They stated that our study merely showed an increase in Part B spending and that they could not claim savings from Part A.

E. Effect on Beneficiaries

In general we agree that if done correctly, beneficiaries should have access to suppliers and experience more consistent quality throughout any given market. However, CMS uses another term it doesn't define – "showed minimal adverse results" – and we need to know how it defines "adverse."

To reinforce another point made numerous times throughout this document, the Deficit Reduction Act changes the entire situation for patients, referral agents and providers. Until CMS addresses the DRA's impact on beneficiaries both on its own and as it ties into the competitive bidding program, it would be reckless to assume that beneficiaries will experience "minimal adverse results." Regardless, it is too broad to say that there will be "no negative impacts on beneficiary access..." A very personal relationship develops between a beneficiary and homecare provider over time. If the beneficiary's provider is not selected through the competitive bidding process and chooses not to grandfather, a very disruptive and stressful experience could ensue for the beneficiary. If the beneficiary has to obtain three different products from three different suppliers in the future, that will also cause confusion and increased paperwork for people who are frail and elderly.

The MMA's requirement concerning mandatory accreditation for DMEPOS suppliers by 2010 already provides a platform by which beneficiaries would receive increased or consistent quality services and products. CMS seems to be crediting the competitive bidding program with that goal when in fact it is already covered in a separate provision of the MMA.

Regarding beneficiary co-insurance savings, we again ask the OMB to calculate the savings that will already result from the changes in capped rental payments as mandated by the DRA. On page 154, CMS shows beneficiary co-insurance savings levels that are likely overstated since the DRA will already capture a certain amount. An updated table is needed.

F. Effect on Suppliers

CMS lists three primary impacts of the competitive bidding program on suppliers. In addition to the three, we add the following:

- Contract suppliers may incur additional labor and other operating costs associated with meeting product-specific quality standards. Since they are not yet published, we can only assume that they will result in higher costs.

- Contract suppliers will incur costs to transition patients and ramp up capacity via new capital expenditures, facility expansions, additional staff and overhead.

- Accreditation fees and preparatory costs will be incremental for non-accredited suppliers.

- An increase in referral agent frustration with the new administrative burden could have a spillover effect on suppliers who also care for non-Medicare patients.

CMS confirms that "because [it does] not know [whether suppliers will increase or decrease volume], the net effect on an individual contract supplier's revenue is uncertain prior to bidding.

This is a primary reason why we believe that the GAO, MedPAC or another independent agency should conduct a thorough review of the 2007 competitive bidding program before proceeding in 2009. Two demonstration markets in two relatively uncomplicated areas of the country do not provide either the agency or the industry with enough information to predict what will happen to suppliers once the program is scaled up substantially. We believe that the 2007 program should be thoroughly analyzed in terms of its impact on all stakeholders and the savings actually, not theoretically delivered, before proceeding with the additional 80 markets.

1. Affected Suppliers

In this section, CMS estimates that 50 percent of bidding supplier will be selected as winners. It states that there will be 8272 contract suppliers in the CBAs that CMS initially designates. It also assumes that if a supplier submitted a bid in multiple product categories, its probability of winning would increase.

We are concerned about a few of these assumptions. First, the business has changed dramatically since the demonstration projects were conducted. The cost of fuel, labor, insurance, certain new technology has risen, while HME and oxygen have been subjected to a CPI-U freeze for most of the years.

Medicare has changed its coverage policies for several key product categories that may be included in competitive bidding, such as mobility assistive equipment (MAEs) such as walkers, canes and wheelchairs; respiratory assist devices (RADs) and CPAPs. MAEs in particular represent extensive policy and documentation changes that took effect in 2005. In addition, the MMA and DRA both affected suppliers outside of the competitive bidding provisions, as in the case of inhalation drugs, the reimbursement structure for which has undergone a massive transformation in the past three years.

In addition, numerous suppliers are no longer in business. At Apria alone, we acquired over 40 small or medium providers in 2004 and 2005.

This is the first reference that CMS makes to selecting 50 percent of the suppliers that bid. Yet, in another section of the rule, CMS states that it must select two or more suppliers and purposefully stated that it would not select a predetermined number of suppliers but rather, capacity would be the key. Using

CMS' 8272 number, that translates to 827 contracted suppliers per each of the 10 initial MSAs. The 44,705 contract suppliers projected for 2008, based on 70 additional MSAs, translates to a net of 36,400 suppliers per 80 markets, or 455 contracted suppliers per market.

We simply do not understand why CMS would contract with that many suppliers in a given MSA if it is expecting to achieve any level of savings. Perhaps we misunderstood how this number was derived; if, for example, the 8272 counts the same supplier multiple times if it bids on multiple products, that may account for it.

Obviously, more clarification is needed.

CMS uses Bureau of Labor Statistics (BLS) data to estimate the average hourly wage for an accountant and auditor. Given the importance of competitive bidding to a supplier's overall livelihood, it is likely that a higher-salaried employee or team of employees will be responsible for preparing the company's bids. Our earlier estimate used $35 per hour is on the conservatively low end, and that translates to provider costs of $41 million in the first year and $178 million in the next round.

The number of suppliers per CBA is really not as relevant as the size of those suppliers. In recent years, a significant number of acquisitions took place in the DMEPOS market. We estimate that by buying 40 companies in a two-year period of time, over 300 Medicare supplier numbers were eliminated by consolidating those sites into our own. Other major acquirers of the past few years include Lincare, OmniCare and certain integrated healthcare systems.

2. Small Suppliers

Again we urge both CMS and the SBA to re-review their definition of a "small supplier." Because CMS must have used supplier number data rather than tax ID number data, Apria actually owns and operates over 400 "small supplier" locations that generate less than $6 million per year. The same would hold true for all of the major public companies which collectively only account for about 40% of the total DMEPOS market in the United States (all payors).

The team needs to derive a method for looking at supplier size by tax ID # and also must realize that many suppliers may be much larger in size and capacity if they serve non-Medicare patients whose revenue does not appear on any Medicare report.

We find Medicare's equation involving the cost of bidding expressed as a share of Medicare revenue to be odd and irrelevant.

Regarding how CMS considered minimizing the burden of competitive bidding on small businesses, we have already expressed our comments about networking. We want to reinforce that any network should be formally organized in a legal manner, that the network's members must meet all applicable Medicare supplier standards, be accredited, meet the quality standards and those related to financial performance and compliance. The latter topic may be more important in a network scenario than the quality standards, since a network of providers who all operate individually could lend itself to inconsistent sales practices, inducements or kickbacks.

We agree that CMS should not exempt small suppliers from the requirement that a contract supplier must service an entire CBA. Doing so could lend itself to the "cherry-picking" phenomenon described in an earlier section and cause confusion among referral agents and patients.

We agree that CMS should not allow a small supplier to submit a bid and then decide after the bidding whether or not they would accept the new competitive bidding single payment amounts. This would represent a significant "workaround" to the standardized bid submission and review process. Managed care would never allow such an exception, and we appreciate that Medicare recognizes this too.

G. Accounting Statement

In the final section of the Regulatory Impact Analysis, CMS presents a table in which it provides an "Accounting Statement – Classification of Estimated Expenditures, from FY 2007 to FY 2011." Since there was little explanation surrounding this table, we offer the following questions and comments:

1) Does the $570.3 million in savings double-count savings already effected by the MMA/FEHBP and the DRA? If yes, the savings are overstated.

2) Using $570.3 million over five years, that translates to $114 million per year.

3) Does the $570.3 million include earlier-referenced "spillover" savings attributed to the Medicare Advantage program? If yes, this is overstated.

4) CMS will incur well over $10 million per year to implement the program, and suppliers, by 2007, will expend $178 million simply preparing bids, excluding other program-related costs.

5) How does the $570.3 million compare to the original CBO score that was used as a basis for including the provision in the MMA?

6) Has CMS accounted for any delay in the implementation schedule in these numbers?

Summary

We appreciate the effort that CMS made in estimating the regulatory impact and cost/benefits associated with competitive bidding. Given the concurrent reimbursement cuts that have occurred in the past few years, we understand that it is challenging to develop certain estimates that reflect future savings and costs directly attributable to this program.

However, given the length of time that CMS staff has had to develop the proposed rule and all of its various provisions, we are disappointed in the lack of detail in the Regulatory Impact Analysis. As a large supplier that has already invested a significant amount of management and executive time in reviewing the NPRM and preparing comprehensive comments, we believe that CMS has:

1) Underestimated suppliers' total costs of participating in competitive bidding

2) Underestimated CMS' start-up costs for the program

3) Underestimated CMS' ongoing program maintenance, monitoring costs and those associated with the CBICs, DMERCs, new Ombudsmen, etc.

4) Overestimated the number of small suppliers by counting large companies' individual locations that generate less than $3 million per year in Medicare revenues

5) Overestimated the number of suppliers that will be contracted in each area

6) Not accounted for numerous Medicare policy changes that will further erode the savings originally estimated for this program

7) Not accounted for the large increase in providers' costs for fuel, labor, insurance and other expenses since the demonstration projects were conducted

8) Not accounted for a much more complex program than what was implemented in San Antonio and Polk County, and, ultimately,

9) Overestimated the total savings that will result from the program

We appreciate the opportunity to provide these comments on the Paperwork Requirements and the Regulatory Impact Analysis directly to the Office of Management and Budget and the Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group of CMS.

If you have any questions, please contact one of the Apria representatives listed in the opening section of these comments.

Sincerely,

Lawrence M. Higby

Lawrence M. Higby
Chief Executive Officer
Apria Healthcare

Appendix A

Letter from the American Association for Homecare (AAHomecare) to Herb Kuhn, CMS on April 20, 2006, regarding implementation questions associated with the Deficit Reduction Act of 2005 (DRA)

(See PDF File)

Appendix B

Master List of Continuous Positive Airway Pressure (CPAP) Medical Devices and Masks Associated with Treating Obstructive Sleep Apnea (OSA)

EXAMPLE OF FLAWS WITH BRAND-SPECIFIC REQUIREMENTS OF PROPOSED RULE

Note how many unique manufacturers' products are linked to the single HCPCS code EO601

Ops Class	HCPC	Category	Vendor Name	Model No	Product Description
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC231JHU	CPAP UNIT HC231 CONVERTIBLE
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC232JHU	CPAP UNIT HC232 CONVERTIBLE
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC233JHU	CPAP UNIT HC233JHU W/HEATED HUMIDIFIER
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC234JHU	CPAP UNIT HC234JHU W/HEATED HUMIDIFIER
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	9000D	CPAP UNIT NASAL SYSTEM HORIZON
248	E0601	CPAP UNIT	RESPIRONICS INC	1017453	CPAP UNIT REMSTAR AUTO W/CFLEX
248	E0601	CPAP UNIT	RESPIRONICS INC	1005960	CPAP UNIT REMSTAR PLUS
248	E0601	CPAP UNIT	RESPIRONICS INC	1009586	CPAP UNIT REMSTAR PLUS W/C FLEX
248	E0601	CPAP UNIT	RESPIRONICS INC	1012668	CPAP UNIT REMSTAR PLUS W/HTD HUMIDIFIER
248	E0601	CPAP UNIT	RESPIRONICS INC	1020923	CPAP UNIT REMSTAR PRO II W/C-FLEX
248	E0601	CPAP UNIT	RESMED INC	14307	CPAP UNIT
248	E0601	CPAP UNIT	RESMED INC	20000102	CPAP UNIT
248	E0601	CPAP UNIT	RESMED INC	90000103	CPAP UNIT
248	E0601	CPAP UNIT	RESMED INC	14314	CPAP UNIT SULLIVAN III W/ SMART START
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	9001D	CPAP UNIT 9001
248	E0601	CPAP UNIT	RESMED INC	14009	CPAP UNIT APD 2 FLOW GENERATOR
248	E0601	CPAP UNIT	RESPIRONICS INC	532034	CPAP UNIT ARIA
248	E0601	CPAP UNIT	RESPIRONICS INC	622094	CPAP UNIT ARIA LX
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	Y-GK418ANA	CPAP UNIT AUTO GOODNIGHT 418A
248	E0601	CPAP UNIT	RESMED INC	30001	CPAP UNIT AUTO SET SPIRIT
248	E0601	CPAP UNIT	RESMED INC	30034	CPAP UNIT AUTOSET RESPOND
248	E0601	CPAP UNIT	RESPIRONICS INC	30245	CPAP UNIT CLINICAL
248	E0601	CPAP UNIT	VIASYS	9258	CPAP UNIT CLINICAL NIGHTBIRD
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC200-JHU-KL	CPAP UNIT COMB HEAT HUMIDIFIER W/CASE
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	126826	CPAP UNIT COMPANION 314
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	126828	CPAP UNIT COMPANION 314 W/METER
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	126804	CPAP UNIT COMPANION 318
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	126800	CPAP UNIT COMPANION 318 W/ CASE
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	418	CPAP UNIT COMPANION 418
248	E0601	CPAP UNIT	RESPIRONICS INC	40001	CPAP UNIT CPAP-200 120V
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	9054D	CPAP UNIT DEVILBISS AUTO ADJUST
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	Y-GK418S-NA	CPAP UNIT GOOD KNIGHT S RECORD
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	S-126831-00	CPAP UNIT GOODKNIGHT 318
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	S-126844-00	CPAP UNIT GOODKNIGHT 418
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	418G	CPAP UNIT GOODKNIGHT 418G W/COMPL MNTR
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	Y-GK420ENA	CPAP UNIT GOODKNIGHT 420E
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	Y-GK420GUS	CPAP UNIT GOODKNIGHT 420G
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	Y-GK420S-NA	CPAP UNIT GOODKNIGHT 420S
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	Y-420EH20	CPAP UNIT GOODKNIGHT F/HEATED HUMIDIFIER
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	126831-01	CPAP UNIT GOODNIGHT 318 PLUS
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	126831-00	CPAP UNIT GOODNIGHT 318 PLUS W/METER
248	E0601	CPAP UNIT	NELLCOR PURITAN BENNETT	Y-GK418PNA	CPAP UNIT GOODNIGHT 418P
248	E0601	CPAP UNIT	MALLINCKRODT INC	Y-GK420GUS	CPAP UNIT GOODNIGHT 420
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC201JHU	CPAP UNIT HC201 W/HEATED HUMIDIFIER
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC211JHU	CPAP UNIT HC211 CONVERTIBLE
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC220JHU	CPAP UNIT HC220 W/HEATED HUMIDIFIER
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC221JHU	CPAP UNIT HC221 W/HEATED HUMIDIFIER
248	E0601	CPAP UNIT	RESPIRONICS INC	7001	CPAP UNIT HOME SYSTEM
248	E0601	CPAP UNIT	RESPIRONICS INC	7000	CPAP UNIT HOME SYSTEM
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	7353D	CPAP UNIT HORIZON
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	7354D	CPAP UNIT HORIZON AUTO ADJ
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	8054B	CPAP UNIT HORIZON AUTO ADJUST
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC200	CPAP UNIT NASAL
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	7352D	CPAP UNIT NASAL
248	E0601	CPAP UNIT	MOUNTAIN MEDICAL EQUIP	411-001-801	CPAP UNIT NASAL
248	E0601	CPAP UNIT	RESPIRONICS INC	307400	CPAP UNIT NASAL
248	E0601	CPAP UNIT	RESMED INC	14105	CPAP UNIT NASAL APD2S
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	8000-RD	CPAP UNIT NASAL SYSTEM HORIZON
248	E0601	CPAP UNIT	RESPIRONICS INC	7100-10	CPAP UNIT NASAL W/O CASE
248	E0601	CPAP UNIT	RESMED INC	14006	CPAP UNIT NASAL W/O MASK
248	E0601	CPAP UNIT	VIASYS	9460	CPAP UNIT NIGHT BIRD
248	E0601	CPAP UNIT	INVACARE CORPORATION	ISP9800	CPAP UNIT POLARIS
248	E0601	CPAP UNIT	RESPIRONICS INC	367580	CPAP UNIT RELIANCE CHOICE

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248	E0601	CPAP UNIT	EVO MEDICAL SOLUTIONS	C2002	CPAP UNIT REMREST W/CORD
248	E0601	CPAP UNIT	RESPIRONICS INC	367100	CPAP UNIT REMSTAR
248	E0601	CPAP UNIT	RESPIRONICS INC	1018547	CPAP UNIT REMSTAR
248	E0601	CPAP UNIT	RESPIRONICS INC	1007381	CPAP UNIT REMSTAR AUTO
248	E0601	CPAP UNIT	RESPIRONICS INC	367500	CPAP UNIT REMSTAR CHOICE
248	E0601	CPAP UNIT	RESPIRONICS INC	367575	CPAP UNIT REMSTAR CHOICE EXPRESS
248	E0601	CPAP UNIT	RESPIRONICS INC	367550	CPAP UNIT REMSTAR CHOICE LS
248	E0601	CPAP UNIT	RESPIRONICS INC	367200	CPAP UNIT REMSTAR CSA APPROVED
248	E0601	CPAP UNIT	RESPIRONICS INC	1012657	CPAP UNIT REMSTAR LITE W/CARRYING CASE
248	E0601	CPAP UNIT	RESPIRONICS INC	1000920	CPAP UNIT REMSTAR LX
248	E0601	CPAP UNIT	RESPIRONICS INC	DS100	CPAP UNIT REMSTAR M SERIES
248	E0601	CPAP UNIT	RESPIRONICS INC	DS100H	CPAP UNIT REMSTAR M SERIES W/HH
248	E0601	CPAP UNIT	RESPIRONICS INC	DS200S	CPAP UNIT REMSTAR PLUS C-FLEX W/CARD
248	E0601	CPAP UNIT	RESPIRONICS INC	DS200	CPAP UNIT REMSTAR PLUS C-FLEX W/O CARD
248	E0601	CPAP UNIT	RESPIRONICS INC	1000921	CPAP UNIT REMSTAR PLUS LX
248	E0601	CPAP UNIT	RESPIRONICS INC	1005961	CPAP UNIT REMSTAR PRO W/C-FLEX
248	E0601	CPAP UNIT	RESMED INC	21104	CPAP UNIT RESMED S6 ELITE
248	E0601	CPAP UNIT	RESMED INC	21102	CPAP UNIT RESMED S6 LTWT
248	E0601	CPAP UNIT	RESMED INC	21101	CPAP UNIT RESMED S6 LTWT W/HOUR METER
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	7351D	CPAP UNIT REVITALIZER
248	E0601	CPAP UNIT	RESMED INC	21127	CPAP UNIT S6 LTWT II W/HOUR METER
248	E0601	CPAP UNIT	RESMED INC	30002	CPAP UNIT S7 ELITE
248	E0601	CPAP UNIT	RESMED INC	30011	CPAP UNIT S7 LTWT W/HR MTR& ALTITUDE ADJ
248	E0601	CPAP UNIT	RESMED INC	33112	CPAP UNIT S8 AUTOSET VANTAGE F/APAP
248	E0601	CPAP UNIT	RESMED INC	33021	CPAP UNIT S8 ELITE
248	E0601	CPAP UNIT	RESMED INC	33007	CPAP UNIT S8 ESCAPE
248	E0601	CPAP UNIT	RESPIRONICS INC	307600	CPAP UNIT SLEEPEZE III
248	E0601	CPAP UNIT	RESPIRONICS INC	622206	CPAP UNIT SOLO LX
248	E0601	CPAP UNIT	RESPIRONICS INC	622207	CPAP UNIT SOLO LX W/METER
248	E0601	CPAP UNIT	RESPIRONICS INC	622209	CPAP UNIT SOLO PLUS LX
248	E0601	CPAP UNIT	RESPIRONICS INC	622043	CPAP UNIT SOLO PLUS W/TIMEMETER
248	E0601	CPAP UNIT	RESPIRONICS INC	622002	CPAP UNIT SOLO W/ACSRY KIT/MASK
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC210JHU	CPAP UNIT STD W/HOUR METER & 6' HOSE
248	E0601	CPAP UNIT	RESMED INC	17102	CPAP UNIT SULLIVAN AUTOSET T
248	E0601	CPAP UNIT	RESMED INC	14316	CPAP UNIT SULLIVAN IIID
248	E0601	CPAP UNIT	RESMED INC	21001	CPAP UNIT SULLIVAN V
248	E0601	CPAP UNIT	RESMED INC	21009	CPAP UNIT SULLIVAN V ELITE
248	E0601	CPAP UNIT	RESMED INC	21042	CPAP UNIT SULLIVAN V HM
248	E0601	CPAP UNIT	RESMED INC	21005	CPAP UNIT SULLIVAN V PLUS
248	E0601	CPAP UNIT	FISHER & PAYKEL HEALTHCARE INC	HC604JHU	CPAP UNIT THERMOSTART W/HEATED HUMIDIFIE
248	E0601	CPAP UNIT	RESPIRONICS INC	7410	CPAP UNIT TRANQUILITY AUTO
248	E0601	CPAP UNIT	RESPIRONICS INC	7200-10	CPAP UNIT TRANQUILITY MP-R
248	E0601	CPAP UNIT	RESPIRONICS INC	7100	CPAP UNIT TRANQUILITY PLUS
248	E0601	CPAP UNIT	RESPIRONICS INC	7400	CPAP UNIT TRANQUILITY PLUS
248	E0601	CPAP UNIT	RESPIRONICS INC	7100MH	CPAP UNIT TRANQUILITY PLUS W/MASK/HEADGR
248	E0601	CPAP UNIT	RESPIRONICS INC	7300HE	CPAP UNIT TRANQUILITY QUEST
248	E0601	CPAP UNIT	RESPIRONICS INC	7300	CPAP UNIT TRANQUILITY QUEST
248	E0601	CPAP UNIT	RESPIRONICS INC	7300HMH	CPAP UNIT TRANQUILITY QUEST CMPLT W/MTR
248	E0601	CPAP UNIT	RESPIRONICS INC	7300MH	CPAP UNIT TRANQUILITY QUEST COMPLETE
248	E0601	CPAP UNIT	RESPIRONICS INC	7300H	CPAP UNIT TRANQUILITY QUEST W/HOUR METER
248	E0601	CPAP UNIT	RESPIRONICS INC	7300E	CPAP UNIT TRANQUILITY QUEST W/HVY TUBING
248	E0601	CPAP UNIT	RESPIRONICS INC	7300HL	CPAP UNIT TRANQUILITY QUEST W/METER
248	E0601	CPAP UNIT	RESPIRONICS INC	7300L	CPAP UNIT TRANQUILITY QUEST W/O CASE
248	E0601	CPAP UNIT	RESPIRONICS INC	7202-20	CPAP UNIT TRANQUILITY W/ 10" HOSE/METER
248	E0601	CPAP UNIT	RESPIRONICS INC	622093	CPAP UNIT VIRTUOSO LX
248	E0601	CPAP UNIT	RESPIRONICS INC	532326	CPAP UNIT VIRTUOSO T SMART
248	E0601	CPAP UNIT	SUNRISE MEDICAL HHG INC	9001D-HH	CPAP UNIT W/HEATED HUMIDIFIER
249	E0601	CPAP UNIT	REDLINE HEALTHCARE	AC1005960	CPAP UNIT REMSTAR PLUS CIGNA ONLY
252	A7030	FULL FACE MASK	RESPIRONICS INC	302433	CPAP KIT FULL FACE
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	HC431A	CPAP KIT FULL FACE FLEXFIT HC431
252	A7030	FULL FACE MASK	FISHER & PAYKEL HEALTHCARE INC	HC431A	CPAP KIT FULL FACE FLEXFIT HC431
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	302433	CPAP KIT FULL FACE RES
252	A7030	FULL FACE MASK	RESMED INC	16670	CPAP KIT MIRAGE FULLFACE LG SHLW SER II
252	A7030	FULL FACE MASK	RESMED INC	16666	CPAP KIT MIRAGE FULLFACE SM SHLW SER II
252	A7030	FULL FACE MASK	RESMED INC	60604	CPAP KIT ULTRA MIRAGE FULL LG STD
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	60604	CPAP KIT ULTRA MIRAGE FULL LG STD RMD
252	A7030	FULL FACE MASK	RESMED INC	60603	CPAP KIT ULTRA MIRAGE FULL MED SHLW
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	60603	CPAP KIT ULTRA MIRAGE FULL MED SHLW RMD
252	A7030	FULL FACE MASK	RESMED INC	60602	CPAP KIT ULTRA MIRAGE FULL MED STD
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	60602	CPAP KIT ULTRA MIRAGE FULL MED STD RMD
252	A7030	FULL FACE MASK	RESMED INC	60600	CPAP KIT ULTRA MIRAGE FULL SM STD
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	60600	CPAP KIT ULTRA MIRAGE FULL SM STD RMD
252	A7030	FULL FACE MASK	RESPIRONICS INC	1010870	CPAP MASK COMFORT FULL FACE LG
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	1010870	CPAP MASK COMFORT FULL FACE LG RES
252	A7030	FULL FACE MASK	RESPIRONICS INC	1010869	CPAP MASK COMFORT FULL FACE MED
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	1010869	CPAP MASK COMFORT FULL FACE MED RES
252	A7030	FULL FACE MASK	RESPIRONICS INC	1010868	CPAP MASK COMFORT FULL FACE SM
252	A7030	FULL FACE MASK	RESPIRONICS INC	452036	CPAP MASK FULL FACE DISP MED

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252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452036	CPAP MASK FULL FACE DISP MED RES
252	A7030	FULL FACE MASK	RESPIRONICS INC	452034	CPAP MASK FULL FACE DISP SM
252	A7030	FULL FACE MASK	RESPIRONICS INC	452038	CPAP MASK FULL FACE LG DISP
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452038	CPAP MASK FULL FACE LG DISP RES
252	A7030	FULL FACE MASK	RESPIRONICS INC	452037	CPAP MASK FULL FACE LG REUSE
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452037	CPAP MASK FULL FACE LG REUSE
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452035	CPAP MASK FULL FACE MED REUSE
252	A7030	FULL FACE MASK	RESPIRONICS INC	452035	CPAP MASK FULL FACE MED REUSE
252	A7030	FULL FACE MASK	RESPIRONICS INC	452032	CPAP MASK FULL FACE PETITE DISP
252	A7030	FULL FACE MASK	RESPIRONICS INC	452031	CPAP MASK FULL FACE PETITE REUSE
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452033	CPAP MASK FULL FACE SM REUSE
252	A7030	FULL FACE MASK	RESPIRONICS INC	452033	CPAP MASK FULL FACE SM REUSE
252	A7030	FULL FACE MASK	RESMED INC	16630	CPAP KIT MIRAGE FULL FACE LG
252	A7030	FULL FACE MASK	RESMED INC	16669	CPAP KIT MIRAGE FULL FACE LG
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16669	CPAP KIT MIRAGE FULL FACE LG
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16669	CPAP KIT MIRAGE FULL FACE LG II RES
252	A7030	FULL FACE MASK	RESMED INC	16629	CPAP KIT MIRAGE FULL FACE MED NO REORDER
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16629	CPAP KIT MIRAGE FULL FACE MED NO REORDER
252	A7030	FULL FACE MASK	RESMED INC	16668	CPAP KIT MIRAGE FULL FACE MED SHLW SERII
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16668	CPAP KIT MIRAGE FULL FACE MED SHLW SERII
252	A7030	FULL FACE MASK	RESMED INC	16628	CPAP KIT MIRAGE FULL FACE SM
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16628	CPAP KIT MIRAGE FULL FACE SM
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16665	CPAP KIT MIRAGE FULL FACE SM SER II RES
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16665	CPAP KIT MIRAGE FULL FACE SM SER II RES
252	A7030	FULL FACE MASK	RESMED INC	16667	CPAP KIT MIRAGE FULL FACE STD MED SER II
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16667	CPAP KIT MIRAGE FULL FACE STD MED SER II
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16667	CPAP KIT MIRAGE FULL FACE STD MED SER II
252	A7030	FULL FACE MASK	RESMED INC	16665	CPAP KIT MIRAGE FULL FACE STD SM SER II
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16670	CPAP KIT MIRAGE FULLFACE LG SHLW SER II
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	16666	CPAP KIT MIRAGE FULLFACE SM SHLW SER II
252	A7030	FULL FACE MASK	RESMED INC	60605	CPAP KIT ULTRA MIRAGE FULL LG SHLW
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	60605	CPAP KIT ULTRA MIRAGE FULL LG SHLW RMD
252	A7030	FULL FACE MASK	RESMED INC	60601	CPAP KIT ULTRA MIRAGE FULL SM SHLW
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	60601	CPAP KIT ULTRA MIRAGE FULL SM SHLW RMD
252	A7030	FULL FACE MASK	SUNRISE MEDICAL HHG INC	113237	CPAP MASK FULL FACE LG
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452037	CPAP MASK FULL FACE LG REUSE
252	A7030	FULL FACE MASK	SUNRISE MEDICAL HHG INC	113238	CPAP MASK FULL FACE MED
252	A7030	FULL FACE MASK	HANS RUDOLPH INC	113304	CPAP MASK FULL FACE PETITE F/7600
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452035	CPAP MASK FULL FACE REUSE MED
252	A7030	FULL FACE MASK	CARDINAL HEALTH	16707	CPAP MASK FULL FACE SM
252	A7030	FULL FACE MASK	REDLINE HEALTHCARE	452033	CPAP MASK FULL FACE SM REUSE
252	A7030	FULL FACE MASK	RESPIRONICS INC	1012572	CPAP/BIPAP MASK PERFORMANCE FULL LG DISP
252	A7030	FULL FACE MASK	RESPIRONICS INC	1012624	CPAP/BIPAP MASK PERFORMANCE FULL MED DIS
252	A7030	FULL FACE MASK	RESMED INC	M02B014	MASK BUBBLE KIT
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1030493	CPAP KIT COMFORT LITE 2 W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1030495	CPAP KIT COMFORT LITE 2 W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1007931	CPAP KIT COMFORT SELECT SM WIDE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1025112	CPAP KIT COMFORTLITE 2 COMBO
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1030494	CPAP KIT COMFORTLITE 2 SM/MED W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1014913	CPAP KIT COMFORTLITE S,M,L W/HDGR & SMPL
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	HC481A	CPAP KIT INFINITY 481 W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	HC481A	CPAP KIT INFINITY 481 W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	RESMED INC	16549	CPAP KIT LG ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16549	CPAP KIT LG ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	RESMED INC	60505	CPAP KIT MIRAGE SWIFT NASAL PILLOW
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	60505	CPAP KIT MIRAGE SWIFT NASAL PILLOW RMD
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	LG305	CPAP KIT NASAL AIRE II LG
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	MD303	CPAP KIT NASAL AIRE II MED
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	SM302	CPAP KIT NASAL AIRE II SM
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	XL306	CPAP KIT NASAL AIRE II XLG
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	XS301	CPAP KIT NASAL AIRE II XSM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16550	CPAP KIT SHALLOW ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	RESMED INC	16550	CPAP KIT SHALLOW ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002759	CPAP KIT SIMPLICITY MED W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002759	CPAP KIT SIMPLICITY MED W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002757	CPAP KIT SIMPLICITY SM W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002757	CPAP KIT SIMPLICITY SM W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	RESMED INC	16548	CPAP KIT STD ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16548	CPAP KIT STD ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1007965	CPAP MASK COMFORT CLASSIC MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1007965	CPAP MASK COMFORT CLASSIC MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1007966	CPAP MASK COMFORT CLASSIC SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1007966	CPAP MASK COMFORT CLASSIC SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1007932	CPAP MASK COMFORT SELECT MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1007932	CPAP MASK COMFORT SELECT MED RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1007933	CPAP MASK COMFORT SELECT SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1007933	CPAP MASK COMFORT SELECT SM RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1007934	CPAP MASK COMFORT SELECT SM WIDE

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252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1014916	CPAP MASK COMFORTLITE COMBO S, M, W/O HE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1004215	CPAP MASK CONTOUR DELUXE MED NO REORDER
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16560	CPAP MASK FRAME ULTRA MIRAGE ONE SZ RMD
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302356	CPAP MASK GEL GOLD SEAL LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302356	CPAP MASK GEL GOLD SEAL LG RES
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302354	CPAP MASK GEL GOLD SEAL MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302354	CPAP MASK GEL GOLD SEAL MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302355	CPAP MASK GEL GOLD SEAL MED WIDE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302355	CPAP MASK GEL GOLD SEAL MED WIDE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302353	CPAP MASK GEL GOLD SEAL MED/SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302353	CPAP MASK GEL GOLD SEAL MED/SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302352	CPAP MASK GEL GOLD SEAL SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302352	CPAP MASK GEL GOLD SEAL SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302357	CPAP MASK GEL LARGE/NARROW GOLD SEAL
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302351	CPAP MASK GEL PETITE GOLD SEAL
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1004213	CPAP MASK LG-NO RE ORDER
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1010641	CPAP MASK NASAL COMFORT GEL LG
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1010640	CPAP MASK NASAL COMFORT GEL MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1010640	CPAP MASK NASAL COMFORT GEL MED RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1010518	CPAP MASK NASAL COMFORT GEL PET
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1010519	CPAP MASK NASAL COMFORT GEL SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1010519	CPAP MASK NASAL COMFORT GEL SM RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302188	CPAP MASK NASAL LG REUSE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302188	CPAP MASK NASAL LG REUSE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302218	CPAP MASK NASAL LG/NRW REUSE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302218	CPAP MASK NASAL LG/NRW REUSE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	312103	CPAP MASK NASAL MED DISP
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302180	CPAP MASK NASAL MED REUSE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302180	CPAP MASK NASAL MED REUSE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302186	CPAP MASK NASAL MED/SM REUSE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302186	CPAP MASK NASAL MED/SM REUSE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302183	CPAP MASK NASAL MED/WIDE REUSE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302183	CPAP MASK NASAL MED/WIDE REUSE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302219	CPAP MASK NASAL PETITE REUSE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302219	CPAP MASK NASAL PETITE REUSE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302187	CPAP MASK NASAL SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302279	CPAP MASK NASAL SM CHLD REUSE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	312102	CPAP MASK NASAL SM DISP W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302187	CPAP MASK NASAL SM REUSE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002373	CPAP MASK PROFILE LITE LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002373	CPAP MASK PROFILE LITE LG RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002374	CPAP MASK PROFILE LITE LG/NARROW
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002374	CPAP MASK PROFILE LITE LG/NARROW RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002371	CPAP MASK PROFILE LITE MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002371	CPAP MASK PROFILE LITE MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002370	CPAP MASK PROFILE LITE MED/SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002370	CPAP MASK PROFILE LITE MED/SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002372	CPAP MASK PROFILE LITE MED/WIDE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002372	CPAP MASK PROFILE LITE MED/WIDE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002849	CPAP MASK PROFILE LITE PETITE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002849	CPAP MASK PROFILE LITE PETITE RES
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002850	CPAP MASK PROFILE LITE SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1002850	CPAP MASK PROFILE LITE SM
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-232101-00B	CPAP MASK SHELL NARROW W/O THERMISTOR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	S-232101-00B	CPAP MASK SHELL NARROW W/O THERMISTOR NP
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-231700-00B	CPAP MASK SHELL W/O PRESSURE TAP
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	S-231700-00B	CPAP MASK SHELL W/O PRESSURE TAP
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1004217	CPAP MASK SM- NO RE ORDER
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7030-20	CPAP MASK SOFT SERIES LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7030-20	CPAP MASK SOFT SERIES LG
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7035-20	CPAP MASK SOFT SERIES LG NARROW
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7035-20	CPAP MASK SOFT SERIES LG NARROW RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7020-20	CPAP MASK SOFT SERIES MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7020-20	CPAP MASK SOFT SERIES MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7025-20	CPAP MASK SOFT SERIES MED NARROW
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7025-20	CPAP MASK SOFT SERIES MED NARROW
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7022-20	CPAP MASK SOFT SERIES MED/WIDE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7022-20	CPAP MASK SOFT SERIES MED/WIDE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7010-20	CPAP MASK SOFT SERIES SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7010-20	CPAP MASK SOFT SERIES SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1019185	CPAP KIT COMFORT CURVE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1026880	CPAP KIT COMFORT SELECT SM,MED SM/WD
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1026880	CPAP KIT COMFORT SELECT SM,MED SM/WD
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1016691	CPAP KIT CONTOUR DELUX W/HDGR MD/LG 5/PK
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	NPMD103	CPAP KIT FREESTYLE NASAL PAP MED
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	NPSM101	CPAP KIT FREESTYLE NASAL PAP SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16549	CPAP KIT LG ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	RESMED INC	60101	CPAP KIT MASK ACTIVA LG

Ops Class	HCPC	Category	Vendor Name	Model No	Product Description
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	60101	CPAP KIT MASK ACTIVA LG RMD
252	A7034	NASAL INTERFACE MASK	RESMED INC	60102	CPAP KIT MASK ACTIVA SHALLOW
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	60102	CPAP KIT MASK ACTIVA SHALLOW RMD
252	A7034	NASAL INTERFACE MASK	RESMED INC	60100	CPAP KIT MASK ACTIVA STD
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	60100	CPAP KIT MASK ACTIVA STD RMD
252	A7034	NASAL INTERFACE MASK	SLEEPNET	50739	CPAP KIT MASK NASAL IQ W/HOLEY HEADGEAR
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	669132	CPAP KIT MASK SM 7600
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16501	CPAP KIT MIRAGE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16501	CPAP KIT MIRAGE
252	A7034	NASAL INTERFACE MASK	RESMED INC	16501	CPAP KIT MIRAGE
252	A7034	NASAL INTERFACE MASK	RESMED INC	16502	CPAP KIT MIRAGE LARGE NO REORDER
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16502	CPAP KIT MIRAGE LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16502	CPAP KIT MIRAGE LG
252	A7034	NASAL INTERFACE MASK	RESMED INC	16537	CPAP KIT MIRAGE SHALLOW
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16537	CPAP KIT MIRAGE SHALLOW RMD
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	MP304	CPAP KIT NASAL AIR II MED PLUS
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	MP304	CPAP KIT NASAL AIR II MED PLUS
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	LG305	CPAP KIT NASAL AIRE II LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	MD303	CPAP KIT NASAL AIRE II MED
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	PA401	CPAP KIT NASAL AIRE II PETITE PA
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	PB402	CPAP KIT NASAL AIRE II PETITE PB
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	PC403	CPAP KIT NASAL AIRE II PETITE PC
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	PD404	CPAP KIT NASAL AIRE II PETITE PD
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	PE405	CPAP KIT NASAL AIRE II PETITE PE
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	K2A	CPAP KIT NASAL AIRE II PT SET UP XS-XL
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	SM302	CPAP KIT NASAL AIRE II SM
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-102444-00	CPAP KIT NASAL AIRWAY ASSY W/O NASAL PIL
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	NPLG105	CPAP KIT NASAL PAP FREESTYLE LG
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	NPMP104	CPAP KIT NASAL PAP FREESTYLE MED PLUS
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	NPM5102	CPAP KIT NASAL PAP FREESTYLE MED SM
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	NPXL105	CPAP KIT NASAL PAP FREESTYLE XLG
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS3033	CPAP KIT NASAL SNAPP MED
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS3022	CPAP KIT NASAL SNAPP SM
252	A7034	NASAL INTERFACE MASK	THE AFTERMARKET GROUP	WM25830	CPAP KIT NASAL SOMNOPLUS W/HEADGEAR LG
252	A7034	NASAL INTERFACE MASK	THE AFTERMARKET GROUP	WM25820	CPAP KIT NASAL SOMNOPLUS W/HEADGEAR MED
252	A7034	NASAL INTERFACE MASK	THE AFTERMARKET GROUP	WM25810	CPAP KIT NASAL SOMNOPLUS W/HEADGEAR SM
252	A7034	NASAL INTERFACE MASK	SENSORMEDICS CORP	467077	CPAP KIT NASAL W/HEADGEAR SPIRITUS MED
252	A7034	NASAL INTERFACE MASK	SENSORMEDICS CORP	467148	CPAP KIT NASAL W/HEADGEAR SPIRITUS SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	LG1001	CPAP KIT PM NASAL AIRE LG
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	LG1001	CPAP KIT PM NASAL AIRE LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	MD1002	CPAP KIT PM NASAL AIRE MED
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	MD1002	CPAP KIT PM NASAL AIRE MED
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	SM1003	CPAP KIT PM NASAL AIRE SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	SM1003	CPAP KIT PM NASAL AIRE SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	XL1000	CPAP KIT PM NASAL AIRE XLG
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	XL1000	CPAP KIT PM NASAL AIRE XLG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	XS1004	CPAP KIT PM NASAL AIRE XSM
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	XS1004	CPAP KIT PM NASAL AIRE XSM
252	A7034	NASAL INTERFACE MASK	RESMED INC	60201	CPAP KIT PROTEGE LG
252	A7034	NASAL INTERFACE MASK	SUNRISE MEDICAL HHG INC	9352D	CPAP KIT SERENITY
252	A7034	NASAL INTERFACE MASK	SUNRISE MEDICAL HHG INC	9352G	CPAP KIT SERENITY GEL
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16550	CPAP KIT SHALLOW ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002759	CPAP KIT SIMPLICITY MED W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002757	CPAP KIT SIMPLICITY SM W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	16548	CPAP KIT STD ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	RESMED INC	60001	CPAP KIT VISTA DEEP
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	60001	CPAP KIT VISTA DEEP RMD
252	A7034	NASAL INTERFACE MASK	RESMED INC	60000	CPAP KIT VISTA STD W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	60000	CPAP KIT VISTA STD W/HEADGEAR RMD
252	A7034	NASAL INTERFACE MASK	RESMED INC	60930	CPAP KIT VISTA W/DEEP CUSH W/O HEADGEAR
252	A7034	NASAL INTERFACE MASK	RESMED INC	60929	CPAP KIT VISTA W/STD CUSH W/O HEADGEAR
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	776239	CPAP MASK
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	900HC402	CPAP MASK ACLAIM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	900HC402	CPAP MASK ACLAIM FISHER & PAYKEL
252	A7034	NASAL INTERFACE MASK	RESMED INC	BB35	CPAP MASK ADULT SM BUBBLE CUSH SERIES 3
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-2540	CPAP MASK ADVANTAGE HUSH LG
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-2520	CPAP MASK ADVANTAGE HUSH SM
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-2530	CPAP MASK ADVANTAGE REG
252	A7034	NASAL INTERFACE MASK	RESMED INC	16302	CPAP MASK ASSY
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	211009	CPAP MASK ASSY NASAL W/STRAP LG
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	211007	CPAP MASK ASSY W/SWIVEL PORT SM
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	211118	CPAP MASK ASSY W/VFOAM HEADGEAR SM
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	400HC505	CPAP MASK BASE INFINITY 481
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	400HC505	CPAP MASK BASE INFINITY 481
252	A7034	NASAL INTERFACE MASK	RESMED INC	16010	CPAP MASK BUBBLE MED
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-133331-00	CPAP MASK BUBBLE SYSTEM
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-133332-00	CPAP MASK BUBBLE SYSTEM LG
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-133330-00B	CPAP MASK BUBBLE SYSTEM MED

Ops Class	HCPC	Category	Vendor Name	Model No	Product Description
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1007965	CPAP MASK COMFORT CLASSIC MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1007966	CPAP MASK COMFORT CLASSIC SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1025121	CPAP MASK COMFORT LITE 2 W/O HDGR
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1014919	CPAP MASK COMFORTLITE S.M.L W/O HDGR
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-616462-00	CPAP MASK CUSH BUBBLE
252	A7034	NASAL INTERFACE MASK	RESMED INC	M02B923	CPAP MASK CUSH LG FLAT BUBBLE
252	A7034	NASAL INTERFACE MASK	VITAL SIGNS INC	9002	CPAP MASK DOWNS
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-102617-00	CPAP MASK DREAMSEAL ASSY
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-103076-00A	CPAP MASK DREAMSEAL NASAL AIRWAY SHALLOW
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	400HC510	CPAP MASK FLEXIFIT F/HC406
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	400HC510	CPAP MASK FLEXIFIT F/HC406
252	A7034	NASAL INTERFACE MASK	RESMED INC	16089	CPAP MASK FRAME KIT MODULAR
252	A7034	NASAL INTERFACE MASK	RESMED INC	16728	CPAP MASK FRAME ULTRA MIRAGE LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302354	CPAP MASK GEL GOLD SEAL MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302353	CPAP MASK GEL GOLD SEAL MED/SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302355	CPAP MASK GEL GOLD SEAL MED/WIDE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302376	CPAP MASK GEL LARGE/NARROW
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302375	CPAP MASK GEL LG
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302373	CPAP MASK GEL MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302374	CPAP MASK GEL MED WIDE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302372	CPAP MASK GEL MED/SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302370	CPAP MASK GEL PETITE
252	A7034	NASAL INTERFACE MASK	INVACARE CORPORATION	IQ50160S	CPAP MASK GEL SLEEPNET IQ
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302371	CPAP MASK GEL SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302352	CPAP MASK GEL SM GOLD SEAL
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1010871	CPAP MASK IMAGE III W/HEADGEAR LG
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	776257	CPAP MASK INERFACE
252	A7034	NASAL INTERFACE MASK	RESMED INC	16723	CPAP MASK INTERFACE FULL MED STD RPLCMNT
252	A7034	NASAL INTERFACE MASK	AG INDUSTRIES	AG100371	CPAP MASK INTERFACE MED/LG F/AURA
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-3040ADJ	CPAP MASK INTERFACE SNAPP W/HEADGEAR LG
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-3030ADJ	CPAP MASK INTERFACE SNAPP W/HEADGEAR MED
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-3020ADJ	CPAP MASK INTERFACE SNAPP W/HEADGEAR SM
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	DF301	CPAP MASK INTERFACE W/LG DREAM SEAL
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	DF303	CPAP MASK INTERFACE W/SMALL DREAM SEAL
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	DF302	CPAP MASK INTERFACE W/STNRD DREAM SEAL
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-800	CPAP MASK IQ GEL ONE SIZE
252	A7034	NASAL INTERFACE MASK	SUNRISE MEDICAL HHG INC	7351D-670	CPAP MASK LG
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7030-10	CPAP MASK LG
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	669130	CPAP MASK LG 7600
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7035-10	CPAP MASK LG NARROW
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302218-DISC	CPAP MASK LG NARROW
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	6938	CPAP MASK LOW BRIDGE SEAL LG
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	069370	CPAP MASK LOW LG
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	776239-05-DISC	CPAP MASK MED
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-133338-00	CPAP MASK MED
252	A7034	NASAL INTERFACE MASK	AIRSEP CORP	MS001-3	CPAP MASK MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7020-10	CPAP MASK MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1004849	CPAP MASK MED DO NOT ORDER HOSP ONLY
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7025-10	CPAP MASK MED NARROW
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7025-10	CPAP MASK MED NARROW HLT
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	133338	CPAP MASK MED NPB
252	A7034	NASAL INTERFACE MASK	AIRSEP CORP	MS001-2	CPAP MASK MED REMEDY
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7020-10	CPAP MASK MED RESP
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7022-10	CPAP MASK MED WIDE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7022-10	CPAP MASK MED WIDE HLT
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	572003	CPAP MASK MINI MONARCH
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	572004	CPAP MASK MINI MONARCH
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	572022	CPAP MASK MONARCH ULTRA W/O PORT
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	572026	CPAP MASK MONARCH ULTRA W/PORT
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-133335-00	CPAP MASK NARROW SOFT SM
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-232102-00B	CPAP MASK NARROW W/THERMISTOR PORT
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	LG2001	CPAP MASK NASAL AIRE BASIC LG
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	MD2002	CPAP MASK NASAL AIRE BASIC MED
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	SM2003	CPAP MASK NASAL AIRE BASIC SM
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	XL2000	CPAP MASK NASAL AIRE BASIC XL
252	A7034	NASAL INTERFACE MASK	HUDSON RESPIRATORY CARE INC	XS2004	CPAP MASK NASAL AIRE BASIC XS
252	A7034	NASAL INTERFACE MASK	SYSTEMS 2000, INC	VF86040L	CPAP MASK NASAL COMFO-SEAL
252	A7034	NASAL INTERFACE MASK	RESMED INC	M02B948	CPAP MASK NASAL CUSH SM
252	A7034	NASAL INTERFACE MASK	RESMED INC	M02B937	CPAP MASK NASAL CUSHION MED
252	A7034	NASAL INTERFACE MASK	SUNRISE MEDICAL HHG INC	9353D	CPAP MASK NASAL FLEXAIRE DEVILBISS
252	A7034	NASAL INTERFACE MASK	VIASYS	776780	CPAP MASK NASAL INTERFACE LYRA
252	A7034	NASAL INTERFACE MASK	SLEEPNET	50160	CPAP MASK NASAL IQ
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	312104	CPAP MASK NASAL LG DISP
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302188	CPAP MASK NASAL LG REUSE RES
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302218	CPAP MASK NASAL LG/NRW REUSE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	312103	CPAP MASK NASAL MED DISP
252	A7034	NASAL INTERFACE MASK	SENSORMEDICS CORP	467078	CPAP MASK NASAL MED PLUS SPIRITUS
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302180	CPAP MASK NASAL MED REUSE RES

Ops Class	HCPC	Category	Vendor Name	Model No	Product Description
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	312105	CPAP MASK NASAL MED/SM DISP
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302186	CPAP MASK NASAL MED/SM REUSE RES
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	312124	CPAP MASK NASAL MED/WIDE DISP
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302047	CPAP MASK NASAL MED/WIDE REUSE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302183	CPAP MASK NASAL MED/WIDE REUSE RES
252	A7034	NASAL INTERFACE MASK	SLEEPNET	50220	CPAP MASK NASAL MINI ME
252	A7034	NASAL INTERFACE MASK	CARDINAL HEALTH	60404	CPAP MASK NASAL NON VENTED ULTRA MIRAGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	312122	CPAP MASK NASAL PETITE DISP
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302219	CPAP MASK NASAL PETITE REUSE RES
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	302187	CPAP MASK NASAL SM REUSE RES
252	A7034	NASAL INTERFACE MASK	SENSORMEDICS CORP	467081	CPAP MASK NASAL SPIRITUS LG
252	A7034	NASAL INTERFACE MASK	INVACARE CORPORATION	ISP2000L	CPAP MASK NASAL W/HEADGEAR TWLIGHT LG
252	A7034	NASAL INTERFACE MASK	INVACARE CORPORATION	ISP2000	CPAP MASK NASAL W/HEADGEAR TWLIGHT ST
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	400HC503	CPAP MASK NASAL W/O HEADGEAR
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	400HC502	CPAP MASK NASAL W/O HEADGEAR
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	211067	CPAP MASK NASAL W/O HEADGEAR ALIZES LG
252	A7034	NASAL INTERFACE MASK	ROSCOE MEDICAL INC	CPAP-NPTUB	CPAP MASK NOSE INTERFACE
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	900HC406	CPAP MASK ONLY FLEXIFIT SERIES
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	900HC406	CPAP MASK ONLY FLEXIFIT SERIES F&P
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7015-10	CPAP MASK PED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7015-20	CPAP MASK PED SOFT SERIES
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	669134	CPAP MASK PETITE 7600
252	A7034	NASAL INTERFACE MASK	SLEEPNET	50215	CPAP MASK PETITE MINI ME W/HEADGEAR
252	A7034	NASAL INTERFACE MASK	SLEEPNET	50402	CPAP MASK PHANTOM
252	A7034	NASAL INTERFACE MASK	TIARA MEDICAL SYSTEMS INC	TMS-700	CPAP MASK PHANTOM GEL ONE SIZE
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	232101	CPAP MASK PILLOW STEEL NARROW
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-101699-00	CPAP MASK PLENUM ASSY W/O PRESSURE TAP
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1001527-DISC	CPAP MASK PROFILE LARGE NARROW
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1001526-DISC	CPAP MASK PROFILE LG
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002371	CPAP MASK PROFILE LITE MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002370	CPAP MASK PROFILE LITE MED/SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002372	CPAP MASK PROFILE LITE MED/WIDE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	1002850	CPAP MASK PROFILE LITE SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1006322	CPAP MASK PROFILE LITE SM W/O EXHAL VALV
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1001524-DISC	CPAP MASK PROFILE MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1001525-DISC	CPAP MASK PROFILE MED WIDE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1001523-DISC	CPAP MASK PROFILE MED/SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1001521-DISC	CPAP MASK PROFILE PETITE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1001522-DISC	CPAP MASK PROFILE SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	302187 A	CPAP MASK REORDER M124878
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	900HC432	CPAP MASK SEAL KIT MED/LG
252	A7034	NASAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	900HC431	CPAP MASK SEAL KIT SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	S-232101-00B	CPAP MASK SHELL NARROW W/O THERMISTOR NP
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	S-231700-00B	CPAP MASK SHELL W/O PRESSURE TAP
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-231701-00B	CPAP MASK SHELL W/PRESSURE TAP
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-102637-00	CPAP MASK SHELL W/PRESSURE TAP
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-133336-00	CPAP MASK SM
252	A7034	NASAL INTERFACE MASK	AIRSEP CORP	MS001-1	CPAP MASK SM
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	7010-10	CPAP MASK SM
252	A7034	NASAL INTERFACE MASK	SUNRISE MEDICAL HHG INC	7351D-668	CPAP MASK SM
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-133329-00	CPAP MASK SM
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	133336	CPAP MASK SM NPB
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7010-20	CPAP MASK SM SOFT SERIES
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	S-133337-00	CPAP MASK SM WIDE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	133337	CPAP MASK SM/WIDE NPB
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7030-20	CPAP MASK SOFT SERIES LG RESP
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7020-20	CPAP MASK SOFT SERIES MED
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7022-20	CPAP MASK SOFT SERIES MED/WIDE
252	A7034	NASAL INTERFACE MASK	REDLINE HEALTHCARE	7035-20	CPAP MASK SOFT SERIES NARROW LG RESP
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	6-949	CPAP MASK SOFTWEAR 3 PT HEADSTRAP
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06941	CPAP MASK SOFTWEAR LG HIGH BRIDGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	6942	CPAP MASK SOFTWEAR LG HIGH BRIDGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06-937	CPAP MASK SOFTWEAR LG LOW BRIDGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06-933 DISC USE M127398	CPAP MASK SOFTWEAR MED
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06-933	CPAP MASK SOFTWEAR MED HIGH BRIDGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06929	CPAP MASK SOFTWEAR MED LOW BRIDGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06930	CPAP MASK SOFTWEAR MED LOW BRIDGE SEAL
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06925	CPAP MASK SOFTWEAR SM HIGH BRIDGE
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	06-926	CPAP MASK SOFTWEAR SM HIGH BRIDGE SEAL
252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	6-945	CPAP MASK SOFTWEAR W/ HEADSTRAP
252	A7034	NASAL INTERFACE MASK	RESMED INC	16004	CPAP MASK SULLIVAN CHILD BUBBLE SYSTEM
252	A7034	NASAL INTERFACE MASK	RESMED INC	60200	CPAP MASK SYSTEM PROTEGE STD REUSE SILCN
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	211008	CPAP MASK SZ MED HANS
252	A7034	NASAL INTERFACE MASK	RESMED INC	16577	CPAP MASK ULTRA MIRAGE SHALLOW /WIDE
252	A7034	NASAL INTERFACE MASK	RESMED INC	60622	CPAP MASK ULTRA MIRAGE STD N/HEADGEAR
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-233339-00	CPAP MASK ULTRA SOFTFIT MED WIDE
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-233337-00	CPAP MASK ULTRA SOFTFIT SM WIDE

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252	A7034	NASAL INTERFACE MASK	RESPIRONICS INC	1025194	CPAP MASK W/O CUSH COMFORTLITE2
252	A7034	NASAL INTERFACE MASK	NELLCOR PURITAN BENNETT	Y-102622-00	CPAP MASK W/O DREAMSEAL
252	A7034	NASAL INTERFACE MASK	HANS RUDOLPH INC	669133	CPAP MASK XSM 7600
252	A7044	ORAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	HC452A	CPAP KIT ORACLE 452
252	A7044	ORAL INTERFACE MASK	REDLINE HEALTHCARE	HC452A	CPAP KIT ORACLE 452 FISHER & PAYKEL
252	A7044	ORAL INTERFACE MASK	FISHER & PAYKEL HEALTHCARE INC	HC451A	CPAP KIT ORACLE
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	S-133293-00B	CPAP KIT ADAMS CIRCUIT
252	A9999	CPAP KIT	REDLINE HEALTHCARE	S-133293-00B	CPAP KIT ADAMS CIRCUIT NPB
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-00	CPAP KIT BREEZE SM/MED/LG
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-101400-00	CPAP KIT BREEZE SM/MED/LG PILLOW
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1007963	CPAP KIT COMFORT CLASSIC W/ HEADGEAR SM
252	A9999	CPAP KIT	RESPIRONICS INC	1007964	CPAP KIT COMFORT CLASSIC W/HEADGEAR MED
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1007964	CPAP KIT COMFORT CLASSIC W/HEADGEAR MED
252	A9999	CPAP KIT	RESPIRONICS INC	1007963	CPAP KIT COMFORT CLASSIC W/HEADGEAR SM
252	A9999	CPAP KIT	RESPIRONICS INC	1004950	CPAP KIT COMFORT FULL W/HDGR LG
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1004950	CPAP KIT COMFORT FULL W/HDGR LG RES
252	A9999	CPAP KIT	RESPIRONICS INC	1004872	CPAP KIT COMFORT FULL W/HDGR MED
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1004872	CPAP KIT COMFORT FULL W/HDGR MED RES
252	A9999	CPAP KIT	RESPIRONICS INC	1004880	CPAP KIT COMFORT FULL W/HDGR SM
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1004880	CPAP KIT COMFORT FULL W/HDGR SM RES
252	A9999	CPAP KIT	RESPIRONICS INC	1014905	CPAP KIT COMFORT LITE S,M,4,5
252	A9999	CPAP KIT	RESPIRONICS INC	1007919	CPAP KIT COMFORT SELECT MED
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1007919	CPAP KIT COMFORT SELECT MED RES
252	A9999	CPAP KIT	RESPIRONICS INC	1007930	CPAP KIT COMFORT SELECT SM
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1007930	CPAP KIT COMFORT SELECT SM RES
252	A9999	CPAP KIT	RESPIRONICS INC	1007931	CPAP KIT COMFORT SELECT SM WIDE
252	A9999	CPAP KIT	RESPIRONICS INC	1014907	CPAP KIT COMFORTLITE W/HDGR & DRCT SEAL
252	A9999	CPAP KIT	FISHER & PAYKEL HEALTHCARE INC	HC407A	CPAP KIT FLEXFIT NASAL HC407
252	A9999	CPAP KIT	REDLINE HEALTHCARE	HC407A	CPAP KIT FLEXFIT NASAL HC407 FISHER&PAY
252	A9999	CPAP KIT	FISHER & PAYKEL HEALTHCARE INC	HC405A	CPAP KIT MASK FLEXIFIT
252	A9999	CPAP KIT	REDLINE HEALTHCARE	HC405A	CPAP KIT MASK FLEXIFIT FISHER PAYKEL
252	A9999	CPAP KIT	RESPIRONICS INC	1009043	CPAP KIT NASAL COMFORT GEL W/HDGR LG
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1009043	CPAP KIT NASAL COMFORT GEL W/HDGR LG RES
252	A9999	CPAP KIT	RESPIRONICS INC	1009042	CPAP KIT NASAL COMFORT GEL W/HDGR MED
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1009042	CPAP KIT NASAL COMFORT GEL W/HDGR MED RE
252	A9999	CPAP KIT	RESPIRONICS INC	1009040	CPAP KIT NASAL COMFORT GEL W/HDGR PET
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1009040	CPAP KIT NASAL COMFORT GEL W/HDGR PT RES
252	A9999	CPAP KIT	RESPIRONICS INC	1009041	CPAP KIT NASAL COMFORT GEL W/HDGR SM
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1009041	CPAP KIT NASAL COMFORT GEL W/HDGR SM RES
252	A9999	CPAP KIT	RESPIRONICS INC	1004087	CPAP KIT PROFILE LITE W/ HEADGEAR SM
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1004089	CPAP KIT PROFILE LITE W/HDGR MED RES
252	A9999	CPAP KIT	RESPIRONICS INC	1004111	CPAP KIT PROFILE LITE W/HEADGEAR LG
252	A9999	CPAP KIT	RESPIRONICS INC	1004112	CPAP KIT PROFILE LITE W/HEADGEAR LGNRW
252	A9999	CPAP KIT	RESPIRONICS INC	1004110	CPAP KIT PROFILE LITE W/HEADGEAR MDWIDE
252	A9999	CPAP KIT	RESPIRONICS INC	1004089	CPAP KIT PROFILE LITE W/HEADGEAR MED
252	A9999	CPAP KIT	RESPIRONICS INC	1004088	CPAP KIT PROFILE LITE W/HEADGEAR MED,SM
252	A9999	CPAP KIT	RESPIRONICS INC	1004086	CPAP KIT PROFILE LITE W/HEADGEAR PETITE
252	A9999	CPAP KIT	FISHER & PAYKEL HEALTHCARE INC	HC401A	CPAP KIT W/HEADGEAR ACLAIM
252	A9999	CPAP KIT	REDLINE HEALTHCARE	HC401A	CPAP KIT W/HEADGEAR ACLAIM F&P
252	A9999	CPAP MASK	RESPIRONICS INC	1014906	CPAP MASK NASAL CMFRT LITE SZ5,6,M,L,COM
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-100874-00	CPAP KIT ADAM CIRCUIT W/HEADGEAR LG
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	S-133294-00B	CPAP KIT ADAMS CIRCUIT
252	A9999	CPAP KIT	REDLINE HEALTHCARE	S-133293-00	CPAP KIT ADAMS CIRCUIT NPB
252	A9999	CPAP KIT	RESMED INC	16534	CPAP KIT ASSY F/FOREHEAD
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-102616-00	CPAP KIT BREEZE DREAMSEAL
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-103059-00A	CPAP KIT BREEZE DREAMSEAL LG
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-102616-00	CPAP KIT BREEZE DREAMSEAL MAL
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-102616-00	CPAP KIT BREEZE DREAMSEAL NPB
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-103074-00A	CPAP KIT BREEZE DREAMSEAL SHALLOW
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-101400-L	CPAP KIT BREEZE LG
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-L	CPAP KIT BREEZE LG NPB
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-L	CPAP KIT BREEZE LG NPB
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-L	CPAP KIT BREEZE LG NPB 2/PR
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-101400-	CPAP KIT BREEZE MED
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-101400-M	CPAP KIT BREEZE MED
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-00	CPAP KIT BREEZE MED & LG PILLOW
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-M	CPAP KIT BREEZE MED NPB
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-00	CPAP KIT BREEZE MED/LG PILLOW MAL
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-101400-S	CPAP KIT BREEZE SM
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400-S	CPAP KIT BREEZE SM NPB
252	A9999	CPAP KIT	REDLINE HEALTHCARE	Y-101400.00	CPAP KIT BREEZE SM/MED/LG
252	A9999	CPAP KIT	NELLCOR PURITAN BENNETT	Y-101400-XL	CPAP KIT BREEZE XLG
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1007964	CPAP KIT COMFORT CLASIC W/HEADGEAR MED
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1007963	CPAP KIT COMFORT CLASIC W/HEADGEAR SM
252	A9999	CPAP KIT	RESPIRONICS INC	1001652	CPAP KIT CONTOUR DELUXE LARGE
252	A9999	CPAP KIT	RESPIRONICS INC	1002146	CPAP KIT CONTOUR DELUXE SM
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1001652	CPAP KIT CONTOUR DLX LG
252	A9999	CPAP KIT	RESPIRONICS INC	1002148	CPAP KIT CONTOUR DLX MED

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252	A9999	CPAP KIT	REDLINE HEALTHCARE	1002148	CPAP KIT CONTOUR DLX MED RES
252	A9999	CPAP KIT	REDLINE HEALTHCARE	1002146	CPAP KIT CONTOUR DLX SM RES
252	A9999	CPAP KIT	REDLINE HEALTHCARE	HC406A	CPAP KIT FLEXIFIT NASAL PETITE FPH
252	A9999	CPAP KIT	FISHER & PAYKEL HEALTHCARE INC	HC406A	CPAP KIT FLEXIFIT NASAL PETITE HC406A
252	A9999	CPAP KIT	SUNRISE MEDICAL HHG INC	9354G	CPAP KIT FLEXSET W/HEADGEAR GEL
252	A9999	CPAP KIT	SUNRISE MEDICAL HHG INC	9354GS	CPAP KIT FLEXSET W/HEADGEAR GEL SHALLOW
252	A9999	CPAP KIT	SUNRISE MEDICAL HHG INC	9354S	CPAP KIT FLEXSET W/HEADGEAR SHALLOW
252	A9999	CPAP KIT	SUNRISE MEDICAL HHG INC	9354D	CPAP KIT FLEXSET W/HEADGEAR STD
252	A9999	CPAP KIT	RESMED INC	60928	CPAP KIT FRAME ONLY VISTA
252	A9999	CPAP KIT	HUDSON RESPIRATORY CARE INC	NPXS100	CPAP KIT FREESTYLE NASAL PAP XS
252	A9999	CPAP KIT	SUNRISE MEDICAL HHG INC	113241	CPAP KIT MASK FULL FACE PETITE
252	A9999	CPAP KIT	SUNRISE MEDICAL HHG INC	113239	CPAP KIT MASK FULL FACE SM
252	A9999	CPAP KIT	SUNRISE MEDICAL HHG INC	113240	CPAP KIT MASK FULL FACE XSM 7600
252	A9999	CPAP KIT	RESMED INC	16530	CPAP KIT MIRAGE AUTOSET
252	A9999	CPAP KIT	SLEEPNET	50410	CPAP KIT NASAL PHANTOM W/HEAD GEAR
252	A9999	CPAP KIT	TIARA MEDICAL SYSTEMS INC	TMS-30345KIT	CPAP KIT NASAL SNAPP MED, LG
252	A9999	CPAP KIT	ROSCOE MEDICAL INC	CPAP-PRO	CPAP KIT PRO SYSTEM
252	A9999	CPAP KIT	RESPIRONICS INC	7010	CPAP KIT SM W/HEADGEAR
252	A9999	CPAP KIT	RESPIRONICS INC	7020	CPAP KIT SOFT SERIES MED
252	A9999	CPAP KIT	CAREFORE MEDICAL	SR-001LG-E	CPAP KIT SPIRITUS ELITE INTERFACE LG
252	A9999	CPAP KIT	CAREFORE MEDICAL	SR-001MD-E	CPAP KIT SPIRITUS ELITE INTERFACE MED
252	A9999	CPAP KIT	CAREFORE MEDICAL	SR-001SM-E	CPAP KIT SPIRITUS ELITE INTERFACE SM
252	A9999	CPAP KIT	CAREFORE MEDICAL	SR-001ST-E	CPAP KIT SPIRITUS ELITE INTRFCE MED PLUS
252	A9999	CPAP KIT	RESMED INC	16924	CPAP KIT STD LARGE DEEP
252	A9999	CPAP KIT	RESMED INC	16923	CPAP KIT STD MED SHALLOW
252	A9999	CPAP KIT	SLEEPNET	50725	CPAP KIT W/ HEADGEAR IQ
252	A9999	CPAP KIT	SLEEPNET	50777	CPAP KIT W/HEADGEAR & HOLEY CAP
252	A9999	CPAP KIT	VITAL SIGNS INC	9000	CPAP KIT W/HEADSTRAP
252	A9999	CPAP MASK	TIARA MEDICAL SYSTEMS INC	TMS-254077	CPAP MASK ADVANTAGE HUSH LG W/HEADGEAR
252	A9999	CPAP MASK	TIARA MEDICAL SYSTEMS INC	TMS-253077	CPAP MASK ADVANTAGE HUSH MED W/HEADGEAR
252	A9999	CPAP MASK	TIARA MEDICAL SYSTEMS INC	TMS-252077	CPAP MASK ADVANTAGE HUSH SM W/HEADGEAR
252	A9999	CPAP MASK	TIARA MEDICAL SYSTEMS INC	TMS-889	CPAP MASK IQ GEL W/HEADGEAR
252	A9999	CPAP MASK	SUNRISE MEDICAL HHG INC	9351D-670	CPAP MASK LG W/SILCN RING & CUSH
252	A9999	CPAP MASK	SUNRISE MEDICAL HHG INC	9351D-669	CPAP MASK MED W/SILCN RING & CUSH
252	A9999	CPAP MASK	RESPIRONICS INC	302219 M126317	CPAP MASK PETITE SOFT
252	A9999	CPAP MASK	TIARA MEDICAL SYSTEMS INC	TMS-770	CPAP MASK PHANTOM GEL MED W/HEADGEAR
252	A9999	CPAP MASK	RESPIRONICS INC	7030	CPAP MASK W/HEADGEAR LG
252	A9999	CPAP MASK	TIARA MEDICAL SYSTEMS INC	TMS-885	CPAP MASK W/HEADGEAR SLEEPNET IQ MED

APPENDIX

Deficit Reduction Act of 2005 Provisions on Medicare Reimbursement for Oxygen and Durable Medical Equipment

Implementation Questions

I. Medical Necessity and Documentation

1. Will current regulations defining "continuous use" for capped rental DME remain unchanged?

2. How will CMS define "continuous use" for oxygen equipment? What will constitute a break in service so that a new period of continuous use commences for beneficiaries on oxygen?

3. When a beneficiary owns his or her oxygen equipment, will Medicare pay for new equipment on the basis of a change in condition? Does the change in equipment begin a new period of continuous use?

4. Will CMS issue regulations to address the issues raised in questions 1 and 2 above? If so, what is the projected timeline for a proposed rule?

5. If new technology becomes available that is medically appropriate and has the potential to improve health outcomes, will the beneficiary be responsible for paying for the new equipment (assuming there has been no change in condition)?

6. How will CMS define "oxygen" after the 36-month period of continuous use ends? How will the medical necessity documentation for oxygen change? Will lifetime CMNs be valid for beneficiaries who own their own equipment?

II. Reimbursement Questions

7. Will beneficiaries who have both a concentrator and stationary liquid or a concentrator and a portable concentrator be responsible for purchasing one of the two systems after 36 months?

8. How will CMS pay for refills on an oxygen cylinder? Will the payment amount differ between patients who require more refills because they have a greater need for mobility or a higher prescribed liter flow?

9. How will CMS take into consideration those patients who have a concentrator and a liquid system, where the liquid system is being primarily used for ambulatory/portable requirements? Will the Medicare program pay for additional portable cylinders after the 36-month rental period, or will it be the beneficiary's responsibility to purchase these items?

10. Will the beneficiary be responsible for purchasing supplies such as cannulas and tubing for their oxygen equipment or other items such as humidifiers?

11. May providers charge beneficiaries a rental or purchase for a back-up emergency cylinder that is not used to meet the patient's portable oxygen needs? These units would be used solely in the event of an emergency such as a power outage, a natural disaster, or a malfunction of the beneficiary's primary equipment. Will Medicare pay for the contents once these cylinders are used?

12. Will the payment amount differ based on different oxygen technologies that may be more or less costly for the provider to furnish?

13. Providers may be unable to service a patient-owned portable oxygen cylinder that they did not furnish. Will the beneficiary be responsible for purchasing a new oxygen cylinder under these circumstances?

14. Will rental months at a beneficiary's second residence apply towards the 36 months of continuous use? If so, which provider is responsible for transferring title to the beneficiary (i.e., the primary provider, or the provider at the second residence)? Similarly, if a beneficiary moves during the period of continuous use, which provider is responsible for transferring title (the new provider or the original provider)?

15. For short-term travel, the beneficiary pays for the oxygen out-of-pocket and the primary provider may reimburse all or a part of those costs. AAHomecare anticipates that this rule will not change for beneficiaries who own their oxygen equipment. That is, the beneficiary will continue to be responsible for arranging and paying for travel oxygen. With respect to the period of continuous use, please confirm that our understanding is correct. After title to the equipment transfers, will Medicare pay the beneficiary directly for short-term travel oxygen?

16. Will the beneficiary be responsible to pay charges for pick up and delivery of oxygen refills after title to oxygen equipment transfers to the

beneficiary? If not, what data does CMS propose to use to arrive at an appropriate payment amount for pick up and delivery charges?

17. For beneficiary-owned equipment that requires servicing, will Medicare pay pick up and delivery charges? If so, what data will CMS use to arrive at an appropriate payment amount for pick up and delivery charges?

18. Does CMS intend to apply any of the billing rules that applied to capped rental equipment to rent-to-purchase DME? A purchase option letter is unnecessary inasmuch as the beneficiary no longer has the "option" to purchase the equipment. Consequently, we see no need to use the BP, BR, or BU modifiers in the 11th, 12th, and 13th rental months.

III. Service and Maintenance

19. How will CMS define the useful of life of oxygen equipment?

20. If oxygen equipment is "irreparably damaged" after title has transferred to the beneficiary, but before the end of the equipment's "useful life," will Medicare pay for new equipment? If so, will this commence a new period of "continuous use," or will CMS pay a lump sum amount for the new equipment?

21. Does CMS have a timeline for issuing regulations that address questions 17 and 18 above?

22. Oxygen cylinders must undergo hydrostatic testing and other checks periodically. Though technically these tests are not "repairs," will they be reimbursed as repairs to account for the more extensive service they involve?

23. Will the Medicare program pay for emergency service calls for beneficiary-owned equipment that is still under warranty? If not, can providers contract with beneficiaries to provide on-call services for patient owned equipment?

24. If the manufacturer of equipment that is under warranty is no longer in business, will the beneficiary be responsible for paying for replacement parts? If the provider who furnished the equipment to the beneficiary is no longer in business, who is responsible for the repairs?

25. How will providers document that the maintenance and service they performed on oxygen equipment were reasonable and necessary? Will CMS require different documentation depending on whether the provider repairs the equipment it furnished or equipment furnished by another provider?

26. Will CMS issue temporary HCPCS codes to identify the service, maintenance and repairs for oxygen equipment, or will providers have to apply for the codes?

27. How will providers be reimbursed for service or maintenance to non-covered oxygen equipment such as conserving devices or oxygen titrating devices? Will providers bill the beneficiary for these services?

28. Will CMS issue temporary HCPCS codes to identify service and maintenance repairs and parts for equipment in the capped rental category, such as motor and hand controls for a bed, or will providers have to apply for the codes?

IV. Other Questions

29. Will the requirements of the DRA apply retroactively to January 1, 2006, regardless of whether the need for systems changes result in administrative delays in implementation?

30. Will CMS require providers to transfer title to beneficiaries who have unpaid deductible and coinsurance balances?

31. After title to the oxygen equipment transfers to the beneficiary, will beneficiaries be responsible for paying for clinical assessments required under state law? Will the beneficiary be responsible for paying for respiratory assessment ordered by the physician?

32. Please confirm that parenteral and enteral pumps are not subject to the rent-to-purchase methodology established under the DRA.

33. How will providers be reimbursed if beneficiaries begin to use oxygen or capped rental equipment under a Medicare Advantage plan? Will CMS begin a new period of continuous use each time the beneficiary has a payer change in or out of traditional Medicare?

Via E-Mail and Federal Express

April 20, 2006

Mr. Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **Implementation of the Deficit Reduction Act of 2005 to Medicare Reimbursement to Oxygen and Durable Medical Equipment**

Dear Mr. Kuhn:

As you are aware on February 8, 2006, the President signed into law the Deficit Reduction Act (DRA) of 2005, P. L. 109-171. Section 5101 of the DRA amends the provisions of the Social Security Act (SSA) that govern Medicare payment for home oxygen therapy and rental of certain items of durable medical equipment (DME). Beneficiaries who use home oxygen or rent DME now have a higher burden to manage their care and coordinate service and maintenance for their medical equipment. The DRA provisions also significantly impact the operations of suppliers who furnish oxygen and DME to beneficiaries. The American Association for Homecare (AAHomecare) is writing to request clarification on how the Centers for Medicare and Medicaid Services (CMS) intends to implement these new requirements, especially with respect to the specific questions we raise below. For your easy reference, we have also included the questions in an appendix attached to this letter.

By way of background, prior to February 8, 2006, Medicare reimbursed oxygen and oxygen equipment on the basis of a continuous rental. In other words, Medicare would pay for home oxygen therapy as long as a beneficiary met Medicare's coverage criteria. The monthly rental payment for oxygen is a modality neutral bundled payment that covers ongoing service and maintenance for the equipment. In contrast, under §5101, Medicare will pay for the rental of oxygen equipment over a period of "continuous use" of 36 months, after which title to the equipment transfers to the beneficiary. Medicare will pay only for "oxygen" after 36 months. Further, after the statutory period of continuous use, Medicare will pay only for service and maintenance of oxygen equipment that the Secretary deems "reasonable and necessary." This payment methodology became effective January 1, 2006 for all Medicare beneficiaries on home oxygen as of December 31, 2005.

Prior to the DRA, Medicare paid for certain DME items under a "capped" rental payment methodology. This means that beneficiaries could elect to own or rent the medical equipment after a rental period of 10 months. If the beneficiary chose to continue the rental, Medicare payments for the equipment would "cap" after 15 months, and the supplier would receive a maintenance and service fee every six months. Otherwise, title to the equipment transferred to the beneficiary after 13 months.

Section 5101 eliminates the capped rental payment methodology. Instead, Medicare will rent most items of DME for 13 months of continuous use, after which title to the equipment will transfer to the beneficiary. Medicare will pay only for service and maintenance the Secretary determines to be reasonable and necessary after the 13 month rental period. This new "rent-to-purchase" payment methodology is effective for rental periods beginning on or after January 1, 2006.

I. Questions on the Application of the DRA Provisions

The DRA fundamentally revises the payment structure for oxygen and capped rental DME. As a result, existing billing, payment, and documentation rules for oxygen and DME are inadequate to address the changes imposed under the DRA. CMS will need to revise the current rules and establish new HCPCS codes to capture the services and products that are no longer bundled into the monthly fee schedule amount for oxygen and DME. AAHomecare's questions pertain to CMS' plans for making these changes and the timeline for their implementation.

A. Medical Necessity and Documentation

How will CMS apply "break-in-service" rules to oxygen and DME under the new payment provisions? For capped rental DME, Medicare rules allow for temporary interruptions in the period of "continuous use." An interruption of no more than 60 days plus the days remaining in the rental month in which the use ceases is a temporary interruption, regardless of the reason for the interruption. When there is a temporary interruption in continuous use, medical necessity for the rented equipment is presumed to continue.[1] If the interruption is not temporary, then a new rental period begins, subject to the requirements specified in the rule.[2]

We expect these rules to remain in effect for DME and request that you confirm whether that is correct. For example, if a beneficiary using a support surface is "healed" within the meaning of the medical policy, but "breaks down" again after 60 days, will a new period of continuous use begin?

Importantly, §5101 (b) authorizes the Secretary to determine how he will define "continuous use" for oxygen and oxygen equipment. We believe CMS must issue regulations to define "continuous use" and what constitutes a "break in service" for

[1] 42 C. F. R. §414.230 (c) (3) (2006).

[2] The provider must submit a new prescription, new medical necessity documentation and a statement explaining the reason for the interruption and demonstrating that the medical necessity for the prior episode ended.

beneficiaries on oxygen. Specifically, when will a break in service for an oxygen patient commence a new period of "continuous use"?

In the past, if a beneficiary experienced a change in condition that resulted in the need to change his or her oxygen equipment (such as a change from stationary oxygen only to both stationary and portable oxygen), the provider would simply switch the beneficiary's existing equipment to other equipment consistent with the doctor's prescription. For example, a beneficiary on liquid oxygen during the first 30 rental months requires a medically necessary change in equipment in the 31st rental month, and the physician orders a stationary concentrator or a portable concentrator for the beneficiary. In this example, will the beneficiary's change in condition start a new 36 month period of continuous use?

Moreover, after a beneficiary owns the equipment, will Medicare pay for new equipment on the basis of a change in condition? Medicare program rules for capped rental DME contemplate that a new period of continuous use begins when the beneficiary has a new prescription or requires additional equipment;[3] these rules were not intended to apply to oxygen because oxygen was reimbursed as a continuous rental under the original fee schedules. Consequently, CMS must issue new regulations to address these questions. What is CMS' projected timeline for a proposed rule?

If new technology becomes available that is medically appropriate and has the potential to improve health outcomes, is the beneficiary responsible for paying for the new equipment (assuming there has been no change in condition)?

The DRA contemplates that Medicare will continue to pay for medically necessary oxygen after title to the equipment transfers to the beneficiary. How will the medical necessity documentation for oxygen change? Currently, the Medicare program requires a "lifetime" certificate of medical necessity (CMN). Will lifetime CMNs be valid for beneficiaries who own their own equipment?

B. Reimbursement Questions

Some beneficiaries have dual systems. That is, they have both a concentrator and a stationary liquid system or a stationary concentrator and a portable concentrator. Under Medicare's modality neutral payment methodology, providers only bill the Medicare program for one system. At the end of the period of continuous use, what equipment will these beneficiaries own? Will the beneficiary be responsible for purchasing one of the two systems?

We interpret §5101 (b) to require the transfer of title to oxygen equipment, including portable equipment, after 36 months of continuous use. As you are aware, portable equipment may include an oxygen cylinder equipped with a flow meter and a cannula. The DRA requires Medicare to pay for medically necessary oxygen after title to oxygen equipment transfers to the beneficiary. How will CMS pay for refills on oxygen

[3] 42 C. F. R. §414.230 (f) (2006).

cylinders? Will the payment amount differ between patients who require more refills because they have a greater need for mobility or a higher prescribed liter flow? How will CMS address payment for patients who have both a concentrator and a liquid system where the liquid system is being used primarily for ambulatory portable requirements? Will Medicare pay for additional portable cylinders after the 36 months, or will the patient be responsible for purchasing these items? Will beneficiaries be responsible for purchasing supplies such as cannulas and tubing for their oxygen equipment or items such as humidifiers?

May providers charge beneficiaries a rental or purchase for a back-up emergency cylinder that is not used to meet the beneficiary's portable oxygen needs? These units would be used solely in the event of an emergency such as a power outage, natural disaster, or a malfunction of the beneficiary's primary equipment. Will Medicare pay for contents once these cylinders are used? Finally, will the payment amount differ based on different oxygen technologies that may be more or less costly for the provider to furnish?

As you are aware, oxygen is a prescription drug, and oxygen equipment, including oxygen cylinders, is highly regulated by several Federal agencies including the United States Department of Transportation (DOT) and the United States Food and Drug Administration (FDA). An important safety concern for the FDA is the provider's ability to test oxygen cylinders and to verify their chain of custody. This will be very difficult to do for patient-owned equipment, especially if the beneficiary changes supplier after he or she owns the equipment (e.g., the beneficiary moves out of the provider's service area). This also raises significant liability issues for patient-owned equipment, especially if the beneficiary changes supplier after he or she owns the equipment (e.g., the beneficiary moves out of the provider's service area). There may be instances where beneficiaries purchase cylinders second-hand from non-providers (eBay®, for example). As a consequence, there may be instances where providers may be unable to service a patient-owned portable oxygen cylinder that they did not furnish. Will the beneficiary be responsible for purchasing new oxygen cylinders under these circumstances?

The local coverage determination (LCD) for oxygen states that the beneficiary is responsible for coordinating travel oxygen needs. The beneficiary's existing oxygen provider may service the beneficiary's travel oxygen needs, but is not required to do so. For short-term travel, the beneficiary pays for the oxygen out-of-pocket, and the primary provider may reimburse all or a part of those costs.[4] We anticipate that this rule will not change. That is, the beneficiary will continue to be responsible for arranging and paying for short-term travel oxygen. Please confirm that our understanding is correct with respect to the 36-month period of continuous use. After title to the equipment transfers to the beneficiary, will Medicare pay the beneficiary directly for short-term travel oxygen?

Beneficiaries who spend the winter or summer months away from their primary residence may have more than one supplier. Similarly, beneficiaries who move out of a provider's service area will have more than one provider. How will CMS determine the period of continuous use in these scenarios? Will rental months at the second residence apply

[4] See DMERC Region B Bulletin, Spring (1999).

towards the 36 months of continuous use? If so, which provider is responsible for transferring title to the beneficiary? We foresee significant access issues for beneficiaries if providers are forced to transfer title to equipment that they have rented for only a few months. Beneficiaries who move or change providers "midstream" may have difficulty finding a new provider for the same reason.

The Medicare Claims Processing Manual states that Medicare will not make a separate payment for pick-up and delivery of oxygen equipment because these charges are included in the monthly fee schedule payment for oxygen.[5] After title to oxygen equipment transfers to the beneficiary, will the beneficiary be responsible to pay charges for pick up and delivery of oxygen refills? If not, what data does CMS propose to use to arrive at an appropriate payment amount? The Medicare Claims Processing Manual also states that pick up and delivery charges are included in the Medicare fee schedule payment amount for capped rental DME. For beneficiary-owned equipment that requires servicing, will Medicare pay pick up and delivery charges? If so, what data will CMS use to arrive at an appropriate payment amount?

Finally, does CMS intend to apply any of the billing rules that applied to capped rental equipment to rent to purchase DME? A purchase option letter is unnecessary inasmuch as the beneficiary no longer has the "option" to purchase the equipment. Consequently, we see no need to use the BP, BR, or BU modifiers in the 11th, 12th, and 13th rental months.

C. Service and Maintenance

Section 1834 (a) (7) of the SSA states that the reasonable useful lifetime for capped rental DME is five (5) years, unless the Secretary specifies otherwise.[6] This statutory provision does not apply to oxygen and oxygen equipment. How will CMS define the useful life of oxygen equipment? If oxygen equipment is "irreparably damaged" after title has transferred to the beneficiary, but before the end of the equipment's "useful life," will Medicare pay for new equipment? If so, will this commence a new period of "continuous use," or will CMS pay a lump sum amount for the new equipment? Importantly, does CMS have a timeline for issuing regulations that address these questions? Finally we anticipate that the useful life for capped rental DME will remain 5 years consistent with §1834 (a) (7). Please confirm that our understanding is correct.

Providers are required to perform extensive maintenance checks on liquid oxygen equipment furnished to beneficiaries. These checks include testing for purity of content, performing a visual inspection for dents, performing a pressure check and checking for appropriate labels. Until now, these checks have been reimbursed under the monthly fee schedule payment for oxygen and oxygen equipment. Similarly, oxygen cylinders must undergo hydrostatic testing. Though technically these tests are not "repairs," will they be reimbursed as repairs to account for the more extensive service they involve?

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[5] Chapter 20 §60, Medicare Claims Processing Manual, 100-4.
[6] 42 U. S. C. 1395 (m) (7).

Section 5101 requires Medicare to pay for maintenance and service not covered under warranty. Will the Medicare program pay for emergency service calls for beneficiary-owned equipment that is still under warranty? If not, can providers contract with beneficiaries to provide on-call services for patient-owned equipment? When maintenance and service on oxygen equipment is reasonable and necessary, what documentation will providers be required to submit? Will CMS require different documentation depending on whether the provider repairs the equipment it furnished or repairs equipment furnished by another provider? Importantly, after title to equipment transfers to the beneficiary, what will be the impact on the beneficiary if the manufacturer is no longer in business and replacement parts are needed? If the original provider is no longer in business, who will provide service and maintenance on the equipment?

In order to facilitate payment for repairs, we recommend that CMS issue specific HCPCS codes to account for the need to have skilled technicians perform extensive maintenance with specialized tools. Will CMS issue temporary HCPCS codes for this purpose, or will providers have to apply for the codes?

Finally, how will providers be reimbursed for service or maintenance to non-covered oxygen equipment such as conserving devices, oxygen titrating devices, or technology that allows beneficiaries to fill their own cylinders? Will providers bill the beneficiary for these services?

D. Other Questions

Leased Equipment and Outstanding Patient Balances

The DRA provisions for oxygen and oxygen equipment impact provider's business operations in other ways. For example, leasing is a common means of financing medical equipment. It's likely that in many cases providers will need to reconcile lease terms with the statutory period of continuous use. Under this scenario, understanding the implementation date is very important for providers. Does CMS intend to apply these new payment rules as of January 1, 2006 even though their actual implementation is delayed for administrative reasons such as the need to issue carrier instructions and make system changes? In addition, we are concerned about any requirement to transfer title to oxygen equipment to a beneficiary with unpaid balances for co-pays and deductibles. Title to oxygen equipment should remain with the provider until the beneficiary has paid any outstanding deductible and co-payment amounts.

Clinical Assessments for Respiratory Patients

The change in reimbursement for oxygen and oxygen equipment also raises questions about the provider's obligation to furnish continuing care and monitoring. Although ongoing care, monitoring, and assessment of the beneficiary are not explicitly covered by Medicare, most private sector payers and national accrediting bodies expect providers of oxygen to furnish these services. Moreover, providers are required in several states to perform respiratory assessments for patients who receive conserving devices. Other states require the oxygen provider to furnish the patient with a clinical visit shortly after the oxygen is set-up. For Medicare beneficiaries, providers have included these services within the monthly fee schedule payment for oxygen. Will payment for these services

now become the beneficiary's responsibility? Will beneficiaries be required to pay for the services of respiratory therapists and other services that CMS considers non-covered?

Parenteral and Enteral Equipment

Finally, AAHomecare interprets the DRA to apply only to medical equipment in the capped rental Medicare payment category. As you know, parenteral and enteral (PEN) pumps are reimbursed under the prosthetic device benefit, and the payment rules that apply to them differ from the rules that apply to capped rental DME. Consequently, this new rent-to-purchase payment methodology does not apply to PEN pumps. Specifically, PEN pumps fall under the fee schedule category for "parenteral and enteral." PEN pumps can be purchased or rented whereas capped rental items can only be rented. Although rental payments for PEN pumps "cap" after 15 months, subsequent payment for service and maintenance on PEN pumps do not follow the capped rental billing rules. To avoid confusion among the carriers, we request that CMS confirm that PEN pumps are not subject to the DRA's new rent to purchase payment methodology.

Medicare Advantage Plans

As you know, beneficiaries may choose from a number of Medicare Advantage plans, some of which do not follow the payment and coverage policies of traditional Medicare. How will providers be reimbursed if beneficiaries begin to use oxygen or capped rental equipment under a Medicare Advantage plan? Will CMS begin a new period of continuous use each time the beneficiary has a payer change in or out of traditional Medicare?

II. Conclusion

AAHomecare understands that these new payment methodologies do not take effect immediately. However, their impact on our member's operations is immediate because they must begin to structure their operations to respond to the changes. Moreover, providers must plan now for their implementation in order to ensure a smooth transition for Medicare beneficiaries. AAHomecare and its members are prepared to work closely with CMS to address these issues, and we would like an opportunity to meet with you and your staff to discuss these issues further. We will contact you next week to arrange for a mutually convenient time for us to meet.

Sincerely,

Thomas Ryan
Chairman

Michael Reinemer
Vice President, Communications & Policy

AMERICAN
ASSOCIATION
FOR
HOMECARE

Supporting Quality Health Care Services at Home

Via Hand Delivery and Electronic Submission

June 30, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
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Washington, DC 20201
http://www.cms.hhs.gov/eRulemaking

Re: AAHomecare Comments on the Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues [CMS-1270-P]

Dear Dr. McClellan:

The American Association for Homecare (AAHomecare) submits the following comments in response to the Centers for Medicare and Medicaid Services' (CMS') notice of proposed rulemaking (NPRM) on the implementation of a national competitive bidding program for DMEPOS. Congress authorized national competitive bidding for DMEPOS under the Medicare Modernization Act of 2003 (MMA).

AAHomecare is the only national association representing every line of service within the homecare community. AAHomecare members include home health agencies and suppliers and manufacturers of DMEPOS, rehab and assistive technologies, and pharmacies that provide home infusion and inhalation drug therapies to patients in their homes. Our membership reflects a cross-section of homecare providers, including national, regional, and local providers and suppliers. With approximately 800 member companies at 3,000 locations nationwide, AAHomecare and its members are committed to advancing the value and practice of quality health care services at home. AAHomecare members service thousands of Medicare beneficiaries who use DMEPOS items. Our members are committed to providing beneficiaries with high quality DMEPOS items and services that promote positive health outcomes. Consequently, AAHomecare is uniquely qualified to comment on the issues raised under the NPRM.

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As you know, competitive bidding will be an unprecedented departure from the traditional fee-for-service Medicare DMEPOS benefit. We hope that CMS appreciates the experimental nature of this program, especially in light of the limited scope of the two demonstrations. While we understand your desire to meet the deadlines specified under the MMA, we urge you to proceed with caution, especially during the initial implementation phase in 2007. Given the scale of this undertaking and the interests that are at stake, it is more important to protect beneficiary access and the interests of all bidders than to rush through the implementation.

The NPRM predicts that the bid process will begin in 2006, with prices taking effect in October of 2007. This timeline is aggressive in light of the many critical steps that remain to be done. We urge CMS to publish a revised timeline that identifies each of these steps with more realistic target dates for their implementation:

- Publish the supplier standards
- Select accrediting bodies
- Publish regulations
- Publish the initial 10 MSAs
- Publish the initial product categories
- Publish the RFB
- Evaluate bids
- Select contract suppliers
- Educate beneficiaries and referral sources
- Publish program instructions for a transition
- Implement the program in each MSA

We also want to emphasize our concern that the information in the NPRM is inadequate to serve as a basis for public comments on several important issues. A rulemaking procedure must provide notice of a proposed agency action with reasonable specificity to solicit informed public comments. The NPRM falls short of this standard with respect to how §5101 of the Deficit Reduction Act of 2005 (DRA) and the final quality standards will apply under competitive bidding. As you know, §5101 forces Medicare beneficiaries to own their capped rental or oxygen equipment at the end of a statutory period of continuous use. Without establishing the scope of this new requirement and how it will dovetail with competitive bidding, the NPRM is incomplete and vague, limiting our ability to comment.

AAHomecare is aware that CMS will publish regulations to implement the DRA in the future. However we need an opportunity to assess and comment on how the new rules will apply under the framework for competitive bidding. We suggest that CMS issue an interim final rule to allow additional comments on this issue prior to publishing a final rule implementing competitive bidding. In addition, because the NPRM fails to identify the Metropolitan Statistical Areas (MSAs) and the DMEPOS items that will be subject to competitive bidding, we request that CMS also schedule a meeting of the Program Advisory and Oversight Committee (PAOC) when it publishes this information. The

PAOC can provide CMS with additional comments before it begins to implement the program.

It is also imperative that CMS allow stakeholders an opportunity to comment on the quality standards before they become final. We are sensitive to your concerns about meeting the deadlines in the NPRM, but we believe that allowing time for additional comments is unlikely to significantly delay the program. We also believe that it is required given that CMS chose to issue the standards in a program memorandum rather than through a rulemaking proceeding. As a result CMS avoided the requirements under the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget (OMB) that would otherwise be part of rulemaking. CMS should allow the comment period on the NPRM to remain open for an additional 30 days following the publication of the quality standards. CMS should include a response to any comments it receives on the quality standards in its response to the public on the NPRM.

In any event, as we stated above, competitive bidding is a radical departure from the traditional DMEPOS benefit, and CMS has no experience with this program on a wide scale. The quality standards and accreditation will protect beneficiaries by requiring all bidding suppliers to meet an objectively verifiable level of service and quality. The standards and accreditation will also ensure that bidders compete on a "level playing field" by requiring that all bidders factor into their bids the costs of providing the same level of service and quality. Because the standards are at the center of a successful bidding program, CMS should tolerate delays and not rush the quality standards -- or any other aspect of competitive bidding.

Payment Basis

Inflation Update

CMS states that providers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U. Providers have no assurance that Congress will not override the update through subsequent legislation in any given year. CMS needs to address how it plans to assure providers that the inflation update to the competitive bid price will not be subject to subsequent freezes in the CPI-U. If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids.

Grandfathering Medicare Advantage

The NPRM does not address the impact of competitive bidding on Medicare Advantage patients who leave their plan to reenter traditional Medicare. These patients may have a provider who is part of the MA plan network, but that may not be a contract supplier. What rules will apply to this patient population under competitive bidding? Will these patients have the opportunity to continue to use their existing supplier when they reenter the traditional Medicare program? AAHomecare recommends that patients moving from an MA plan to traditional Medicare be given the option of remaining with their existing provider under the grandfathering provisions proposed in the NPRM.

Beneficiary Switch to Contract Suppliers

The NPRM states that a beneficiary can decide to use a contract supplier at any time. Contract suppliers will be required to furnish capped rental or oxygen equipment to beneficiaries in the competitive bidding area regardless of the rental months remaining on the equipment. CMS states that suppliers must factor these additional costs into their bids. Suppliers will be unable to include these additional costs in their bids, because it is not possible to predict whether beneficiaries may decide to switch to a grandfathered supplier and how many rental months remain on a piece of equipment. Moreover, CMS states that suppliers may not submit bids higher than the current fee schedule amount for an item. This artificial ceiling on the bids further complicates bidding under this scenario. AAHomecare appreciates CMS' desire to preserve the beneficiary's freedom to change suppliers even under a competitive bidding program. We recommend that CMS initiate a new period of continuous use if a beneficiary decides to switch from a grandfathered supplier to a contract supplier.

We also suggest that CMS allow contract suppliers access to the common working file or some other streamlined mechanism for determining when a piece of equipment will convert to a sale or that a claim might be subject to a "same or similar" denial. Contract suppliers need to know this information upfront. Not having access to this information will increase suppliers' administrative costs and impact the amount of their bids. CMS should state whether this type of mechanism will be available so that suppliers can factor it into their bids.

Application of DRA to Oxygen Patients

It is unclear from the NPRM how CMS intends to apply the DRA provisions on oxygen to grandfathered suppliers and beneficiaries. Will the "grandfathered" relationship terminate at the conclusion of 36 months? Similarly, how will CMS apply the DRA requirements to beneficiaries who move from one MSA to another? As noted above, the implementation of the DRA forced-ownership provisions on oxygen and capped rental equipment will have important ramifications for competitive bidding. We cannot provide meaningful comments on many issues in the NPRM without understanding how CMS will administer the DRA requirements.[1] Consequently, it is important that CMS publish an interim final rule before it publishes the final rule on competitive bidding.

Authority to Adjust Payment in Other Areas

The NPRM states that CMS has the authority, with respect to items included in a competitive bidding program, to use the payment information obtained through competitive bidding to adjust the payment amounts for those items in areas outside the competitive bidding area. With respect to DME, the authority is based on §1834a(1)(F)(ii). CMS states that the authority under §1834(h)(1)(H)(ii) is the basis for using the information obtained through competitive bidding to adjust the payment amounts for "prosthetic devices and orthotics." CMS should note that the authority under

[1] AAHomecare submitted a letter to CMS in April requesting clarification on how the DRA would apply to a number of scenarios involving oxygen and capped rental equipment. We have not received a response to our question as of the date of these comments. A copy of our correspondence to CMS is attached.

§1834h(1)(H)(ii) applies only to orthotics as defined under §1847a. Specifically, the authority to adjust payment amounts in other areas applies only to "off-the-shelf" orthotics and not also to prosthetic devices as CMS contends.

In implementing its authority under §1834a(1)(F)(ii), CMS should adhere to the inherent reasonableness (IR) methodology authorized by Congress under the Benefits Improvement and Patient Protection Act (BIPA). The IR methodology includes procedural steps to protect stakeholders and requires an analysis of the factors that influence a determination to make a payment adjustment. In using information derived form competitive bidding to adjust payment amounts in other areas, at least one of these factors is the comparability of the CBA to the areas where CMS intends to make a payment adjustment. Our ability to comment further on this issue is limited because CMS has asked only for suggestions on how to implement this authority without publishing notice of a specific proposal. CMS must initiate a separate notice and comment rulemaking to solicit comments on a specific proposal before implementing this authority in a final rule.

Limitation on Beneficiary Liability

We understand that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. Under current Medicare rules, a supplier may furnish the beneficiary with an ABN notifying him that Medicare will not pay for an item. Other portions of the NPRM specifically state that ABNs will be permitted under a competitive bidding program, and the MMA requires that CMS continue to allow suppliers to use ABNs. CMS should clarify what it means when it states that a beneficiary will have no financial liability to a non-contract supplier for competitively bid items furnished by that supplier.

Competitive Bidding Areas

Staggered Implementation

The NPRM is silent on whether CMS will commence competitive bidding in 10 MSAs at the same time, or stagger the initial implementation of competitive bidding in 2007. We recommend that CMS phase-in the first 10 MSAs. This will allow CMS to identify and correct problems as competitive bidding commences before the problems become widespread.

Nationwide or Regional Mail Order Competitive Bidding Program

It is unclear why CMS proposes a separate competitive bidding program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in competitive bidding during 2007 and 2009, a separate program for them in 2010 would be unnecessary. Further, there is no definition for a "mail order" supplier under Medicare program rules. Many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes. As a result, we are also unsure who would qualify to participate in a national competition for mail order supplies.

There are many complicating factors such as changes in a beneficiary's level of supply needs that may inhibit the supplier's ability to deliver reorder supplies to a beneficiary within the required time frame. With glucose monitors, the type/brand that a beneficiary is initially prescribed may change based on the beneficiary's medical status and required changes in the brand of test strips supplied. For example, a beneficiary may develop arthritis and be unable to open the packages of test strips, requiring that they be switched to a different brand in order to comply with the prescribed testing.

While mail order is an appropriate and cost effective vehicle for delivery of some replacement supplies such as test strips and lancets, it may not meet the needs of all beneficiaries who require such supplies. Mail order, while efficient, is subject to the ability to get the supplies to the beneficiary by commercial carrier. Whether or not a beneficiary receiving such supplies lives in a competitive bidding MSA, he or she should have the option of being able to obtain these supplies locally. The Medicare program must allow multiple distribution channels to meet beneficiary needs.

Finally, we note that this proposal represents another example of CMS' failure to provide the level of detail necessary for notice and comment rulemaking. CMS should publish an interim final rule to solicit additional public comment before implementing a national or regional competitive bidding program.

Establishing the Competitive Bidding Area

CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established ***in*** an MSA. Moreover, including a patchwork of areas within a competitive bidding area will make it difficult for contract suppliers to administer competitive bidding from an operations perspective. Finally, CMS must identify the MSAs in which it will commence competitive bidding in 2007 at the time it publishes an interim final rule and schedule a PAOC meeting to solicit additional comments.

Criteria for Item Selection

Items Included in Competitive Bidding

CMS identifies three categories of items that are subject to competitive bidding consistent with the requirements of §1847(a)(2): Covered items as defined under §1834a(13) for which payment would otherwise be made under §1834(a) and supplies used in conjunction with durable medical equipment; enteral nutrition, equipment, and supplies; and off-the-shelf orthotics (OTS). CMS should clarify whether prosthetic devices such as ostomy products and related supplies that were not expressly included under §1847(a)(2) by Congress are subject to competitive bidding.

Potential for Savings

CMS should explain and clarify what specific measures will be used to decide an item's potential savings as a result of competitive bidding. Specifically, CMS should address the following:

- *Annual Medicare DMEPOS allowed charges*: Is there a threshold expenditure level that will trigger competitive acquisition for a product category?
- *Annual growth in expenditures*: Is there a threshold growth percentage and does it vary by the dollar size of the category?
- *Number of suppliers*: How will CMS determine the appropriate number of suppliers for a product category in each MSA? What supplier capacity thresholds will be used to determine this and how were those thresholds determined?
- *Savings in DMEPOS demonstrations*: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects?
- *Reports & studies*: Which ones and types will be considered? Who will review the studies and determine their validity and applicability for modeling Medicare program savings?
- *Allowed Charges*: Does this mean paid claims?

Additional Criteria for Item Selection

Under the proposal in the NPRM, item selection is driven by costs and utilization only. There is a risk that by focusing exclusively on cost and utilization criteria, CMS will allow competitive bidding to become a substitute for appropriate coverage policies as a way of controlling expenditures. In deciding to include a product under a competitive bidding program, CMS should also consider clinical and service factors specific to the product. Some products will be inappropriate for competitive bidding because of the clinical condition of the beneficiaries who use them. For example, invasive ventilator patients have clinical conditions that require clinical monitoring and oversight, making invasive ventilators inappropriate for competitive bidding.

CMS should publish the items it will include in the initial competitive bidding program when it publishes an interim final rule. CMS should also schedule a meeting of the PAOC to solicit additional public comment after it announces the product selections.

Brand-Specific Requirements

The NPRM proposes to allow physicians and practitioners to prescribe a specific brand or type of equipment. According to CMS, this type of provision would preserve beneficiary access to equipment. Although contract suppliers will not be required to carry all brands/models of equipment included in competitive bidding, if a physician orders a brand/model the supplier does not carry, the supplier must choose whether to fill the order, refer the beneficiary to another supplier, or ask the physician to change the order. Medicare will not pay for another item if the supplier failed to provide the brand name item the doctor ordered.

AAHomecare believes it is unnecessary for CMS to include this requirement as part of a competitive bidding program because a physician is always free to order a specific item he/she wants the beneficiary to have. Importantly, this requirement will promote a demand for premium or brand name items based on direct to consumer advertising, even though the "brand name" product has the same clinical benefit as other products. Physicians often are not well-informed about the features and benefits of new

technologies; the homecare supplier is responsible for matching the patient's needs to the equipment or supplies. The proposal is also contrary to how suppliers do business, not only under the Medicare program, but with all payers. Suppliers carry items and equipment that the FDA deems to be functionally equivalent to other products. Forcing suppliers to carry all possible items and equipment will be costly and burdensome and will reduce potential savings from competitive bidding. Finally, the current HCPCS codes do not support brand specificity. A comprehensive overhaul of the HCPCS codes would be necessary to successfully implement this provision. Inasmuch as CMS' authority to implement this requirement is discretionary under the MMA, we recommend that CMS not include this provision in the final rule.

Coding Issues and Item Selection

The methodology that CMS proposes for item selection relies on historical data and does not take into account recent changes in a benefit that will affect utilization. For power wheelchairs, recent changes in the HCPCS codes, a new LCD, and new fee schedules will significantly change utilization for these items. Specifically, CMS would lack the cost and volume data required under the formula in the NPRM to select an item. CMS would be unable to determine which codes within this product category are the highest cost and highest volume for Medicare using current data. Moreover, assuming that the coding, pricing and coverage changes result in accurate utilization for these products, in future years there may not be a rationale for including power wheelchairs in competitive bidding under the formula CMS has proposed. AAHomecare recommends that CMS not include power wheelchairs in the initial rounds of competitive bidding because it would lack recent data from which to determine the HCPCS codes that represent the highest costs and highest volume for CMS. We also recommend that CMS exclude new products that come on the market in the middle of a bidding cycle from competitive bidding.

Submission of Bids

General Issues

Clear definition of the product categories must be outlined for bidding suppliers. All HCPCS codes and their typical quantities should be identified for each product category that the supplier bids. For example, glucose monitors and supplies should include glucose monitors, test strips, lancets, lancing device, and replacement batteries. Glucose monitors for visually impaired (i.e.: E2100) should be identified and bid separately because their cost is drastically different. If the bid pricing is related to the product category and not each HCPCS code that makes up the category, then it may be cost prohibitive to service visually impaired beneficiaries with the monitors, resulting in service issues for beneficiaries. Further, CMS needs to break down the product categories for manual wheelchairs and seating systems so that appropriate seating systems can be included with the wheelchair base.

Weighing Criteria

The request for bid must identify the weighing factors the CMS will apply to the bids.

Requirements to Bid on all Products in a Category

Suppliers may choose to bid on one, some, or all of the product categories, but if a provider bids on a category, that provider must bid on each item included in the category. CMS must define product categories narrowly, to make sure that they are consistent and representative of the products that a supplier might actually furnish. Including a broad category for wheelchairs or power wheelchairs could be very problematic. Suppliers who do not specialize in rehab may not carry power wheelchairs under certain codes. Similarly, suppliers who do specialize in providing equipment to patients with complex needs may not carry all of the power wheelchairs designated by that product category.

- Power wheelchair codes are in the process of being revised. A high probability exists for compromise of patient care due to the breadth of the category combined with the complexity of needs for the high-end rehab patient. Complex rehab wheelchairs are predominantly custom-configured, and they utilize a minimal amount of standard in-stock components. Due to the high probability of inappropriate equipment being provided to the complex rehab patient in the first level of review as well as subsequent provision of appropriate equipment, it is highly probable that a categorical bidding process will be more costly in the long run for complex rehab and assistive technology.
- Manual wheelchairs HCPCS codes will be subjected to a similar recoding process beginning in 2007. Due to its greater breadth as a category, manual wheelchairs will probably cost more to bid categorically for similar reasons. Complex rehab technology patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the proposal in the NPRM, a provider who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. In many cases complex Rehab manual wheelchairs require multiple components from multiple manufacturers to achieve appropriate fit and function for the individual.
- Those providers who are awarded a winning bid in a category for "Wheelchairs" could end up not being a winning bidder for the associated seating. In effect, many patients may need to deal with two or more providers for a single rehab wheelchair. This situation could lead to access issues in areas of the country where a winning provider is not equipped to provide the complexity of multiple seating and positioning services required in that area.
- Current HCPCS codes are too broad, encompassing items that represent vastly different technologies. CMS should develop narrow product categories so that providers may submit proposals for more standard bases with general purpose seating and positioning products compared to high end complex rehab technology services. It is dangerous to the end user for non-qualified providers to be submitting bids for services that they do not provide.

Skilled Nursing Facilities and Physicians

CMS proposes that only skilled nursing facilities (SNFs) and physicians selected as contract suppliers would be eligible to provide DMEPOS in a competitive biding area. Physicians and SNFs can limit their services to their own residents or patients and would not be required to service all beneficiaries in an MSA. In contrast, DMEPOS suppliers awarded contracts, cannot refuse to serve any beneficiary. This means that contract suppliers would be required to accept beneficiaries regardless of the costs the supplier may have to absorb (*e.g.*, assuming a caped rental in the 10th rental month) whereas SNFs and physicians could limit their service costs. Including SNFs and physicians in the same competition with DMEPOS suppliers will distort the bid evaluation and selection of the pivotal bid because SNFs and physicians will have significantly lower costs to operate under the bidding program. We recommend that CMS conduct separate competitions for those items that will be furnished by SNFs or physicians such as enteral nutrition, equipment and supplies.

Conditions for Awarding Contracts

Quality Standards and Accreditation

The NPRM states that CMS will allow a "grace period" during which unaccredited providers can participate in the bidding process. Unaccredited providers who are winning bidders may complete accreditation during this unspecified grace period. If it fails to get accredited during the grace period, the bidder will loose its contract supplier status. Whether a supplier is accredited influences its bid amount inasmuch as accredited suppliers must bear the cost of complying with the quality standards. Including bids from accredited and unaccredited suppliers in the same bid pool distorts the selection of a pivotal bid, because unaccredited suppliers do not factor the costs of complying with quality standards into their bids. These costs are unknown until CMS publishes final quality standards. Consequently, unaccredited suppliers who lack experience with accreditation will not be able to accurately project those costs, skewing the pivotal bid point and the median bid downward. We strongly recommend that CMS allow only accredited suppliers to submit bids. In other words, accreditation must be a minimum eligibility requirement to submit a bid. CMS should not proceed with competitive bidding in an MSA until it is sure that that all suppliers who want to submit bids have had an opportunity to get accredited.

Financial Stability

The evaluation of the supplier's financial stability must take place *before* the bid prices are arrayed and the pivotal bid is selected. Bids from disqualified providers should not be considered in selecting the winning bid point or setting the payment amount. Again, suppliers who do not meet financial standards are likely to have a different cost structure from those that do. It is unfair to include the bids from these suppliers in the bid pool from which the pivotal bid is selected or a payment amount established. CMS should publish the criteria it will use to assess the supplier's financial stability and how it will rank the supplier based on the criteria. The information on rankings should be published in the interim final and final regulations as well as in the request for bids (RFB).

To assess a supplier's financial stability and capacity, CMS should require as a minimum *reviewed* financial statements. This will ensure that the financial statements have been examined by an outside accounting firm. CMS may also want to evaluate the supplier's cash flow. Cash flow can be measured by examining the balance sheet and confirmed by looking at banking statements from the last six months (or longer period). As a practical matter, including bank statements as a requirement may prove burdensome for suppliers and CMS. Consequently, CMS may want to limit its request for bank statement to those situations where it needs to resolve doubts about the supplier's other submissions. In any case, CMS would have to define the period for the bank statements it is requesting, *e.g.*, third and fourth quarters of the previous year, in order to ensure consistency in its analysis across suppliers.

To assess capacity to meet increased demand under competitive bidding, CMS should consider the supplier's debt-to-equity ratio (long term debt divided by shareholders equity). The debt-to-equity ratio provides a measure of the extent of the supplier's leverage which, in turn, is a measure of a company's capacity to borrow. This measure may have significant drawbacks when applied to private firms because it is difficult to place a value on equity, making the formula easy to manipulate. An alternative ratio is the EBITDA (earnings before interest taxes depreciation and amortization)-to-debt-ratio, because EBITDA may be more difficult to manipulate. To simplify the analysis, CMS could use the quick ratio (current assets minus inventory divided by current liabilities) which some AAHomecare members have indicated is favored by their lending institutions.

CMS representatives have stated that there was great variability in how suppliers booked their accounts receivables (A/R) when supplier financial criteria were assessed during the demonstrations. As a result, A/R was not a useful measure of supplier financial health (because it could not be used to compare suppliers). To address this issue, CMS should define A/R under the quick ratio as less than 180 days sales outstanding (DSO). DSO is a measure of how long it takes the company to collect money it is owed. The quick ratio provides a measure of the supplier's liquidity, *i.e.*, its ability to meet short term operating needs.

Additionally, the bidding supplier should identify for CMS all of its interest bearing debt which, in combination with the quick ratio, would give CMS a picture of the supplier's capacity to borrow. Finally, CMS should look at the Dunn & Bradstreet accounts payable ratings by the supplier's creditors. The D & B information provides an additional measure of whether the supplier is in fact able to meet its current obligations because creditors will report on the length of the supplier's accounts payable cycle.

<u>Accreditation</u>

CMS needs to identify the criteria it will use to select accrediting bodies *now*. CMS should be encouraging accreditation rather than discouraging it and should grandfather all providers accredited by organizations that meet the criteria CMS identifies. We recommend that CMS "fast track" accreditation in the manner that was suggested during

the PAOC meeting so that CMS can publish a notice soliciting public comments on the organizations that are seeking designation as an accrediting body. CMS' goal should be to promote an aggressive accreditation campaign to assure that providers in any MSA with a competitive bidding program are accredited *before* the bid solicitations are published. As we stated above, CMS should not commence competitive bidding in any MSA until all potential bidders have been accredited.

Market and Supplier Capacity

The NPRM states that CMS will evaluate market capacity and supplier capacity to determine the number of suppliers necessary to service beneficiaries in an MSA. We agree that CMS must carefully evaluate capacity issues to ensure adequate access to DMEPOS items in a competitive bidding area. Under the methodology proposed in the NPRM, CMS would array the composite bids from lowest to highest and count up from the bottom until it identifies the point where the bidders' cumulative capacity is sufficient to service the MSA. This will be the winning, or "pivotal" bid. This methodology does not include any mechanism to "rationalize" the bids to ensure that there are no unreasonably low bids. Although competitive bidding is premised on the theory that suppliers will submit their "best bid," in fact there will be suppliers with small individual capacity who may submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity.

AAHomecare recommends that the bid solicitation and evaluation process include safeguards against this type of bidding strategy. At the very least, CMS should eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. If these safeguards are not part of the process, CMS can have no assurance that the competitive bidding payment amounts are sustainable over time.

The NPRM also states that if at least two suppliers are at or below the pivotal bid amount, CMS would designate the two suppliers as winning bidders. We urge caution in adopting this minimalist approach. CMS should select more suppliers than necessary to meet minimum capacity requirements in the competitive bidding area. Any number of circumstances, such as a natural disaster, could create unanticipated access problems for beneficiaries in the MSA. It is unlikely that CMS could address these types of access problems quickly enough to avoid serious disruption to patient care. Additionally, CMS should at least consider other variables beyond capacity that may affect the selection of winning bidders. For example, beneficiary convenience and proximity to contract suppliers would greatly diminish under a scenario where CMS selects only two or three contract suppliers. We recommend that CMS use 130% of anticipated Medicare volume as the threshold for the number of suppliers needed in a competitive bidding area.

Supplier Evaluation

CMS must describe what criteria it will use to compare bidders (aside from the amount of their bid) and how CMS would apply the criteria. As we have stated before, this evaluation must take place before the composite bids are arrayed and the pivotal bid is selected. The supplier evaluation should include, at a minimum, three hurdles that a

bidder must clear, before its bid is included in the final array. First, is the company accredited? If not, the bid is rejected. Second, does the company meet the financial standards? If not, the bid is rejected. Third, is the claimed "capacity" realistic? If not, the capacity is lowered to an appropriate number. Only bids from bidders who clear these hurdles should be included in the final array.

Assurance of Savings

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Instead, CMS should adopt the methodology used in the demonstrations. CMS should look for savings in the overall product category even though a single payment amount for a specific item may be higher than its current fee schedule amount.

Determining the Single Payment Amount

CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the "winning suppliers." This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects. More importantly, we believe Congress did not have this methodology in mind when it authorized competitive bidding under the MMA. CMS should set the payment amount at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This method was used in the two demonstration projects. No contract supplier should be forced to accept a payment amount that is lower than its bid.

Rebate Program

The NPRM describes a rebate program that would allow contract suppliers to give the beneficiary a rebate in an amount equal to the difference between their bid and the single payment amount. CMS proposes to make the rebate program voluntary and would not allow suppliers to advertise the rebate to beneficiaries. Instead, CMS would distribute program materials in the competitive bidding area that would identify contract suppliers that offer rebates. We have grave concerns about the program integrity ramifications surrounding this proposal and do not understand how CMS can reconcile a rebate program of this type with the statutory prohibition on beneficiary inducements under §1128A(a)(5) of the Act.

Specifically, §1128A(a)(5) prohibits the offering or transfer of remuneration when an individual or entity knows or should know that it is likely to influence the beneficiary's selection of a provider or supplier. Remuneration includes anything of value and would apply to the rebate proposed by CMS. While the statute contains exceptions to the

definition of the term "remuneration," the rebate program proposed in the NPRM does not fit any of the statutory exceptions. For example, "remuneration" does not include unadvertised waivers of coinsurance or deductible amounts for individuals who have been determined to be in financial need. The rebate offered by contract suppliers under the CMS program would not fit into this exception or any of the other exceptions under §1128A(a)(5). We are also unaware of any guidance from the Office of Inspector General (OIG) of the Department of Health and Human Services that would authorize the program CMS proposes. In light of the statutory prohibitions of §1128A(a)(5), CMS lacks the authority to implement a rebate program. Consequently, CMS should withdraw the proposal.

The OIG has published guidance in the form of advisory opinions, fraud alerts and special advisory bulletins to assist providers and suppliers in understanding their obligations to comply with the statutory prohibition on beneficiary inducements. OIG guidance has consistently held that inducements distort beneficiary decision making, increase costs to the Medicare program, and undermine competition among providers. In a Special Advisory Bulletin, *Offering Gifts and Inducements to Beneficiaries*, published in August 2002 (Bulletin), the OIG took an uncompromising stance against the practice of offering *any* inducements, other than items of nominal value, to Medicare beneficiaries. The OIG provided the following rationale for its position:

> Offering valuable gifts to beneficiaries to influence their choice of a Medicare or Medicaid provider raises quality and cost concerns. Providers may have an economic incentive to offset the additional costs attributable to the giveaway by providing unnecessary services or by substituting cheaper or lower quality services. The use of giveaways to attract business also favors large providers with greater financial resources for such activities, disadvantaging smaller providers and businesses.

Bulletin at 1.

CMS proposes two ways to ameliorate the fraud and abuse issues inherent in the rebate program. First, CMS would require any contract supplier that offers rebates to offer the rebate to all Medicare beneficiaries in the competitive bidding area. The supplier could not pick and choose which beneficiaries would get a rebate as a way of enticing desirable patient populations. For example, the supplier could not only offer the rebate to patients with a specific chronic diagnosis requiring long-term rental equipment. Second, the supplier could not advertise the fact that it offers a rebate.

Once an inducement is in the public domain, its harmful effects cannot be contained, even with the safeguards CMS intends to implement. The fact that a provider does not "actively" promote an inducement does not change the illegal nature of the activity or the disruptive repercussions it has on competition and quality of care. The OIG would be

unlikely to approve of a rebate program like the one CMS proposes even if the supplier did not advertise the rebate:

> The "inducement" element of the offense is met by *any offer* of valuable . . . goods and services as part of a marketing or promotional activity, *regardless of whether the marketing or promotional activity is active or passive.* For example, *even if a provider does not directly advertise or promote the availability of a benefit to beneficiaries, there may be indirect marketing or promotional efforts or informal channels of information dissemination, such as "word of mouth" promotion by practitioners or patient support groups.*

Bulletin at 5 (Emphasis supplied).

CMS' proposal to allow contract suppliers to offer rebates fundamentally conflicts with the longstanding rationale underlying the prohibitions on inducements and kickbacks in federal health care programs. This type of activity distorts patient decision making and undermines true competition among health care providers. Importantly, the rebate program would promote *exactly* what Congress chose to prohibit when it enacted prohibitions on beneficiary inducements under §1128A(a)(5) – competing for business by offering Medicare beneficiaries remuneration. Consequently CMS should withdraw the proposal.

Terms of Contract

Repair or Replacement of Equipment

CMS will require contract suppliers to accept all beneficiaries within the competitive bidding area. CMS will also require contract suppliers to repair or replace beneficiary owned equipment under the competitive bidding program. As we mentioned above, we recommend that CMS allow a new period of continuous use to begin when a beneficiary switches to a contract supplier. This preserves the beneficiary's choice and protects the contract supplier who may have to furnish equipment to the beneficiary without adequate compensation for the item or the service it requires. The repair of patient owned equipment should be treated as a separately bid item on the RFB. In other words, CMS should solicit bids for the repair of patient owned equipment. We assume that replacement equipment will be provided and paid for in an amount equal to the single payment amount.

Different Contract Terms

CMS states that the length of the contract may be different for different product categories. We strongly urge CMS to have the same length contract for all products in a competitive bid area to minimize confusion among beneficiaries, referring physicians and suppliers. As it is, there are numerous variables that these stakeholders will have to understand (which products are part of the competitive bid; the boundaries of the

competitive bid, etc.), and it will simply create confusion if there are different lengths of contracts for different product categories in the same MSA.

Termination of Contract

CMS must include procedural safeguards for contract suppliers prior to terminating their contract. Minimum requirements for the process are notice that CMS believes the supplier is in breach, an opportunity for the supplier to cure the breach, and a review or appeal mechanism if the supplier is terminated. The contract terms should also include a provision to allow a supplier to terminate the contract without breaching it.

Judicial and Administrative Remedies

CMS should include a procedure for debriefing suppliers who did not win a bid as well as an opportunity for a review to determine, at a minimum, whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

Change of Ownership

It is reasonable for CMS to review a change of ownership to determine whether the new entity meets the quality standards before granting the new company contract supplier status. However, CMS cannot unreasonably withhold its approval of a change of ownership and should not deny contract supplier status to the new entity on the basis that its capacity is not necessary within the competitive bidding area. CMS' proposal would improperly restrict an owner's right to transfer its property and greatly diminish the value of winning a bid. We are aware from the discussion at the last PAOC meeting of CMS' concerns that some suppliers will use acquisition as a strategy to gain contract supplier status. While this may have been successful in the demonstrations, it is unlikely that a supplier with business interests in an MSA would rely on an acquisition strategy outside a demonstration environment. In any event, the new entity would be forced to bid in any subsequent rounds of bidding to maintain its contract supplier status. We recommend that CMS approve changes of ownership if the new entity will meet applicable quality standards and conform to other requirements of competitive bidding. CMS' approval should not be withheld based on a determination that the new entity's capacity is not necessary.

Participation of Small Suppliers

CMS has taken a very narrow view of its obligation to ensure that small suppliers are adequately represented among contract suppliers. CMS' proposal for allowing networks does not consider the practical hurdles involved in creating a new entity. Under the timelines that CMS has announced, it will be difficult to establish networks that can meet the eligibility requirements for submitting bids. Consequently, this may not be a viable option for most suppliers. CMS has also stated that the market share for supplier networks cannot exceed 20%. CMS should expand this to allow greater participation by small suppliers. CMS should also include meaningful small supplier set asides in the competitive bidding areas. We again request that CMS schedule a PAOC meeting as soon as it identifies the products and the MSAs so that stakeholders can provide additional comments on issues pertaining to small supplier participation.

New Gap-Filling Methodology

CMS proposes to implement a new gap-filling methodology that would rely on a technology assessment process to establish fee schedule amounts for new HCPCS codes and for new DMEPOS products. CMS has used gap-filling since 1989 to estimate what the average reasonable charges would be for a new item if the item had been paid for under Medicare during the fee schedule base period. Under the current gap-filling methodology, CMS "deflates" the current manufacturer suggested retail price (MSRP) for an item using the CPI-U to estimate its 1989 MSRP. CMS then trends that price forward using the legislatively mandated covered item update for the item through the current year. Because the gap-filling methodology assumes that the MSRP increases are consistent with increases in the CPI-U, and because the covered item update has been 0% or "frozen" numerous times by Congress since the fee schedules were created, gap-filling can result in Medicare payment amounts that are too high or unrealistically low.

According to the NPRM, CMS has engaged contractors to evaluate technologies for the purpose of making payment and HCPCS coding decisions for new items. CMS states that its purpose in engaging the contractors was to identify technologies that provide demonstrated clinical benefits and recognize those benefits over existing technologies. Although the NPRM does not identify what products CMS assessed, they were assessed in three main areas:

- Functional Assessment – to evaluate the device's operations, safety, and user documentation relative to the Medicare population. Health care providers were asked to determine how and under what circumstances they would prescribe the product for a Medicare beneficiary.
- Price Comparison Analysis – to evaluate the costs of the product compared to similar products on the market or alternative treatment modalities.
- Medical Benefit Assessment – to evaluate the effectiveness of the product. Scientific literature reviews and interviews with health care providers were conducted to determine if the product significantly improved clinical outcomes compared to other products and treatment modalities.

CMS is proposing to use these three types of assessments to help set fee schedule amounts when new HCPCS codes are created for a category of items. CMS would also use the technology assessment to determine whether new HCPCS codes need to be established for new products and to determine the payment amount for new items. CMS intends to use the technology assessment process any time after January 1, 2007, to adjust payment amounts that were previously established using the gap-filling methodology if it determines that those pricing methods resulted in payment amounts that do not reflect the cost of furnishing the item.

We are encouraged to know that CMS recognizes that the current gap-filling methodology can have arbitrary results. We also agree that CMS should depart from the practice of "deflating" current MSRP to arrive at a gap-filled amount and that CMS

should use the median current retail price for new items to establish the payment amount. We remain concerned, however, because the proposal for a technology assessment process is vague and lacks any opportunities for stakeholder participation. More importantly, CMS' only authority to adjust payment amounts for an item or a category of items is the IR authority under §1842(b)(8) and (9), and CMS is not authorized to depart from the authority.

Under the IR methodology established by Congress, CMS must make a determination that using the "standard rules for calculating payment" results in a payment amount that is not inherently reasonable. Congress explicitly directed the Secretary to identify the factors that it would use to determine when a payment amount is not "inherently reasonable" because it is either grossly excessive or grossly deficient. CMS must use "valid and reliable data" in making this determination and in establishing a new payment amount.[2] Importantly, IR includes specific procedural safeguards that apply to determinations to adjust a payment amount by more than 15%. For payment adjustments greater than 15%, CMS must consider (among other factors) the "potential impact of such a determination on quality, access, and beneficiary liability, including the likely effect on assignment rates and participation rates."

Under the proposal in the NPRM, CMS could avoid complying with the IR methodology simply by migrating existing products into new HCPCS codes. Congress specifically required notice and comment and the use of valid and reliable data under the methodology to protect beneficiaries and providers from poorly conceived payment reductions that affect access. CMS cannot use a technology assessment to make a payment adjustment based on a determination that a payment amount does not "reflect the cost of furnishing the item" because those factors cannot serve as the basis for a special payment adjustment under §1842b (8) and (9).[3]

We do not disagree that CMS should establish fee schedule amounts for new products using the median retail price for the item. However, to the extent that CMS intends to use a technology assessment to establish a payment amount or a new HCPCS code for new products, we cannot provide meaningful comments without additional information. At a minimum CMS must identify the factors it would consider in deciding to initiate a technology assessment and establish mechanisms to solicit participation from interested stakeholders. More importantly, this proposal has ramifications beyond the DMEPOS competitive bidding program and CMS may have limited stakeholder input by including

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[2] 42 C. F. R. §405.502 (g).

[3] We also note that we do not understand how the technology assessment CMS proposes can be used to arrive at a determination that the payment amount for an item does not reflect the cost of furnishing an item. The criteria proposed for the technology assessment focus on a cost benefit analysis of the technology relative other similar products. This analysis is different from an analysis of provider costs to furnish the product which would include not only the acquisition cost of the product, but also the cost of servicing the beneficiary, the cost of accreditation and other regulatory compliance, as well documentation, billing, and other similar costs.

it in this NPRM. Consequently, CMS should initiate a separate rulemaking proceeding to address this issue and allow broader stakeholder participation.

Changes in HCPCS Codes During A Bidding Cycle

We disagree with the proposals for paying new HCPCS categories that are established during a competitive bidding cycle. The rationale for establishing new codes during a competitive bidding cycle would be to create codes that are more representative of specific technologies. Thus it would be unfair to pay new codes for more expensive technology at the same payment amount applicable to older codes that included products spanning a broader spectrum of technology. CMS should re-bid these codes, assuming they are appropriate for bidding.

Impact Analysis

We believe that CMS has minimized the impact of competitive bidding on beneficiaries and small businesses. According to the CMS Regulatory Impact Analysis, about half of bidding suppliers will not be selected as contract suppliers, adversely affecting the majority of suppliers in this country. These non-contract suppliers will therefore not likely be able to sustain their businesses based upon the items not included in competitive bidding. We believe the proportion of adversely affected suppliers will be significantly greater for smaller suppliers, given the fact that price will be the key factor in determining which suppliers become contract suppliers. Competitive bidding will force about half of the current suppliers to go out of business.

CMS predicts that impact on beneficiaries who will be forced to switch suppliers will be minimal. We are not sure how CMS can arrive at the conclusion in light of its estimates that 50% of bidding suppliers will loose their bids. Moreover, CMS is allowing "grandfathering" for a very limited subset of products, again impacting those beneficiaries who will be unable to elect a "grandfathered" status.

CMS' Regulatory Impact Analysis is limited in terms of the scope of the real economic impact throughout the country. CMS has not considered the larger macroeconomic impacts of forcing half of the DMEPOS suppliers out of business; these impacts include lost jobs, lost personal and corporate taxes, and other direct losses to communities across the country that will result from a large number of small business entities being forced to close their doors.

Further, CMS' Regulatory Impact Analysis overstates the potential savings from implementing competitive bidding. CMS cannot assume that competitive bidding will achieve the same level of savings as were experienced in the demonstration projects in Polk County, Florida, and San Antonio, Texas. Congress has imposed a series of significant cuts on the major product categories. For example, the Medicare Modernization Act imposed significant cuts to oxygen (11-13%, hospital beds 20%, nebulizers 22%, etc.). Further, there have been CPI freezes imposed on the DMEPOS fee schedules, which are in reality a cut as labor, fuel and other costs have increased

dramatically over the last few years. As a result of this series of significant cuts, we strongly recommend that CMS re-calculate the potential savings; and recommend that the Administration request Congress to request that the Congressional Budget Office revise its estimate of savings in light of these facts that will have a direct impact on the potential savings associated with implementing competitive bidding.

Finally, we believe that CMS has significantly under-estimated the administrative costs associated with developing and implementing the competitive bidding program. The administrative costs to review all bidders' information to ensure compliance with quality, financial and other standards, physical site visits to potential contract suppliers, bid review, calculation of pivotal bids and single payment amounts, and ongoing oversight in the competitive bidding areas will be enormously complex and resource intensive. CMS should re-examine its assumptions, and based upon comments received, recalculate the anticipated costs of administering this program. CMS should then provide that information to the Congress, along with its revised estimate of the potential for savings associated with the program. Looked at together, the administrative costs will not be able to be rationalized, given the meager potential savings that the program might yield.

Conclusion

For the reasons we stated above, AAHomecare requests that CMS adopt the recommendations we make in these comments. We appreciate the opportunity to submit these comments and remain available to discuss them with you in greater detail.

Sincerely,

Michael Reinemer
Vice President, Communications & Policy

Enclosure

Via E-Mail and Federal Express

April 20, 2006

Mr. Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **Implementation of the Deficit Reduction Act of 2005 to Medicare Reimbursement to Oxygen and Durable Medical Equipment**

Dear Mr. Kuhn:

As you are aware on February 8, 2006, the President signed into law the Deficit Reduction Act (DRA) of 2005, P. L. 109-171. Section 5101 of the DRA amends the provisions of the Social Security Act (SSA) that govern Medicare payment for home oxygen therapy and rental of certain items of durable medical equipment (DME). Beneficiaries who use home oxygen or rent DME now have a higher burden to manage their care and coordinate service and maintenance for their medical equipment. The DRA provisions also significantly impact the operations of suppliers who furnish oxygen and DME to beneficiaries. The American Association for Homecare (AAHomecare) is writing to request clarification on how the Centers for Medicare and Medicaid Services (CMS) intends to implement these new requirements, especially with respect to the specific questions we raise below. For your easy reference, we have also included the questions in an appendix attached to this letter.

By way of background, prior to February 8, 2006, Medicare reimbursed oxygen and oxygen equipment on the basis of a continuous rental. In other words, Medicare would pay for home oxygen therapy as long as a beneficiary met Medicare's coverage criteria. The monthly rental payment for oxygen is a modality neutral bundled payment that covers ongoing service and maintenance for the equipment. In contrast, under §5101, Medicare will pay for the rental of oxygen equipment over a period of "continuous use" of 36 months, after which title to the equipment transfers to the beneficiary. Medicare will pay only for "oxygen" after 36 months. Further, after the statutory period of continuous use, Medicare will pay only for service and maintenance of oxygen equipment that the Secretary deems "reasonable and necessary." This payment methodology became effective January 1, 2006 for all Medicare beneficiaries on home oxygen as of December 31, 2005.

Prior to the DRA, Medicare paid for certain DME items under a "capped" rental payment methodology. This means that beneficiaries could elect to own or rent the medical equipment after a rental period of 10 months. If the beneficiary chose to continue the rental, Medicare payments for the equipment would "cap" after 15 months, and the supplier would receive a maintenance and service fee every six months. Otherwise, title to the equipment transferred to the beneficiary after 13 months.

Section 5101 eliminates the capped rental payment methodology. Instead, Medicare will rent most items of DME for 13 months of continuous use, after which title to the equipment will transfer to the beneficiary. Medicare will pay only for service and maintenance the Secretary determines to be reasonable and necessary after the 13 month rental period. This new "rent-to-purchase" payment methodology is effective for rental periods beginning on or after January 1, 2006.

I. Questions on the Application of the DRA Provisions

The DRA fundamentally revises the payment structure for oxygen and capped rental DME. As a result, existing billing, payment, and documentation rules for oxygen and DME are inadequate to address the changes imposed under the DRA. CMS will need to revise the current rules and establish new HCPCS codes to capture the services and products that are no longer bundled into the monthly fee schedule amount for oxygen and DME. AAHomecare's questions pertain to CMS' plans for making these changes and the timeline for their implementation.

A. Medical Necessity and Documentation

How will CMS apply "break-in-service" rules to oxygen and DME under the new payment provisions? For capped rental DME, Medicare rules allow for temporary interruptions in the period of "continuous use." An interruption of no more than 60 days plus the days remaining in the rental month in which the use ceases is a temporary interruption, regardless of the reason for the interruption. When there is a temporary interruption in continuous use, medical necessity for the rented equipment is presumed to continue.[1] If the interruption is not temporary, then a new rental period begins, subject to the requirements specified in the rule.[2]

We expect these rules to remain in effect for DME and request that you confirm whether that is correct. For example, if a beneficiary using a support surface is "healed" within the meaning of the medical policy, but "breaks down" again after 60 days, will a new period of continuous use begin?

Importantly, §5101 (b) authorizes the Secretary to determine how he will define "continuous use" for oxygen and oxygen equipment. We believe CMS must issue regulations to define "continuous use" and what constitutes a "break in service" for

[1] 42 C. F. R. §414.230 (c) (3) (2006).

[2] The provider must submit a new prescription, new medical necessity documentation and a statement explaining the reason for the interruption and demonstrating that the medical necessity for the prior episode ended.

beneficiaries on oxygen. Specifically, when will a break in service for an oxygen patient commence a new period of "continuous use"?

In the past, if a beneficiary experienced a change in condition that resulted in the need to change his or her oxygen equipment (such as a change from stationary oxygen only to both stationary and portable oxygen), the provider would simply switch the beneficiary's existing equipment to other equipment consistent with the doctor's prescription. For example, a beneficiary on liquid oxygen during the first 30 rental months requires a medically necessary change in equipment in the 31st rental month, and the physician orders a stationary concentrator or a portable concentrator for the beneficiary. In this example, will the beneficiary's change in condition start a new 36 month period of continuous use?

Moreover, after a beneficiary owns the equipment, will Medicare pay for new equipment on the basis of a change in condition? Medicare program rules for capped rental DME contemplate that a new period of continuous use begins when the beneficiary has a new prescription or requires additional equipment;[3] these rules were not intended to apply to oxygen because oxygen was reimbursed as a continuous rental under the original fee schedules. Consequently, CMS must issue new regulations to address these questions. What is CMS' projected timeline for a proposed rule?

If new technology becomes available that is medically appropriate and has the potential to improve health outcomes, is the beneficiary responsible for paying for the new equipment (assuming there has been no change in condition)?

The DRA contemplates that Medicare will continue to pay for medically necessary oxygen after title to the equipment transfers to the beneficiary. How will the medical necessity documentation for oxygen change? Currently, the Medicare program requires a "lifetime" certificate of medical necessity (CMN). Will lifetime CMNs be valid for beneficiaries who own their own equipment?

B. Reimbursement Questions

Some beneficiaries have dual systems. That is, they have both a concentrator and a stationary liquid system or a stationary concentrator and a portable concentrator. Under Medicare's modality neutral payment methodology, providers only bill the Medicare program for one system. At the end of the period of continuous use, what equipment will these beneficiaries own? Will the beneficiary be responsible for purchasing one of the two systems?

We interpret §5101 (b) to require the transfer of title to oxygen equipment, including portable equipment, after 36 months of continuous use. As you are aware, portable equipment may include an oxygen cylinder equipped with a flow meter and a cannula. The DRA requires Medicare to pay for medically necessary oxygen after title to oxygen equipment transfers to the beneficiary. How will CMS pay for refills on oxygen

[3] 42 C. F. R. §414.230 (f) (2006).

cylinders? Will the payment amount differ between patients who require more refills because they have a greater need for mobility or a higher prescribed liter flow? How will CMS address payment for patients who have both a concentrator and a liquid system where the liquid system is being used primarily for ambulatory portable requirements? Will Medicare pay for additional portable cylinders after the 36 months, or will the patient be responsible for purchasing these items? Will beneficiaries be responsible for purchasing supplies such as cannulas and tubing for their oxygen equipment or items such as humidifiers?

May providers charge beneficiaries a rental or purchase for a back-up emergency cylinder that is not used to meet the beneficiary's portable oxygen needs? These units would be used solely in the event of an emergency such as a power outage, natural disaster, or a malfunction of the beneficiary's primary equipment. Will Medicare pay for contents once these cylinders are used? Finally, will the payment amount differ based on different oxygen technologies that may be more or less costly for the provider to furnish?

As you are aware, oxygen is a prescription drug, and oxygen equipment, including oxygen cylinders, is highly regulated by several Federal agencies including the United States Department of Transportation (DOT) and the United States Food and Drug Administration (FDA). An important safety concern for the FDA is the provider's ability to test oxygen cylinders and to verify their chain of custody. This will be very difficult to do for patient-owned equipment, especially if the beneficiary changes supplier after he or she owns the equipment (e.g., the beneficiary moves out of the provider's service area). This also raises significant liability issues for patient-owned equipment, especially if the beneficiary changes supplier after he or she owns the equipment (e.g., the beneficiary moves out of the provider's service area). There may be instances where beneficiaries purchase cylinders second-hand from non-providers (eBay®, for example). As a consequence, there may be instances where providers may be unable to service a patient-owned portable oxygen cylinder that they did not furnish. Will the beneficiary be responsible for purchasing new oxygen cylinders under these circumstances?

The local coverage determination (LCD) for oxygen states that the beneficiary is responsible for coordinating travel oxygen needs. The beneficiary's existing oxygen provider may service the beneficiary's travel oxygen needs, but is not required to do so. For short-term travel, the beneficiary pays for the oxygen out-of-pocket, and the primary provider may reimburse all or a part of those costs.[4] We anticipate that this rule will not change. That is, the beneficiary will continue to be responsible for arranging and paying for short-term travel oxygen. Please confirm that our understanding is correct with respect to the 36-month period of continuous use. After title to the equipment transfers to the beneficiary, will Medicare pay the beneficiary directly for short-term travel oxygen?

Beneficiaries who spend the winter or summer months away from their primary residence may have more than one supplier. Similarly, beneficiaries who move out of a provider's service area will have more than one provider. How will CMS determine the period of continuous use in these scenarios? Will rental months at the second residence apply

[4] See DMERC Region B Bulletin, Spring (1999).

towards the 36 months of continuous use? If so, which provider is responsible for transferring title to the beneficiary? We foresee significant access issues for beneficiaries if providers are forced to transfer title to equipment that they have rented for only a few months. Beneficiaries who move or change providers "midstream" may have difficulty finding a new provider for the same reason.

The Medicare Claims Processing Manual states that Medicare will not make a separate payment for pick-up and delivery of oxygen equipment because these charges are included in the monthly fee schedule payment for oxygen.[5] After title to oxygen equipment transfers to the beneficiary, will the beneficiary be responsible to pay charges for pick up and delivery of oxygen refills? If not, what data does CMS propose to use to arrive at an appropriate payment amount? The Medicare Claims Processing Manual also states that pick up and delivery charges are included in the Medicare fee schedule payment amount for capped rental DME. For beneficiary-owned equipment that requires servicing, will Medicare pay pick up and delivery charges? If so, what data will CMS use to arrive at an appropriate payment amount?

Finally, does CMS intend to apply any of the billing rules that applied to capped rental equipment to rent to purchase DME? A purchase option letter is unnecessary inasmuch as the beneficiary no longer has the "option" to purchase the equipment. Consequently, we see no need to use the BP, BR, or BU modifiers in the 11th, 12th, and 13th rental months.

C. Service and Maintenance

Section 1834 (a) (7) of the SSA states that the reasonable useful lifetime for capped rental DME is five (5) years, unless the Secretary specifies otherwise.[6] This statutory provision does not apply to oxygen and oxygen equipment. How will CMS define the useful life of oxygen equipment? If oxygen equipment is "irreparably damaged" after title has transferred to the beneficiary, but before the end of the equipment's "useful life," will Medicare pay for new equipment? If so, will this commence a new period of "continuous use," or will CMS pay a lump sum amount for the new equipment? Importantly, does CMS have a timeline for issuing regulations that address these questions? Finally we anticipate that the useful life for capped rental DME will remain 5 years consistent with §1834 (a) (7). Please confirm that our understanding is correct.

Providers are required to perform extensive maintenance checks on liquid oxygen equipment furnished to beneficiaries. These checks include testing for purity of content, performing a visual inspection for dents, performing a pressure check and checking for appropriate labels. Until now, these checks have been reimbursed under the monthly fee schedule payment for oxygen and oxygen equipment. Similarly, oxygen cylinders must undergo hydrostatic testing. Though technically these tests are not "repairs," will they be reimbursed as repairs to account for the more extensive service they involve?

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[5] Chapter 20 §60, Medicare Claims Processing Manual, 100-4.
[6] 42 U. S. C. 1395 (m) (7).

Section 5101 requires Medicare to pay for maintenance and service not covered under warranty. Will the Medicare program pay for emergency service calls for beneficiary-owned equipment that is still under warranty? If not, can providers contract with beneficiaries to provide on-call services for patient-owned equipment? When maintenance and service on oxygen equipment is reasonable and necessary, what documentation will providers be required to submit? Will CMS require different documentation depending on whether the provider repairs the equipment it furnished or repairs equipment furnished by another provider? Importantly, after title to equipment transfers to the beneficiary, what will be the impact on the beneficiary if the manufacturer is no longer in business and replacement parts are needed? If the original provider is no longer in business, who will provide service and maintenance on the equipment?

In order to facilitate payment for repairs, we recommend that CMS issue specific HCPCS codes to account for the need to have skilled technicians perform extensive maintenance with specialized tools. Will CMS issue temporary HCPCS codes for this purpose, or will providers have to apply for the codes?

Finally, how will providers be reimbursed for service or maintenance to non-covered oxygen equipment such as conserving devices, oxygen titrating devices, or technology that allows beneficiaries to fill their own cylinders? Will providers bill the beneficiary for these services?

D. Other Questions

Leased Equipment and Outstanding Patient Balances

The DRA provisions for oxygen and oxygen equipment impact provider's business operations in other ways. For example, leasing is a common means of financing medical equipment. It's likely that in many cases providers will need to reconcile lease terms with the statutory period of continuous use. Under this scenario, understanding the implementation date is very important for providers. Does CMS intend to apply these new payment rules as of January 1, 2006 even though their actual implementation is delayed for administrative reasons such as the need to issue carrier instructions and make system changes? In addition, we are concerned about any requirement to transfer title to oxygen equipment to a beneficiary with unpaid balances for co-pays and deductibles. Title to oxygen equipment should remain with the provider until the beneficiary has paid any outstanding deductible and co-payment amounts.

Clinical Assessments for Respiratory Patients

The change in reimbursement for oxygen and oxygen equipment also raises questions about the provider's obligation to furnish continuing care and monitoring. Although ongoing care, monitoring, and assessment of the beneficiary are not explicitly covered by Medicare, most private sector payers and national accrediting bodies expect providers of oxygen to furnish these services. Moreover, providers are required in several states to perform respiratory assessments for patients who receive conserving devices. Other states require the oxygen provider to furnish the patient with a clinical visit shortly after the oxygen is set-up. For Medicare beneficiaries, providers have included these services within the monthly fee schedule payment for oxygen. Will payment for these services

now become the beneficiary's responsibility? Will beneficiaries be required to pay for the services of respiratory therapists and other services that CMS considers non-covered?

Parenteral and Enteral Equipment

Finally, AAHomecare interprets the DRA to apply only to medical equipment in the capped rental Medicare payment category. As you know, parenteral and enteral (PEN) pumps are reimbursed under the prosthetic device benefit, and the payment rules that apply to them differ from the rules that apply to capped rental DME. Consequently, this new rent-to-purchase payment methodology does not apply to PEN pumps. Specifically, PEN pumps fall under the fee schedule category for "parenteral and enteral." PEN pumps can be purchased or rented whereas capped rental items can only be rented. Although rental payments for PEN pumps "cap" after 15 months, subsequent payment for service and maintenance on PEN pumps do not follow the capped rental billing rules. To avoid confusion among the carriers, we request that CMS confirm that PEN pumps are not subject to the DRA's new rent to purchase payment methodology.

Medicare Advantage Plans

As you know, beneficiaries may choose from a number of Medicare Advantage plans, some of which do not follow the payment and coverage policies of traditional Medicare. How will providers be reimbursed if beneficiaries begin to use oxygen or capped rental equipment under a Medicare Advantage plan? Will CMS begin a new period of continuous use each time the beneficiary has a payer change in or out of traditional Medicare?

II. Conclusion

AAHomecare understands that these new payment methodologies do not take effect immediately. However, their impact on our member's operations is immediate because they must begin to structure their operations to respond to the changes. Moreover, providers must plan now for their implementation in order to ensure a smooth transition for Medicare beneficiaries. AAHomecare and its members are prepared to work closely with CMS to address these issues, and we would like an opportunity to meet with you and your staff to discuss these issues further. We will contact you next week to arrange for a mutually convenient time for us to meet.

Sincerely,

Thomas Ryan
Chairman

Michael Reinemer
Vice President, Communications & Policy

APPENDIX

Deficit Reduction Act of 2005 Provisions on Medicare Reimbursement for Oxygen and Durable Medical Equipment

Implementation Questions

I. Medical Necessity and Documentation

1. Will current regulations defining "continuous use" for capped rental DME remain unchanged?

2. How will CMS define "continuous use" for oxygen equipment? What will constitute a break in service so that a new period of continuous use commences for beneficiaries on oxygen?

3. When a beneficiary owns his or her oxygen equipment, will Medicare pay for new equipment on the basis of a change in condition? Does the change in equipment begin a new period of continuous use?

4. Will CMS issue regulations to address the issues raised in questions 1 and 2 above? If so, what is the projected timeline for a proposed rule?

5. If new technology becomes available that is medically appropriate and has the potential to improve health outcomes, will the beneficiary be responsible for paying for the new equipment (assuming there has been no change in condition)?

6. How will CMS define "oxygen" after the 36-month period of continuous use ends? How will the medical necessity documentation for oxygen change? Will lifetime CMNs be valid for beneficiaries who own their own equipment?

II. Reimbursement Questions

7. Will beneficiaries who have both a concentrator and stationary liquid or a concentrator and a portable concentrator be responsible for purchasing one of the two systems after 36 months?

8. How will CMS pay for refills on an oxygen cylinder? Will the payment amount differ between patients who require more refills because they have a greater need for mobility or a higher prescribed liter flow?

9. How will CMS take into consideration those patients who have a concentrator and a liquid system, where the liquid system is being primarily used for ambulatory/portable requirements? Will the Medicare program pay for additional portable cylinders after the 36-month rental period, or will it be the beneficiary's responsibility to purchase these items?

10. Will the beneficiary be responsible for purchasing supplies such as cannulas and tubing for their oxygen equipment or other items such as humidifiers?

11. May providers charge beneficiaries a rental or purchase for a back-up emergency cylinder that is not used to meet the patient's portable oxygen needs? These units would be used solely in the event of an emergency such as a power outage, a natural disaster, or a malfunction of the beneficiary's primary equipment. Will Medicare pay for the contents once these cylinders are used?

12. Will the payment amount differ based on different oxygen technologies that may be more or less costly for the provider to furnish?

13. Providers may be unable to service a patient-owned portable oxygen cylinder that they did not furnish. Will the beneficiary be responsible for purchasing a new oxygen cylinder under these circumstances?

14. Will rental months at a beneficiary's second residence apply towards the 36 months of continuous use? If so, which provider is responsible for transferring title to the beneficiary (i.e., the primary provider, or the provider at the second residence)? Similarly, if a beneficiary moves during the period of continuous use, which provider is responsible for transferring title (the new provider or the original provider)?

15. For short-term travel, the beneficiary pays for the oxygen out-of-pocket and the primary provider may reimburse all or a part of those costs. AAHomecare anticipates that this rule will not change for beneficiaries who own their oxygen equipment. That is, the beneficiary will continue to be responsible for arranging and paying for travel oxygen. With respect to the period of continuous use, please confirm that our understanding is correct. After title to the equipment transfers, will Medicare pay the beneficiary directly for short-term travel oxygen?

16. Will the beneficiary be responsible to pay charges for pick up and delivery of oxygen refills after title to oxygen equipment transfers to the

beneficiary? If not, what data does CMS propose to use to arrive at an appropriate payment amount for pick up and delivery charges?

17. For beneficiary-owned equipment that requires servicing, will Medicare pay pick up and delivery charges? If so, what data will CMS use to arrive at an appropriate payment amount for pick up and delivery charges?

18. Does CMS intend to apply any of the billing rules that applied to capped rental equipment to rent-to-purchase DME? A purchase option letter is unnecessary inasmuch as the beneficiary no longer has the "option" to purchase the equipment. Consequently, we see no need to use the BP, BR, or BU modifiers in the 11th, 12th, and 13th rental months.

III. Service and Maintenance

19. How will CMS define the useful of life of oxygen equipment?

20. If oxygen equipment is "irreparably damaged" after title has transferred to the beneficiary, but before the end of the equipment's "useful life," will Medicare pay for new equipment? If so, will this commence a new period of "continuous use," or will CMS pay a lump sum amount for the new equipment?

21. Does CMS have a timeline for issuing regulations that address questions 17 and 18 above?

22. Oxygen cylinders must undergo hydrostatic testing and other checks periodically. Though technically these tests are not "repairs," will they be reimbursed as repairs to account for the more extensive service they involve?

23. Will the Medicare program pay for emergency service calls for beneficiary-owned equipment that is still under warranty? If not, can providers contract with beneficiaries to provide on-call services for patient owned equipment?

24. If the manufacturer of equipment that is under warranty is no longer in business, will the beneficiary be responsible for paying for replacement parts? If the provider who furnished the equipment to the beneficiary is no longer in business, who is responsible for the repairs?

25. How will providers document that the maintenance and service they performed on oxygen equipment were reasonable and necessary? Will CMS require different documentation depending on whether the provider repairs the equipment it furnished or equipment furnished by another provider?

26. Will CMS issue temporary HCPCS codes to identify the service, maintenance and repairs for oxygen equipment, or will providers have to apply for the codes?

27. How will providers be reimbursed for service or maintenance to non-covered oxygen equipment such as conserving devices or oxygen titrating devices? Will providers bill the beneficiary for these services?

28. Will CMS issue temporary HCPCS codes to identify service and maintenance repairs and parts for equipment in the capped rental category, such as motor and hand controls for a bed, or will providers have to apply for the codes?

IV. Other Questions

29. Will the requirements of the DRA apply retroactively to January 1, 2006, regardless of whether the need for systems changes result in administrative delays in implementation?

30. Will CMS require providers to transfer title to beneficiaries who have unpaid deductible and coinsurance balances?

31. After title to the oxygen equipment transfers to the beneficiary, will beneficiaries be responsible for paying for clinical assessments required under state law? Will the beneficiary be responsible for paying for respiratory assessment ordered by the physician?

32. Please confirm that parenteral and enteral pumps are not subject to the rent-to-purchase methodology established under the DRA.

33. How will providers be reimbursed if beneficiaries begin to use oxygen or capped rental equipment under a Medicare Advantage plan? Will CMS begin a new period of continuous use each time the beneficiary has a payer change in or out of traditional Medicare?

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File No. 034731-0021

June 29, 2006

BY FEDERAL EXPRESS

Centers for Medicare & Medicaid Services
Office of Strategic Operations & Regulatory Affairs
Division of Regulations Development—B
Attention: William N. Parham, III
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments Regarding CMS—10169 (Agency Information Collection Activities; Proposed Collection): Forms for the Medicare Part B Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

Dear Mr. Parham:

On behalf of our client, Rotech Healthcare, Inc. ("Rotech" or the "Company"), we submit these comments on the Centers for Medicare & Medicaid Services' ("CMS") proposed forms to be used to implement the Medicare Part B competitive acquisition program for durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS").[1] As a Medicare supplier of home medical equipment, oxygen and respiratory supplies, as well as a variety of other DMEPOS items, Rotech anticipates that it will participate in the competitive acquisition program. To this end, Rotech respectfully offers the following comments on the proposed competitive bidding forms, which the Company hopes will serve to improve the forms as well as enhance CMS's ability to implement the program.

I. FORM A (APPLICATION)

Rotech suggests that CMS refine the requests for information on this form by incorporating a set of definitions and removing certain superfluous information requests that would be gathered and reviewed elsewhere, including as part of the accreditation process that will soon be applicable to all DMEPOS suppliers. Specifically, Rotech suggests the changes described below.

A. Supplier's Identifying Information (Part A)

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[1] *See* 71 Fed. Reg. 26,543 (May 5, 2006).

In the event that a network of suppliers intends to bid on a product category in the competitive acquisition program, it is unclear from the brief instructions to the form whether each supplier in such network is required to complete a separate Form A in order to participate or whether the network as a separate legal entity must do so. Proposed 42 C.F.R. § 414.418, which discusses supplier networks, requires each member supplier in a network to be independently eligible to bid. In order to ascertain eligibility, it would appear necessary for each member supplier to complete a Form A. If this is CMS's intention, Rotech suggests that Form A be revised to clarify that each member supplier in a network must complete Form A.

B. Supplier's Business Information (Part B)

This section of Form A requires that an applicant indicate the period of time for which it has been "doing business" in the proposed competitive bidding area ("CBA"). What remains unclear, however, is how CMS defines "doing business." Rotech believes that this expression is overly broad and fails to achieve CMS's intention of ascertaining whether a supplier has the capacity to furnish DMEPOS to Medicare beneficiaries in a CBA.[2] To this end, Rotech suggests that CMS replace "doing business" with a more specific inquiry. For instance, the form should ask how long the applicant has been supplying DMEPOS items of the type that it intends to furnish under the competitive acquisition program to Medicare beneficiaries in the CBA.

C. Bank References/Financial Information (Page 4 of Form A)

CMS requires that a supplier provide certain contact information for its financial institutions in this section of Form A. This information is most likely unnecessary, given that CMS also intends to collect audited financial reports (depending on the size of the supplier) and the supplier's credit rating and score from the past two years. Rotech therefore suggests that the Bank References section be deleted.

With respect to financial information requests from CMS in this section, Rotech believes that CMS should specify the period of time for which such reports must be submitted to CMS—*i.e.*, the number of quarters or years worth of data. Rotech suggests a two-year (eight-quarter) limit, given that CMS has suggested that it will look at two years of data to determine capacity and CBA demand. Moreover, to the extent that such financial information is duplicative of financial information and policies and procedures that will be reviewed by CMS-approved accrediting bodies under the new DMEPOS accreditation requirements, collection of such information on Form A may prove redundant and potentially overly burdensome on suppliers. Rotech suggests that, once CMS has finalized its proposed quality standards and accreditation requirements, CMS should ensure that the information requested in this section of Form A is not redundant.

D. Past or Pending Investigations and Actions (Page 5 of Form A)

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[2] In the preamble to the proposed regulations for the competitive bidding program, CMS notes that it intends to review two years worth of historical claims data for the CBA to determine the expected demand in the geographic area. *See* 71 Fed. Reg. 25,654, 25,675 (May 1, 2006).

Here, CMS asks the supplier to briefly explain past or pending investigations, legal actions and certain other matters. CMS has not provided suppliers with a period of time for which the agency would like to review such information. Rotech suggests that CMS limit the disclosure obligation to such matters that have commenced within the past five years. The Company believes that this timeline is a reasonable one that should serve to provide sufficient information to the agency.

E. Key Personnel (Page 5 of Form A)

CMS also requests the resumes of key personnel in this section of Form A. Rotech notes that this is the type of information reviewed by accreditation bodies during the ordinary course of their surveys. Therefore, the request that suppliers submit such information is redundant. This request should be removed altogether.

II. FORM B (BIDDING SHEET)

On the Form B Bidding Sheet, CMS seeks certain information to estimate supplier capacity (sales history, revenues, etc.). Form B fails to account for the fact that most (and probably all) networks of suppliers will be formed only upon the issuance of a Request for Bids ("RFB") from CMS. Such data would be unavailable for networks and, therefore, CMS should clarify the forms accordingly. Specifically, CMS should add instructions notifying networks that they are to respond to the data-specific questions with aggregate information from all member suppliers. Alternatively, CMS could request that each member supplier submit responses to Form B's questions on sales and revenue data. Regardless of the course chosen, Rotech suggests that CMS add more detailed instructions with respect to these questions on Form B.

In addition, in the proposed competitive bidding rule, CMS proposes to ask new suppliers for expected capacity and review trend data for new suppliers to ascertain the level of business such supplier can expect.[3] Rotech believes that CMS should consider evaluating networks—at least those formed immediately after the release of an RFB—according to this proposal. Even if each of the network suppliers has historical data, CMS should evaluate the true potential of the network as a whole for a particular CBA.

III. FORM C (BANK REFERENCE)

As part of the proposed competitive acquisition application process, CMS has proposed to require applicants' primary banks or other financial institutions to complete a Form C "Bank Reference" questionnaire. Rotech strongly urges CMS to eliminate Form C for several reasons. Generally speaking, Form C is redundant of the financial information collected on Form A. Further, the accreditation process promises to provide CMS with substantial information concerning a supplier's financial history.

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[3] *See id.* at 25,676.

In addition, Form C might place an undue burden on suppliers' ability to complete the application process prior to the submission of a bid. The form requests that banks complete questionnaires and return them directly to CMS prior to the submission of bids. A bank's late return of the questionnaire could unfairly hold up a supplier's ability to participate in the competitive acquisition program. This situation is exacerbated by the fact that a supplier would most likely be required to rely on *multiple* banks' completion of the questionnaires, as most suppliers probably do business with more than one bank.

Finally, Rotech believes that the questions required to be answered by a supplier's banks are not helpful for CMS. Specifically, questions 8-11, which ask whether the supplier has missed any loan payments or bounced a check, may result in misleading and anecdotal information. This is particularly the case, because CMS does not define the extent to which it will account for *de minimis* discrepancies or minor delays in, for instance, the making of a loan payment or the bouncing of a check. The question does not distinguish a loan payment that was a few days late from a loan payment that was months in arrears. Also, question 12, which asks for an evaluation of the supplier's credit, is already covered by the overall credit score information provided on Form A.

For these reasons, Rotech strongly recommends that CMS eliminate this form altogether. The burden imposed on suppliers and the lack of articulated standards could lead to a reduction in the number of suppliers who can (or who choose to) participate. This would unintentionally undermine one of CMS's primary purposes of the program—to ensure access to quality goods and services for Medicare beneficiaries.

IV. BENEFICIARY SURVEY

In the proposed Beneficiary Survey, CMS seeks to obtain feedback from Medicare beneficiaries on the quality of goods and services furnished under the competitive acquisition program. Rotech believes that the form itself, which is not referenced in the proposed rule, is unnecessary because the information sought will be covered by accreditation surveys conducted by CMS-approved accreditation organizations. Patient perception of care and quality of service currently is part of the accreditation process. As such, the information sought is duplicative and, therefore, the form should not be adopted.

In the event that CMS decides to use the beneficiary survey, CMS should clarify how it is to be used with specific instructions. These instructions should offer context and include a number of items. Perhaps the most significant is a discussion of the intended purpose and use of this beneficiary survey, so that beneficiaries and suppliers alike are on notice. For instance, the surveys could be used as a means of assessing whether the competitive bidding program has accomplished its goals. In addition, Rotech suggests that beneficiaries should be required to submit these forms only after completion of service so that there is a more complete assessment of the supplier's performance. This would make the forms more meaningful.

Thank you for the opportunity to submit these comments. Should you have any questions

or comments, I can be reached at (202) 637-2200.

Truly yours,

Stuart S. Kurlander
Of LATHAM & WATKINS LLP

Cc: Rotech Healthcare, Inc.

KCI

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Stephen D. Seidel
Vice President, General Counsel & Secretary

June 29, 2006

Delivery by Federal Express

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues
File Code CMS-1270-P

Dear Administrator McClellan:

I am writing on behalf of Kinetic Concepts, Inc. ("KCI") for the purpose of commenting on the proposed rule for Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies ("DMEPOS") and Other Issues recently issued by the Centers for Medicare and Medicaid Services ("CMS").[1]

Background

KCI is a manufacturer of two groups of medical devices used to treat Medicare beneficiaries in hospitals, nursing facilities and outpatient settings. The first group includes devices and supplies that comprise the V.A.C.® Wound Therapy System, used to treat complicated wounds. The second group includes a comprehensive line of specialized support surfaces used to treat and prevent many of the most serious complications of immobility. KCI is a direct supplier of these products to Medicare Part B beneficiaries in all fifty states and Puerto Rico.

The V.A.C.® system, which was invented at Wake Forest University, is used to heal serious wounds, including diabetic and neuropathic ulcers, acute wounds, decubitus ulcers, dehiscences, burns, necrotizing fascitis and other types of chronic and acute wounds. Many wound care physicians consider

[1] *See* 71 Fed. Reg. 25,654 (May 1, 2006).

V.A.C.® to be the major innovation in advanced wound care in the past 20 years. In the last ten years, it has been used by more than one million patients in the U.S. Within the Medicare population, the V.A.C.® system is often used with patients who have multiple comorbidities that make their wounds difficult and expensive to heal. Thus, V.A.C.® therapy is an important tool physicians use to manage the condition of patients with difficult, and sometimes life-threatening, wounds.

Wound care remains a challenging field of medicine. Approximately 7.8 million Americans annually are treated for wounds - usually present in our most seriously ill citizens - which costs our healthcare system $28 billion annually on equipment alone. Advanced wound care, where Negative Pressure Wound Therapy ("NPWT") is appropriate, represents the 1.4 million most severe wounds where alternative therapies are often inadequate. Care related to these most severe wounds is typically complicated, resulting in a very expensive overall cost of care and often a loss of life or limb or reduced quality of life. For one sub-category alone, diabetic foot ulcers, it is estimated that there are 800,000 prevalent cases with national annual costs of $5 billion. NPWT is typically used on the most challenging wounds in advanced wound care. Numerous studies and clinical data show that the V.A.C.® NPWT system improves patient outcomes, reducing the length of inpatient stays and post-surgical readmissions. In a broad range of clinical studies of wound care in the home, it has been demonstrated that the V.A.C.® system: (i) decreases the number of days required to heal a wound[2,3] (ii) improves the rate of wound healing, [2,4] (iii) reduces complications[2,3] and (iv) reduces hospitalization/emergent care.[3,5] As these studies and a variety of other studies demonstrate, the V.A.C.® significantly reduces the overall cost of care for patients with serious wounds.

The V.A.C.® system is comprised of three elements to enable safe and effective outcomes: (i) the system components, (ii) training and support for caregivers, and (iii) safety features specific to home use. More specifically, the following are essential features of the V.A.C.®

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[2] Armstrong, D. and Lavery, L., "Negative Pressure Wound Therapy Heals Complex Wounds Faster Than Standard Wound Care Following Partial Diabetic Foot Amputation," Abstract presentation at American Podiatric Medicine Association, August 5, 2005.

[3] Page, Jeffery DPM, et al., "Retrospective Analysis of Negative Pressure Wound Therapy in Open Foot Wounds with Significant Soft Tissue Defects," Advances in Skin & Wound Care, 17:7, 2004.

[4] Fife, C., "Healing Rate of Dehisced Surgical Wounds Using the V.A.C. Compared to Moist Wound Care," Poster presentation at SAWC, 2005.

[5] Schwien, T., et al., "The Role of Negative Pressure Wound Therapy in Home Health Quality Outcomes, Emergent Care and Hospitalization: A Comparison Study," accepted for publication in the September 2005 issue of Ostomy & Wound Management.

- **System components** include a computerized electric vacuum pump, an occlusive dressing, a surgical dressing, an exudate canister and connective tubing. A V.A.C.® dressing is typically changed three to four times per week by a home health care nurse, or at a wound care clinic or physician's office.

- **Training and support** include extensive education and certification by KCI of caregivers on wound assessment, placement, and wound progress monitoring. Because each patient's wound(s) and comorbidities vary, outcomes are impacted by the skill provided by the caregiver when changing a patient's V.A.C.® dressing and their ongoing assessment of wound(s). As a result, training is an essential element of V.A.C.® therapy.

- **Safety features** specific to the V.A.C.® system enable it to be used safely in the home. The safety features include a series of safety alarms and patient lockout features, and a canister designed for single-use only to capture and isolate wound exudates - fluids that are typically highly infectious.

The V.A.C.® System uniquely provides advanced wound healing - even for outpatients who may not have around-the-clock clinical caregivers. The V.A.C.® Freedom was specifically designed with therapy alarms and several safety features to ensure effective, consistent delivery of therapeutic benefits. The drainage collection canister was designed to neutralize and isolate the wound drainage from the environment in order to protect the health and safety of everyone near the patient. The V.A.C.® Freedom was also designed to be portable, enabling mobile Part B beneficiaries to benefit from use of the V.A.C.® even when away from their homes. This is particularly important since all of the evidence of improved clinical outcomes is based on administration of V.A.C.® therapy for at least 22 hours per day.

Although the V.A.C.® Wound Healing System was designed to be simple to operate for both patients and caregivers, application and change of dressings is a critically important function restricted to clinical caregivers. Because complexity of the wound(s) being treated varies from patient to patient, clinical caregivers must be skilled at wound assessment and application of the appropriate dressing(s). In order to ensure the necessary level of clinical knowledge and expertise, KCI Team Members throughout the country provide extensive training and ongoing support for the physicians, nurses and therapists involved in managing V.A.C.® patients. Without this high level of support, efficacy of the therapy and safety of the beneficiaries cannot be assured.

KCI also offers a complete line of therapeutic support surfaces. KCI's wound care surface line includes 28 different categories of mattress overlays, mattress replacements, and full bed systems that prevent or treat the skin care

complications of immobility. These products provide pressure relief and redistribution, pulsation, rotation, and air fluidized therapy. KCI's critical care surface line includes mattress replacements and full bed systems that rotate immobile, critically ill patients with severe pulmonary compromise. KCI's bariatric product line helps reduce the risks associated with caring for large patients to enhance patient and caregiver safety. KCI also provides bariatric patient lifts, wheelchairs, commode chairs and walkers.

Comments on the Proposed Rule

With the exception of several General Comments, all of KCI's comments are subdivided by the headings suggested in the Proposed Rule. Defined terms have the same definition as set forth in the proposed rule.

General Comments

1. The Proposed Rule includes general concepts for administration of the first phase of competitive bidding in 2007, including alternative approaches to some aspects of the program. However, without specific proposals for CBAs, products/product categories, and many other important topics, it is difficult to comment on whether there are any significant issues that may jeopardize the quality of care or access to care for Medicare Part B beneficiaries under this program. *Therefore, we recommend that CMS publish an Interim Final Rule with an additional comment period prior to publication of a Final Rule and implementation of any part of the first phase of the competitive acquisition program in 2007.*

2. The Proposed Rule was published for comment without publication of the Supplier Quality Standards. Although first drafts of those standards were published in the Fall of 2005, CMS has publicly acknowledged that significant revisions will be made in response to the large number of public comments it received. Accreditation of suppliers using these standards is a fundamental building block of the competitive bidding program, and the requirements embedded within those standards will have significant implications for potential bidding suppliers. *Therefore, we recommend that CMS publish a second set of the draft standards for comment prior to publication of a Final Rule and implementation of any part of the first phase of the competitive acquisition program in 2007. We also recommend that a draft of the Negative Pressure Wound Therapy Standards be published for comment prior to implementation.*

3. The Proposed Rule includes several product categories and bid procedures that were not tested in either of the competitive bidding

demonstration projects. In some cases, approaches proposed in the rule are significant expansions or departures from those tested and found to be effective in the demonstration projects. Also, the two demonstrations projects involved considerable management and oversight, which will not be sustainable when applied to ten of the largest MSAs simultaneously. The intent of Congress in authorizing the demonstration projects was to test whether specific products and specific approaches to bidding were compatible with their goals of both reducing expenses and maintaining beneficiary access and quality of care. *Therefore, we recommend that CMS limit first phase of the program in 2007 to implementation of products and the approaches that were successfully tested in the demonstration projects and that CMS conduct additional limited tests of other products and approaches to determine if they are compatible with the goals of the program.*

Specific Comments

1. Criteria for Item Selection (Section II E)

A. *Negative Pressure Wound Therapy ("NPWT") Devices should not be chosen as a product category for competitive bidding.*

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), certain DMEPOS items may be subject to the competitive acquisition program.[6] In the proposed competitive acquisition rule, CMS does not specify which products it plans to include in the program. Rather, CMS proposes to phase in the program first among the highest cost and highest volume products and those that have the largest savings potential.[7] Included as one of the 20 highest cost and highest volume HCPCS codes for 2003 was K0538 (now E2402) - the code for NPWT devices.[8] Therefore, it appears that CMS may seek to include NPWT on the list of competitively bid items.

KCI strongly urges CMS to exclude NPWT devices from competitive bidding for five reasons:

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6 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-73 (2003).

7 *See* 71 Fed. Reg. at 25,669.

8 The HCPCS Code for NPWT was created on October 1, 2000 as a result of the adoption of four identical Local Medical Review Policies ("LMRPs") by the DMERC Medical Directors. From that time until January 1, 2006, the only product which was permitted to use the NPWT code (originally K0538; now E2402) was the V.A.C.® system manufactured by KCI.

(1) There are major substantive differences between the three devices that currently fall into the NPWT category. Although these devices are treated similarly for purposes of coding and billing, they are vastly different in terms of sophistication and clinical effectiveness.

(2) Inclusion of the NPWT product category in the competitive bidding program is premature because specific quality standards for NPWT have not been proposed or adopted.

(3) Competitive bidding cannot be optimized to achieve true competition and cost savings given the small number of suppliers that provide NPWT.

(4) The use of NPWT devices is not developed enough to ensure that beneficiaries would have sufficient access to NPWT or that bids on NPWT will be reasonable.

(5) The NPWT HCPCS code needs to be subdivided before it can be competitively bid.

B. *The substantive differences between the products in the NPWT HCPCS Code make it inappropriate for competitive bidding.*

There currently are only three products covered by Medicare Part B under the NPWT Code and there are substantial differences in the proven effectiveness of these products. The HCPCS Code for NPWT was created on October 1, 2000 as a result of the adoption of four identical Local Medical Review Policies ("LMRPs") by the DMERC Medical Directors. From that time until January 1, 2006, the only product which was verified to use the NPWT code (originally K0538; now E2402) was the V.A.C.® system manufactured by Kinetic Concepts, Inc. ("KCI"). On January 1, 2006, a second device, the Versatile 1, which is relabeled and distributed by BlueSky Medical, Inc. ("BlueSky"), was coded as an E2402 device. On April 20, 2006, a third device, the "Wound Sucker", which is relabeled and distributed by Superior Healthcare Concepts ("SHC"), was coded into this category. The pumps used by BlueSky and SHC are made by the same manufacturer and are substantially similar.

As illustrated in Attachment A, there are more than twenty substantial clinical differences between the V.A.C.® System and the other two devices more recently assigned to the E2402 Code. These differences impact both safety and efficacy.

Most significantly, the dressing utilized in the V.A.C.® System is a surgical foam which was designed and tested over a period of several years by Wake Forest University and KCI to promote wound healing. This surgical foam allows the wound to contract uniformly, while at the same time evenly dispersing sub-

atmospheric pressure throughout the foam to the surface of the wound. The Versatile 1 and Wound Sucker devices were designed to mimic the V.A.C.® However, they use woven cotton gauze over a non-adherent mesh layer. To our knowledge, there are no studies which suggest that cotton gauze used with a non-adherent layer performs as effectively under vacuum as the dressing designed at Wake Forest. In contrast, there are hundreds of clinical studies which support the efficacy of the V.A.C.® system. Many of these studies emphasize the significance of the surgical foam dressing. In particular, a recent study conducted by researchers at Harvard and MIT concluded that it was the surgical foam interface in the V.A.C.® system which caused the tremendous growth in cell proliferation (primarily granulation tissue) experienced by V.A.C.® users.[9] Only the dressings used with the V.A.C.® system is supported by evidence-based medicine.

The V.A.C.® system is also specifically designed for use in the home with a series of safety alarms and other important features. The Versatile 1 and Wound Sucker devices, on the other hand, use off-the-shelf naso-gastric suction pumps, which were not designed for extended wound therapy use in the home. As a result, they do not contain any of the safety alarms or safety features found in the V.A.C.®, features that are extremely important to homecare patients who are not under the watchful eye of trained clinicians.

There is substantial clinical evidence that the V.A.C.® System is safe and effective and virtually no clinical evidence which supports the safety or efficacy of the Versatile 1 or Wound Sucker. As of this writing, there are 281 peer-review journal articles, 347 abstracts, 49 medical text book citations, and 11 published randomized controlled clinical trials which support the safety and efficacy of the V.A.C.® System. To date, the only medical evidence which exists with respect to the Versatile 1 are a handful of inconclusive single patient case studies. To the best of our knowledge, there is no clinical evidence which supports the safety or efficacy of the Wound Sucker.

The medical community also agrees that the products in the NPWT product category do not produce the same clinical outcomes. After CMS' announcement that the Versatile 1 would be included in the HCPCS Code covering NPWT, more than fifty doctors (many of whom have had experience with both the Versatile 1 and V.A.C.®) wrote to CMS to protest this decision. Although it is not possible to briefly summarize all of the conclusions contained in these letters, the doctors and clinicians who wrote to CMS agreed that the products should not be classified in the same category and do not produce clinically equivalent results. For this reason, it would be inappropriate for CMS to competitively bid the NPWT product category.[10]

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9 Saxena et al., J Plastic and Reconstructive Surgery 2004; 1086-1096.

10 If CMS does competitively bid these three items, Medicare Part B beneficiaries would not be assured access to quality services, which CMS states is one of its primary goals behind the program. *See* 71 Fed. Reg. 26,543, 26,544 (May 5, 2006).

C. *Inclusion of the NPWT product category into Competitive Bidding is premature because specific quality standards for NPWT have not been proposed or adopted.*

The Social Security Act, as amended by the MMA, requires that a competitive bidding contract cannot be awarded unless the bidding entity meets certain applicable quality standards.[11] In order to implement this provision of the Act, CMS issued a draft of proposed recommendations for "Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies ("DMEPOS") and Other Items and Services" on September 26, 2005. CMS received more than 6,000 comments on its proposal. The proposed recommendations cover general Supplier Business Quality Standards as well as product specific service requirements for suppliers for fourteen different types of equipment. Significantly, specific service requirements for NPWT were not included. CMS has indicated that a second set of product-specific standards, which may include NPWT, are being prepared but have not yet been published for comment. Because the patients treated with NPWT products are often seriously compromised, and safe, effective use of these products is dependent on training and education of both patients and caregivers, NPWT quality standards must be published for comment before final implementation. Moreover, if the NPWT product category were competitively bid before the final product specific quality standards were published, it would be difficult, if not impossible, for suppliers to assess the cost of complying with the new standards. As a result, it may not be feasible for them to develop appropriate bids for the first round of competitive bidding.

D. *The NPWT product category should not be competitively bid because competitive bidding cannot be optimized to achieve true competition and cost savings given the small number of suppliers that provide NPWT.*

One of the principal tenets of competitive bidding is that a large number of viable suppliers is necessary to optimize the Competitive Bidding Process. This was aptly stated in the CMS Competitive Bidding Release:

> The number of suppliers furnishing a particular item or group of items would also be an important variable in identifying items with high savings potential. We believe that a relatively large number of suppliers for a particular group of items would likely increase the degree of competition among suppliers and increase the probability that the suppliers would compete on quality for business and market share. We saw evidence in the competitive bidding demonstrations

[11] Section 1847(b)(2)(A)(i) of the Social Security Act.

> that products furnished by a large number of suppliers had large savings rates and fewer problems with quality.[12]

Only three manufacturers/distributors have received a coding verification from the SADMERC for the HCPCS Code covering NPWT – KCI, BlueSky and SHC. KCI serves as the exclusive supplier of the V.A.C.® system through its many wholly-owned service centers across the United States. BlueSky operates through distribution agreements with DME suppliers in numerous cities across the U.S. SHC is a local DME supplier located in Champaign, Illinois, which is not a potential initial CBA under the proposed rules. Since their NPWT products were only approved by the SADMERC very recently, both BlueSky and SHC have little operating history with Medicare. In the MSAs most likely to be bid under the proposed rules, there are no more than a handful of BlueSky affiliated DME suppliers (and no SHC affiliated suppliers) currently providing NPWT, with some MSAs having only one or two. As a result, it is highly unlikely that the vigorous competitive bidding contemplated by the proposed regulations would occur in many markets if NPWT were competitively bid. Moreover, it would not comply with the intent of proposed §414.414(g), which was to allow "access of individuals to a choice of multiple suppliers."[13]

E. *The NPWT category is not yet mature enough for CMS to ensure that beneficiaries would have sufficient access to the products that they require or to ensure that bids on NPWT are reasonable.*

As mentioned previously there are numerous studies and clinical data to show that the V.A.C.® NPWT system improves patient outcomes, reducing the length of inpatient stays and post-surgical readmissions. In a broad range of clinical studies of wound care in the home, it has been demonstrated that the V.A.C.® system: (i) decreases the number of days required to heal a wound[14,15] (ii) improves the rate of wound healing,[14,16] (iii) reduces complications[14,15] and (iv)

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12 *See* 71 Fed. Reg. 25,654, 25,671.

13 *See id.* at 25,678; *see also* Section 1847(b)(2)(A)(iv) of the Social Security Act.

14 Armstrong, D. and Lavery, L., "Negative Pressure Wound Therapy Heals Complex Wounds Faster Than Standard Wound Care Following Partial Diabetic Foot Amputation," Abstract presentation at American Podiatric Medicine Association, August 5, 2005.

15 Page, Jeffery DPM, et al., "Retrospective Analysis of Negative Pressure Wound Therapy in Open Foot Wounds with Significant Soft Tissue Defects," Advances in Skin & Wound Care, 17:7, 2004.

16 Fife, C., "Healing Rate of Dehisced Surgical Wounds Using the V.A.C. Compared to Moist Wound Care," Poster presentation at SAWC, 2005.

reduces hospitalization/emergent care.[15,17] As these studies and a variety of other studies demonstrate, the V.A.C.® System significantly reduces the overall cost of care for patients with serious wounds. The same types of clinical results have not been proven for the other products in the NPWT HCPCS Code. Ironically, as a result of competitive bidding, Medicare Part B beneficiaries in some CBAs may not have access to the only proven system which provides NPWT. This could occur because small, inexperienced DME suppliers bid unrealistically in a particular CBA and either (i) KCI is not chosen as a contract supplier or (ii) the single payment amount is unrealistically low and KCI is unable to provide the V.A.C.® system to Medicare beneficiaries at an unconscionably low price. Because the V.A.C.® system is the only product in the NPWT code which has been proven to be cost effective, this would be a significant cost for the Medicare program to bear.

The only supplier that has consistently proven its ability to provide NPWT to the Medicare Part B market over any sustained period of time is KCI. No one other than KCI was approved to market NPWT devices to Medicare beneficiaries under E2402 prior to late Fall 2005. As a result, neither the BlueSky distributors nor SHC has significant experience in providing NPWT to the Medicare community.

This is important for two reasons. First, NPWT patients have unique service requirements, which the two new suppliers have not had enough time to understand properly (particularly with regard to forecasting the long term cost of providing these services). Most other types of DMEPOS items and supplies require only a basic level of inservice. This is not the case with NPWT. NPWT dressings need to be changed at least three times a week by a clinician or a caregiver who has been instructed in the proper application of an NPWT dressing. Wounds can vary significantly and those differences present many different challenges to the clinician making the dressing change. In addition, the NPWT device must be monitored continually to insure both safety and efficacy. Because of their relative inexperience in the Medicare market, it will be difficult for either SHC or BlueSky distributors to properly understand the service component of providing NPWT and to properly calculate the cost of those services for competitive bidding purposes.

A substantial amount of caregiver and clinical training must be provided with respect to an NPWT device. For example, in the first three years after the adoption of the NPWT HCPCS Code, KCI formally trained more than 57,000 clinicians in the use of the V.A.C.® System. Since that time, KCI has instituted a train-the-trainer program and provided training to more than 200,000 clinicians. KCI has approximately 750 clinicians trained in advanced wound care in its

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[17] Schwien, T., et al., "The Role of Negative Pressure Wound Therapy in Home Health Quality Outcomes, Emergent Care and Hospitalization: A Comparison Study," accepted for publication in the September 2005 issue of Ostomy & Wound Management.

employ who assist in these efforts. Because of the major differences in the systems (including the type of dressing, safety alarms and features, pump controls and features), the training given to clinicians on the V.A.C.® System does not translate into training for the use of the Versatile 1 or Wound Sucker. We do not believe that the BlueSky suppliers or SHC have sufficient healthcare professionals trained in wound care to properly serve the NPWT market, nor do they have sufficient experience providing the necessary services to be able to accurately bid in 2007. Bids by under-informed suppliers will likely be unrealistically low with the result that suppliers will not be financially able to honor their contracts and provide NPWT throughout the three year contract.

Second, the inclusion of the BlueSky and SHC products under the E2402 code will continue to change the manner in which NPWT products are prescribed. This impact would be made unpredictably more dramatic by competitive bidding. At present, KCI believes that most physicians prescribe NPWT devices for their patients based on what they believe to be best for their patients in accordance with demonstrated clinical research and proven effectiveness. Under the current Medicare fee schedule, prescribing physicians have been able to choose the device they believe is best for their patients. Under competitive bidding, doctors may not be able to prescribe the therapy they prefer because it is unavailable under competitive bidding. In some CBAs, competitive bidding may result in a loss of the proven therapeutic effect and the safety features of the V.A.C.® System

The positions set forth above should lead CMS to conclude that there is sufficient evidence, at this point, to determine that for at least the near future the Medicare program is unlikely to realize any significant cost savings by submitting NPWT to the competitive bidding process. The MMA authorizes CMS to phase in competitive bidding "first among the highest cost and highest volume items or those items that the Secretary determines have the largest savings potential" and to exempt items that will not likely result in significant savings. In evaluating savings for these purposes, KCI strongly urges CMS to consider its total costs, and not merely reduced payments under Medicare Part B for the DMEPOS items and supplies at issue. Specifically, CMS' calculation of whether it will achieve significant cost savings in any product category should include not only the reduction in fee schedule amounts which may be achieved, but also the additional costs likely to be incurred by the Medicare program as a whole (including Part A costs) due to the implementation of competitive bidding. This should include administrative costs of bidding, awarding, surveying and monitoring of suppliers and the likely increased costs to the Medicare program from additional or prolonged inpatient stays due to unavailability of or movement away from those devices that result in the best beneficiary outcomes. For example, if pressure ulcer rates among beneficiaries who use wheelchair pads which have been competitively bid increase in a statistically significant manner in the CBAs, the cost of treating the additional pressure ulcers should outweigh the price reduction.

F. *Certain HCPCS Codes must be subdivided before they can be competitively bid.*

KCI also believes the structure proposed for item selection may lead to serious problems. CMS proposes to use HCPCS codes in "product categories" as the basis for competitive bidding. Because there are significant differences in the specificity of existing codes included in the product groups listed in the proposed rule, we are concerned that use of poorly defined HCPCS codes in competitive bidding could reduce beneficiary access to medically necessary products and adversely impact the quality of care.

Inadequate code specificity exists when products with a limited set of basic features and benefits are assigned to the same code with related products that have advanced features. Some examples are:

- E0607 (Home Blood Glucose Monitor)
- E0277(Powered Air Mattress)
- E2402 (Negative Pressure Wound Therapy Pump)

In each of these codes, the advanced products have different technological features that provide greater therapeutic benefits and/or support the special needs of some beneficiaries. Market utilization data shows that both clinicians and beneficiaries prefer the advanced products because of these improved patient benefits. For each of the codes listed above, the advanced products account for a majority of the Medicare Part B claims.

Because of the additional costs associated with these features, the advanced products are also at the higher end of the price range for each of these codes. Current fee schedules allow for adequate payment of the advanced products. Given the proposed bid methodology, there is a real risk that suppliers may choose to provide only the less-advanced, less-costly products classified in the code. If this occurs, there could be such significant reductions in payment that advanced products will no longer be available to Medicare beneficiaries. Competitive bidding should not restrict or reduce beneficiary and/or clinician access to the most appropriate, medically necessary products.

CMS has the authority to establish separate subcategories for items within a given code if there is differential clinical benefit and or value for specific items within the code. Therefore, we recommend that before any of the codes listed above are included in any stage of competitive bidding, CMS should exercise its authority to subdivide the codes and either: (i) exclude the advanced products from bidding or (ii) require and evaluate separately bids for each subcategory. In order to ensure that codes are appropriately subdivided, we also recommend that CMS seek stakeholder input and publish for comment all proposed subdivisions prior to bidding.

2. Determining Single Payment Amounts for Individual Items (Section II H)

A. *Using the median of supplier bids to establish single payment amounts will frustrate Congressional intent, contravene basic economic principles and undermine the viability of the Competitive Bidding Program.*

The CMS proposal contemplates a Competitive Bidding Program in which the single payment amount for an individual item will be based upon the median of the supplier bids which are at or below the pivotal bid for that item. CMS asserts that using the median of bids at or below the pivotal bid will result in a single payment that represents the winning bid for a particular item and has the advantage of being "easily understood" by suppliers and implemented by contractors. CMS also asserts that the median bid method results in a reasonable payment amount based on market prices.[18]

KCI disagrees. We believe that this approach violates Congress' intent and basic economic theory. Congress' overarching purpose in enacting the Competitive Bidding portions of the MMA was to allow market forces to determine the price of DMEPOS rather than a somewhat artificial system based on allowables, fee schedules and gap-filling. Congress' view was that a robust Competitive Bidding Process would enable the government to get the best available price while at the same time not compromising the quality of service received by Medicare beneficiaries. For example, Senator Kyl, during the debate on the MMA, stated "What is the solution? . . . . Simply allow competitive bidding. Let the markets decide what the right levels are."[19] In a similar fashion, the CMS release on competitive bidding stated that "Competitive bidding provides a way to harness market dynamics...." The median bid approach, however, fails to permit the market to set the price for a particular product and violates traditional economic thinking on multiple bidder/multiple item sales. As a result, the proposed rule distorts, rather than harnesses, market dynamics.

For hundreds of years, Dutch Auctions have been used to set prices in multiple bidder/multiple item auctions. In a traditional Dutch Auction, the process begins with a set asking price (in this case, the fee schedule amount) which is lowered to the point at which sufficient bids have been received to sell the entire inventory of goods which were being offered. The final price is the price at which all items for sale could be sold. This type of auction originated in the Holland tulip market several hundred years ago but continues to thrive today in such diverse markets as eBay and the sale of stock and bonds by publicly held companies. (The initial public offering of shares of Google's common stock, one of the largest IPO's in recent memory, was a form of Dutch Auction.) A form of

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18 *See* 71 Fed. Reg. 25,654, 25,679.

19 149 Cong. Rec. S8544 (daily ed. June 25, 2003) (Statement of Sen. Kyl).

Dutch Auction should be used for CMS' Competitive Bidding Program. In essence, bids would be taken as set forth in the CMS Release and bids would be accepted up to the pivotal bid. The pivotal bid would, and should, become the single payment amount inasmuch as it represents the "market-clearing price" – the traditional economic concept for the price at which supply and demand meet.

KCI emphasizes that the median bid approach to setting the single payment amount has the potential to create havoc within the proposed Competitive Bidding System. First, it is unclear from the proposed regulations whether CMS intends to compel suppliers to provide items to CMS beneficiaries at prices substantially below the price at which they bid. If CMS intends to force suppliers to supply DMEPOS at prices below their bids, a very significant question remains as to whether or not the suppliers will be willing or, for that matter, economically able to provide items on that basis. Unfortunately, the unwillingness or inability of contracted suppliers to supply DMEPOS at the single payment amount proposed by CMS will rebound to the detriment of Medicare beneficiaries who will be unable to access medical devices which they require.

In addition, the process proposed by CMS could result in significant pricing anomalies. Consider the following hypothetical. In a particular CBA, there are thirteen suppliers who bid an item. Five of the suppliers have been in the DME business for a number of years and fully understand their cost structures and service requirements of the market. The five suppliers currently share 80% of the market in that MSA. The remaining eight suppliers are small suppliers with little experience in this market and share approximately 10% of the market. The use of this bid item requires a significant amount of service, patient training and clinical inservice. The fee schedule amount for this item is $100. The first five suppliers bid between $87.50 and $85.00. The remaining eight suppliers bid between $52.00 and $64.00. The CIBC selects nine bidders as contract suppliers (using the assumption that the smaller suppliers can grow their businesses.) Under CMS' proposed rule, the single payment amount would be $62.00 (the bid amount of supplier number five), despite the fact that this bid (and the bids which were lower) represent less than 10% of the sales of this item in the CBA. Although it is possible to debate the likelihood of this scenario occurring, it is absolutely true that there are thousands of small suppliers (and some less-sophisticated larger suppliers) who will seek to participate in competitive bidding (and in many cases whose very existence will depend upon being selected as a winning bidder) and likely distort the bidding process by submitting unrealistically low bids.

In this scenario, the price established under the CMS proposed regulations would have a number of unintended consequences. It is likely that the five major suppliers in the above scenario would be unwilling or, at best, unenthusiastic about serving the needs of Medicare beneficiaries in the CBA. In addition, it is unlikely that any of the smaller suppliers would be able to provide the service, training and inservice necessary in order to use the bid item safely

and effectively, especially at an inappropriately low single payment amount. This problem will be exacerbated if the larger suppliers begin to withdraw from the market and the smaller DME suppliers are forced to attempt to expand rapidly.

The principal reason that we are faced with the issues alluded to above is that the proposed rule is a dramatic departure from the pricing rules used in the two completed demonstration projects (Polk County, Florida and San Antonio, Texas). In the demonstration projects, individual bidders were awarded contracts based on the actual prices they had bid. Although the MMA requires a single payment amount, the approach used in the demonstration projects remains viable (as CMS has noted in the preamble to the proposed regulations). A payment rate based on the pivotal bid is the only viable methodology.

In addition, other aspects of the proposed regulations may result in unrealistically low prices. As was noted by a committee member at the May 2006 Program Advisory & Oversight Committee ("PAOC") meeting, 40-70% of the revenue which most DME suppliers rely upon comes from Medicare. Because of the significance of this revenue to their businesses, many DME suppliers are going to bid unreasonably low, unsustainable prices in an attempt to make sure that they can maintain their principal source of revenue. In addition, and as acknowledged by CMS staff at the May PAOC meeting, most DME suppliers do not fully understand their own cost structures. In addition, the DME community will not be able to accurately assess the cost of complying with the proposed (but not yet final) quality standards or the cost of becoming accredited. This will be particularly true in a relatively immature product category such as NPWT. As a result of these facts and the impact of the proposed methodology for calculating the single payment amount, it is likely that the single payment amount for many items will be extremely low and, in some cases, below the supplier's cost of providing the bid item.

Although the goal of competitive bidding is to reduce the price paid by CMS to suppliers for medical devices, the goal should not be to reduce the prices paid below the suppliers' cost. Unrealistically low prices would have a number of negative consequences. First, it will cause a number of suppliers to fail and, as a result, there may not be a sufficient number of suppliers to properly serve the beneficiaries in their CBA. Second, artificially low prices will cause suppliers to provide only the least expensive devices within a HCPCS code to patients - even in situations where a patient requires a more expensive, sophisticated device. Because the goal of many DMEPOS items is aimed at keeping beneficiaries functioning safely in their own homes (and out of the inpatient setting), unrealistically low prices may increase, rather than decrease, the total cost to Medicare of treating a particular patient. Finally, unrealistically low prices will erode the supplier base financially and, ultimately, weaken competitive dynamics that improve efficiency and quality.

In addition, CMS should alter its proposed pricing methodology to eliminate unreasonable bids. As stated above, it is highly likely that a number of small, relatively unsophisticated DMEs will bill unrealistically low prices. This would be similar to the elimination of "outlier bids" in the demonstration projects.

B. *Suppliers should not be required to bid on all products within a product category*

CMS proposes to group items into "product categories" specifically for bid purposes. The proposed rule states that bidders would not be required to bid on all product categories but would be required to bid on each item within a category for which they submit a bid. This proposal does not take into consideration two important facts:

(i) Some medical policies include HCPCS codes which exist only to accommodate prescriber preference, do not have distinct coverage criteria within the medical policy, and are infrequently, if ever, ordered by local prescribers. For example, the DMERC Group 2 Support Surface Local Coverage Determination includes several different HCPCS codes. However, the LCD does not define different coverage criteria for each code, allowing clinicians and beneficiaries to choose products within that group based on individual beneficiary needs and clinician preference. In this example, very few suppliers actually carry products classified under all of the HCPCS codes, choosing instead to carry only products ordered routinely by their local clinicians. Making suppliers bid on every code in the product category could require suppliers to unnecessarily expand their product portfolio to include products that may never actually be ordered by their prescribing clinicians.

(ii) This problem becomes even more challenging for manufacturers who are also suppliers of only their own products. This occurs primarily in specialized product lines where technical product support and extensive clinical support can best be provided by the manufacturer. In many cases, these manufacturer/suppliers have significant market share because their products and services are widely perceived to benefit both beneficiaries and clinicians.

Requiring bidders to submit bids on each item in categories like this one could eliminate from the bid process both normal suppliers and manufacturers who are also suppliers. In some cases, specific brands of products are only available through the manufacturer/supplier. Removal of these products from the bid process could have serious adverse clinical consequences for beneficiaries for whom these products are necessary.

C. *CMS should reject the proposed rebate program.*

Under the Proposed Rule, bidders who bid less than the single payment amounts could offer beneficiaries rebates up to that difference, but could not

directly or indirectly market the availability of the rebates. This proposal received universal public criticism at the PAOC meeting in May 2006. KCI commends CMS on its attempts to help beneficiaries and give incentives to suppliers to bid their lowest price. However, this is simply a bad idea. Contractors would be prohibited from directly or indirectly marketing these rebates to beneficiaries or referral sources, but, of course, they would want to market the rebates to secure a larger share of the market. This limitation would lead to covert actions to market the rebates and would become an open invitation to commit program fraud. These same types of incentives have been repeatedly turned down in other contexts by the Office of Inspector General and likely would not comply with numerous state laws against kickbacks.

In addition, in product categories like NPWT where there are very few potential bidders on products whose prices differ substantially, it is quite possible that rebates could lead to windfalls for beneficiaries by exceeding the amount of the beneficiary's co-payment. For example, consider a situation in which the three winning bids in a product category were $105, $100, and $75, with the single payment amount being set at $100. In this case, the beneficiary would have a $20 co-payment (or 20 percent of $100). The supplier that bid $75 dollars could offer a beneficiary a $25 rebate. Thus, the beneficiary could essentially turn a profit merely by choosing that supplier. This goes against every principle by which the Medicare program and the co-payment concept specifically, have been constructed.

Instead of this approach, CMS should clarify make clear that winning contract suppliers are not bound to bill at the contracted price, regardless of their bids. It should be clarified that they can bill "no more than" the contracted price. Consistent with current Medicare reimbursement methodologies, where Medicare pays the lower of the supplier's actual charge or the fee schedule, suppliers should retain the right to charge less than the single payment amount. By reducing their charge, suppliers can legally provide incentives to beneficiaries who will benefit from the lower charge by having a lower co-payment or deductible amount. As long as the supplier only charges Medicare its reduced price, that would prove acceptable to all parties and fulfill the purpose of the proposed Rebate Program. The regulations should be clarified accordingly.

3. Conditions for Awarding Contracts (Section II G)

A. *CMS's proposed method of calculating CBA demand is unduly restrictive and could result in a failure to meet beneficiary's needs.*

Proposed 42 C.F.R. §414.414(e) indicates that CMS will calculate beneficiary demand for a particular CBA based on two years of beneficiary claims data. Two issues here are significant. First, we urge CMS to calculate potential growth in demand for each bid product and the Medicare population in

each CBA over the three year bid period. This calculation should be made in conjunction with industry, which may have additional insights and market data. Under-projected growth in the demand for an item or the Medicare population in a CBA could result in the inability of contract suppliers to meet the needs of beneficiaries. This should be of particular concern in less mature practice areas, such as NPWT, where the known benefits of the therapy are only beginning to be widely understood.

Second, we urge CMS to create a margin for error in its demand calculation of at least twenty (20%) percent. This margin of error is critical because contract suppliers may drop out of the program or underparticipate because of: (i) financial difficulties, (ii) unrealistically low prices, (iii) failure to gain or maintain accreditation, or (iv) difficulties meeting the new quality standards. In addition, the margin for error will be important in the event that product demand or the population in a CBA grows more quickly than anticipated.

B. *CMS should modify its proposed accreditation and eligibility requirements.*

The proposed rule also sets forth accreditation, eligibility and financial standards for potential bidders. We believe these standards are critical to the provision of services to Medicare beneficiaries and we have several comments. First, the grace period for accreditation should be as short as possible (30 days or less) to ensure that beneficiaries are properly served and that markets are not disrupted by the failure of suppliers to gain accreditation.

Second, in addition to the eligibility requirements in the proposed rule, CMS or the CBIC should review the billing history of the bidder with the relevant DMERC. While not a guarantee of future events, consistent billing irregularities, recoupments and other issues are indicative of problematic DME suppliers that require inordinate amounts of time, energy and resources on the part of the relevant DMERC. In addition, a financial review should focus on the DME supplier's liquidity/solvency, including their ability to fund historic operating losses (if sustained) and growth in their business.

Finally, there should be a minimal level of business which the bidder has in the CBA with respect to the bid item (such as $10,000).

C. *Only accredited suppliers should be allowed to submit bids.*

Only accredited suppliers should be eligible to submit bids or be considered in the bidding process. Because we have concerns about the ability of most suppliers to be able to secure timely accreditation, we strongly urge CMS to delay implementation of the bidding process until all potential bidders have had sufficient time to secure accreditation. In order to help facilitate timely accreditation for the first bidding cycle, we believe that CMS should "grandfather"

any supplier that has received accreditation by any organization that is ultimately selected as an accrediting organization. We believe a selected accrediting organization should be "grandfathered" even if the standards used by that organization at the time of accreditation are not totally consistent with the standards required by CMS.

CMS must afford suppliers adequate time to review and analyze the final quality standards, and their options for accrediting bodies, before considering whether to bid. Ultimately, the cost of accreditation may be significant (especially for smaller suppliers) and must be factored into bids for those bids to be commercially reasonable and sustainable. We urge that accreditation must take place before bidding, so that only accredited suppliers are allowed to bid. Otherwise, the bids of unaccredited suppliers who may never be eligible for acceptance within the bidding program could distort the bidding process by affecting pivotal bids and the single payment amount.

D. *CMS' efforts to ensure that suppliers meet the financial standards set forth in the proposed rule are essential.*

KCI supports the financial standards set forth in the proposed rule. We concur with CMS' concerns that suppliers that are unable to demonstrate their financial stability could ultimately cause significant harm to the competitive bidding process. Many suppliers, particularly the new NPWT suppliers, have little operating history with Medicare. Such suppliers' failure to remain financially viable would cause particular harm in product categories where there are already few suppliers. Again, this is one of the reasons that we believe that NPWT should not be included as a bidding category.

E. *CMS' proposed method of weighting individual items to determine the composite bid will distort the economics of competitive bidding.*

CMS has proposed weighting items based on unit volume rather than using a price-based approach. We believe any approach which does not incorporate the relative value of the bid items will distort the economics of the bidding process. For example, the use of CMS' proposed rule for any capped rental item which is used with a disposable will unfairly favor suppliers with lower disposable costs but not necessarily lower CMS' total cost. In the NPWT category, patients are supplied with a pump (capped rental) and up to 15 dressings and 10 canisters per month. On a volume only basis, the significance of the (relatively expensive) pump unit will be overwhelmed and suppliers who offer cheap, unsophisticated and unproven pumps will benefit. Moreover, and as stated above, the V.A.C.® system, which utilizes a specially engineered surgical foam dressing, is the only NPWT dressing which has demonstrated clinical efficacy. CMS' proposed rule will encourage suppliers to use cheap, unproven cotton gauze in their dressings to lower their costs. Because such dressings are not effective, the use of such dressings will increase Medicare's total cost. We

urge CMS to use the relative value of bid items (based on fee schedules, market prices or any other valid indicia of value) in creating composite bids.

4. Physician Authorization/Treating Practitioner (Section II 0)

CMS' proposed rule does not meet the requirements set forth in Section 1847(a)(5)(A) of the Act.

Proposed 42 C.F.R. §414.420, as required by the MMA, provides that a physician is permitted to make a determination that a particular item would avoid an adverse medical outcome for a beneficiary and specify a particular product brand or mode of delivery for that beneficiary.[20] Congress' intent was to make sure that the competitive bidding process did not prevent beneficiaries from receiving specific products which were necessary for their treatment. In the proposed rule, a physician is permitted to write a prescription for a specific brand and the contract supplier would be required to furnish that item or assist that beneficiary in finding another contract supplier in the CBA that can provide the item or consult with the physician. The need which is unmet by the proposed rule is the situation in which the physician prescribes a particular brand for a patient which is not carried by any contract supplier in the CBA. Because this physician has already made a determination that only a specific brand would avoid an adverse medical outcome for this beneficiary, we urge CMS to revise the proposed rule to provide that non-contract suppliers in the CBA can supply the prescribed item to the beneficiary at the single payment amount. This revision to the proposed rule is critical for HCPCS codes, such as the NPWT code, that contain products with widely differing therapeutic capabilities. The current proposed rule puts the beneficiary at risk for an adverse event and exposes the Medicare system to significant additional expense.

5. Terms of Contract (Section II I)

A. *The proposed rule places an intolerable burden on contract suppliers to repair/replace items they do not stock.*

Proposed 42 C.F.R. §414.422 states that contract suppliers cannot refuse to repair or replace patient-owned items subject to competitive bidding.[21] This places an undue burden on suppliers that may only carry one or two brands of a particular item. In effect, suppliers will be required to supply parts for, and have technicians trained to repair, medical devices they have never stocked or supplied. In fact, we believe that it would be dangerous to require contract suppliers to repair items which they do not normally stock. In essence, their

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[20] *See* 71 Fed. Reg. 25,654, 25,701.

[21] *See id.*

repair specialists would be required to repair items for which they have received little or no training and on which they do not regularly perform repair services. The results of such repairs could be disastrous for Medicare beneficiaries. Most manufacturers have specialized training for the repair of their respective devices and it would be virtually impossible for a small supplier to have technicians who were trained to repair eight or ten different brands of a particular item. The costs of such an undertaking would be enormous. Finally, many types of DMEPOS cannot be repaired efficiently and, as a result, they are more often replaced than repaired. For example, this would be the case with respect to low-end support surfaces. As a result, the rule would have the effect of requiring contract suppliers to replace products which have been damaged, despite the fact that they were not the supplier that sold the original item. Once again, the cost of undertaking this obligation would be enormous and would make it very difficult for a supplier to accurately assess its costs in submitting a bid.

B. *The proposed rule places an undue burden on suppliers to assume capped rental contracts which are about to expire.*

We recognize the wisdom of grandfathering suppliers who have been furnishing items and supplies to beneficiaries within a competitive bidding area and do not become the contact supplier for that beneficiary upon implementation of the competitive bidding program. In fact, we believe that grandfathering is not only necessary, but should be extended to all products subject to the competitive bidding program. Medicare beneficiaries rely on the continuity of their care in order to help to maintain their health. While we recognize that a change of more substantial items, such as capped rental items, will be traumatic for a beneficiary, we also believe that the potential trauma and displacement would be similar in many other cases. For example, while home blood glucose monitors, and the reagent strips that are proprietary to those monitors, do not fall in any of the three categories set forth in the proposed rule, a beneficiary with diabetes who is forced to switch suppliers at the inception of the competitive bidding program may not be able to quickly locate a new supplier that will be able to furnish the types of reagent strips that will fit his/her existing monitor. Although most monitors work similarly from a clinical standpoint, their size, functions and practicality differ significantly. Many seniors will find it to be an extreme hardship if they are forced to change products. This hardship would be felt not only by the beneficiary, many of whom may neglect testing at the frequency prescribed by their physician, but also by the Medicare program, which will likely incur significant increases in Part A costs resulting from hospitalizations due to complications of uncontrolled diabetes that can result when a patient fails to test his/her blood sugars as prescribed.

As a result, we believe that every beneficiary should have the right to maintain continuity with their DMEPOS supplier irrespective of the product. Accordingly, we believe that every beneficiary should be offered the opportunity to continue to get their same products or supplies from their existing supplier at the single payment amount under the competitive bidding program and that the

supplier should not have the ability to decline unless they do not remain in business. We propose that all suppliers of items, other than those covered under §414.408(k), be "grandfathered" for products and supplies that they have already been furnishing to a beneficiary in a competitive bidding area prior to the implementation of the competitive bidding program, with the beneficiary having the option to choose a winning supplier under the competitive bidding program.

With regard to the three product groups identified by CMS in the proposed rule under §414.408(k), we suggest that a special rule be created which would require beneficiaries to continue to receive their product and services from their existing supplier throughout their use of that product, unless the supplier does not remain in business. First, the average beneficiary will not understand the implications of a choice between a grandfathered supplier and a winning supplier under the competitive bidding program, and it will be impossible for the contractor to adequately counsel each beneficiary regarding the choice. Second, allowing the grandfathered supplier the ability to decline continued provision of the products will permit "gaming" of the program. The old supplier, who is nearing the end of the rental period and has recovered its costs, will reject grandfathering, repossess its rented equipment, and require the competitive bidding program contract supplier to provide a new product to the beneficiary with little or no reimbursement and ongoing expenses for repair and maintenance. Finally, there is no way for bidding suppliers to reasonably estimate how many rentals will be "dumped" on them, and at what point in the rental period such dumping may occur. As a result, they will not be able to reasonably factor such losses into their bids.

With regard to products enumerated in §414.408(k), the competitive bidding program should only apply to those products whose rental period begins after the competitive bidding program implementation date. Pre-existing rental arrangements should be required to be continued with the old supplier throughout the remaining use by the beneficiary. It should continue to be paid by the local DMERC, at the full fee schedule amounts, not the single payment amount. In other words, these items should not be subject to competitive bidding program. Similarly, contract suppliers that lose their contract status in a subsequent competitive bidding program, but during a current rental period, should be required to continue to provide those products to the beneficiaries throughout the period used, at the competitive bidding program rate initially contracted.

6. Competitive Bidding Areas (Section II D)

There are a number of very troubling inferences in the proposed rule pertaining to "mail order suppliers." Significantly, the proposed rule fails to define "mail order suppliers" in any meaningful way. The proposed rule simply refers to "suppliers that furnish items through the mail," which includes nearly every DMEPOS supplier. Most, if not all, suppliers send some products or supplies

through the mail at one time or another, if nothing else, as a courtesy to long-time customers. Further, all suppliers (even those whose businesses focus primarily on the sale of products and supplies delivered via the mail) are required under the current supplier standards to have a storefront location with hours posted and inventory present so that a beneficiary may purchase supplies. Other suppliers, such as retail pharmacies, may have both substantial storefront and mail order businesses under a single roof. Thus, it seems nearly impossible to distinguish between suppliers in this regard. KCI, and most other suppliers, are unable to tell whether we are a "mail order supplier" or not. Therefore, we ask that CMS avoid all distinctions for mail order suppliers, unless there are compelling objective reasons to make such distinctions.

If CMS decides to retain a special category of suppliers referred to as "mail order," then CMS should not require such suppliers to "submit a bid to furnish these items in any area in which a competitive bidding program is implemented which includes the items" and to use the "same bid" price for all such areas. All suppliers have different costs for providing supplies in different areas, even when the mail is used. Suppliers should be able to reflect these different costs in their bids and in their decisions about whether or not to bid in a particular MSA. Further, Congress intended that competitive bidding be rolled out slowly, with the understanding that there may be some difficulties in the early stages of bidding. These difficulties are likely to be had by both CMS and suppliers (as well as beneficiaries, who are likely to suffer most). All suppliers, whether they are considered to be "mail order" or not, should be afforded the opportunity to assess the competitive bidding program based upon those areas and product categories first bid, and to make future business decisions based on those successes or failures.

Finally, the concept of having some type of nationwide or regional competitive bidding process applicable only to mail order suppliers is unworkable and unfair to all suppliers. This system would set up a two-tiered pricing structure. The furnishing of products and supplies via the mail is merely one facet of being a DME supplier. Many suppliers have different business models. Mail order should not be singled out from local delivery services. Both types of delivery serve the same function, namely assisting beneficiaries who have difficulty leaving their homes in the receipt of DMEPOS items that they require. It is not necessarily the case that suppliers who use the mail for delivery of products have any lower costs than other suppliers. Accordingly, we ask that CMS remove this from its proposal and identify this as an area for further study and discussion.

7. Administrative or Judicial Review (Section II J)

CMS should clarify its proposed language to safeguard existing appeal rights

Proposed 42 C.F.R. §414.424 prohibits appeals on most competitive

bidding decisions. This would include the awarding of contracts, the establishment of payment amounts, and the selection of items to be competitively bid.[22] Although the preamble to the proposed regulations acknowledges that existing rights are not disturbed by competitive bidding, KCI asks that the proposed regulation specifically preserve existing appeal rights for beneficiaries and suppliers regarding denied claims. To this end, KCI suggests adding subsection (c) to 414.424, which would read: "*All rights of appeal regarding denied claims are unaffected by this provision.*"

8. Gap-filling (Section II R)

We agree that the concept of gap-filling warrants reevaluation. However, CMS' proposal, as currently structured, lacks substance and statutory support.

The CMS Competitive Bidding Release proposes that the "gap-filling" process used by CMS and its contractors for the last fifteen years be replaced by a process which permits CMS to use a new concept - functional technology assessment ("FTA"). FTA focuses on three criteria: functional assessments, price comparison analysis and medical benefit assessments. Although we agree that the current gap-filling process is less than perfect and we applaud CMS' attempts to gain additional insight into the products which it purchases on behalf of Medicare Part B beneficiaries, CMS' proposal lacks substance and is ill-timed. Such a major change warrants significant discussion and attention, which would not be likely if this vague proposal continues forward at the same time as the competitive bidding proposal.

The proposed rule suggests that functional assessments and price comparison analysis will be used to set DMEPOS prices in the future but offers no insight as to how that would be accomplished. For example, the proposed rule states that:

> The price comparison analysis of devices will help us determine if the manufacturers' suggested retail prices are overly inflated, will provide a basis for establishing adequate payment amounts for new items, and will assist in establishing payment amounts for new items that are introduced after a bidding cycle has begun . . . . We would use the functional technology assessment process, in part or in whole, as another method for establishing payment amounts for new items.

Other than some very broad statements about function, price and clinical benefit, the proposed rule does not give any information from which to analyze the CMS proposal. In essence, CMS has proposed the use of a "black box" into which

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[22] 71 Fed. Reg. at 25,682.

CMS will input data and prices will magically appear – without stakeholder input or visibility. The CMS proposal actually raises more questions than it answers. For example, the proposed rule does not provide us with any information with respect to:

a. Who will perform the functional assessments, price comparison analysis and medical benefit analysis?

b. What criteria will be used in making evaluations in these three areas?

c. What formula will be used to translate the functional assessment, price comparison analysis and medical benefit analysis into actual prices?

We view the gap-filling proposal to be very interesting and worthy of significant discussion, study and consideration. However, based on the information contained in the Competitive Bidding Release, it is impossible for stakeholders to provide meaningful input to CMS. As a result, we do not believe that the current gap-filling process should be modified until such time as CMS has proposed a specific process, stakeholders have an adequate opportunity to comment, and CMS has had a chance to reflect upon the comments which it receives.

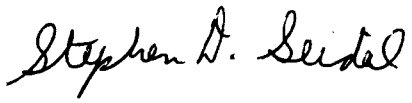
We also question whether the new pricing methodology will meet the requirements of the Act. Although we agree that the Act did not establish a method for pricing new DMEPOS, it established the fee schedule amounts used in 1989 as the basis for DMEPOS reimbursement. CMS' proposed rule is a significant departure from the structure contemplated in the Act.

Conclusion

In conclusion, we believe that: (i) NPWT should not be included initially as a competitive bidding category for the reasons stated above; (ii) CMS must modify many of its proposals to arrive at a workable competitive bidding program; (iii) the gap-filling proposal backs the necessary specificity to allow a meaningful opportunity to comment and (iv) CMS must ensure a workable competitive bidding program which will provide beneficiaries with the products and services they require. This would require sufficient time to meet quality standards, obtain accreditation and satisfy other requirements that should not be rushed. Accordingly, we recommend that CMS push back its proposed timeframes to help to ensure a better outcome for the Medicare program, suppliers and beneficiaries.

We sincerely appreciate this opportunity to comment on the proposed rules.

Sincerely yours,



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June 29, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Sir/Madam:

Attached are comments on behalf of Air Products Healthcare regarding the Department of Health and Human Services recently released Notice of Proposed Rule Making (NPRM) concerning Competitive Bidding.

Please note that Air Products Healthcare represents the following legal entities:

Air Products Healthcare Southeast, Inc.
dba American Homecare Supply, Georgia
MedSafety

Air Products Seating and Mobility, Inc.
dba Air Products Seating and Mobility

American Homecare Supply IV Georgia, Inc.
dba American Homecare Supply IV Georgia

American Homecare Supply Mid-Atlantic, LLC
dba Air Products Healthcare Pharmacy
MidAtlantic Healthcare
Young's Medical Equipment

American Homecare Supply New York, LLC
dba A & J Care
American Homecare Supply, Western New York

American Homecare Supply West Virginia, Inc.
dba Home Health Care Services

AmHealth Group, Inc
dba Collins I.V. Care, Inc.
Genox Homecare, Inc.

COPD Services, Inc.
dba COPD Services

Denmark's Inc.
dba Denmarks Home Medical Equipment
Vanguard Home Medical Equipment

Dependicare Home Health, Inc.
dba DependiCare

Lakeway Medical Rentals, Inc.
dba In Home Medical Equipment

Mosso's Medical Supply Company, Inc.
dba Mosso's Medical Supply Company
RX Pharmacy Services

Nightingale Medical of Indiana, LLC
dba Nightingale Medical

Ultra Care, Inc.
dba Ultra Care

We provide DMEPOS equipment and supplies along with infusion and custom rehab services to approximately 100,000 patients primarily on the East Coast with additional coverage in the Chicago, Indiana and Tennessee markets.

We appreciate the opportunity to review and comment on the proposed NPR. We would urge CMS to carefully review and consider our comments and recommendations. While we believe competitive bidding, if properly executed, would save money for the government, however, we are gravely concerned about how DRA will be incorporated into competitive bidding.

We would further urge CMS to publish an interim final review prior to the final rule to ensure all companies have an opportunity to review and comment one last time.

Questions may be directed to:

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Thank you very much
Joey Ryan

General Comments

Supplier Standards and DRA Implementation
Our first overall comment relates to the information contained in the Competitive Bidding NPRM. We believe the NPRM does not provide enough information to adequately comment. We would urge CMS to publish an interim final review so that suppliers will have adequate time to review and provide comments before the final rule is published.

Section H Quality Standards for Suppliers of (DMEPOS)
We would further urge CMS to allow suppliers an opportunity to review the proposed quality standards prior to submitting comments on the NPRM. Without reviewing the final version of the standards we are unable to understand and incorporate into our comments reactions to the Quality Standards.

Accreditation for Suppliers of DMEPOS and Other Items
APH fully supports suppliers meeting accreditation standards. We would encourage CMS to identify quickly the MSAs to be included in the first round, so that the accrediting organizations can begin processing the applications and schedule the surveys necessary for the suppliers who are not presently accredited. We would recommend all suppliers who submit bids should be accredited; that there should be no transition period.

At the very minimum prior to CMS selecting and arranging winning bids, a supplier's credentialing (accreditation) should be reviewed and only those suppliers who are accredited should be considered for bid purposes by CMS.

Competitive Bidding Areas

While the MMA of 2003 requires that Competitive Bidding (CB) programs be established and implemented in areas throughout the United States, it also provides the Secretary with the authority to phase in competitive bidding programs.

We would recommend and urge CMS to begin the CB program in a phased approach for the first 10 MSAs. This will result in a program that will be able to be managed by CMS since CMS has only conducted two demonstration projects on a radically smaller basis prior to this implementation.

Our concern is that implementation in the 10 largest MSAs will be too large a program to implement, manage and monitor with no history of having successfully run or managed in the past. Our recommendation would be to implement 3 CBAs in October 2007; 3 CBAs in February 2008 and 4 CBAs in June 2008.

Our recommendation would be to exclude St. Louis, Kansas City, Baltimore, Washington DC, because of overlap with multiple DMERC regions or recent transition to a new DMERC MAC. Additionally, we would recommend that Orlando, and San Antonio be excluded since they were part of the demonstration projects.

Further we would recommend the exclusion of San Juan because of logistical and language concerns.

Our recommendation would be to implement the first round in 3 MSAs Miami, Houston and Dallas; allow these programs to transition through 120 days, then implement the next 3 MSAs in February and finally the last 4 MSAs. This will allow CMS to monitor programs and proactively make changes before full implementation in the 10 MSAs.

MSAs – 2007

We would request CMS define "combined rankings of DMEPOS allowed charges per FFS beneficiary." Do these represent the submitted allowed charges of suppliers to Medicare or the allowed payments. If this definition represents allowed payments (i.e. paid claims); we believe CMS will understate beneficiary need for a CBA.

Further, regarding the establishment of Competitive Bidding Areas, we do not believe that CMS has the authority to extend Competitive Bidding Areas outside an MSA either in 2007 or in the next round of bidding in 2009.

MMA 2003 states the competitive acquisition areas will be established in an MSA. We also believe this would be extremely confusing for beneficiaries. Third we do not believe the incremental administrative costs would be offset by the savings, and would request the data used by CMS to make this statement.

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Finally regarding CMS' statement regarding the exclusion of "...an area within an urban area that has low population density is not competitive", we have a number of concerns. First, we do not believe CMS has the authority to exclude certain areas within an MSA from Competitive Bidding. Second, we do not understand how areas would be defined by CMS for exclusion, i.e. by zip code, by county, by street address. Third we believe not only would this be extremely confusing for beneficiaries who may be excluded but potentially have neighbors next door who are included; but inefficient to CMS in terms of administering and monitoring the program. We would urge CMS to reconsider this exclusion provision.

"Nationwide or Regional Mail Order Competitive Bidding Program" (§414.410(d)(2)

We request CMS define whether this would be a nationwide or regional program. We would further request CMS define a national vs. a regional mail order supplier. Many suppliers provide items to beneficiaries via multiple delivery methods, i.e. their own trucks, UPS or other delivery services or other personnel. We do not understand why CMS would dictate the delivery method to be used by a supplier. Further, many beneficiaries require in person demonstration and instruction on the use of products. We would question why CMS would want to restrict this in-home instruction to beneficiaries. We do not believe delivery methods should be stipulated by CMS. A competitive environment supported by a free market economy, drives businesses to choose the optimum delivery methods.

Limitation on Beneficiary Liability

Currently, Medicare allows a supplier to provide an item to a beneficiary for which the supplier believes Medicare may not pay, by executing an Advance Beneficiary Notice (ABN) with the beneficiary. Additionally, the MMA 2003 requires CMS to continue to allow use of ABNs by suppliers. However, it is indicated in the NPRM that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. However, it also states the beneficiary will have no financial liability to a non-contracted supplier for competitively bid items provided by that supplier. We would request clarification on this and the continued use of ABNs.

Authority to Adjust Payment in Other Areas

The NPRM indicates that CMS has the authority to adjust payments for items outside of competitive bidding areas based on information obtained from competitive bidding. We disagree with this statement by CMS and believe this statement only applies to prosthetics and orthotics as defined in §1834a(1)(F)(ii) and §1834(h)(l)(H)(ii).

We believe CMS has the authority to adjust payments via the inherent reasonableness (IR) methodology authorized under the Benefits Improvement and Patient Protection Act (BIPA)

We would recommend CMS issue a separate notice and provide the adequate comment period for suppliers to understand the business implications.

Substantial Savings

CMS has outlined in the CB NPRM that "...CB resulted in substantial savings to the program." Original results reported savings of 20.3% from the two demonstration projects in Polk County, FL and San Antonio, TX. However, the net savings were based on comparison to 2002 fee schedules and when compared to 2005 fee schedules (after the FEHB Predictions) resulted in only 8% savings. We would request definition of substantial savings.

Requirement to Obtain Items from a Contracted Supplier

While we understand the intent of CMS to ensure traveling beneficiaries are serviced by contracted suppliers our concerns are as follows:
How does CMS intend to inform traveling beneficiaries of contracted suppliers in a CBA? Currently there is coordination between suppliers to ensure beneficiaries' medical needs are not interrupted.

For beneficiaries traveling from a CBA to a non-CBA what process will be made available (i.e. access to common working file) to suppliers in the non-CBA to know the services rendered to their beneficiary will be reimbursed at a different fee schedule than the one currently set up in their system. Potentially in 2007 Suppliers will need to setup 14 Medicare fee schedules to accommodate 4 DMERC/MACs and 10 CBAs. By 2009 the number of these fee schedules will grow to 84. This will also require corresponding fee schedules to be set up by each DMERC/MAC which represents an operating burden on both. It likewise will be extremely confusing to Medicare beneficiaries who will potentially receive different coinsurance bills for the same item as the beneficiary travels to different CBAs.

Criteria for Item Selection

We would request clarification from CMS regarding the three categories subject to competitive bidding. Our interpretation of §1847(a)(2) would lead us to conclude that prosthetics and prosthetic devices along with ostomy products would be excluded.

We would request clarification from CMS regarding the methodology to determine an item's potential savings resulting from competitive bidding. Please define "greatest potential for savings".

Additionally, we would request clarification of the following:

Annual Medicare DMEPOS Allowed Charges – Does this reflect submitted allowed charges to Medicare or paid claims or some other measure? Are these charges by Competitive Bidding Area or in total for the nation?

Annual Growth in Expenditures – We would request definition of this.

Number of Suppliers – We would request definition of this. Is this the current (as of 2005) number of legal entities in total? The number of approved Medicare Supplier numbers issued in total? The number of legal entities for each competitive bidding area? The number of legal entities per competitive bidding area? Or some other measure?
Additionally, what methodology will be used by CMS to determine the number of suppliers needed for each competitive bidding area and will this information be released to suppliers prior to the bidding process?

Savings in DMEPOS demonstrations – we would request the methodology to be used by CMS to determine the savings for those items not included in the Demonstration Projects.

Reports and Studies – We would request CMS define the reports and studies to be used and provide access to them for suppliers.

We would also request that CMS provide the reference that quantifies the statement "we saw evidence in the competitive bidding demonstrations that products furnished by a large number of suppliers had large savings rates and fewer problems with quality". We would further request that CMS provide the measure to which the fewer problems with quality was compared to.

It appears from the numerous references to quality within the NPRM that CMS is concerned about preserving quality for beneficiaries, however, we could find no reference to a quality measure being used or considered in the selection of winning bidders. We could only identify references to cost and utilization of items. We would recommend that CMS develop an evaluation method that would include a quality measure as a portion of the overall score in determining a winning supplier.

Regarding product selection, we would recommend that power equipment, such as power wheelchairs and POVs along with "custom" cushioning equipment be excluded. We make this recommendation for three reasons:

- New changes to HCPCS codes along with the new LCD and fee schedules for these items will result in new utilization data from which CMS is relying to select items for competitive bidding
- Historical utilization data used by CMS may have included documented fraudulently billed items (operation wheeler dealer) which would distort reliance on this utilization data
- Power wheelchairs and "custom" cushioning equipment are complex items requiring significant involvement by specialized personnel and do not in our opinion, lend themselves to a competitive environment.

We would recommend that if CMS includes the wheelchair product category in competitive bidding that only low end wheelchairs (K0001 thru K0004) and one basic wheelchair cushion be included.

Additionally we would recommend that OTS orthotics and enteral products be excluded from the first round of competitive bidding. OTS orthotics because many physicians and large chain drugstores currently supply these items and would be unable to provide these to patients in an emergency. Enteral because currently many nursing homes provide enteral products to their patients and may be prevented because they would probably become a non-contracted supplier.

Our recommendation would be that CMS initiate competitive bidding using three product categories and that these product categories be the same across all competitive bidding areas. This will allow better management of the program in the initial rollout, comparison of cost savings across competitive bidding areas and consistency of products for beneficiaries.

Submission of Bids Under the Competitive Bidding Program

CMS has defined in the NPRM that suppliers must bid on all items within a product category. Which we understand the reasoning used for this proposal, suppliers need to know the product categories to determine if they would want to bid on all items in the category. If the product categories are defined too broadly, suppliers will not be able to rationally bid on the items.

The second largest policy group based on "Allowed Charges" in the NPRM is Wheelchairs/POVs. This category includes equipment ranging from manual wheelchairs (K0001) through highly specialized power wheelchairs (K0011).

This further supports our recommendation that CMS more narrowly define product categories to be used in competitive bidding.

Power wheelchairs are complex items requiring custom configuration to the patient along with special adaptations that would not easily be able to be competitively bid. Additionally, manual wheelchairs are scheduled to be recoded in 2007 which will affect the utilization data used by

CMS. Suppliers bidding in this category will still need to inventory many custom additions which will be difficult to bid competitively.

Further concern is that potentially a winning supplier for wheelchairs, may not be the winning supplier for any associated "add-ons", such as specialized seating or backs. Beneficiaries would then be required to use two different suppliers for one piece of equipment.

Regarding oxygen, we are unclear how the DRA would affect the implementation of competitive bidding and would request clarification. The requirement in the NPRM regarding oxygen and oxygen equipment indicates "... the single payment amounts for oxygen and oxygen equipment be calculated based on separate bids submitted and accepted for furnishing on a monthly basis of each of the oxygen and oxygen equipment categories of services described in §414.226(b)(l)(i) through (b)(l)(iv)." We are unclear as to how a rational bid can be made for oxygen and oxygen equipment under DRA.

Finally, the capped pricing, increased quality standards, requirement to service all beneficiaries (including travelers) and costs of servicing beneficiaries from grandfathered suppliers will increase the costs of suppliers. The DRA imposes a cap on the months of payment for oxygen and capped rental equipment. In view of this, allowance should be made to bid item prices above the existing fee level.

Product Categories for Bidding Purposes

Requirements to Bid on all Products in a Category
We would request clarification of the statement, "We believe that suppliers that are located outside of a competitive bidding area, but do business in the competitive bidding area and are able to service beneficiaries residing within the CBA should be permitted to submit bids and participate in the competitive bidding program for that area."

As an example if we have locations not far from a CBA and depots within the CBA would this presence allow us to bid and participate in competitive bidding? Additionally if we have desire to bid for a CBA which would be in our defined company geographic boundaries, but do not presently have a presence within that CBA would we be allowed to bid and participate in competitive bidding? What is CMS' definition of "do business in the competitive bidding area"? Would this include non-Medicare business? And what are the quantitative measures that will be used for evaluation purposes.

Conditions for Awarding Contracts

Quality Standards and Accreditation
The NPRM states "A grace period may be granted for suppliers that have not had sufficient time to obtain accreditation before submitting a bid." We are concerned with this recommendation because potentially suppliers could be chosen as winning bidders who are subsequently not accredited. This would result in CMS having to redetermine the pivotal bid or bids from suppliers who are disqualified having been considered in the determination of the pivotal bid.

We would therefore recommend that only accredited suppliers be allowed to bid and only accredited suppliers' bids be considered by CMS and used in the determination of pivotal bids.

To meet the expected demand from suppliers needing to become accredited we would urge CMS to quickly identify the criteria to be used in identifying the accrediting organizations and to expedite the accrediting process.

Financial Standards

We request clarification of the statement; "§1847(b)(2)(A)(ii) specifies that we may not award a contract to an entity unless the entity meets applicable financial standards specified by the Secretary." Please define the "applicable financial standards". We would request the objective, quantitative measures that will be used by CMS to assess the "expected quality of suppliers, estimating the total potential capacity of selected suppliers and ensuring that selected suppliers are able to continue to serve market demand for the duration of their contracts."

We are unclear and would request the methodology and quantitative measures and/or standards CMS will use to "maintain beneficiary access to quality services."

Regarding the request for bank information, we are concerned about the timeframe needed to obtain this information from the banks as well as the coordination needed by CMS to match the requested banking information (which is to be sent directly from the bank to CMS) to the RFB from the supplier. This potentially could involve ten (10) or more from each bidding supplier. While we understand the need to assure financial stability of winning suppliers we do not believe banking information (as outlined in the proposed RFB document OMB No. 0938-xxxx) will successfully demonstrate this.

Our recommendation regarding financial standards and evaluation is as follows:

CMS should define the financial standards and/or measures that will be required from suppliers to bid. Only those suppliers who meet those standards and/or measures should be allowed to bid. This will ensure only financially stable suppliers are chosen as winning bidders.

We would propose using the following

- Audited financial statements only.
  (Reviewed financial statements do not provide the same assurance that an organization is complying with GAAP and the cost is not prohibitive to small suppliers.)
  Audited financial statements should include those of the legal entity bidding in the CBA and those of the parent corporation if there is one. This request is made because some legal entities within a CBA may be relatively small because they are a start-up or small acquisition, but are financially supported by a very large profitable parent organization. These statements should include balance sheet, P&Ls, Statements of Cash Flows. Additionally trade references should be submitted along with Letters of Credit.
- Insurance Certificates and direct follow up with the underwriter
  (as is done now by the NSC)

An additional question concerns the RFB and whether the bidding would occur by legal entity or supplier number or parent corporation. Our recommendation would be that while bidding be submitted by legal entity, parent corporation financial stability and resources be factored into the financial considerations of the legal entity bidding and the capacity to meet the demand of the CBA.

Market Demand and Supplier Capacity

In determining the beneficiary demand, we would urge CMS to carefully consider how projected growth in a competitive bidding area is determined. Many "sunbelt" areas have experienced substantial increases in seniors over the past few years and the census bureau has projected this trend will continue. In determining the number of suppliers needed for a competitive bidding area, we would urge CMS to "over project" so there is no shortage.

Regarding CMS' approach to estimating supplier capacity to meet the projected demand in a CBA, we do not understand the necessity of comparing a supplier's current activity in a CBA with their projected capability unless it is to identify suppliers whose projected capability is less than current activity. To compare current activity to projected capability if used for exclusion purposes would defeat the purpose of competitive bidding, i.e. a large supplier may want to enter a new geographic area as part of their overall expansion plans. While they may not currently be providing many services (or none) to Medicare beneficiaries, they would have more than adequate financial resources available to service the CBA.

We would urge CMS not to disregard suppliers based on low or no current activity in a CBA if their financial statements reflect adequate capital to service an area.

Determine the Pivotal Bid

Our concern with the proposed methodology to determine the pivotal bid is there is no mechanism for excluding arbitrarily low bids. We would recommend some mechanism to exclude "radical outlier" bids.

We also would request clarification on whether bids will be in whole dollars or include cents. If bids are to include dents, will they then be rounded to the closest dollar?

We would also urge CMS to allow any willing supplier be accepted as a wining supplier if they agree to provide competitively bid items at the winning price.

Finally CMS has stated they plan to select at least two suppliers for each CBA. We would urge CMS to select more suppliers than it projects are needed to ensure beneficiary access throughout the contract period.

Assurance of Savings

The goal of competitive bidding is to reduce overall costs to the Medicare program but not necessarily item costs. We believe CMS should not limit bids by disqualifying bids above the current fee schedule amount for that item. There are items for which costs have risen above the current fee schedule because of BIPA and FEHBP reductions and no CPI increases for suppliers. By not allowing bids above the current fee schedules CMS is forcing suppliers into an artificial,

illogical pricing structure. Instead, CMS should continue to use the methodology used in both demonstration projects.

CMS should recognize that overall savings in a product category can be achieved even though one item may have a payment amount above the current fee schedule.

Selection of New Suppliers After Bidding

Our questions regarding the NPRM proposal for selecting new suppliers are as follows:

- Would all contract suppliers be contacted at the same time? By what method?
- How would CMS determine the allocation of beneficiaries? By Beneficiary zip code? Or some other arbitrary measure?
- What is the timeframe for "timely manner"?

We are also concerned with the time frame needed for the next supplier on the list to be able to provide updated information and the need to be able to quickly meet the beneficiary demand in the CBA. We believe the need for this procedure can be eliminated by CMS carefully evaluating the financial statements and viability of suppliers and selecting more suppliers than the projected demand of a CBA.

Setting Single Payment Amounts for Individual Items

The NPRM proposes setting the single payment amount for any competitively bid item at the median of the array of bids of the "winning suppliers". Use of median pricing is not in accord with the original third principle that contract suppliers will be paid at least as much as they have bid for an item. This principle was stated as necessary to "ensure fairness and access". [see PAOC presentation on Determining Payment Amounts]. Median pricing methodology is contrary to the objectives and results achieved through normal competitive bidding processes and does not follow the selection method used in both demonstration projects.

Our recommendation would be for CMS to set the pivotal bid at the highest price bid for a product category that will include enough suppliers to meet the projected demand for that CBA.

An alternative would be to determine the "mean" bid price for a product category.

Rebate Program

The NPRM proposes to allow contract suppliers to provide rebates to beneficiaries that equal the difference between the supplier's bid price and the single payment amount. Contract suppliers however could not advertise their rebate program directly to beneficiaries; rather CMS would provide information identifying rebate suppliers to beneficiaries in a CBA. The program is voluntary, however a supplier would need to identify whether they intend to offer rebates in their RFB.

We have very serious concerns about this and do not understand why a program such as this would be included in the NPRM when it is in direct contradiction with the statutory prohibition on beneficiary inducements in §1128A(a)(5) of the Act.

Specifically, §1128A(a)(5) prohibits the offering or transfer of remuneration when an individual or entity knows or should know that it is likely to influence the beneficiary's selection of a provider or supplier. Remuneration includes anything of value and would apply to the rebate proposed by CMS. While the statute contains exceptions to the definition of the term "remuneration," the rebate program proposed in the NPRM does not fit any of the statutory exceptions. For example, "remuneration" does not include unadvertised waivers of coinsurance or deductible amounts for individuals who have been determined to be in financial need. The rebate offered by contract suppliers under the CMS program would not fit into this exception. We are also unaware of any guidance from the Office of Inspector General (OIG) of the Department of Health and Human Services that would authorize the program CMS proposes. In light of the statutory prohibitions of §1128A(a)(5), CMS lacks the authority to implement a rebate program. Consequently, CMS should withdraw the proposal.

The OIG has published guidance in the form of advisory opinions, fraud alerts and special advisory bulletins to assist providers and suppliers in understanding their obligations to comply with the statutory prohibition on beneficiary inducements. OIG guidance has consistently held that inducements distort beneficiary decision making, increase costs to the Medicare program, and undermine competition among providers. In a Special Advisory Bulletin, *Offering Gifts and Inducements to Beneficiaries*, published in August 2002 (Bulletin), the OIG took an uncompromising stance against the practice of offering *any* inducements, other than items of nominal value, to Medicare beneficiaries. The OIG provided the following rationale for its position:

> Offering valuable gifts to beneficiaries to influence their choice of a Medicare or Medicaid provider raises quality and cost concerns. Providers may have an economic incentive to offset the additional costs attributable to the giveaway by providing unnecessary services or by substituting cheaper or lower quality services. The use of giveaways to attract business also favors large providers with greater financial resources for such activities, disadvantaging smaller providers and businesses.

Bulletin at 1.

CMS proposes two ways to ameliorate the fraud and abuse issues inherent in the rebate program. First, CMS would require any contract supplier that offers rebates to offer the rebate to all Medicare beneficiaries in the competitive bidding area. The supplier could not pick and choose which beneficiaries would get a rebate as a way of enticing desirable patient populations. For example, the supplier could not offer the rebate only to patients with a specific chronic diagnosis requiring long-term rental equipment. Second, the supplier could not advertise the fact that it offers a rebate.

Once an inducement is in the public domain, its harmful effects cannot be contained, even with the safeguards CMS intends to implement. The fact that a provider does not "actively" promote an inducement does not change the illegal nature of the activity or the disruptive repercussions it has on competition and quality of care. The OIG would be unlikely to approve of a rebate program like the one CMS proposes even if the supplier did not advertise the rebate:

> The "inducement" element of the offense is met by *any offer* of valuable . . . goods and services as part of a marketing or promotional activity, *regardless of whether the marketing or promotional activity is active or passive.* For example, *even if a provider does not directly advertise or promote the availability of a benefit to beneficiaries, there may be indirect marketing or promotional efforts or informal channels of information dissemination, such as "word of mouth" promotion by practitioners or patient support groups.*

Bulletin at 5 (Emphasis supplied).

CMS' proposal to allow contract suppliers to offer rebates fundamentally conflicts with the longstanding rationale underlying the prohibitions on inducements and kickbacks in federal health care programs. This type of activity distorts patient decision making and undermines true competition among health care providers. Importantly, the rebate program would promote *exactly* what Congress chose to prohibit when it enacted prohibitions on beneficiary inducements under §1128A(a)(5) – competing for business by offering Medicare beneficiaries remuneration. Consequently CMS should withdraw the proposal.

Terms of Contract

The NPRM states "§1847(b)(3)(B) requires the Secretary to recompete contracts under the Medicare DMEPOS Competitive Bidding Program at least every 3 years. The length of the contracts may be different for different product categories..."

We are concerned that CMS could set the contract period at different lengths than 3 years, which would be extremely confusing to both suppliers and beneficiaries. We would urge CMS to standardize the contract terms for all competitive bidding areas and for all product categories.

Repair and Replacement of Equipment
The NPRM states "the contract supplier cannot refuse to repair or replace patient-owned items subject to competitive bidding." The NPRM also will require contract suppliers to accept all beneficiaries within the competitive bidding area.

We would recommend that contract suppliers accepting new beneficiaries be entitled to a new rental period proportionate to the equipment, i.e. 13 months for capped rental items and 36 months for oxygen equipment.

This will ensure contract suppliers are not adversely affected financially when beneficiaries change suppliers. This will also ensure beneficiaries continue to have a wide variety of suppliers to choose from for their services.

We would recommend that CMS consider separately supplier bids to repair items.

We also request clarification regarding repairs:
Could a contract supplier sub-contract out the repairs needed on beneficiary owned equipment? We do not believe contract suppliers should be required to repair patient owned equipment.

Termination of Contract
CMS must define the process to be used in termination of a contract supplier including an opportunity and adequate timeframe to cure any identified breach of contract.

Information Collection from the Supplier
We do not understand and would request clarification on the following "conditions and information that we propose a supplier must agree to provide to CMS for purposes of assessment prior to becoming a contract supplier:"

- Information on product integrity
- Information on business integrity
- Organizational conflicts of interest
- Names of all owners
- Employee information
- Training and qualifications
- Customer Service protocol

We also suggest CMS consider requesting complete disclosure on CIA agreements, OIG convictions and consider conducting criminal background checks.

Change in Ownership
We are concerned with CMS' request that notification be provided in writing 60 days prior to any changes of ownership, merges or acquisitions being finalized. We understand and agree that CMS should be notified of ownership changes, however in our experience there are instances when this timeframe is unrealistic. We are additionally concerned that CMS could according to this rule, potentially be notified of numerous acquisitions that upon further due diligence are not consummated. We are concerned about the additional administrative costs and burden this rule would place on CMS. We are likewise concerned with the proposal that "the successor entity must agree to assume the contract supplier's contract including all contract obligations and liabilities that may have occurred after the awarding of the contract to the previous supplier." Our interpretation of this statement is that all future changes of ownership will take the form of stock acquisitions. We are very concerned that CMS would limit suppliers' ability to enact asset acquisitions. We are also concerned about the successor's liability for potentially fraudulent activities that could have occurred on the previous company's watch. Additionally, we are concerned about instances where the new company determines revised CMNs are needed and the physician is no longer in practice or refuses to execute new CMNs. And finally we are concerned about the accounting and tax implications by restricting change of ownership transactions to only stock transactions. There may be instances where sale of a company because of death of the owner would be prohibitively expensive if executed as a stock transition, leaving the widow with little money and no other recourse to dispose of the business.

Opportunity for Networks

Regarding CMS' proposal concerning networks we would request clarification on the legal structure that would allow a joint venture to be formed. Currently joint venture arrangements are not compliant or approved by the OIG. We are also concerned that there may not be enough time to form a network prior to submitting bids. We are also concerned about CMS' limitation on networks to 20% of the Medicare market and would request CMS disclose the basis for this limitation.

Further we request clarification regarding networks in a CBA. Could a supplier be part of or form a network for each CBA?

Finally we request clarification regarding liability regarding the billing arrangement for networks. CMS has stated "the legal entity would be responsible for billing Medicare and receiving payment on behalf of the network suppliers." Would the legal entity also have liability for actions related to network suppliers in post payment audits?

Education and Outreach

We are concerned with the enormity of communicating to all referral sources which include thousands of physicians and hospitals and range to sleep labs, outpatient facilities, ambulatory surgical centers, nursing homes, etc. We are likewise concerned about CMS' ability to effectively communicate this change to beneficiaries, particularly those traveling patients who will not initially be part of competitive bidding because their permanent residence is not one of the 10 MSAs selected, but who travel frequently or infrequently to one of the MSAs. We do not believe there exists an effective means for communicating this enormous change. We believe that despite a thorough, comprehensive communication plan, beneficiaries will be confused and not understand this program. Further we believe competitive bidding as outlined in the NPRM will force beneficiaries with multiple pieces of equipment to use multiple suppliers. This will be confusing for the beneficiaries who may contact the wrong supplier in an emergency and not receive the treatment needed timely, causing an emergency room visit and potentially a costly hospital stay.

CMS may considering partnering with AARP to enhance its outreach to beneficiaries, however, this will not prevent the multiple supplier issue that beneficiaries will have. CMS should also be mindful that these planned outreach activities are additional costs to the competitive bidding program.

Finally we are concerned about CMS' ability to communicate this change to suppliers, within one of the initial ten MSAs, and those that may have small operations in an MSA but may be part of a larger organization not in the MSA.

We would request CMS define and publish their plans for communicating these changes.

Monitoring and Complaint Services for the Competitive Bidding Program

We would request CMS define and publish the proposed "formal complaint monitoring system to address complaints in each competitive bidding area."

We applaud this measure by CMS but would urge careful examination and review of any complaints. We are concerned that disgruntled suppliers, referral sources or beneficiaries may file fictitious complaints about a winning supplier.

Physician Authorization/Treating Practitioner

CMS has proposed to allow physicians to prescribe a specific brand or type of equipment. This provision seeks to preserve beneficiary access to equipment. We do not believe this provision should be included in competitive bidding. A physician always has had the freedom to prescribe a particular brand or item and we believe this would continue under competitive bidding. Suppliers are always looking satisfy a physician's request for specific equipment particularly if the equipment requested is clinically superior. We would request that CMS establish a process to reimburse at a higher rate a specific piece of equipment requested by a physician if that physician can demonstrate the medical necessity and clinical superiority of the equipment. We believe that if a specific piece of equipment is requested by a physician, there should be documented medical need and clinical justification for the equipment. Suppliers should also be reimbursed at a higher rate to compensate them for the additional expenses associated with obtaining such an unique item. Further, we are concerned that there could be increased beneficiary risk of injury because supplies will be forced to repair brand specific items for which they are not knowledgeable of or qualified to repair. Finally, we are concerned that manufacturers could promote their expensive brands to physicians which could inappropriately drive up the requests for these types of equipment.

In conclusion, we would propose that this proposal to allow physicians to request brand specific items be removed in CMS' final rule.

Implementation Contractor

We would request CMS define the quantitative, objective measures and evaluation tools that the CBIC(s) will use in evaluating the bids submitted by suppliers.

Suppliers need to understand the data and information that will be reviewed by the CBIC(s) as well as the actual scoring and evaluation process to be used. Without this guidance, suppliers have no assurance that bid evaluations will be performed in a fair, objective and quantitative manner and not using qualitative, unmeasurable, judgment related methods.

We would agree that the evaluation process should not be performed by the DMERCs but would request that the actual scoring mechanism that will be used to evaluate bids be published with sufficient time for supplier review prior to the RFB.

Payment Basis

Inflation Update

We are concerned that there is no assurance in the competitive bidding NPRM to guarantee suppliers will receive the inflation update in years two and three of the contract period. We would request that CMS define its plan to guarantee that Congress will not override this price increase through subsequent legislation in any contract year.

Grandfathering Medicare Advantage Beneficiaries

CMS has not defined the process by which a contract supplier will service a Medicare Advantage beneficiary who chooses to become a Medicare fee-for-service beneficiary. These patients may have a supplier who is part of the Medicare Advantage plan network, but may not be a contract supplier. Will these beneficiaries be allowed to continue to receive services from their existing supplier? Or will they be forced to change suppliers? Our recommendation would be that these beneficiaries be allowed to remain with their existing supplier and excluded form competitive bidding.

Process for Grandfathering Suppliers

The DRA will cause a major change in the behavior of grandfathered suppliers when compared to their behavior in the demonstration areas. It will now be to the advantage of grandfathered suppliers to withdraw from providing the service when the peak of their beneficiary oxygen population approaches 36 months to recover and sell the equipment on the used market. Withdrawal could take two forms - formal withdrawal at the time of contract awards (i.e. the start of the contract period) or informal withdrawal sometime later by providing a poor service and encouraging beneficiaries to switch to a new supplier at 35 months. For the contract suppliers this would result in an uncontrolled transition of beneficiaries and, in the unfair situation where the contract supplier is paid little or nothing for equipment they are forced to supply. With the current draft rules there is a high risk that beneficiary service quality will decrease and there will be confusion in the market.

To avoid this situation we would propose that grandfathered suppliers should be required to phase out their beneficiaries within 6 months of the contract award and that contract suppliers who take over existing beneficiaries are permitted to bill for a new rental period not to exceed either 13 months for capped rental items or 36 months for oxygen beneficiaries (or until the beneficiary no longer requires the equipment whichever is sooner), at the contract rates.

This recommendation regarding a six-month transition will prevent the perpetual roll-over of non-contractual suppliers, who could potentially rebid for the next 36 month period. This will also ensure continued access to quality services for beneficiaries with contracted suppliers and an uncontrolled transition of beneficiaries.

Beneficiary Switch to Contract Suppliers

The NPRM indicates beneficiaries may choose to use a contract supplier at any time and that a contract supply must provide capped rental or oxygen equipment to the beneficiary in the competitive bidding area regardless of the remaining rental months. The NPRM also indicates that suppliers must factor these additional costs into the bids they submit.

Suppliers will not be able to forecast whether a beneficiary will choose to remain with a supplier or choose a new contracted supplier. Nor can they forecast the number of rental months remaining for capped rental or oxygen equipment for these beneficiaries.

This is why we are recommending a six-month transition period for all non-contracted suppliers and a new rental period for contracted suppliers.

Application of DRA to Oxygen Patients

It is unclear from the NPRM how CMS intends to apply the DRA provisions on oxygen to grandfathered suppliers and beneficiaries. Will the "grandfathered" relationship terminate at the conclusion of 36 months? As noted above, the implementation of the DRA forced ownership provisions on oxygen and capped rental equipment have important ramifications for competitive bidding. Stakeholders cannot provide meaningful comments on many issues in the NPRM without understanding how CMS will administer the DRA requirements. Consequently, it is important that CMS publish an interim final rule before it publishes the final rule on competitive bidding.

Gap-Filling Methodology

Finally, we do not believe gap filling to determine Medicare fee schedule payments should be included in competitive bidding. We would recommend that CMS consider and address this separately from competitive bidding.

One final question that we have concerns the process for determining capacity in a competitive bidding area for a subsidiary supplier of a very large parent organization that is not located in the competitive bidding area. Our question concerns how the subsidiary supplier's ability to meet the projected demand for that CBA will be determined. We believe and would recommend that CMS heavily weight the parent organization's financial strength and capability to meet any demand projections and not rely solely on the subsidiary supplier's size. This will ensure that CMS selects financially stable suppliers who will be able to meet the demand projected for a CBA.

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Home Care Delivered, Inc.℠
More than just home delivery™

June 28, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Proposed Rule for Competitive Acquisition Program
CMS-1270-P

Dear Sir/Madam:

Home Care Delivered, Inc is pleased to submit comments on the proposed rule for the Competitive Acquisition Program developed by the Centers for Medicare and Medicaid Services. Home Care Delivered, Inc. is one of the premier home-delivery medical supply companies in the nation with total sales in CY 2005 exceeding $10 million. We are a company committed to providing quality products and a continuity of care and support for our customers to help them better manage their medical conditions within the confines of their home. The following are our comments.

Determining Single Payment Amounts for Individual Items – Rebates:

We would like to express our deep concerns for CMS' proposal to allow for suppliers who submit bids less than the established single payment amount to give rebates to beneficiaries. We are against this proposal for the following reasons:

- Although suppliers would be prohibited from advertising such rebates either to beneficiaries or referral sources, it would appear that such a restriction would be very difficult for CMS to control and enforce. How would a supplier handle a question from a referral source that asks "Do you provide rebates to your customers"? We would presume the supplier could legally answer "yes" but then what prevents the referral source from providing this information to all their patients and other referral sources, and then having it come back that the supplier is advertising this to referral sources and beneficiaries.
- We believe that rebates would be extremely difficult and cumbersome for suppliers to administer and even more difficult for CMS to audit. Larger suppliers would be required to hire additional staff just to track rebates. This would unnecessarily add costs to the health care supply chain.

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800-565-5644 · Fax 804-354-1574 · www.homecaredelivered.com

- Beneficiaries are already being rewarded with reduced coinsurance rates because of the lower fee schedule imposed by competitive bidding. Therefore, we believe the intent of the law is met and no further reductions are necessary, especially in light of the potential for fraud and abuse and the added expense some suppliers will have to incur in order to participate in the rebate program.

Opportunities for Networks:

We would like to comment on the fact that Home Care Delivered, Inc. has concerns about the proposal to allow suppliers to form networks. We are neither for nor against this rule. Our concern is the lack of definition and absence of clear understanding that the proposed rule reflects. As an example, if the legal entity dissolves its relationship after being awarded a contract, would the remaining supplier be in jeopardy of losing its contracted status in the competitive bidding area. We are also concerned that this could add unnecessary disruption to beneficiaries if network arrangements do not work out.

In terms of the 20 percent rule, we agree that there should be a provision to insure competition, but just as important, CMS should insure an adequate number of suppliers for beneficiaries to choose from. As stated in the evaluation of the demonstration projects, many times referral sources would switch from one supplier to another until a supplier could be found to meet their requirements and the needs of their patients, in terms of product quality and adequate business standards (i.e. timely delivery, customer service). We question whether the 20 percent rule is adequate to insure freedom of choice for beneficiaries.

Competitive Bidding Areas – National or Regional Mail Order Competitive Bidding

Home Care Delivered, Inc. is very much in favor of the CMS proposal to allow for a national or regional mail order competitive bidding program. We favor this proposal for the following reasons:

- Beneficiaries would benefit from having certain maintenance supplies such as, diabetic, urological and wound care, sent directly to their home without the need of traveling to a supplier to purchase them. This would be especially true of beneficiaries living in more rural areas.
- Beneficiaries would not have to worry about running out of their supplies. The supplier would maintain records on each patient and call prior to shipping a replenishment order.

- Beneficiaries would be assured that they are not on their own when it comes to their in home medical supply needs. Not only are calls made to the patient at the time of their re-order, but many suppliers attempt to contact customers on a monthly basis.
- Providing certain supplies through the mail has proven to be safe, efficient and cost effective. Beneficiaries are used to getting their supplies this way and there are a sufficient number of mail order suppliers in the marketplace to insure that beneficiaries will have a choice of suppliers to choose from.
- Requiring quality standards and accreditation from a national accrediting organization will insure that all mail order companies meet and maintain the high standards that Medicare beneficiaries deserve.
- Based on the fact that a significant percent of certain supply items are purchased through the mail, there could be sufficient savings to warrant a national or regional mail order competitive bidding program.

Criteria for Item Selection

We would like to express concern that based on the documentation from CMS it appears that diabetic supplies will be included as a product category in the first round of competitive bidding. Although CMS proposes to phase in only those items that are determined to have the highest cost and highest volume, we question whether Medicare savings in *total* will be realized by requiring competitive bidding for diabetic testing equipment and supplies. Home Care Delivered, Inc. recommends that CMS consider the impact of changes on not only Part B savings, but also Part A, in implementing a competitive bidding program applicable to diabetic supplies.

Persons with diabetes often face other related health risks including heart disease and circulatory problems. Successful disease management programs for these patients include ongoing consultation between the patient and their physician and consistent self-monitoring based on recommendations from the physician. It is through the success of these programs that help avoid acute care hospitalization.

As shown in the two demonstration projects, competitive bidding will require some beneficiaries to change suppliers. While this presented some concerns in the demonstration areas, the impact was minimized because existing suppliers who did not qualify with a winning bid were allowed to continue to service their patients as long as they agreed to accept the single payment amount. However, with CMS' proposed rule, only those suppliers with winning bids will be awarded contracts, thus creating the potential of requiring many beneficiaries who require daily testing to switch suppliers. Because CMS has not specifically evaluated the potential for negative consequences created by barriers to access to needed diabetic testing equipment and supplies, Home Care Delivered, Inc. is

concerned by the potential for gaps in service and the resulting noncompliance which may result from competitive bidding.

We urge CMS to take the time to evaluate the best approach to competitive bidding in terms of diabetes care relative to the impact on beneficiaries and the overall cost savings to the program.

Thank you for allowing us the opportunity to submit these comments. We look forward to working with CMS during the bid and selection process.

Sincerely,

Gordon L. Fox, Jr.
President

James P. Cohen
Director
Payer Relations & Compliance

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ADVANCED FOOT & ANKLE CENTER

Nathan B. Thomas, D.P.M.

110 South Avenue West • Missoula, MT 59801 • (406) 542-2108

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS – 1270 – P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan,

I am writing to urge the Centers for Medicare and Medicaid Services (CMS) to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) from 1861 (r)(1) to 1861(r).

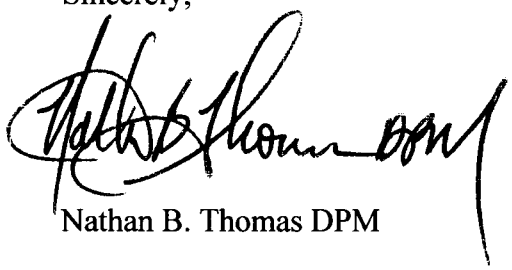
As a podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. These individuals are my patients and they rely on me to use my best medical judgment and clinical skills in treating them. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to my patients only and the right to execute a physician authorization.

In my practice, I use a variety of DMEPOS items. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall may occur, which could result in other additional injuries.

I urge CMS to modify the physician definition from 1861 (r) (1) to 1861 (r) before finalizing the regulations for the competitive acquisitions program. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required

to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

Sincerely,



Nathan B. Thomas DPM

Medical Equipment Distributors
2200 – 109 E. Millbrook Rd
Raleigh, NC 27604
Phone: 919- 873- 9168
Phone: 800 – 822 - 6535
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June 27, 2006

Centers for Medicare and Department of Health & Human Services
Attn: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

CMS-1270-P

As a small provider I am extremely concerned of the proposed competitive bidding.

Durable Medical Equipment has been a flat market for years. The suppliers have taken a reduction in payments over the last years. Homecare product demand has increased but homecare spending has not.

1) First of all, why are you excluding the small providers? Providers who produce less than six million dollars per year are excluded. This is extremely unfair for small businesses. Remember, small businesses tend to provide better service. We care about the patient and their medical needs. Have you contacted the Small Business Association to consider what will happen to small businesses?
2) Rebates – This is an open door for suppliers who are dishonest. I thought kickbacks where illegal.
3) Someone needs to consider the cost of implementing this program. Are you really going to save money?
4) Have accreditation in place if you want suppliers to be accredited. Why would you do this after the bidding process?
5) Why would you exclude the top three MSA's. If you think it is not going to work in those cities, why would you try this in other cities?
6) Consider the alternatives to competitive bidding.

If you want to save money, then simply cut the reimbursement. You would save money, NO additional costs if competitive bidding would take place and the majority of suppliers who are considered as small businesses would not GO OUT OF BUSINESS. Small businesses employ many people who will be out of jobs. This is a disgrace!

Sincerely,

Sharon Lubbers

Sharon Lubbers
Medical Equipment Distributors

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NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

NCPA NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

May 19, 2006

Via Messenger
Herb Kuhn
Director Center for Medicare Management
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) in Relation to Regulation and Licensure of Pharmacies and Pharmacists and State Pharmacy Laws

Dear Mr. Kuhn:

The National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) appreciate the opportunity to provide further comments and information to the Centers for Medicare and Medicaid Services (CMS) on the Quality Standards for Suppliers of durable medical equipment, prosthetics, orthotics, supplies (DMEPOS) and accreditation of suppliers. In particular, we are providing information regarding their inapplicability to pharmacy providers in view of the comprehensive state pharmacy laws and licensure requirements for pharmacies and pharmacists. We agreed to provide CMS with this comparison of the quality standards in relation to state pharmacy laws. The comparison table is attached to this letter and a summary of the comparison is provided below. In addition, we have a document with all of the state pharmacy laws to support this comparison. If you would like to have a copy, please contact Diane Darvey at 703-837-4182 or ddarvey@nacds.org. We thank you for consideration of our comments.

General Comments

NACDS and NCPA and their members strongly believe that pharmacies and pharmacists have an important patient care role in assuring the appropriate use of DME products as well as prescription drugs and other health care items and services for Medicare beneficiaries, and that it is critical for Medicare beneficiaries to have access to these products and services in their community pharmacies. We also believe that the quality standards and accreditation requirements are unnecessary for community pharmacies in view of the extensive state pharmacy laws and the licensure through state boards of pharmacy.

Community retail pharmacies and pharmacists must comply with comprehensive state pharmacy laws in providing services to their patients, including professional and licensing requirements as a condition of operation.

Community retail pharmacies play a unique role in providing health care for Medicare beneficiaries. This includes providing non-service or cash and carry DME items such as diabetic supplies and other products, as well as dispensing prescription drugs to Medicare beneficiaries. In consideration of these factors, the existing comprehensive laws and regulations with which pharmacies have to comply, the state licensure of pharmacies and pharmacists, and pharmacists' extensive educational training, community pharmacies should not be faced with the same quality standards and accreditation requirements as DME suppliers that are not licensed health care professionals or those that provide more specialized DME products.

For these reasons, we ask that CMS determine that community retail pharmacies providing non-service DME items and related products and supplies be deemed exempt from the quality standards and accreditation. Our understanding is that Section 1834(a) (20) (A) of the Social Security Act, added by Section 302(a) (1) of the Medicare Modernization Act of 2003, provides the Secretary with this discretion. That provision requires the Secretary to "establish and implement quality standards for suppliers of items and services." However, it gives the Secretary authority to determine what items and services are covered "as the Secretary determines appropriate." Accordingly, we ask that this provision be used as means for the Secretary to deem that it is appropriate to exempt community pharmacies from the quality standards and accreditation provisions.

We further believe that the statute gives CMS considerable leeway in determining whether or not to apply these new standards to community pharmacies through accrediting organizations. For example, CMS has stated that it will be grandfathering in suppliers that have already been accredited by recognized accrediting organizations. Thus, CMS' consideration of "grandfathering" in certain entities indicates that it believes it can substitute CMS' criteria for these other standards. There is nothing in the statute or legislative history that would prevent CMS from adopting by reference another source of standards such as the state pharmacy laws and regulations. For example, there is nothing in the statute to prevent CMS from determining that the state pharmacy laws and regulations and licensure of community pharmacies and pharmacists will satisfy the quality standards for licensed community pharmacy DME suppliers.

The following is our summary of the comparison of the quality standards and pharmacy laws.

Comprehensive State Pharmacy Laws

Pharmacies and pharmacists in every state and U.S. territory are subject to stringent state laws and regulations that control the scope of pharmacy practice, required licensure and compliance standards. Accordingly, pharmacies and pharmacists providing DME products and services to their patients already meet different comprehensive standards than other non-licensed health care provider suppliers of DMEPOS items.

Pharmacy laws and regulations thoroughly and comprehensively regulate every aspect of the standards of pharmacy practice and the licensure of pharmacists and pharmacies. Before any pharmacy is permitted to operate and provide drugs, devices, services or supplies to patients, the pharmacy must meet rigorous standards of state licensure, including inspections and compliance with standards for pharmacy practice. As such, State Boards of Pharmacy regulate both the provision of products and the providing of professional services by pharmacies and pharmacists.

State laws set the scope of pharmacy practice for pharmacists. Pharmacies and pharmacists are subject to stringent professional practice standards that obviate the need for these additional quality standards. While the language of each state may differ, all states have laws that establish the scope of pharmacy practice including pharmacists' selection of drugs and devices, provision of patient counseling, professional responsibilities and other acts necessary to provide pharmacy patient care services such as consultation with prescribers about a patient's care and treatment.

Pharmacists Education and Training

State pharmacy laws and regulations establish the qualifications, training and experience requirements for pharmacists and pharmacy technicians including licensure, educational degrees, training, experience and continuing education for pharmacists for these individuals to be permitted to provide professional pharmacy services.

Pharmacists are highly educated to provide patients with counseling on proper use of drugs and medical devices and to provide counseling services. Pharmacists must graduate from an accredited pharmacy school and be licensed in the states where they practice pharmacy. All pharmacists are now required to graduate from a Doctor of Pharmacy degree program consisting of a minimum of 6 years of education with 2 years pre-pharmacy school and 4 years of pharmacy school. The pharmacists' educational program is extensive and includes clinical training directly with patients for advice on their care and training. After graduation from pharmacy school, pharmacists in all states must pass the National Association of Boards of Pharmacy Pharmacist Licensure Exam ("NAPLEX"). In addition, after graduation and passing the national exam, most graduates enter 1 or 2 year residency programs. In total, this represents at least six years of education and training and, in most instances, closer to eight years. All states require pharmacists to complete continuing education to maintain licensure, and usually this is 30 hours every two years.

Accordingly, today's pharmacist is uniquely qualified to serve as the medication and medical device use expert for advising and counseling Medicare patients and providing advice to other health care providers on the use of these health care products. Pharmacists are ideally situated to provide Medicare patients using non-service items such as diabetic supplies and other cash and carry items with counseling and important information on the proper use of these items. In addition, with the implementation of the Part D drug benefit, community pharmacies are where the majority of these patients will obtain their prescription drugs for diabetes and other health conditions. Such qualifications, education and training clearly differentiate pharmacists from general unlicensed retailers providing DME products, and should supplant application of the additional quality standards and accreditation to community pharmacies providing DME items and services.

Expecting national, regional or small chains – some with thousands of outlets – to seek accreditation for an important but small part of their business or to comply with the additional quality standards when they are already subject to comprehensive pharmacy law requirements is simply unrealistic. Accrediting agencies will face significant hurdles in accrediting all these pharmacies, and some pharmacies may believe that the cost of accreditation – both in time and resources – is too burdensome. This process could disrupt the important access that Medicare beneficiaries have had to items such as diabetic testing supplies and other health care items, and the critical coordination of receiving their prescription drugs for diabetes and other disease conditions from their community pharmacy.

State Laws Require Pharmacies to Have a Designated Pharmacist for Compliance
State pharmacy laws mandate that each pharmacy have a designated pharmacist who is responsible and accountable for the management and operation of that pharmacy and compliance with the laws and regulations. The state pharmacy laws, depending on the state, identify this pharmacist as the *pharmacist-in-charge (PIC)* or the *pharmacist manager* (hereafter referred to as the PIC). The PIC is responsible for pharmacies and pharmacists maintaining and providing proof of licensure in their pharmacies, and the pharmacy licensure requires a specific address and other information such as telephone number which would be available for beneficiary access.

State Pharmacy Laws Require Pharmacies to Have a Pharmacist on Duty
For Medicare beneficiaries, purchase of DME items in a community retail pharmacy provides the benefit of having a highly trained professional health care provider, the pharmacist, available to assist them. State pharmacy laws require pharmacies to have a pharmacist on duty when they are open for business and pharmacies must post their hours of operation. Community pharmacies are open early in the morning into the late evening and in many areas there is a 24 hour pharmacy available. When beneficiaries purchase their "over-the-counter" diabetic supplies and other cash and carry non-service items, the delivery occurs in the pharmacy with the pharmacist and the other pharmacy staff available to assist the beneficiary and answer any questions. Should any concerns or problems arise with the supplies, the beneficiaries are able to return them to the pharmacy. We believe that the most optimal service to Medicare beneficiaries with diabetes and other chronic disease conditions occurs as a result of regular interaction with the pharmacist in the local community pharmacy setting.

State Pharmacy Laws Establish Professional Conduct and Services for Pharmacists and Pharmacy Technicians
State pharmacy laws on professional conduct provide oversight for pharmacists' services. Community retail pharmacies provide beneficiaries with an additional benefit of having a licensed pharmacist available to provide services to the beneficiary as needed and the oversight of the pharmacist-in-charge (PIC).

Community pharmacies are required by state pharmacy laws to maintain adequate operating hours. Moreover, an increasing number of community pharmacies are providing 24-hour services and a significant number remain open until the early evening hours. As a result, community pharmacies are very accessible to beneficiaries.

State pharmacy laws and regulations establish the qualifications, education and training, and examination requirements for pharmacy technicians to be permitted to work in a pharmacy. In most states, pharmacy technicians must be licensed or registered.

Pharmacists and pharmacy technicians are supervised by a pharmacist-in-charge or pharmacist manager who will require the pharmacy staff to adhere to applicable laws and regulations and pharmacy policies and procedures. This would include maintaining any required licensure or registration, competence and following policies and procedures.

Pharmacies are required by pharmacy laws and regulations to maintain complete records in computerized or hard copy for all prescriptions that are filled and refilled. The pharmacy records for prescription DME would be included in these requirements. Pharmacy laws and regulations also require pharmacies to keep hard copy records of new prescriptions and inventory records and invoices.

State Pharmacy Laws Require Pharmacists to Comply with Applicable Laws and Regulations

State laws and regulations require pharmacists to comply with all applicable laws and regulations including federal laws and regulations, to comply with the prescriber's instructions for filling prescriptions, and to consult with the prescriber for approval of any prescription changes. Pharmacists are required to document their communications and instructions from physicians and other health care providers for any clarifications or changes to prescription orders. State pharmacy laws and regulations would subject pharmacies and pharmacists to discipline for misrepresentations about their services. Pharmacists are not permitted to provide recalled products to patients. State pharmacy laws give the state boards of pharmacy authority to discipline pharmacists and pharmacies for improperly providing professional services to patients.

State laws and regulations require pharmacists to review and fully comply with the prescriber's instructions for filling all prescriptions including for any DME and to consult with the prescriber for approval of any prescription changes. Pharmacists are required to document their communications and instructions from physicians and other health care providers for any clarifications or changes to prescription orders. Pharmacists as licensed health care professionals comply with professional conduct standards that would require them to provide follow-up and referrals for their patients if they determined that was necessary for the patient's care and treatment.

Pharmacists are required to provide their patients with counseling on new prescriptions and if requested by the patient. For diabetic supplies and other non-service items, pharmacists would assist patients with training on how to use their diabetic testing supplies and other items upon request. In many states pharmacists engage in collaborative practice with physicians for certain patients, and in these instances additional patient education and training could be required pursuant to the protocol agreed upon between the physician and the pharmacy.

State pharmacy laws and regulations establish stringent requirements for pharmacy computer systems including maintenance of the information. These laws and regulations also establish requirements for maintenance of pharmacy records. Pharmacies' compliance with federal laws

and regulations for Medicare patients would include maintaining records for the time periods set under Medicare.

Pharmacies, pharmacists and other pharmacy staff are required to comply with HIPAA and the applicable state laws and regulations to maintain patient privacy and confidentiality of patient records.

Pharmacies and Pharmacists are Subject to Disciplinary Actions by Boards of Pharmacy
The pharmacy and pharmacist licensure laws establish the requirements for pharmacies and pharmacists including the disciplinary authority of the state boards of pharmacy. Pharmacies and pharmacists are subject to board of pharmacy disciplinary actions against their licenses for violations of laws and regulations.

Beneficiaries with comments about pharmacy services and pharmacist providers have the right to contact the state board of pharmacy. The state boards of pharmacy as consumer protection agencies are available to provide this service for patients. This consumer protection option does not exist with other non-licensed DME businesses that are not licensed pharmacies staffed with licensed pharmacists. Should problems with the monitors or other diabetic supplies arise they can be brought to the attention of the pharmacist. As appropriate depending on the non-service item such as diabetic supplies or other items, the pharmacist could bring this to the manufacturers' attention or assist the beneficiary in how to contact the manufacturer.

Pharmacists are Specifically Educated and Regulated to Work with Physicians in the Delivery of Care to Patients
State pharmacy laws establish the scope of pharmacy practice, and require pharmacists to follow the instructions of the patient's physician including any treatment plan involving a prescription that comes within the pharmacist's scope of practice. Pharmacists' professional responsibilities would include providing the patient with products that follow the prescriber's prescription and have been provided by FDA approved manufacturers. This would include providing the patient with any needed information and pharmacist consultation on the use of the equipment and any needed supplies.

Summary and Recommendations

State-licensed community retail pharmacies should not be faced with the same quality standards and accreditation requirements as DME suppliers that are not licensed professional health care providers or those that provide more specialized DME products.

We respectfully ask that the Secretary determine pursuant to the statutory grant of authority under Section 1834(a) (20) (A) of the Social Security Act, added by Section 302(a) (1) of the Medicare Modernization Act of 2003, that community pharmacies providing non-service items are not covered by the quality standards and accreditation in consideration of the extensive and comprehensive state pharmacy laws, pharmacy and pharmacist licensure, pharmacist education and training, and the unique role of community pharmacies and pharmacists in providing care to Medicare beneficiaries.

Please direct any questions about these comments to NACDS' Diane Darvey at 703-837-4182 (ddarvey@nacds.org) or John Coster at 703-837-4126 (jcoster@nacds.org), or NCPA's William Popomaronis at 703-683-8200 (Bill.Popomaronis@ncpanet.org). Thank you for the opportunity to submit this information.

John M. Coster

B. Douglas Hoey

John M. Coster, Ph.D., R.Ph
Vice President, Policy and Programs
NACDS

Douglas Hoey, R.Ph, MBA
Senior Vice President and COO
NCPA

cc: Linda Smith, RN, MSN, MBA

CMS QUALITY STANDARDS for
SUPPLIERS OF DIABETIC EQUIPMENT AND SUPPLIES
Comparison with State Pharmacy Laws

The following is a side-by-side comparison of the Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies and applicable pharmacy practice laws and regulations to provide information on their relative inapplicability to community retail pharmacists and pharmacy practice setting in view of the highly regulated pharmacy practice setting.

The following Appendices with copies of the state pharmacy laws for all 50 states are available upon request. Please contact Diane Darvey at 703-837-4182 or ddarvey@nacds.org.

Appendix A	Pharmacists Scope of Practice Laws
Appendix B	Board of Pharmacy Authority to Discipline
Appendix C	State Pharmacy Laws Pharmacist-in-Charge/Pharmacist Manager
Appendix D	State Pharmacy Laws for Pharmacist Professional Conduct
Appendix E	Examples of State Pharmacist Licensure Laws

Part 1. ***Supplier Business Quality Standards***		
Administration 1. Governing body or designated persons with legal authority, responsibility and accountability for establishing and implementing policies and procedures regarding the organization's management and operation; and policies and procedures reviewed and revised annually to ensure they meet CMS regulations, policies and procedures and accreditation standards.		**Administration** 1. State pharmacy laws and regulations require each retail pharmacy to have a designated person with legal authority, responsibility and accountability for the management and operation of the pharmacy. Depending on the state, this pharmacist is called the pharmacist-in-charge or pharmacist manager. (See **Appendix C.**) Each pharmacy has a pharmacist in charge. All pharmacies are required by the state board of pharmacy pursuant to state pharmacy laws and regulations to have a pharmacist-in-charge (PIC) for each pharmacy. Pharmacies usually must notify the board of pharmacy of the identity of the PIC for each

		licensed pharmacy. The PIC is responsible for the practice of pharmacy including compliance with applicable federal and state laws and regulations. The PIC has responsibility for assuring that policies and procedures for all operations of the pharmacy are followed and for ensuring the pharmacy operations and practices comply with all applicable federal and state pharmacy laws and regulations.
2. Provide only equipment, supplies and services to Medicare beneficiaries disclosed on CMS-855S; and all licenses, certificates and permits to be displayed publicly and accessible on request to government officials		*2.* State pharmacy laws and regulations require that the PIC is responsible for the operation of the pharmacy including compliance with applicable laws and regulations and public display or proving proof of a permit or license as applicable. This would include compliance with applicable Medicare laws and regulations. (See **Appendix C.**)
3. Procurement and testing of quality DME and supplies – The supplier shall develop and implement policies and procedures that: - Describe methods to ensure that manufacturers provide evidence of how equipment is tested to meets standards for quality and safety; at a minimum meet FDA medical device standards, ANSI, RESNA, ISO - Describe process for documentation of product's features, instructions and warranties for each non-custom equipment.		3. State pharmacy laws and regulations define the scope of pharmacy practice and require pharmacists to meet professional standards. (See **Appendix A** on pharmacists' scope of practice, and **Appendix D** on pharmacists' professional conduct.) Pharmacists and pharmacies could be subject to disciplinary actions for unprofessional conduct if they sold non-FDA approved products. Every state board of pharmacy has authority to issue disciplinary sanctions for engaging in misrepresentation in providing professional services or

		professional activities. For OTC diabetic testing and supplies, the documentation of the product's features and warranties is included in the manufacturer's packaging that the patient takes home when with the purchase of the OTC diabetic testing items.
4. Delivery of services to beneficiaries The supplier shall be responsible for delivery of items to beneficiaries and maintain proof of delivery. The supplier shall develop and implement policies and procedures that: • define scope of services, beneficiary eligibility, how services are coordinated with treating physician, health care team and business and emergency operating hours; • maintain business hours for minimum 40 hours a week • post business hours • have staff available for telephone customer service during posted business hours and after hours emergency services • ensure no mail order for initial delivery, set-up and beneficiary education, training for certain DME • For mail order replacements ensure that supplies are consistent with the treating physician and that qualified staff are available to respond to beneficiary concerns and needs. • Accept returns of substandard equipment • Describe procedures and timeframes for DME rental, delivery, pickup, maintenance, storage, repairs, replacement, warranties, costs and discharge of beneficiary from services • Ensure that in emergency supplier staff refers beneficiary to physician or 911 • Ensure that supplier maintain a list of all equipment and supplies and how they are provided to beneficiary and if covered by Medicaid or Medicare • Provides beneficiary with toll free number or		4. For a beneficiary's purchase of over -the-counter (OTC) non-service items such as diabetic testing and supplies, the proof of delivery would be met when the patient purchases the diabetic supplies and is provided with a sales receipt that the patient maintains. In those instances, the beneficiary selects the product and there would be no delivery or pickup for repairs. The proof The manufacturer's product packaging would include product information for the purchaser on warranties and use of the product. In addition, pharmacists as health care professionals would provide the patient with any needed assistance and counseling on the use of the products including services for delivery, pick-up, repairs and service if the pharmacy provided DME requiring such services. State pharmacy laws and regulations on pharmacists' professional conduct and scope of practice would require pharmacies to take back defective products. (See **Appendix A** on scope of practice, and **Appendix D** on professional conduct.) In addition, state pharmacy laws

national access number for all equipment 5. Supplier shall comply with: • Federal, state and local laws • Supplier enrollment standards at 42 CFR 424.57 • Disclosure of ownership and control information at 42 CFR 420.201, 42 CFR change of 424.204, 42 CFR 420.205 and 42 CFR 420.206 including written notice to CMS, National Supplier Clearinghouse (NSC), and its accreditation organization of change in officers, directors, agents or management, or corporation, association or other company responsible for the management, identity of each new individual or company and each supplier location shall meet the quality standards regulations and be accredited. • Other HHS regulations including nondiscrimination including but not limited to race, color, national origin,, handicap and age, 45 CFR part 80, part 84, and part 91.		and regulations require pharmacies to maintain adequate operating hours and to post the hours that the pharmacy is open. 5. State pharmacy laws and regulations require each retail pharmacy to have a designated person with responsibility and accountability for the operation of the pharmacy including compliance with laws and regulations for the practice of pharmacy. Depending on the state, this pharmacist is called the pharmacist-in-charge or pharmacist manager. (See **Appendix C.**) Each pharmacy has a pharmacist in charge. All pharmacies are required by the state board of pharmacy pursuant to state pharmacy laws and regulations to have a pharmacist-in-charge (PIC) for each pharmacy. Each pharmacy must notify the board of pharmacy of the identity of the PIC for each licensed pharmacy. The PIC is responsible for overseeing compliance with all applicable laws and regulations. The PIC has responsibility for implementing policies and procedures for the practice of pharmacy and for ensuring the pharmacy practices comply with the requirements of federal and state pharmacy laws and regulations.

6. Supplier shall develop and implement compliance plan to control fraud, waste, and abuse including: • written policies and procedures and standards of conduct with all applicable federal and state standards • designation of compliance office and compliance committee or individuals accountable to senior management/ownership • effective training and education for the employees, contractors, agents and directors as applicable for compliance with standards • procedures to applying consistent enforcement of standards such as disciplinary guidelines • procedures for effective internal monitoring and auditing		6. State pharmacy laws and regulations require each retail pharmacy to have a designated person with responsibility and accountability for the operation of the pharmacy. This would include compliance with federal and state Medicaid and Medicare provisions. (See **Appendix C**) Depending on the state, this pharmacist is called the pharmacist-in-charge or pharmacist manager. The PIC or pharmacist manager is accountable to the board of pharmacy and to the pharmacy owner for the practice of pharmacy and the pharmacists, pharmacy technicians, and other pharmacy staff while they are working in the pharmacy and in conjunction with the pharmacy permit holder for knowing that the pharmacy staff are properly licensed or registered as appropriate and trained as required by the state pharmacy laws and regulations. Relative to disciplinary proceedings, state boards of pharmacy have authority to discipline pharmacists and pharmacy technicians and pharmacies for unprofessional conduct or violations of laws and regulations. (See **Appendix B** on board of pharmacy disciplinary authority, and **Appendix D** on pharmacists' professional conduct.)

Financial Management Supplier shall: • Develop and implement financial management policies, procedures and practices to ensure accurate accounting, business integrity and accountability • Use accounting system to track revenue and expenses • Provide evidence of the following to CMS, the accreditation organizations and others acting on behalf of the government upon request of: 1. Financial management plan with annual operating budget per GAAP, data sheet of annual projected and actual income, data sheet of annual expenses and cash flow, balance sheets, statements of changes in net position, invoices and receipts related to each beneficiaries equipment and supplies and services. 2. Financial statements that are accounted for, recorded and audited by accounting personnel to ensure financial propriety 3. Notice to CMS and accreditation organization of potential adverse financial operations. • The supplier shall maintain adequate financial resources to meet financial obligations for each quarter. • The supplier shall advise CMS and the supplier's accrediting organization when it first becomes aware of adverse financial conditions which could result in delayed payments to manufacturers or suppliers or bankruptcy.		Licensed pharmacies could not operate and be licensed in states without financial viability and to meet their professional conduct and pharmacy practice requirements. (See **Appendix A** and **Appendix D.**) They are required to be licensed as pharmacies and to maintain licensure through payment of initial and renewal licensure fees. If they have been found to have violated applicable laws and regulations, they would be required to pay fines and penalties. Pharmacies are also required to have other state and federal licenses including DEA registration, business licenses, and approval as state Medicaid providers.
Human Resource Management Supplier shall: • Develop and implement policies and procedures that specify personnel qualifications, training, experience and continuing. education consistent with specialized equipment, supplies and services provided to beneficiaries • Obtain criminal background checks on all employees in compliance with federal and		State pharmacy laws and regulations establish the qualifications, training and experience requirements for pharmacists and pharmacy technicians including licensure, educational degrees, training, experience and continuing education for pharmacists and pharmacy technicians for these

state laws • Have sufficient full time and part time personnel to meet beneficiary needs • Professional personnel shall be licensed, certified, registered per applicable state and federal laws and policies • Professional personnel shall be knowledgeable in equipment and supplies provided by the supplier for beneficiaries • Maintain documentation of annual verification of licensure, registrations, certifications and any other qualifications and competencies for its personnel and management involved in providing beneficiary services. • Have and implement assessment program to evaluate and document staff competence in areas related to its product specialization and beneficiary services • Have documentation that each staff member is current and in good standing with credentialing/licensure organizations. • Inform and train all management and staff on their responsibilities, types of services provided by the supplier, the policies and procedures and any other pertinent information. • Prohibit employees with a communicable disease or infected skin lesions from entering the home if could transmit disease, • Maintain current documentation on employees TB screening, Hepatitis B vaccination or decline per OSHA and CDC. • Ensure that all drivers who deliver to SNFs, hospitals, or any other entities have valid drivers license. • Ensure that personnel are employed and assigned responsibilities commensurate with their education and experience. • Credentialed individuals shall have documented knowledge and demonstrated competencies to - inspect, deliver and setup, evaluate, adjust and monitor the prescribed equipment - instruct the beneficiary and caregiver in the proper use, operation, maintenance, repair,		individuals to be permitted to work in pharmacies. (See **Appendix E.**) In addition, pharmacists and pharmacy support staff are supervised by the onsite pharmacist-in-charge or pharmacist manager. (See **Appendix C.**)Many pharmacy owners do criminal background checks on individuals as part of the hiring process. Pharmacies, pharmacists, and pharmacy technicians are required to display their licenses, permits or registration cards in the pharmacies or with them to provide proof of current licensure, permit, or registration. Pharmacists must graduate from an accredited pharmacy school and be licensed in every state where they practice pharmacy. (See **Appendix E.**) All pharmacists are now required to graduate from a Doctor of Pharmacy degree program consisting of 6 years of education with 2 years pre-pharmacy school and 4 years of pharmacy school. The pharmacists educational programs are extensive and include clinical training to work with patients directly on their care and training. After graduation, the majority of pharmacy graduates then complete a one year residency program. All pharmacy graduates must be licensed to practice pharmacy in every state where they practice pharmacy. To obtain a pharmacy

troubleshooting and reporting of problems for the equipment and - communicate results of services to the treating physician and other health care team members		license, each pharmacy school graduate must pass the national North American Pharmacists Licensure Exam (NAPLEX) and the Multistate Jurisprudence Exam (MJPE). In addition, each pharmacist must be licensed in each state where they practice. (See **Appendix E.**) States require that pharmacists maintain competency by completing a required number of continuing education hours during each license renewal period. State pharmacy laws and regulations establish the qualifications, education and training, and examination requirements for pharmacy technicians to be permitted to work in a pharmacy. In most states, pharmacy technicians must be licensed or registered. Pharmacists and pharmacy technicians are supervised by a pharmacist-in-charge or pharmacist manager who will require the pharmacy staff to adhere to applicable laws and regulations and pharmacy policies and procedures. This would include maintaining any required licensure or registration, competence and following policies and procedures. (See **Appendix C.**) ***Pharmacies Licensure Required*** All pharmacies must be licensed by the state to provide pharmacy services. Their licenses must be maintained and must be posted.

Beneficiary Services Supplier shall 1. Process and document physician orders in accord with instructions in the CMS Program Integrity Manual Ch 5. • Document communication with physicians and other referral sources including review of prescription or referral and consultation with physician or referral source for clarification or modification • Consultation as necessary with other health care professionals and practitioners about the beneficiary's condition to formulate a service plan and document all finding and actions taken, and communicate this with appropriate health care professionals to ensure beneficiaries status is updated and current.		State laws and regulations require pharmacists to comply with all applicable laws and regulations (which would include CMS requirements) and to fully comply with the prescriber's instructions for filling all prescriptions and to consult with the prescriber for approval of any prescription changes. (See **Appendix A** on scope of pharmacy practice, **Appendix C** on the pharmacist in charge, and **Appendix D** on pharmacists' professional conduct.) Pharmacists are required to document their communications and instructions from physicians and other health care providers for any clarifications or changes to prescription orders.
2. The supplier shall ensure the following when providing access to equipment, supplies, services and information for beneficiaries: • In advertisement, websites and ordering instructions access to services is clearly explained • All DME and services include clear instructions on use, maintenance, potential hazards and how to report any failures and malfunctions. • There is a policy and process to remove recalled products from distribution, which includes parameters on how to notify beneficiaries and provide information on how to return or dispose of the product. • For DME suppliers, there are defined and guaranteed estimates for the time needed to ship items and they are disclosed to the beneficiary • Receipt of DMEPOS and services will be confirmed with the beneficiary and		2. State pharmacy laws and regulations would subject pharmacies and pharmacists to discipline for misrepresentations about their services. Pharmacists are not permitted to provide recalled products to patients. (See **Appendix B** on board of pharmacy disciplinary authority, and **Appendix D** on pharmacists' professional conduct.) Many of the requirements in this section are inapplicable to OTC items typically supplied by retail pharmacies that are selected and purchased by the patient as such products would not be shipped or rented.

• For DME, suppliers shall have identification stickers on capped rental equipment showing the company's name, address and tel. number. 3. Supplier shall ensure coordination of services with the treating physician and other healthcare team and shall: • Review all physician orders to ensure clear understanding of equipment and supplies requested and shall use this in the delivery planning process • Consider the beneficiary or caregiver's needs when scheduling delivery • Consult with the treating physician and healthcare team to obtain pertinent beneficiary health care information that may impact medical use of the prescribed equipment i.e. diagnosis, prognosis, mental status, functional limitations, types of services and equipment required, amount, frequency and duration of treatments, frequency of visits, rehabilitation potential, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge and or referral, and any other necessary information for delivery of appropriate services. 4. The supplier shall develop and implement policies and procedures describing: • The referral and acceptance process • How delivery of equipment and services are prioritized and • Staff response during emergencies, inclement weather, or any other emergent event that may disrupt services. 5. The supplier shall ensure that education and training is provided to the beneficiary on how to		3. State laws and regulations require pharmacists to review and fully comply with the prescriber's instructions for filling all prescriptions including for any DME and to consult with the prescriber for approval of any prescription changes. (See **Appendix A** on scope of pharmacy practice.) Pharmacists are required to document their communications and instructions from physicians and other health care providers for any clarifications or changes to prescription orders. 4. Pharmacists as licensed health care professionals comply with professional conduct standards that would require them to provide follow-up and referrals for their patients if they determined that was necessary for the patient's care and treatment. (See **Appendix A** on pharmacists' scope of practice.) 5. Pharmacists are required to provide their patients with

use Medicare covered items safely and effectively. This education and training shall be Documented in the beneficiary's service plan including identification of those who conducted the training. Evidence that the beneficiary or caregiver demonstrated their understanding of instructions shall be documented in the service plan.		counseling on new prescriptions and if requested by the patient. For OTC items, pharmacists would assist patients with training on how to use their non-service items and supplies upon request. In many states pharmacists engage in collaborative practice with physicians for certain patients, and in these instances additional patient education and training could be required pursuant to the protocol agreed upon between the physician and the pharmacy. (See **Appendix A** on pharmacists' scope of practice.) In addition, state pharmacy laws and regulations have comprehensive provisions governing pharmacists' counseling of patients.
Performance Management The supplier shall develop and implement a performance management system that measures its effectiveness and efficiency in meeting goals, compliance with policies and procedures and with federal, state and local law requirements, and compare projected to actual results, investigate deviations from plans, evaluate individual staff performances, examine progress to meeting objectives and implement corrective actions. 1. Provide evidence of performance criteria monitored and evaluated, and outcomes and actions taken and include quantitative and qualitative measures. 2. Identify, monitor and evaluate problems to determine root causes including any adverse effects of equipment and supplies 3. Respond to identified problems by developing, implementing and monitoring strategies to improve quality of services and products. 4. Implement procedures and a schedule to evaluate the effectiveness of strategies		**Performance Management** The pharmacy and pharmacist licensure standards and professional standards impose stricter requirements on pharmacies and pharmacists than a performance system. Pharmacies and pharmacists would be subject to board of pharmacy actions against their licenses for violations of laws and regulations and improper patient care. (See **Appendix E** on pharmacist licensure and **Appendix B** on board of pharmacy disciplinary authority.) Beneficiaries with complaints about pharmacy services and pharmacist providers have the right to complain to the state board of pharmacy. The state boards of pharmacy are consumer protection agencies. This

used. 5. Conduct beneficiary satisfaction surveys and make results available on request and/or listed on website if applicable, and document and review quarterly percentage of beneficiaries satisfied with services. 6. Performance management system shall use mechanisms to track trends and patterns related to quality and outcomes of service, staff performance, beneficiary satisfactions, and financial stability of the organization such as: *Reported as percentages* - accuracy of bills submitted to Medicare - accuracy of bills submitted to beneficiaries - beneficiary complaints - complaints resolved to all complaints - beneficiary complaints used to improve organizational performance - responses to beneficiaries within 60 minutes - beneficiary calls with questions on equipment or supplies after provision of education and training - distribution errors - product returns re all products shipped - product failures - product recalls re all products shipped - staff that achieve competency in annual assessments *Reported as a number* - number of adverse effect on beneficiaries as a result of inadequate or malfunctioning equipment, supplies, or services e.g. actual or potential cause or contribution to a death or serious injury to the beneficiary as a result of malfunctioning equipment or services.		consumer protection option does not exist with non-licensed DME businesses that do not use licensed pharmacists and pharmacies.
<u>Equipment and Safety</u> The supplier shall develop and implement equipment management program that ensures the prevention and control of safety risks and hazards both for its staff and for beneficiaries. 1. The supplier shall maintain a current and accurate inventory of all equipment		**<u>Equipment and Safety</u>** Pharmacists as licensed by the state boards of pharmacy would be required to comply with state laws and regulations including those applicable to warranties and recall notices relative to the recall

including model, stock number, serial number, batch number, expiration date and other information as applicable. 2. The DME supplier shall implement and maintain a system for tracking and monitoring the history of all equipment including an item's functions, failures, recalls, repairs, preventive maintenance, inspection, testing and calibrations; have a policy and process to report product failures to manufacturers and to appropriate agencies. 3. The DME supplier shall implement a system that describes how equipment will be serviced and routine follow-up procedures as well as emergency response procedures to prevent any interruption of services to beneficiaries. 4. The supplier shall implement and maintain a process for honoring all warranties express and implied under applicable State laws; shall not charge the beneficiary or Medicare for the repair or replacement of items or for services covered under warranty. This applies to all purchased and rented items, including capped rental items 42 CFR 414.229. Supplier shall maintain documentation that it has provided beneficiaries with information about Medicare supplied items covered under warranty in form of letters, logs or signed notices. 5. The supplier shall conduct an environmental safety evaluation of a beneficiary's home including emergency power and notify the treating physician of potential or actual problems that may interfere with effective functioning or usage of the beneficiary's equipment (not applicable to O&P). 6. The supplier shall comply with all federal, state and local laws and instructions regarding safe transportation, storage, use, generation, and labeling of hazardous chemicals, materials, and waste including cytotoxic medications,		of defective products and would follow the manufacturer's and the Food and Drug Administration's instructions on product recalls. (See **Appendix E** on pharmacist licensure.) Pharmacists would also be subject to state public health and safety laws that could prohibit pharmacies from taking back opened and used items and supplies due to public health and safety risks. The PIC is responsible for overseeing compliance with all applicable laws and regulations. (See **Appendix C.**) The pharmacist-in-charge or pharmacist-manager would have responsibility for requiring compliance with policies and procedures for all operations of the pharmacy and for ensuring the pharmacy practices comply with requirements of federal and state pharmacy laws and regulations including those for the safe storage, use and labeling of hazardous chemicals, materials, cytotoxic agents, and parenteral and enteral nutrition solutions. . The requirement for the supplier to conduct an environmental safety evaluation of the beneficiary's home would not be applicable to non-service items cash and carry items and supplies that the beneficiary purchases at a retail pharmacy and takes home for personal use. The state boards of pharmacy that

medical gases, blood and blood soaked items. 7. The supplier shall ensure there is adequate space within its facilities to support the delivery of beneficiary services as well as separation of the manufacturing or storage of equipment from any hazardous materials and waste. 8. The supplier shall implement policies and procedures for the proper storage of parenteral and enteral nutrition therapy solutions and formulas, and medications with appropriate sanitation, temperature, light, moisture, ventilation, segregation, safety, and security (does not apply to O&P facilities). 9. The supplier shall implement policies and procedures regarding the preparation of medications and parenteral and enteral nutrition therapy solutions.		issue pharmacy licenses and permits establish the requirements for pharmacy layout and physical requirements and perform inspections before the license or permit is issued. Pharmacies are required to have proper equipment and references for pharmacist provided services. For OTC non-service items and supplies that are selected and purchased by patients and taken home for personal use, the products would not be used by pharmacy staff because they are taken home by the purchaser for personal use and not returned to the pharmacy. Additionally, because the patient has purchased the product for self-use, they would be serviced by the manufacturer if service is needed. In the event of a product recall, pharmacists would follow FDA recall instructions.
Beneficiary Rights and Ethics The beneficiary has a right to self-determination as well as access to and communication with persons and services of the supplier and healthcare team. A supplier shall protect and promote the rights of each beneficiary. 1. Prior to furnishing equipment, supplies, or services, the supplier shall inform the beneficiary of the following: • Products and services that will be furnished • Any changes in products and services • Schedule and procedures staff will follow to provide the products and services including frequency of proposed visits		**Beneficiary Rights and Ethics** Pharmacists are required to provide their patients with counseling on new prescriptions and if requested by the patient. For OTC non-service items, pharmacists would assist patients with training on how to use their diabetic testing and supplies upon request. In many states pharmacists engage in collaborative practice with physicians for certain patients, and in these instances additional patient education and training could be required pursuant to the

• The rental versus purchase options available for equipment and supplies including associated costs (not applicable to O&P) • Policies for after-hours and emergency coverage; and • Telephone numbers for repair, emergencies and customer service assistance 2. The supplier shall respect the need of beneficiaries for confidentiality, privacy, and security. The supplier shall: • Respect the beneficiary's right to personal privacy during rendering of services and • Respect the beneficiary's personal property and security during home visits 3. The beneficiary has the right to request and to have the supplier resolve oral, written, and telephone complaints concerning the products and services provided by the supplier. The supplier shall develop and implement a complaint resolution system for identifying, responding to, and resolving complaints. The supplier shall maintain documentation of all written, oral, and telephone complaints it receives including: • The name, address and telephone number of the beneficiary • A summary of the complaint including date received, name of person making the complaint, the name of the person receiving the complaint, and a summary of the actions taken to resolve the complaint • If an investigation was not conducted, the name of the person making the decision not to investigate and the reason for not doing so.		protocol agreed upon between the physician and the pharmacy. (See **Appendix A** on scope of pharmacy practice.) Pharmacists as licensed health care professionals would comply with state pharmacy laws and regulations for proper storage of drugs and medical equipment and devices including parenteral and enteral solutions. (See **Appendix A** on scope of pharmacy practice, **Appendix D** on professional conduct, and Appendix E on pharmacist licensure.) Relative to patient privacy and confidentiality, pharmacies are subject to state and federal patient privacy and confidentiality laws including HIPAA in how they handle, process and store patient's protected health information. Pharmacies routinely handle requests from their patients about the pharmacy products and services that they purchase. If appropriate, pharmacists would assist patients with how to reach the manufacturer of the products.
Information Management The supplier shall develop and implement an information management system that ensures the accuracy, accessibility, confidentiality, and security of the organization's beneficiary's records, data, and dissemination of information.		**Information Management** Pharmacies are one of the most highly computerized segments of health care. Pharmacies have been computerized for several decades with increasingly

The supplier shall comply with the appropriate provisions and requirements of HIPAA and other applicable federal and state requirements.		advanced systems that provide for the accuracy and security of pharmacy patient records. Each state has laws and regulations establishing requirements for computer and hardcopy pharmacy records including that they be maintained for a specified number of years and be readily accessible to the state board of pharmacy. Relative to patient privacy and confidentiality, pharmacies are subject to state and federal patient privacy and confidentiality laws including HIPAA in how they handle, process and store patient's protected health information. Some of these requirements would not be applicable to purchase of cash and carry non-service items.
1. The supplier shall maintain records on each beneficiary that are complete, accurate, readily accessible, and systematically organized. A beneficiary's record shall include detailed descriptions of the specific products used by the beneficiary, customized designs of appliances and devices in use, pertinent medical history, relevant financial records, services provided including any follow-up, and evidence of any beneficiary education and training regarding DMEPOS and other items and services.		1. Pharmacies are required by pharmacy laws and regulations t maintain complete records computerized and/or hard copy for all prescriptions that are filled and refilled. The pharmacy records for prescribed DME would be included in these requirements.
2. For suppliers that maintain records by computer instead of hard copy, the supplier shall develop and implement policies and procedures for electronic signatures and describe the attestation policy(ies) for electronic signatures and other safeguards in force at each supplier location. In cases where such attestation is done on computer records, safeguards to prevent unauthorized access and reconstruction of information shall be in place including at		2. Pharmacy laws and regulations also require pharmacies to keep hard copy records of new prescriptions and inventory records and invoices. Many state laws allow pharmacies to maintain prescription records electronically either as a scanned image of the prescription or via an electronic prescription.

minimum: • Each computer or network shall have built-in safeguards to minimize the possibility of fraud; • Each person responsible for an attestation has a unique individual identifier; • The date and time is recorded from the computer's internal clock at the time of an entry, and date/time stamping is maintained to be accurate and current; • An entry is not to be changed after it has been recorded; • There is a backup system for all records and a process in place to provide for disaster recovery and business continuity; and • Information systems and computer servers are secure.		Pharmacies have used computerized systems for many years and have highly developed systems that provide safeguards, audit logs and back up requirements. State pharmacy laws and regulations establish stringent requirements for pharmacy computer systems including maintenance of the information. These laws and regulations also require that pharmacy records be maintained for at least two years and many states require records to be maintained for three years or longer. Pharmacies compliance with federal laws and regulations for Medicare patients would include maintaining records for the time periods set under Medicare.
3. The supplier shall implement safeguards to prevent loss, tampering, alternation, destruction, and unauthorized use or inadvertent disclosure of information and beneficiary records.		3. Pharmacies, pharmacists and other pharmacy staff are required to comply with HIPAA and the applicable state laws and regulations to maintain patient privacy and confidentiality of patient records.
4. The supplier shall develop, implement, and enforce policies to prevent falsification of data and information.		4. State pharmacy laws and regulations as well as federal and state Medicare and Medicaid laws and regulations require that pharmacy patient records be accurate. In addition, pharmacies and pharmacists as licensed by state boards of pharmacy are subject to discipline for violation of laws. (See **Appendix B** on board of pharmacy disciplinary

		authority.)
5. The supplier shall develop and implement procedures governing the use and removal of records and the conditions for release of information.		5. Pharmacies, pharmacists and other pharmacy staff are required to comply with HIPAA and the applicable state laws and regulations to maintain patient privacy and confidentiality of patient records.
6. The supplier shall implement a system to collect and aggregate administrative and beneficiary service data to ensure accuracy of interpretation, and to support decision-making, business operations, and performance improvement.		6. State pharmacy laws and regulations establish requirements for pharmacy computer systems including maintenance and accuracy of the information which would include information on prescriptions for Medicare beneficiaries. These laws and regulations also require that pharmacy records be maintained.
7. The supplier shall retain records of each beneficiary's equipment, supplies, education/training, and complaints for five years.		7. State pharmacy laws and regulations establish requirements for pharmacy computer systems including maintenance and accuracy of the information which would include information on prescriptions for Medicare beneficiaries. These laws and regulations also require that pharmacy records be maintained and allow pharmacies to maintain electronic or paper records.
8. The supplier's marketing materials shall be clear, factual and not misrepresent the educational intent or Medicare costs and requirements for its products and supplies. The supplier's materials and websites (if applicable) provide: • Documentation of accreditation, licensure and/or certification • Information for direct beneficiary access to a certified/licensed person, as		8. Licensed pharmacies and pharmacists are subject to state laws and regulations prohibiting unprofessional conduct. and are required to comply with state laws and regulations regarding unfair or deceptive trade practices. (See **Appendix D** on pharmacists' professional conduct and **Appendix B** on board of

applicable; • A toll-free telephone number for direct beneficiary communication to DMEPOS service staff; • The location and address of the DMEPOS supplier; and • Forms for beneficiaries to download that are easy to access and use.		pharmacy disciplinary authority.) In addition, the PIC is responsible for pharmacies and pharmacists maintaining and providing proof of licensure in their pharmacies, and the pharmacy licensure requires a specific address and other information such as telephone number which would be available for beneficiary access. In addition, state pharmacy laws and regulations require that prescription labels include the pharmacy address and telephone number.

APPENDIX H: DIABETIC EQUIPMENT AND SUPPLIES

Inspection And Preparation	
<u>General Product Specific Requirements</u> The supplier shall ensure that the equipment is safe and fully functional, and adjust, repair, or replace parts if the condition of a product is below factory new-equivalent performance, or defects would render equipment unsafe. If adjustment, repair, or replacement of parts is not feasible or not sufficient to make the equipment safe and functional, the equipment shall be replaced. <u>Intake</u> General Product Specific Requirements The supplier shall: • Obtain a written prescription from the Medicare beneficiary's treating physician for the equipment; • Consult wit the treating physician as needed, to confirm the prescription and to recommend any changes or refinements to the prescribed regimen; and	State pharmacy laws and regulations require pharmacies to have prescriptions if a drug or device is prescription only. In addition, state pharmacy laws and regulations establish the scope of pharmacy practice, and require pharmacists to consult with the patient's physician as needed for any changes or refinements to a patient's prescription and to follow any treatment plan of the patient's physician which would include providing a home blood glucose monitor appropriate for the patient as ordered by the patient's physician. (See **Appendix A**, on Pharmacists' Scope of Practice Laws) Pharmacist professional patient

• Assure that the prescribed equipment is appropriate for the medical needs of the beneficiary. • Ensure changes in equipment and services are accepted by the treating physician via either verbal or written communication. The supplier shall ensure that only individuals who are authorized under applicable state laws and regulations accept verbal orders. A written order from the treating physician shall be on file upon billing for delivered services.	services are patient-centered and include patient counseling and assistance so that the patient has the supplies and information necessary for the treatment plan. Diabetic supplies generally do not require a prescription. However, in the event that a prescription is required, pharmacies compliance with the applicable state pharmacy laws should be considered compliance with these standards.
<u>Service Plan</u> General Product Specific Requirements The supplier shall: • Develop and implement a service plan for each beneficiary based on the treating physician's plan of care; and • Periodically review the service plan and incorporate any necessary revisions. The treating physician shall be contacted to discuss: o Changes in the beneficiary's clinical condition; o Proposed changes in the service plan that affect the prescribed equipment or services; and o Identification of new beneficiary problems and needs or recurrence of previously resolved problems and needs.	State pharmacy laws and regulations require pharmacists to follow the prescription of the prescriber for the patient's care and treatment. (See **Appendix A**) Pharmacists as part of their professional responsibilities would be required to provide properly inspected equipment and to provide equipment that follows the prescriber's prescription. (See **Appendix A** scope of pharmacy practice and **Appendix D** on professional conduct.)
<u>Equipment Management</u> General Product Specific Requirements The supplier shall • Inspect the equipment to ensure that all necessary components are present; • Check that the equipment is consistent with the treating physician's prescription and any other criteria for use; and • Adjust, repair, or replace all components to ensure that they do not pose a hazard or usage problem for the beneficiary.	As discussed above for service plans, pharmacists' professional responsibilities would include providing the patient with products that follow the prescriber's prescription and have been provided by FDA approved manufacturers. (See **Appendix A** scope of pharmacy practice and **Appendix D** on professional

In addition to General Product Specific Requirements - Supplier shall furnish a home blood glucose monitor that is appropriate for any physical limitations such as visual impairment.	conduct.)
Delivery/Setup General Product Specific Requirements The supplier shall ensure the equipment is properly delivered, setup and fully functional. The supplier shall: • Obtain physician orders for all necessary equipment, supplies and accessories; • Deliver and set up, or coordinate set up with a clinician or another provider, all equipment and supplies in a timely manner as agreed upon by the beneficiary and/or caregiver and supplier; • Provide all supplies necessary to operate the equipment and that are needed along with the equipment; • Ensure that instructions on the operation, safety, maintenance, repair, and replacement are provided to the beneficiary along with any warnings about use, and any additional manufacturer's instructions; • Ensure that all equipment and supplies are clean and sterile as indicated; • Take reasonable measures to present instructions and information to the beneficiary and/or caregiver in clear, understandable language; • Supply any follow-up service; • Assess and reassess parameters for the specific equipment and/or any physician guidelines. • Perform or arrange for any needed maintenance and repairs or replacement; • Have access to replacement parts, either through maintaining inventory or arrangements with other suppliers; • Provide a written estimate to the beneficiary of the cost and time required for any repair work; • Provide, or arrange for, loaner equipment	State pharmacy laws and regulations require pharmacists to follow the instructions of the patient's physician including any changes or refinements to a patient's prescription and to follow any treatment plan of the patient's physician. This would include providing the patient with any needed information and pharmacist consultation on the use of the equipment and any needed supplies. Pharmacy laws and regulations as well as pharmacists' professional standards require pharmacists to provide patient consultation and information required for the use of equipment and supplies. (See, **Appendix A**, Pharmacists Scope of Pharmacy Practice Laws.) Each pharmacy has a pharmacist in charge or pharmacist manager. All pharmacies are required by the state board of pharmacy pursuant to state pharmacy laws and regulations to have a pharmacist-in-charge (PIC) or pharmacist manager that would oversee the practice of pharmacy which would include services to Medicare beneficiaries. (See **Appendix C** for state laws for pharmacists in charge or pharmacist managers.) The pharmacist's professional responsibilities and following the prescription instruction would

comparable to the original equipment for any repair period; • Establish an adequate means for the beneficiary to communicate needs and desires and to obtain help in case of emergency; • Advise the beneficiary on how to communicate their needs and concerns and to summon help in case of an emergency; • Document the beneficiary's use of all equipment for home use; • Provide a specific written statement of warranty on the equipment provided, including commercial warranties on manufactured equipment or components, and any dealer warranties on adapted or custom-fabricated items; and • Provide, or advise the beneficiary about how to access information, equipment, and supplies to maintain Universal precautions.	include coverage for these beneficiary needs for information, communication and instructions on use of the equipment.
<u>Condition of the Home</u> The supplier shall: • Assess the beneficiary's home for safety concerns related to the use of the equipment and supplies provided; and • Evaluate the adequacy or electricity and/or water that is needed to safely operate the equipment provided. Notify the treating physician immediately if there are health-related or other problems that impose a threat to the safe operation and function of the equipment.	This would not be applicable to sales of over-the-counter items as the pharmacist would not be in the patient's home. For products that are provided in the patient's home, pharmacists would follow the prescription instructions and provide the patient with information required for use of the equipment in accord with their professional responsibilities as licensed pharmacists.
In addition to the General Product Specific Service Requirements: • When replacing supplies through mail order delivery, the supplier shall ensure the instructions on the operation, safety, maintenance, repair, replacement, warning, and manufacturer's instructions are packaged with the products.	For products that are provided in the patient's home, pharmacists would follow the prescription instructions and provide the patient with information required for use of the equipment in accord with their professional

	responsibilities as licensed pharmacists. (See **Appendix A** scope of pharmacy practice and **Appendix D** on professional conduct.)
Training/Instruction to Beneficiary and Caregiver(s)	
The supplier shall ensure that the beneficiary and/or caregiver(s) receive all necessary instructions and training related to the use and maintenance of the equipment. The supplier shall: • Provide, or coordinate the provision of, appropriate instruction and information related to the set-up, features, routine use, troubleshooting, safety, cleaning and maintenance of the equipment and supplies provided. Such instruction may be in written, video, or electronic format supplemented with oral instructions; • Document in the service plan that such instructions were provided; • Inform the beneficiary and/or caregiver how to contact the supplier for routine and after-hours equipment problems; • Provide information and/or instruction about infection control issues related to use of the equipment and/or supplies; and • Ensure that the beneficiary and/or caregiver know when and how to obtain help if a medical emergency arises. The supplier shall provide to the beneficiary/caregiver and/or review: • A copy of the user instruction manual and warranty; • The beneficiary's rights and responsibilities as a consumer; • The supplier's privacy practices; • The process to communicate compliments and complaints or concerns; and • Important telephone numbers for repair, emergencies, and customer service.	State pharmacy laws and regulations require pharmacists to have prescriptions and consult with the patient's physician as needed for any changes or refinements to a patient's prescription and to follow any treatment plan of the patient's physician which would include providing the patient with any needed information and pharmacist consultation on the use of the equipment and any needed supplies. Pharmacy laws and regulations as well as pharmacists' professional standards require pharmacists to provide patient consultation and information required for the use of equipment and supplies. (See, **Appendix A**, Pharmacists Scope of Pharmacy Practice Laws.) Each pharmacy has a pharmacist in charge or pharmacist manager. All pharmacies are required by the state board of pharmacy pursuant to state pharmacy laws and regulations to have a pharmacist-in-charge (PIC) or pharmacist manager that would oversee the practice of pharmacy which would include services to Medicare beneficiaries. (See **Appendix C** for state laws for pharmacists in charge or pharmacist managers.)

	The pharmacist's professional responsibilities and following the prescription instruction would include coverage for these beneficiary needs for information, communication and instructions on use of the equipment.
In addition to the General Product Specific Service Requirements, the supplier shall provide instruction to the beneficiary and/or caregiver for specific equipment as follows: ***Lancet (Lancing Device and Platforms)*** Equipment Usage 1. How to use lancet to properly obtain a blood sample. 2. How to dispose of lancet/platform safely. 3. How to clean and maintain lancet device and platform. Safety 1. How to dispose of lancets: • Do not discard into household trash, as a used lancet might accidentally stick someone; and • Place used lancets into a plastic container, such as an empty laundry detergent bottle or plastic water bottle. Seal the container when about ¾ full. 2. Check with local trash disposal agency about proper disposal of lancets. ***Laser skin-piercing device and disposable film cartridge*** Equipment Usage • How to select proper depth of penetration, set and use the device, and obtain a blood sample for the glucometer. • How to clean and maintain the device. • Need to keep battery properly charged or to replace as indicated. • How and when to replace the disposable	For all of these diabetic testing and supplies including lancets, laser skin piercing devices, and glucose monitors, calibration solutions and test strips, pharmacists in compliance with their professional responsibilities, provide the patient with any needed information and consultation on the use of the equipment and any needed supplies including any particular instructions required for proper use of the products. Pharmacy laws and regulations as well as pharmacists' professional standards require pharmacists to provide patient consultation and information required for the use of equipment and supplies. (See, **Appendix A**, Pharmacists Scope of Pharmacy Practice Laws.)

film/lens shield cartridge. ***Home Blood Glucose Monitor*** Equipment Usage • Usage is likely to vary slightly for each model • How to prepare for use, insert a lancet in the lancet device, use test strips, use lancet device to obtain a blood sample, use blood glucose monitor to the results, and record test results if the monitor does not automatically record them. ***Home Blood Glucose Monitor with integrated lancing/blood sample*** • These monitors have an integrated lancing device and therefore do not require a separate lancing device as with typical monitors. • Some of these monitors also do not require test strip handling or coding. • Need to follow manufacturer's manual for specific usage instructions. ***Home Blood Glucose Monitor with integrated voice synthesizer*** • These monitors use a voice prompt to aid visually impaired users through the testing process, step-by-step. See owner's manual for specific usage instructions. ***All Glucometers*** Cleaning/Maintenance • How to keep glucose monitor clean • Need to avoid getting moisture in the code key slot or in the test strip opening. Troubleshooting • What to do if unexpected result is obtained. • How and when to check and replace battery. Factors that can affect the accuracy of a test include: • Any alcohol in the drop of blood from cleaning skin with rubbing alcohol • Dirty hands. Wash hands thoroughly with soap and water before testing • Wet hands. Even a small amount of water can affect blood sugar results. Dry hands thoroughly after washing them • Scraping the skin or milking the blood drop and contaminating it with other materials such as	

fluids or skin • Using too small or too large a drop of blood • Blood glucose monitors cannot detect very low (below 40mg/dl or 2.2mmol/L) or very high (above 400mg/dl or 22.2mmol/L blood sugar levels • Blood sugar levels vary according to diet, activity level, and insulin or diabetes medication • Improper coding of the monitor • A monitor that has been dropped or damaged • Test strips that have been stored improperly or have expired • Multiple vials of testing strips from different calibration codes are being used at the same time • Using test strips that are damaged or previously used • Not using the correct brand of test strips • Monitor has been stored at improper temperature (extreme hot or cold) • Extremes of humidity (>90% or <10% relative humidity) • Extremes of altitude (greater than 10,000 feet or 3000m ft above sea level) • Significant body fluid loss or dehydration ***Normal, low and high calibrator solution/chips*** <u>Equipment Usage</u> • How to use control solution/chips to maintain accurate readings from home blood glucose monitor • Need to check the test strip vial label for the correct calibrator solution/chip range before running a test. If the monitor is functioning properly, results will fall within this specified range. • How to insert test strip with calibrator solution or calibrator chip into monitor to get results. • When to run a calibrator solution/chip test: before first use of system, weekly thereafter; if test strip vial cap left open, blood glucose monitor dropped, test results are higher or lower than expected; and to check the performance of the blood glucose monitor and test strips. <u>Storage</u> • How and where to store	

• How long to store a batch of calibrator solution/chips after opening the vial ***Blood Glucose test/reagent strips (for monitor)*** Cleaning/Maintenance These test strips are to be used with the home blood glucose monitor. The supply shall educate beneficiary and/or caregiver on usage and storage of test strips. Usage • Need to use correct test strips. Each home blood glucose monitor requires a specific type of test strip, usually brand specific (check manual) • Need to check expiration date on the bottle of testing strips. Do not use test strips after the expiration date on the bottle • Need to match code number on the testing strips bottle with the number on the meter • How to change code number on monitor, if indicate • How to handle and store test strips	
Follow-up General Product Specific Service Requirements The supplier shall provide beneficiary follow-up services, consistent with the service(s) already provided, the beneficiary's diagnosis, and any recommendations from clinical referral sources. The supplier shall: • Communicate with the treating physician or clinical team regarding outcomes of monitoring, maintenance, and operation of all equipment provided to the beneficiary; • Periodically review the service plan with treating physician or clinicians regarding the beneficiary's medical condition and the continued use and tolerance of the equipment and supplies; and Communicate any clinically significant beneficiary concerns, needs, and condition changes that affect the beneficiary's use of equipment and supplies to the treating physician within 24 hours of determination.	For all of these products, pharmacists in compliance with their professional responsibilities, pharmacists provide the patient with any needed information and consultation on the use of the equipment and any needed supplies including any particular instructions required for proper use of the products. Pharmacy laws and regulations as well as pharmacists' professional standards require pharmacists to provide patient consultation and information required for the use of equipment and supplies. (See, **Appendix A**, Pharmacists Scope of Pharmacy Practice Laws.)

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NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

WWW.NCPANET.ORG

Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and other Issues; Proposed Rule (CMS-1270–P)

By Electronic submission and hand delivery:

www.cms.hhh.gov/eRulemaking

Centers for Medicare and Medicaid Services (CMS)
Attention: CMS-1270-P
PO Box 8013
Baltimore MD, 21224-8013

Dear Sir or Madam:

The National Community Pharmacists Association hereby submits its comments to CMS proposed rule CMS-1270-P. The National Community Pharmacists Association (NCPA), founded in 1898, represents the nation's community pharmacists, including the owners of more than 24,000 pharmacies, more than 68,000 pharmacists and more than 280,000 full-time employees. The nation's independent pharmacies, independent pharmacy franchises and independent chains dispense nearly half of the nation's retail prescription medicines.

I. Summary of Position:

In addition to greatly inhibiting beneficiary access to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), the proposed rule would also greatly impact patient access to Part B drugs, immunizations, therapeutic shoes, and diabetes self-management training services. The proposed rule's broad scope would compromise patient access to common items, such as diabetic supplies (including blood glucose strips and lancets), nebulizers and enteral nutrition (providing nutrition to the patient through tubes).

Requiring accreditation for pharmacy supplier participation would limit beneficiary access, create unnecessary bureaucracy and impose prohibitive costs in terms of financial resources and time. Prohibiting pharmacists who submit a bid above a "pivotal bid" – i.e. a reimbursement ceiling – from participating in the competitive acquisition program (CAP) might reduce initial costs to the government, but enactment of CMS-1270-P would result in a dramatic decrease in beneficiary access, inconvenience to patients, loss of personalized attention from independent pharmacists, and higher health care costs associated with deteriorating health of patients. For a serious, yet largely manageable disease like diabetes, which already inflicts great harm through under-utilization of

treatment, discouraging patient access and care through implementation of CMS-1270-P would cause tragic and preventable results.

Congress has supported prevention of complications in persons with disabilities through supporting patient access to diabetes and related supplies through laws such as the Medicare Therapeutic Shoe Bill of 1993 and the Diabetes Self Management Training program provisions of the Balanced Budget Act of 1997. Unfortunately, access to these benefits is not supported through CMS 1270 P proposals to: 1) mandate mail order of diabetic supplies; 2) subject diabetic supplies to competitive bid; and 3) require DSMT providers and pharmacists to accredit.

NCPA includes as an attachment the Joint NCPA and NACDS comments re Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) in Relation to Regulation and Licensure of Pharmacies and Pharmacists and State Pharmacy Laws, which highlights the quality health care that community pharmacists provide. This document demonstrates the extensive oversight of the practice of pharmacy by state pharmacy boards, which addresses CMS concerns of protecting beneficiaries.

II. Section-by-Section Comments

Page 25658 - Comment on Quality Standards for Suppliers of DMEPOS – Exemptions for Pharmacists - (Part B Drugs), Diabetes Self Management Training Providers, Diabetic Testing Supplies

State Boards of Pharmacy are appointed by the Governor to protect the consumer. Pharmacists are already licensed and regulated by State Boards of Pharmacy (BOP) and provide DMEPOS as a routine course of business. Sixty-four percent (64%) of all independently owned pharmacies provide DMEPOS and ninety percent (90%) maintain supplier billing numbers. Pharmacists maintain professional and product liability insurance and beneficiaries may seek disciplinary action through BOP for inadequate pharmacist services.

Additionally, CMS did exempt pharmacists from industry surety bond requirements imposed on DMEPOS dealers in the late 1990s. This exemption is a clear precedent in distinguishing pharmacists that maintain supplier numbers from dealers.

For these reasons, NCPA: 1) recommends that CMS exempt pharmacies providing Part B drugs, DSMT, and diabetic testing supplies from the requirement to obtain accreditation; and 2) strongly urges CMS to remove diabetic supplies from competitive bid consideration.

If CMS-1270-P is implemented, the federal government might realize initial costs savings through the economies of scale inherent in competitive bidding. Those initial cost savings would result, however, in greater inconvenience, reduced care and greater overall costs.

Part B Drugs - Beneficiary Access Compromised

The following statement from page 25658 regarding new accreditation requirements has unclear consequences for licensed pharmacies that also maintain Part B supplier billing numbers.

> Suppliers of DMEPOS must comply with quality standards in order to furnish ANY item which payments are made under Part B AND to retain a provider or supplier billing number used to submit claims for reimbursement for ANY such items made under Medicare. (Page 25658)

NCPA respectfully suggests that CMS reexamine the consequence of implementing this language. In addition to DMEPOS, Part B also covers certain outpatient prescription drugs that are used with DME or that are not usually self administered by the patient (immunosuppressive, chemotherapeutic and pharmacist administered influenza and pneumonia vaccinations). Some of these drugs are classified as supplies and ALL of these services are available from community pharmacies.

Part B drugs will not be competitively bid in 2007, however, the proposed language states that at some future time **every** supplier MUST comply with quality standards and obtain accreditation, **including pharmacists.**

Accordingly, NCPA strongly urges that CMS clarify the language with regard to the dispensing of Part B drugs by pharmacists as follows: CMS should exempt pharmacists from requirements to obtain accreditation to maintain a billing supplier number to dispense Part B drugs and perform additional duties already described in each state's Pharmacy Practice Act.

Diabetes Self Management Training (DSMT) - Beneficiary Access Compromised

Pharmacists provide Diabetes Self Management Training (DSMT). The Balanced Budget Act (BBA) of 1997 provided coverage for diabetes self-management training for beneficiaries in a variety of settings -- including community pharmacies. The final regulations were published in the Federal Register dated December 29, 2000.

Under the law, a certified provider must meet CMS and American Diabetes Association (ADA) quality standards to provide DSMT. Through DSMT, pharmacists and other professionals provide beneficiaries the necessary training and skills to self administer blood glucose tests and medication, handle diabetic crisis, and make lifestyle changes to effectively manage the disease.

A pharmacy must be a DMEPOS supplier before it can apply for DSMT provider status. Put another way, a pharmacy must first have a supplier billing number and then, with ADA Recognition, it can bill for DSMT. Under the current system, as

long as a DSMT provider obtains and maintains a supplier billing number, it can provide beneficiaries convenient access to diabetic supplies.

The accreditation language, however, disturbs this system that serves patients well.[1] CMS-1270-P minimizes the value of DSMT by discouraging pharmacists, nurses, dieticians and other providers from completing rigorous CMS and ADA quality standards to provide this training. Beneficiaries that receive DSMT services from a non-participating or losing CAP bidder will have to visit multiple locations to take advantage of both Medicare benefits.

Accordingly, to continue to allow beneficiaries convenient access to DSMT AND diabetic testing supplies from the same provider, NCPA recommends that CMS exempt pharmacists from CMS 1270-P requirements to obtain accreditation and requests CMS remove diabetic supplies from competitive bid (CB) consideration.

The Medicare Therapeutic Shoe Bill (TSB) of 1993 – Beneficiary Access Compromised

Therapeutic shoes are not subject to competitive bidding. CMS has deemed pharmacists qualified to dispense therapeutic shoes to persons with diabetes. On May 1, 1993, CMS determined that therapeutic footwear and protective insoles were effective methods for preventing foot problems among diabetes. The extra levels of protection will help keep beneficiaries out of the hospital and off of the operating table. According to the ADA, 86,000 lower limb amputations occur annually due to diabetes. Experts agree that most of these amputations would not have to happen if properly fitted, appropriate footwear were dispensed and worn.

If the proposed rule is implemented as it stands, because pharmacists are required to obtain accreditation to maintain a supplier billing number, then beneficiaries with diabetes that routinely access community pharmacies to purchase therapeutic shoes could very well be challenged with traveling to as many as four different suppliers to buy shoes, testing strips, Part B drugs and DSMT.

Page 25668 - Comment on Authority to Exempt Rural Areas and Areas with Low Population Density within Urban Areas

[1] The "accreditation language" is, once again found on page 25658 of CMS-1270-P: "Suppliers of DMEPOS must comply with quality standards in order to furnish ANY item which payments are made under Part B AND to retain a provider or supplier billing number used to submit claims for reimbursement for ANY such items made under Medicare."

NCPA supports CMS's exercise of the authority granted it in Section 1847(a)(3) of the Social Security Act to "exempt rural areas and areas with low population density within an urban area." It opposes, however, the qualifier, "unless there is a significant market through mail order for that particular item".

Because CMS is asking for comment on appropriateness of mandatory mail order service for DMEPOS, including replacement supplies in 2010, and CMS acknowledges many assumptions and unknowns relating to the impact of competitive bidding (CB) on small suppliers, it is inappropriate to extend the competitive bid area (CBA) through mail order in areas where access to local suppliers is already a challenge. At the very least, this proposed change can not be properly evaluated until CMS can assess program impact on suppliers in the ten metropolitan statistical areas (MSA) to be selected in 2007.

Accordingly, NCPA opposes the use of mail order to expand the delivery of DMEPOS. This proposal might be revisited only after the impact on suppliers from the 2007 selected MSAs can be assessed.

Page 25669 – Comment or Nationwide or Regional Mail Order Competitive Bid Program ("MAIL ORDER")

NCPA opposes any CMS mail order proposal that would mandate beneficiaries use mail order suppliers as their only choice when purchasing DMEPOS (i.e. diabetic supplies) and replacement supplies in 2010.

Additionally, NCPA recommends that any DMEPOS product dispensed through the mail must contain warnings within the delivery box that provide a 1-800 toll free number for beneficiaries to notify mail order suppliers if product has been compromised due to exposure to excessive heat, cold or humidity. This warning will further protect the beneficiary.

Community pharmacists maintain one out of every three supplier billing numbers. Many provide convenient access to inexpensive or routinely purchased DMEPOS. Most beneficiaries purchase their diabetes testing supplies at community pharmacies.

In particular, convenient access to diabetic supplies through multiple available methods -- community pharmacies, DMEPOS dealers AND mail order -- is essential to manage the needs of persons with diabetes. Again, as currently proposed, beneficiaries may have travel to **four (4)** different locations for medicines, diabetic supplies, and therapeutic shoes and DSMT.

Mail order suppliers are able to access manufacturer volume discounts concessions that place small suppliers at an economic disadvantage and may

result in limited pharmacy supplier participation in the competitive acquisition program (CAP), especially in areas where CMS proposes to extend competitive bidding to "rural areas where there is a significant market through mail order for that particular item". These mail order supplier concessions may lead to monopolistic and predatory practices waged against small suppliers.

Throughout 1270-P, CMS acknowledges that "offering choices to beneficiaries is important to maintaining competition" Additionally, CMS "recognizes the important benefits and convenience offered by the local presence of small suppliers".

CMS narratives repeatedly emphasize the supplier - beneficiary relationship, yet in the proposed rule, CMS seeks to discount that same relationship through mandatory mail order delivery, which drives business away from small suppliers and jeopardizes their solvency.

Page 25674 – Comments for Awarding Contracts - **Grace period**

NCPA supports a grace period for suppliers to obtain accreditation.

Although we strongly believe pharmacies should be exempted from accreditation requirements, other suppliers should receive a grace period of no less than one year from the date of supplier bid submission is a reasonable grace period for suppliers to obtain accreditation. Bidding suppliers should make application to accreditation organizations (AOs) immediately upon making the business decision to bid. AOs must immediately prioritize bidding contract suppliers to complete the accreditation process prior to competitive acquisition program (CAP) implementation.

CMS should not prohibit a winning contract supplier from participation due to AO delays in accrediting winning suppliers. It is a reasonable expectation that bidders provide due notice to AOs of their intention to bid and submit application early in the bid process to allow AOs to meet supplier demand.

Page 25675 - Comments on Financial Standards Proposed

NCPA understands that requiring financial standards is in part related to CMS's concerns regarding supplier's ability to serve market demand. However, CMS must recognize the financial goals of publicly traded companies and their fiduciary obligations to shareholders may not accurately reflect the financial stability and goals of privately held community pharmacies.

Accordingly, NCPA opposes the burdensome financial standards that discourage small suppliers from participating in competitive bidding.

After thorough discussion with accountants who are familiar with the business of pharmacies that additionally maintain supplier billing numbers, NCPA proposes that separate financial standards for small supplier pharmacies as defined by the Small Business Administration (SBA) be limited to the following queries:

1. **Credit Report**
2. **Lien searches**
3. **Credit references (three suppliers)**
4. **Tax returns (3 years)**

Page 25679 - Comments on Determining Single Payment Amounts for Individual Items Proposed 414.416

If competitive bidding is imposed as per the proposed rule, NCPA supports the CMS proposal in Sec. 414.416 that uses an adjustment factor that adjusts all bids up to the point of the pivotal bid so as all winners would be paid by Medicare as much as the total product category as the pivotal bidder.

Without use of the adjustment factor (pivotal composite bid divided by average composite bid), CMS-1270-P does not offer sufficient protections to encourage small suppliers to bid.

This consideration is important in light of: 1) CMS's rejection of a proposal described on pages 25695-25696, requiring small suppliers to serve the entire MSA, concomitant with; 2) CMS's subsequent rejection of allowing small suppliers the option not to submit a bid and then decide, after bidding was complete, whether or not they would accept the new competitive bidding single payment amount.

Accordingly, NCPA supports the use of the adjustment factor described and illustrated in table 9 (page 25680) to encourage small suppliers to bid.

Page 25680 - Comments on Determining Single Payment - Rebate Program

NCPA strongly opposes any rebates to induce beneficiaries to use contract suppliers submitting bids less than the pivotal bid.

The rebate program may incentivize large suppliers (i.e. mail order, publicly traded) to "lowball" their bids, resulting in reduced marketplace competition by

discouraging small suppliers from participating in the competitive bidding program.

Rebates may also exceed the co-payment if the contract supplier bids low enough.

Two of the goals of the competitive acquisition program are to protect the beneficiary and prevent fraud. The rebate program, however, might induce beneficiaries to purchase additional unnecessary supplies and entice suppliers to "game" the program.

Page 25682 - Comments on Opportunities for Participation by Small Suppliers

NCPA supports CMS proposals to promote small supplier participation in the competitive acquisition program (CAP). Currently, 90% of suppliers are defined by the Small Business Administration (SBA) as being small businesses.

NCPA requests that CMS allow small suppliers to designate geographic coverage areas.

Repeatedly, CMS acknowledges in the proposed rule the "important benefits and convenience offered by small suppliers," however, it does not allow small suppliers to designate coverage area. NCPA respectfully disagrees with the CMS position that suppliers would likely "carve out a geographic area to gain economic advantage." Instead, NCPA believes that small suppliers require a carve-out as a result of limited resources (which are expended paying for vehicles, drivers, insurance, etc.) to extend reach to reasonable delivery limits.

Independent pharmacists serve their local communities. Certain large DME supplies, such as wheelchairs, are products that are typically delivered to the patient. Many independent pharmacists sell low margin diabetic testing supplies exclusive of more expensive DME supplies. Diabetes patients are understandably accustomed to picking up these small supplies regularly at their local community pharmacy.

Requiring small suppliers to service an entire competitive bid area (CBA) discourages small suppliers from bidding and provides competitive advantage to large suppliers with greater resources to serve the entire CBA. Forcing the small supplier to service the entire CBA would result in limiting competition and, more importantly, would limit patient access to the supplies, thus resulting in an interruption in health care and a concomitant increase in health care costs.

CMS's unwillingness to support small supplier carve outs is perplexing in light of proposing an optional rebate program that in 2007 establishes multiple pricing

schemes for suppliers below the established pivotal bid in 10 metropolitan statistical areas (MSA) in 2007.

In CMS sponsored focus groups, small suppliers repeatedly voiced concern over the costs of obtaining accreditation. In order to prevent 1270-P, in its current form, from creating a prohibitive barrier to the ability of **small suppliers to bid, NCPA requests CMS reconsider SBA carve outs for small suppliers. Additionally, NCPA proposes CMS offer small suppliers the opportunity to accept the new CB single bid amount as long as they submitted a bid.**

Page 25683 - Comments on Opportunity for Networks

NCPA supports the CMS proposal to allow suppliers to form networks for bidding purposes with two amendments to the proposed rule.

1. **Allow network members to obtain market share not to exceed 35% in case-specific Department of Justice monopoly guidelines. DOJ is typically not compelled to intervene unless market share exceeds 35%.**

2. **Requiring small supplier networks to deploy expensive computer technology for the purpose of appropriately distributing reimbursements to members could very well be cost prohibitive. CMS should therefore continue to distribute reimbursements to the network members' location of record.**

Page 25690 - Comments on the Regulatory Impact Analysis - Affect on small suppliers

NCPA disagrees with the CMS assumptions that ninety percent (90%) of small suppliers in an MSA will participate in the competitive acquisition program (CAP). From the perspective of independent community pharmacy, which makes up one-third of all Medicare suppliers, NCPA believes CMS participation assumptions to be overly optimistic. Community pharmacies maintaining supplier billing numbers meet this small supplier description and sell inexpensive or routinely purchased DME with the majority of sales allocated to diabetic supplies.

Obtaining accreditation for a small, single unit supplier includes annual fees, survey year fees, renewal year fees, and pre-survey preparation to come into compliance. The entire accreditation process has been estimated to cost $5,000 - $15,000. Eligible small suppliers must further carefully weigh the CMS-estimated $2,187.50 cost and CMS-estimated 70 hours of preparation required to submit the bid.

Accordingly, NCPA disagrees with CMS assumptions that pharmacies maintaining supplier billing numbers will "for the purpose of maintaining or

expanding market share," participate in the competitive acquisition program (CAP). For many pharmacies that primarily sell low cost, low margin diabetic testing supplies, the costs of accreditation and bid submission to maintain or expand market share will almost certainly be cost prohibitive.

Low margin products and services, such as DSMT, Part B drugs, and diabetic supplies will create a difficult financial case for pharmacists to justify the economics of a business decision that requires significant resources to participate in CAP **and additional accreditation requirements for pharmacies billing that will result in a limited return on their investment. Medicare Part B beneficiaries will lose access to the valuable services and supplies described in these comments if pharmacists are prevented from being able to obtain fair compensation on prescription drugs, strips, shoes and from providing Diabetes Self Management Training.**

A three-day survey conducted on Tuesday, June 23, 2006 – Friday, June 26, 2006 shows that CMS's assumption of 90% participation in competitive bid by small suppliers is some three times overly optimistic. **Only 31% of pharmacists responding from the ten MSAs likely to be selected will participate in the competitive acquisition program (CAP).[2] The primary reasons for their plans not to participate are c**oncerns about profitability and lack of resources to commit to the CAP bid process and accreditation.

Most of the Patients that would be Negatively Affected by the Proposed Rule Receive Care at Community Pharmacies

CMS's NSC active supplier report for April 2006 identifies 52,519 pharmacy suppliers out of the total of 165,981 suppliers. Nearly one-third of all suppliers (32%) are therefore pharmacists.

There are 34,581 medical supply company suppliers. That is 21% of the total. It also means that there are almost exactly 3 pharmacy suppliers for every 2 medical supply company suppliers.

Finally, there are 78,881 remaining suppliers, or 47.5% of the total. Removing nursing homes and specialized physician practices, along with the medical supplier companies (21%) from the total, demonstrates why CMS should ensure convenient access through community pharmacies for beneficiaries. These patients will bear the brunt of the impact of the newly proposed rule.

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[2] Approximately one thousand (1000) pharmacists practicing in the ten MSAs likely to be selected based on proposed rule guidelines were surveyed. The response rate was twelve percent (12%). 98% of respondents currently provide DMEPOS and maintain a Part B supplier billing number. Only 9% have obtained accreditation with 82% clearly small suppliers with Medicare reimbursed sales of < $500,000 and 6 FTE. 56% of respondents claim the vast majority of their DMEPOS sales are from diabetes testing supplies.

III. Summary:

Without small supplier protections recommended throughout this letter convenient beneficiary access to DMEPOS and other basic, yet critical supplies will be compromised, patient care will suffer and health care costs will escalate.

In addition to greatly inhibiting beneficiary access to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), the proposed rule would also greatly impact beneficiary access to Part B drugs, immunizations, therapeutic shoes, and diabetes self-management training services, Beneficiary access to common items as diabetic supplies (including blood glucose strips and lancets), nebulizers and enteral nutrition could be compromised).

Enactment of CMS-1270-P would result in loss of access and greater costs and inconvenience to patients, loss of personalized attention from independent pharmacists, and higher health care costs associated with deteriorating health of patients. For a serious, yet largely manageable disease such as diabetes, that already inflicts great harm through under treatment, discouraging patient access and care through implementation of CMS-1270-P would have tragic results for far too many of our most vulnerable population.

Sincerely,

Douglas Hoey, R.Ph, MBA
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Mark B. McClellan, MD, PhD
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Attention: CMS–1270–P,
Mail Stop C4–26–05,
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Baltimore, MD 21244–1850.

June 26 2006

Re: COMPETITIVE ACQUISITION FOR CERTAIN DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, and SUPPLIES

Dear Sir/Madam:

After a thorough review of the proposed "Competitive Acquisition Program, I am significantly troubled about the impact this will have on my patient's ability to receive and my ability as a podiatric physician to deliver effective and quality health care. There are several major areas of concern:

1) Podiatric Patients to Receive Prejudicial Treatment by CMS

During a recent meeting, CMS officials confirmed that podiatric physicians will be eligible to participate in the competitive bidding program, but these officials also indicated that CMS **DID NOT** use the 1861(r) definition of physician, which includes podiatric physicians, in defining individuals who may bid to supply DMEPOS to only their patients. Instead, CMS officials used the more restrictive 1861(r)(1) definition of physician, which restricts its definition of physician to MDs or DO's.

This does not allow podiatrists the same abilities as MD and DO physicians to competitively bid in order to supply DMEPOS items to their patients, and has the real potential to be a real and present danger to podiatric patients.

As a result, of using1861(r)(1) definition of physician, podiatric physicians will be expected to bid to supply DMEPOS items to an entire metropolitan statistical area (MSA) rather than their own patients. This will necessitate podiatric physicians to compete with large, traditional DMEPOS suppliers for the right to supply items to Medicare beneficiaries.

This is clearly biased against podiatrists and our patients. It has the potential to cause significant harm to our patients, both those who may be acutely injured, and cannot tolerate delays in obtaining care, and those who with chronic disease processes.

A daily example in my office is that of an acutely injured patient with a foot or ankle fracture that has been reduced and now requires immobilization. Instead of the patient receiving a cam walker and crutches from my office, under the proposed competitive bidding system, they may now be required to go cross town to obtain these medically necessary services. That same patient seen by an MD or DO physician would not face the potential harm solely created by a proposed new system of reimbursement, and not due to my level of expertise as a podiatric physician.

Podiatrists just as MD and DO physicians, primarily supply DME supplies only to their current patients. As physicians we do not generally advertise ourselves as DME suppliers to the general public and only offer DME products as services which are integral to their medical services.

Under the proposed system, patients of podiatric physicians, many of whom are poor and elderly would be unduly punished. These patients will now be required to make several visits to both their podiatrist and another supplier in order to be furnished with needed medical supplies. These same patients seeking similar care from an MD would not be so punished. Since many podiatric patients suffer from multiple diseases this will be create significant problems in acquiring medically necessary products which they would otherwise have unfettered access to from the physician who is treating them. This will certainly create logistical problems for the patients and their families, potentially resulting in further medical complications.

Federally funded transportation assistance is now the only way many of our patients obtain medical care. Should the podiatric physician not be unable to deliver their acutely required care, patients will be required to go to other providers in order to receive their DME items. This will result in the federal government paying for additional trips to multiple providers in order for patients to obtain necessary supplies. As a result the total cost of furnishing DME products to podiatric patients under the proposed system may exceed the current fee for service system, and would actually higher than that when provided by an MD/DO supplier. I do not believe that any of these scenarios were the intent of the original authors of the competitive bid system.

As a result of this bias, the physician definition selected by CMS officials will negatively impact podiatrists' ability to render both effective and quality medical care to our patients. I am therefore urging you to change the definition of physician within the proposed competitive bidding program to include podiatrists.

2) Physician Need to Participate in Competitive Bidding

A recent review of the 2004 data on DMEPOS services reveals that all physician categories (MD DPM DO) are responsible for less than 4% of the DMEPOS services provided. Creating more restrictions and burdens on these physician categories, many of whom are small businesses, will result in most electing not to participate in the competitive bidding process. This will certainly be to the detriment of patient care and will most certainly not be an effective means of cost containment. I therefore question the efficacy of requiring any physician group in participating in competitive bidding s as a means of reducing expenditures on DMEPOS.

3) Cost of Travel to obtain DMEPOS

Patients who require acutely injured and/or have other urgent medical needs are often in no position to travel to another provider after being initially assessed and immobilized. In particular, the elderly often have multiple co-morbidities and may have required special arrangements for transportation to get to their doctors' offices. Requiring these frail patients to go to another provider for services which otherwise are readily obtained at my and many other physicians' offices will create an undue stress for them and increase the real costs of delivering their health care. Many may select to delay medically necessary treatment, others will elect to go to emergency rooms, and others will select to go to another provider to obtain the necessary DMEPOS service, via publicly funded transportation as per the proposed guidelines. Any of these possibilities will increase the real costs of delivering any given DMEPOS.

Should the patient elect to delay seeking care, this will ultimately allow their wounds, fractures and other disease states to progressively worsen. The potential escalation for an inexpensive minor problem into one which would require additional and more expensive sophisticated medical/surgical services is especially problematic to me as a podiatric physician. Having thoroughly read the proposed competitive bid program, I see no evidence that this has been factored into any theoretical cost savings postulated by CMS.

Particularly troublesome is what factoring in transportation costs may do to the real costs of delivering inexpensive off-the-shelf devices and/or dressings with present reimbursements at under a few hundred dollars. Adding in transportation and aide costs funded through the federal Medicaid programs, as well as municipally assisted transportation services through "Access A Ride Programs" would cause the real costs of providing these services, all paid for, or subsidized by the Federal Government to be exorbitantly higher that at present.
This would also create an undue financial stress on already strapped local and state government budgets to meet any additional costs not already paid for by the Federal Government.

4) Additional Expenses for Rural Patients

Patients who live in rural areas could be required to travel long distances in order to obtain necessary services, which up to this time could have been provided for locally in their doctor's office. This too would create long delays in delivering effective and timely patient care. There would also be a disproportionate increase in the financial costs necessary to transport patients' long distances in these areas.

5) The end of the small DMEPOS Supplier and easy patient access

Podiatrists and other small DMEPOS suppliers cannot afford retaining cost consultants employed by many large DMEPOS suppliers in order to determine what might be a winning bid. This will effectively eliminate the ability of small companies providing easy access to patients out of business.
This will in the long run result in large corporations rendering ineffective less accessible care to those who most need it.
Impeding access to any medically necessary service, will ultimately in the long run, cost Medicare more money as complications from lack of easy access multiply.

6) The cost of monitoring bids

A competitive bidding system would invite more fraud and abuse by large DME dealers who could get the "inside tract" on bidding, identical to what transpires with many other publicly funded works projects. The cost of monitoring this bidding system would also create another financial burden for the government significantly reducing any projected savings otherwise created.

7) Generic vs. Brand Name Supplies

The ability of the DME service provider to provide a generic device due to cost/profit restrictions on bids, rather than what was originally prescribed for by the physician, may cause significant problems for patients.

In the case of specially required off the shelf devices for patients who would not fit into a generic device (i.e. an obese patient with a fracture would not be able to fit into most commercially available CAM walkers, and requires a more expensive type such as one of the Bledsoe devices). It is already almost impossible to fit patients like this at today's current rates, without the supplier taking an economic loss. Further rate reductions will either force suppliers to refuse supplying this type of patient, or force the supplier to ask for a prescription for a custom fracture brace, costing hundreds if not thousands of dollars more.

This will expose the patient to an increased risk of functional limb loss if they cannot find a suitable supplier as well as increased costs for those previously outlined in paragraphs 1-5 not yet factored in.

8. Therapeutic Foot Wear and Surgical Dressings.

Upon reviewing the proposal it appears that these two items are exempt from competitive bidding, I cannot find an exact resource which would specifically state these items are exempt. Despite assurances from Dr. Edwards the SADMERC director, to their exclusion, I would urge CMS to specifically state which product items, by category, are exempt. This should be posted not only in the Federal Register, but on a website which would be updated on a regular routine basis.

Therapeutic Shoes for diabetics require fitting by professionals who have an intimate knowledge of foot anatomy and diabetic foot pathology. Doctors of Podiatric Medicine treat millions of patients with diabetic foot pathology and have intimate knowledge of their patient's medical histories, pathologies far superior to medical suppliers. Doctors of Podiatric Medicine are in a unique position to determine which shoe would be most suitable for their patients' individual needs. Many podiatrists have unfortunately been witness to the devastating effects a poorly fitting shoe has caused by medical suppliers who are untrained in proper shoe fitting techniques. These often result in significant ulcerations, infections and limb loss, at a substantial cost to the Medicare program. Simultaneously we are aware of the significant preventative benefits appropriately fitted shoes can provide, and the millions of dollars in costs savings that this type of preventative care provides to the Medicare program. The American Podiatric Medical Association and I along with other professional organizations have been working for the last several years with SADMERC's medical director, Dr. Edwards to revamp the Medicare Therapeutic Shoe Bill to insure that patients receive shoes from qualified providers (such as podiatrists). The result to diabetic patients could be catastrophic if podiatrists were unable to continue to service these patients with appropriate therapeutic shoes and would certainly result in much higher financial expenditures for the Medicare program.

Surgical Dressings:
Similarly because of our ongoing treatment of diabetic foot ulcers, patients need to have easy access to dressings which are most efficacious for their specific wounds, and not driven solely by the profit motives of a large medical/surgical supplier. Doctors of Podiatric Medicine are in a unique position to understand the needs of their patients' wounds, and should be able to continue to provide their patients with the best surgical dressings available.

By allowing podiatrists, who generally have long term relationships with a higher level of responsibility level to their patients than paraprofessional DMEPOS suppliers, to continue to function as their patients' DMEPOS suppliers, patients can be assured that they are receiving the correct products based on medically necessity, and not motivated purely by profit.

Summary and Suggested Changes:

A) Summary

For the above stated reasons the competitive bidding process, particularly as it would apply to podiatric physicians is flawed. It is therefore my opinion that the proposed competitive system will most certainly result in a system which:

1) Will not realize the savings projected;
2) May result in higher expenditures than through the current system for many services;
3) Unduly interferes with the doctor patient relationship, particularly for podiatrists' and our patients;
4) Places patients in harms way solely based on a system of reimbursement, and not based on provider licensure or expertise.

Suggested Changes:

I am therefore urging you to implement the following changes to the competitive bidding system:

1) Podiatrists should be included in your definition of physician with regards to participation in the competitive bidding system, and all physician specialty types should be exempt from the requirement in participating in the competitive bidding process so long as they are only supplying their own patients.
2) Some safe harbor should be created for small suppliers in order to assure patients easy access in obtaining DMEPOS supplies.
3) An any willing provider ruling stipulating that any provider, so long as they have submitted a bid, may choose to accept the winning bid fee schedule in their area.
4) Podiatrists and other physicians should be exempt from the inventory, toll free and other high cost requirements of quality standards proposals and proposed competitive bidding system. The APMA AMA and other physician specialty societies should be entrusted with setting up standards in mutual cooperation with CMS that would be unique for physicians.
5) Insure that podiatrists and other physicians have the ability to provide necessary DME services within the legal scopes of their practices.
6) Exclude off the shelf devices such as therapeutic shoes, surgical dressings orthopedic immobilization devices including CAM Walkers, crutches, canes from the competitive bidding proposal.

I look forward to continuing this dialogue and am prepared to answer any further questions you may have.

Sincerely,

Paul Kesselman DPM FACFAS

Paul Kesselman DPM FACFAS

WESTERN SCIENTIFIC AND HOSPITAL SUPPLY
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MEDICAL AND SCIENTIFIC SUPPLIES
ESTABLISHED 1965

139

June 26, 2006

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

The I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

Since Puerto Rico is composed of almost 100% Hispanic communities, there is a high predisposition to certain health conditions, such as Diabetes and Heart diseases, which have a direct impact in the Allowed Charges made to Medicare. Based on studies performed by the Department of Health in Puerto Rico, statistics showed that 18 of every 100 women 65 years of age or older ere diagnosed with chronic heart conditions and 22 out of every 100 men 65 years of age or older were also diagnosed with chronic heart conditions. Regarding diabetes, statistics demonstrated that 20 out of every 100 women 65 years of age or older were diagnosed with diabetes and 22 out of every men 65 years or age or older were also diagnosed with diabetes. This data demonstrates a steady increment in the diagnosis oh these chronic conditions on the island, therefore it is important that when analyzing the Allowed Charges one has to consider the reality that many beneficiaries in Puerto Rico posses these serious and chronic illness. In fact, the supply costs in Puerto Rico are currently competitive and even though the Allowed Charges number are high, one cannot conclude that the high Allowed Charges is a result of suppliers not being competitive.

Sincerely,

Pedro A. Muniz

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140

June 26, 2006

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

The I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

In addition, long-standing relationships between beneficiaries and familiar supplier will be interrupted causing disruptions in services and dissatisfaction for patients. Given Puerto Rico's location in the heart of the Caribbean Sea the island is impacted yearly by hurricanes and tropical storms that makes is impossible for distant suppliers to provide the service needed because of sudden flooding in many of the small, rural roads in the cast region of the island, theses common events impacts the beneficiaries access to DME supplies, such as oxygen tanks that are needed on a regular basis. In summary, the result of the implementation of the Competitive Bidding Program would be that small, community-based suppliers would be displaced by larger chain suppliers that can take advantage of economies of scale, but which may not be in the interests of beneficiaries. The Competitive Bidding Program will make it impossible for the beneficiary that decides to continue with Traditional Medicare to do so, because although is essence the beneficiary would be entitled to continue under the label of "Traditional Medicare", they would not have the actual benefits of selecting from an array of suppliers since only one or two suppliers would be available to provide services. It is this freedom of selections that is currently provided by Traditional Medicare that must be vigilantly safeguarded.

Sincerely,

Pedro A. Muniz

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141

June 26, 2006

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

The I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

Another important factor that needs to be addressed is the language barrier that currently exists between Puerto Rico and the United States, given the majority of the islanders are native Spanish speakers. The implementation of this program will be at a high cost for many suppliers and will cause a decrease in supplier access to beneficiaries, resulting in a less competitive market.

Sincerely,

Pedro A. Muniz

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142

June 26, 2006

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

The I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

Geographically, Puerto Rico is a relatively small island, ranging 100 miles east to west and 35 miles north to south, and is composed of 78 municipalities of which the vast majority rural areas. Two of these municipalities may be considered slight metropolitan areas. The major city and capital, San Juan, is considered the largest metropolitan area in Puerto Rico, however large sections of this city are still rural in nature and does not fully encompass the conceived idea of a major metropolitan city such as Houston, Detroit or Boston, which are cities fully recognized as metropolitan in nature. Therefore, upon considering the total amount of MA Organizations that cover Puerto Rico, the small size of the island, the aggressive marketing and reach-in programs used by these MA Organizations, and the steady increment of enrollment by beneficiaries, it is strongly believed that by 2007 the number of MA enrollees could come close to cover all beneficiaries on the island.

Sincerely,

Pedro A. Muniz

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Crowne

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS -1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Windsor Mills, MD 21244-1850

June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P

P.O. Box 8013
Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Brown Nursing Home a 68 bed Skilled Nursing Facility in Alexander City Alabama employing 75 persons.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Brown Nuring Home we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerly,

Jason Banks
Administrator
Brown Nursing Home

1144

Crowne

June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Jackson Health Care Facility located in Jackson, Alabama. We are a 91 bed skilled nursing facility, providing both long term and short term care. Our facility has the reputation of providing excellent rehabilitative services including physical, speech and occupational therapy.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Jackson Health Care Facility we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,

Bonnie Pope, Administrator

Jackson Health Care Facility, LLC • 2616 North College Avenue • Jackson, Alabama 36545 • (251) 246-2476

GRAND BAY CONVALESCENT HOME

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June 28, 2006

Department of Health and Human Services
Attn: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Grand Bay Convalescent and Rehabilitation, located at 13750 Highway 90, Grand Bay, Al. 36541. We are a 92-bed facility with approximately 130 employees and specialize in long or short-term care with rehabilitation therapy.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Grand Bay Convalescent, we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The propose rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

GRAND BAY CONVALESCENT HOME

Marlene H. Hart/Owner

146

Matthew Safapour, DPM

PODIATRIC MEDICINE & SURGERY
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16661 Ventura Blvd. Suite 710, Encino, CA 91436

Mark B. McClellan, MD, PhD

June 27, 2006

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1270-P (Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)***

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r)(3). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only. If I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide.

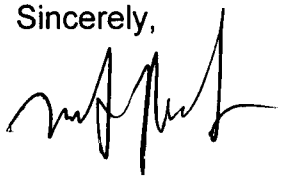
Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

Similar to MD and DO suppliers, I am required to obtain a valid supplier number and must adhere to all of the current supplier standards. I am subject to the Stark laws and other Federal and State regulatory requirements. If CMS plans on making specific allowances for physician suppliers, podiatric physicians must be included. My use of DMEPOS items as an integral part of patient care is no different than that of my MD and DO colleagues.

For example, if I treat a patient with an ankle injury, I may determine that an ankle brace is necessary to stabilize the ankle and crutches are necessary to limit weight-bearing on the injured extremity. If I am not a DMEPOS supplier in the new competitive acquisition program because I was unsuccessful in competing to bid to supply to the entire MSA rather than just to my patients, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

Please change the physician definition from 1861(r)(1) to 1861(r)(3) so that I am eligible to bid to supply items to my patients only and execute physician authorizations. I want to be able to continue to provide medically necessary and appropriate care to the patients I serve.

Sincerely,



Matthew Safapour DPM

1477

NOMA
c/o Latham & Watkins
555 Eleventh Street NW
Suite 1000
Washington, DC 20004

NOMA
National Orthotics
Manufacturers Association

June 30, 2006

BY HAND DELIVERY

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445—G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments Regarding CMS—1270—P: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues

Dear Administrator McClellan:

The National Orthotic Manufacturers Association (NOMA) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) regarding the above-referenced proposed regulations, which establish the Medicare Part B DMEPOS Competitive Bidding Program.[1] As a trade association of manufacturers of therapeutic and rehabilitation products for individuals suffering from musculoskeletal diseases or injuries, including a variety of orthoses, NOMA is particularly concerned with the impact of the proposed regulations on beneficiaries' access to orthotic products. NOMA members include a number of manufacturers who are also Medicare Part B orthotic suppliers, including Orthofix/Breg, EBI/Biomet, and DJO Incorporated, each of which expects to participate in this new program. Other members manufacture orthotic products only and want to ensure that beneficiaries are able to obtain needed orthoses from the suppliers with whom they work.

NOMA urges CMS to refrain from competitively bidding orthotic products for the initial phase of the program. Under competitive bidding, Medicare will pay for DMEPOS items used by beneficiaries in the home based on bid amounts submitted by suppliers in competitive bidding areas (CBAs). It is therefore essential that suppliers be able to bid accurately and for CMS to be able to evaluate those bids accurately as well. Because of the large number of orthotic products and the many codes describing them, there is significant variation in the industry as to which codes are used to bill particular products. NOMA fears that, unless and until sufficient clarity as to coding is provided, orthotic suppliers will be unable to determine an appropriate bid for each HCPCS code. Similarly, it will be difficult, if not impossible, for the agency to evaluate these bid submissions properly. This will likely result in competitive bidding payment amounts for

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1 71 Fed. Reg. 25654 (May 1, 2006).

orthotics that are entirely irrational.

NOMA is also deeply concerned that the proposed definition of off-the-shelf (OTS) orthotics is overbroad and uses an inappropriate benchmark (*i.e.*, involvement of a certified orthotist) to determine whether a product may be competitively bid. Most critically, the proposed definition contradicts both the statutory definition of OTS orthotics and existing Federal law specifying which practitioners are qualified to perform fitting and adjustment services for certain orthotic products. CMS should not and must not finalize its proposal and should instead adopt the statutory definition.

Summary of NOMA's Recommendations

Below we provide recommendations for revisions to the proposals (with CMS comment areas noted in brackets):

(1) *OTS orthotics should be defined as required by the Medicare statute.* [Criteria for Item Selection]

(2) *CMS should ensure that suppliers with sufficient capacity can participate in the program, regardless of whether they are physically located in the CBA.* [Submission of Bids Under the Competitive Bidding Program]

(3) *If CMS includes OTS orthotics in the initial phase of the program, existing SADMERC policy groups should be used to categorize competitively bid products and CMS should allow single bids to be made on sub-groupings of orthotic products.* [Submission of Bids Under the Competitive Bidding Program]

(4) *CMS should evaluate each bidding supplier's compliance with financial and quality standards and accreditation status, allowing for an extended grace period for suppliers in industries, such as orthotics, in which accreditation is not the norm.* As urged in NOMA's comments on the draft quality standards (which were submitted under separate cover in fall of 2005), CMS should focus on the quality of the products furnished to beneficiaries. These standards must be in place prior to the launch of competitive bidding and, more critically, CMS must give suppliers time to come into compliance and become accredited. [Conditions for Awarding Contracts]

(5) *CMS should ensure that competitive bidding payment amounts reasonably reflect actual bids.* [Determining Single Payment Amounts for Individual Items]

1. Define OTS Orthotics As Required By the Medicare Statute

[Criteria For Item Selection]

OTS orthotics are among the types of DMEPOS products that may be competitively bid under the statutory provisions for the competitive bidding program.[2] CMS's proposed definition of OTS orthotics would dramatically and impermissibly expand upon the statutory definition so

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[2] 42 U.S.C. § 1395w-3(a)(2)(C).

that it includes all orthotics that do not require assistance of a certified orthotist. CMS should not and must not depart from the statutory definition in this manner. The proposal is particularly troublesome because it would also contravene an existing statutory provision governing Medicare payment for certain custom-fabricated orthotics. NOMA registers its strong objections to this proposal with this comment letter. We believe that CMS must implement the definition in line with the criteria already provided by Congress. To determine whether a product is off-the-shelf, the congressional approach uses task-related criteria, such as whether and what level of self-adjustment is needed to fit the product to the patient. Tying the definition of OTS orthotics to an amorphous standard—involvement of a certified orthotist—as CMS proposes to do here does not bring clarity to which products should be included. There is no Federal definition of certified orthotist, nor of the orthotist's scope of practice. At the state level, such definitions either do not exist at all or vary widely between states. Thus, the proposal does not bring CMS closer to a process that will lead to an appropriate list of products that are off-the-shelf as defined by the statute. NOMA strongly urges that CMS implement the clearly stated statutory definition in its regulation and not try to add words that change the original meaning and intent of the statute. We would be pleased to work with CMS to help determine which HCPCS codes describe OTS products under that definition and which of those, if any, should be competitively bid.

CMS Must Abide By Existing Medicare Requirements Regarding Qualified Practitioners

The Medicare statute defines OTS orthotics as those that "require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual."[3] Proposed 42 C.F.R § 414.402 uses this language. However, in the discussions in the Notice of Proposed Rulemaking, CMS significantly expands upon and departs from this language. There, the agency hinges the definition of OTS orthotics on whether adjustments requiring the expertise of a certified orthotist would be needed to fit the product to the patient. Specifically, the agency proposes to define OTS orthotics as those that both: (1) can be adjusted by a beneficiary, caretaker, or orthotic supplier without the assistance of an orthotist certified by the American Board for Certification in Orthotics and Prosthetics, Inc. ("ABC") or the Board for Orthotist/Prosthetist Certification ("BOC"); and (2) do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual, which, CMS states, are activities that can only be performed by certified orthotists.[4]

NOMA strongly urges CMS not to finalize this sub-regulatory definition. We believe that it is inconsistent with existing orthotics payment provisions in the Medicare statute (the Qualified Practitioner Rule).[5] The Medicare statute already identifies a list of practitioners

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3 *See* 42 U.S.C. § 1395w-3(a)(2)(C).

4 71 Fed. Reg. at 25669-70.

5 There are special Medicare payment rules for certain custom-fabricated orthotics, which include a definition of "qualified practitioners" that possess expertise to furnish such products to beneficiaries. Under these rules, Medicare payment for an item on a list of certain custom-fabricated orthotics is only to be made if it is (1) furnished by a qualified practitioner; and (2) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the HHS Secretary determines appropriate. "Qualified practitioner" is defined to include physicians, qualified physical and occupational therapists,

qualified to furnish certain custom-fabricated orthotic products to beneficiaries. This list includes physicians and qualified physical and occupational therapists, in addition to certified orthotists. CMS is not at liberty to cherry-pick from this list and define OTS orthotics as those not requiring involvement of a certified orthotist. Congress has already determined which practitioners possess the expertise to furnish orthotic fitting and adjustment services for certain orthotic products.

Fundamental principles of statutory interpretation require that "effect must be given, if possible, to every word, clause and sentence of a statute," and that "[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.[6] The Qualified Practitioner Rule clearly designates several types of practitioners (not just ABC- or BOC-certified orthotists) as qualified to trim, bend, mold, assemble, or customize certain orthotics to fit them to an individual. Furthermore, although the particular sub-set of custom-fabricated orthotics to which the Qualified Practitioner Rule applies has yet to be established, the statute clearly excludes OTS orthotics and thus serves as congressional recognition that these practitioners are capable of performing services for non-OTS orthotics. In light of this statutory language, CMS may not include only ABC- and BOC-certified orthotists as practitioners with the expertise to fit non-OTS orthotics.[7] Finally, we note that CMS is required by statute to promulgate regulations to implement the Qualified Practitioner Rule. It is improper to circumvent this process by partially implementing the Rule through the competitive bidding regulations.

CMS's Definition of OTS Orthotics Must Not Exceed the Congressional Mandate

NOMA has yet another significant concern with the proposed definition of OTS orthotics: it exceeds the congressional mandate as to which products are to be included in competitive bidding. The statutory definition specifically demarcates which orthotics may be competitively bid by limiting it to products that do not require much, if any, adjustment in order to be used appropriately and that do not require fitting and adjustment expertise in order to be fit to the patient. CMS's proposed definition linking OTS orthotics to the work of a certified orthotist would dramatically *expand* the list of products that are considered OTS and that are subject to competitive bidding. Such an approach may also result in quality of care issues for

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licensed orthotists (in states requiring orthotist licensure), and other individuals who are specially trained or educated in the area and certified by ABC, BOC or other approved credentialing programs (in states without orthotist licensure requirements). *See* 42 U.S.C. § 1395m(h)(1)(F) (as added by Section 427 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA")).

6 NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION , § 46:06, 181-86 (6th ed. 2000); *See also Washington Hosp. Center v. Bowen,* 795 F.2d 139 (D.C. Cir. 1986) (concluding that, in order to fulfill "our obligation to construe a statute so as 'to give effect, if possible, to every word Congress uses,'" it must strike down the Secretary's regulation requiring hospitals to wait until completion of the cost year before appealing prospective payment amounts to the Provider Reimbursement Review Board because the regulation ignored the provision of the Medicare statute permitting such appeals prior to filing a cost report).

7 The Qualified Practitioner Rule is only intended only to require involvement of qualified practitioners for a small sub-set of custom-fabricated orthotics. For purposes of the competitive bidding definition of OTS orthotics, CMS should recognize that it serves as Congress' recognition that other practitioners have the experience to adjust and fit non-OTS orthotics.

Medicare beneficiaries. This is because products furnished through the competitive bidding process that require more than minimal self-adjustment may result in a poor fit, product ineffectiveness or even potential injury.

CMS's proposal would set aside the task-related criteria used to define OTS orthotics in the statute (*i.e.,* minimal self-adjustment for appropriate use and no expertise in trimming, bending, molding, assembling, or customizing to fit to the individual) and replace them with an entirely different criterion—the need for a certified orthotist's involvement. The landmark U.S. Supreme Court case concerning agency interpretation of congressional language explicitly precludes agencies from exceeding congressional mandates, as would the proposal here. In that case, the court stated: "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."[8] Hinging the determination as to whether an item is off-the-shelf on involvement of a certified orthotist is different from and inconsistent with basing the determination on whether certain tasks must be performed. The stark difference in these criteria is evidenced by the fact that CMS's proposal would result in a much broader list of orthotic products being competitively bid than Congress intended. Furthermore, if Congress had intended to use the need for an orthotists as the determinative factor, it would have done so. The Qualified Provider Rule illustrates that Congress does not shy away from referring to the need for practitioner expertise when it is appropriate.

NOMA urges CMS not to finalize its proposal in the text of the Notice of Proposed Rulemaking. Instead, we recommend that CMS adopt the proposed regulation because it closely mirrors the statutory language. If, despite these serious misgivings, CMS does seek to enhance the definition, the agency must recognize all other practitioners with expertise to provide orthotic products who are currently recognized under Federal law. Under this alternate approach, any orthotic that requires the assistance of a qualified practitioner (as defined under the Qualified Provider Rule) would not be considered OTS.

In addition, NOMA strongly encourages CMS to consult stakeholders as to which orthotics codes should be considered off-the-shelf for purposes of competitive bidding. We would be pleased to provide a list of OTS orthotics to the agency for its consideration upon request.

2. Finalize Proposal Not to Require Suppliers to be Physically Located in CBAs

[Submission of Bids Under the Competitive Bidding Program]

NOMA applauds CMS for its recognition that a supplier need not be physically located in a CBA in order to service it well. Location is not a precise gauge for a supplier's capability to provide orthotic products to beneficiaries a given CBA. Several NOMA members are large capacity suppliers that provide a significant volume of orthotic products to beneficiaries. NOMA

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[8] *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-3 (1984); *see also* NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION, § 46:01, 121-22 (6th ed. 2000) (stating that "[t]here is no safer nor better settled canon of interpretation that that when language is clear and unambiguous it must be held to mean what it plainly expresses").

asserts that such large capacity suppliers are essential to the success of competitive bidding; without them, there will likely be a shortage or total lack of certain competitively bid items in the CBAs.

Many large capacity suppliers, including NOMA members, offer services nationwide, but operate through central headquarters. NOMA members who function as Medicare suppliers use centralized operations (at which billing, patient contact, complaint and other matters are addressed), with sales representatives operating in locations throughout the country. Often, based on a prescription, orthotic products are shipped from the manufacturing plant or headquarters of a supplier to a patient's home or to a physician's office, the location at which they are provided to the patient. Under this longstanding physician's office model, the supplier does not maintain physical locations in all 50 states, but still ably serves locations across the country.

CMS has long recognized through its Medicare supplier standards that suppliers are not and need not be physically located in every state or region. Under the Medicare statute, all suppliers furnishing medical equipment and supplies to beneficiaries must comply with supplier standards in order to obtain a supplier number. The statute calls for CMS to create a supplier standard requiring the supplier to "maintain a physical facility on an appropriate site."[9] Through Medicare Supplier Standard #7, CMS implements this requirement and recognizes that some suppliers will be operating in various geographic areas but that they can be organized using a centralized location.[10] NOMA believes that centralized operations are beneficial in that they can enhance and streamline suppliers' interactions with Medicare contractors and enable them to provide consistent, high quality services to beneficiaries.

NOMA supports CMS's proposal to use a supplier's past business to beneficiaries in the CBA (as well as any detailed business plan for expansion) to gauge whether a supplier is willing and able to serve beneficiaries in the CBA. We believe that the draft Form B (Bidding Sheet) is an appropriate method for collecting this information.[11] On this form, CMS solicits data regarding the total revenue collected by the supplier, the total number of customers served in the CBA for the product category in the past year, and the percentages of those numbers attributable to Medicare. This form also asks bidding suppliers to describe their expansion plans for the CBA, if they plan to expand their business during the contract term.[12] These are accurate measures of supplier capacity, and NOMA therefore asks that the proposal be finalized as written.

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9 42 U.S.C. § 1395m(j).

10 *See* 42 C.F.R. § 424.57(c)(7). Supplier Standard #7 states that a supplier must certify that it: "Maintains a physical facility on an appropriate site. The physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communication records. For purposes of this standard, a post office box or commercial mailbox is not considered a physical facility. In the case of a multi-site supplier, records may be maintained at a centralized location."

11 71 Fed. Reg. at 25676.

12 *See* http://www.cms.hhs.gov/PaperworkReductionActof1995/PRAL/itemdetail.asp?filterType=none&filterbyDID=-99&sortByDID=2&sortOrder=descending&itemID=CMS063052.

3. Use Existing SADMERC Policy Groups For Competitive Bidding Product Categories and Allow Single Bids To Be Made on Sub-Groupings of Orthotic Products

[Submission of Bids Under the Competitive Bidding Program]

As stated above, NOMA believes that OTS orthotics should be excluded from the initial phase of competitive bidding until the logistical difficulties concerning the orthotics code-set can be resolved. There are a significant number of HCPCS codes and considerable variation in the industry as to how the codes are interpreted. Perhaps more critically, most suppliers are unlikely to have a product for each code. The NOMA members that serve as Medicare suppliers are among the largest suppliers of orthotic products in the U.S., and even they believe that they may not have a product for each code in a policy group. If, despite these concerns, CMS decides to proceed with inclusion of OTS products in 2007, NOMA recommends that existing SADMERC policy groups be used to categorize competitively bid products. Furthermore, we suggest that CMS permit suppliers to submit single bids on sub-groupings of orthotic products within the product categories.

CMS proposes to group products into product categories (defined as groups of similar items used in the treatment of a related medical condition) for purposes of competitive bidding. Each group would be comprised of items defined by HCPCS codes. To bid on a product, a supplier would need to submit bids on the full spectrum of HCPCS codes contained in that product category, with a separate bid amount for each HCPCS code. CMS also proposes that the composition of the product categories may differ from one CBA to another, depending on whether the agency believes it will be able to realize savings for a particular product in a particular CBA.[13] Existing SADMERC policy groups are the logical choice for the product categories for competitive bidding. Some of the SADMERC policy groups for orthotics classify HCPCS codes according to the medical policy to which they belong (*e.g.*, knee-ankle-foot orthoses), making them rational groupings from a clinical perspective. Other policy groups for orthotics reflect different areas of the body for which the products may be used (*e.g.*, lumbar-sacral orthoses and thoracic-lumbar-sacral orthoses). These groupings provide ready categories, with sound clinical bases and with which both CMS and suppliers are familiar, for use in competitive bidding.

NOMA further suggests that CMS divide each OTS product category into sub-groupings that represent families of similar codes that would be reflective of the multiple functionalities of the various products, as well as the multitude of coding, coverage and reimbursement complexities necessary to support providing products to beneficiaries in the CBA. As an illustration, select, small number ankle brace codes with the same clinical function could be grouped together. Rather than submitting a separate bid for each HCPCS code within such a product category, the supplier would offer a single bid amount for this sub-grouping which would be reflective of the costs needed to support providing products in this sub-grouping to beneficiaries in the CBA. This approach would ensure that existing suppliers, that may not have products to fit the full panoply of codes, can participate in the program.

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[13] 71 Fed. Reg. at 25672-73.

Two changes need to be made to the proposed regulations to adopt NOMA's recommendation. First, proposed 42 C.F.R. § 414.412 would need to be revised so that subsection (c) reads (with proposed language in italics):

> Product categories include items that are used to treat a related medical condition. The list of product categories, and the items included in each product category that is included in a particular competitive bidding program, are identified in the request for bids for that competitive bidding program *and will correspond to the policy groups of the Statistical Analysis Durable Medical Equipment Regional Carrier, unless CMS determines that there is good cause to align items differently for a particular competitive bidding program*.

Second, proposed 42 C.F.R. § 414.412 would need to be revised so that subsection (d) reads:

> Suppliers must submit a separate bid for every item included in each product category that they are seeking to furnish under a competitive bidding program, *unless CMS permits a bid for a sub-category for bidding purposes.*

4. Evaluate Bidding Suppliers' Compliance with Financial and Quality Standards and Accreditation Status, Allowing For an Extended Grace Period for Orthotics Suppliers

[Conditions For Awarding Contracts]

NOMA has been a longstanding advocate for stringent quality standards for DMEPOS suppliers, and we submitted lengthy comments regarding the proposed standards in fall of 2005. Maintaining quality while achieving savings for the Medicare fisc is the primary goal of competitive bidding. NOMA applauds CMS for proposing that suppliers be required to meet basic eligibility requirements (*e.g.,* Medicare supplier standards), comply with DMEPOS quality standards and be accredited by a CMS-approved accrediting organization, and meet applicable financial standards eligibility requirements in order to participate in competitive bidding.

NOMA strongly believes that the best indicator that a product is of high quality is the certification and compliance status of the product's manufacturer. NOMA therefore supports CMS's proposal in the draft quality standards to include manufacturer compliance with mandatory FDA good manufacturing practices and ISO standards as a benchmark to ensure quality products are provided to Medicare beneficiaries.[14] NOMA strongly believes that the quality standards must be finalized and implemented prior to the launch of competitive bidding, as is planned. Most critically, CMS must give suppliers sufficient time to develop the policies and procedures needed to comply with the standards and become accredited.

As a practical matter, for this initial phase of competitive bidding, a large number of suppliers may be in the process of obtaining accreditation and coming into compliance with the quality standards. We believe that CMS's proposal to permit a grace period for compliance with

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[14] All NOMA members are FDA registered, are compliant with FDA good manufacturing practices and, significantly, are ISO certified.

the quality standards is an appropriate compromise for the initial phase of the program.[15] In particular, an extended grace period should be afforded to suppliers in industries like orthotics in which accreditation is not currently the norm. Suppliers in such industries lack experience with accreditation, and it will take additional time for them to become accredited. A grace period is also essential for these entities as they will need to come into compliance with the final quality standards that have not yet been released. NOMA strongly supports an extended grace period for orthotics suppliers.

5. Ensure That Competitive Bidding Payment Amounts Reasonably Reflect Actual Bids

[Determining Single Payment Amounts for Individual Items]

NOMA recommends that CMS adopt the competitive bidding payment methodology used in the demonstration programs, in lieu of the formula proposed, for setting payment rates for competitively bid items. We are concerned that the proposed formula may not reasonably reflect actual bid amounts. CMS proposes to use the median of winning suppliers' bids as the payment amount—an approach that will always result in a rate that is lower than the bid prices of half of the winning bidders. There is a risk that, if payment rates are far below bid prices, suppliers may not be able to continue to service beneficiaries in the CBAs. In order to raise the chances that they will be selected to participate in competitive bidding, suppliers are likely to submit bids at or near their margins. Thus, if CMS sets the payment rates at the median of winning bidders' bid prices, up to half of the winning bidders may consider these rates unacceptable and may not be able to continue to provide products to beneficiaries in those areas.

The adjustment factor approach used in the demonstration projects does not suffer from this flaw and would lead to reasonable payment rates.[16] As CMS describes it in the Notice of Proposed Rulemaking, under this approach, CMS would calculate payment rates by adjusting each winning supplier's overall bids for a product category up to the pivotal bid, thereby ensuring that the overall payment amount that contract suppliers receive is at least as much as their bid prices. The advantage of this approach is that suppliers may be less likely to leave the Medicare program because it provides assurances that payment rates will be at least adequate. We therefore ask that this formula be used instead of the median approach proposed.

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[15] *See* 71 Fed. Reg. at 25675.

[16] *See* 71 Fed. Reg. at 25679-80.

Thank you for your attention to these comments. Should you have any questions regarding NOMA's positions or concerns, we can be reached through our outside health care regulatory counsel, Stuart Kurlander of Latham & Watkins LLP, at (202) 637-2169, or me at (469) 742-2840.

Truly yours,

Rhonda Fellows/RB

Rhonda Fellows
President
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File No. 034731-0021

June 29, 2006

BY FEDERAL EXPRESS

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS—1270—P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments Regarding CMS—1270—P: "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues"

Dear Administrator McClellan:

On behalf of our client, Rotech Healthcare Inc. ("Rotech" or the "Company"), we submit these comments on the proposed competitive acquisition program for certain durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") under Medicare Part B.[1] Rotech is a large chain supplier of home medical equipment, oxygen and respiratory products and a variety of other DMEPOS. Rotech provides equipment and services in 48 states through approximately 490 operating centers. The Company provides a wide range of respiratory therapy equipment, including oxygen concentrators, liquid oxygen systems, portable oxygen systems, ventilator therapy systems, nebulizer equipment, and sleep disorder breathing therapy systems, for rental or sale. The majority of the Company's respiratory therapy equipment is rented and reimbursed on a monthly basis. Rotech also provides a comprehensive line of durable medical equipment, such as hospital beds, wheelchairs, walkers, patient aids and other ancillary supplies, for rental or sale, to serve the specific needs of our patients. The Company's principal customers are older patients with breathing disorders, such as chronic obstructive pulmonary diseases, chronic bronchitis, emphysema, obstructive sleep apnea and other cardiopulmonary disorders. Based on the Company's broad experience with DMEPOS, Rotech fully anticipates that it will participate in the proposed competitive acquisition program.

The proposed rule is a complex one, and the Company applauds the Centers for Medicare & Medicaid Services ("CMS" or the "Agency") for its efforts to recondition the current Medicare payment structure. However, Rotech does have some major concerns with the proposed implementation of the program. The Company respectfully submits comments to CMS

[1] *See* 71 Fed. Reg. 25,654 (May 1, 2006).

on the following topics[2]:

- Conditions for Awarding Contracts
- Submission of Bids Under the Competitive Bidding Program
- Terms of Contracts
- Criteria for Item Selection
- Payment Basis
- Administrative or Judicial Review
- Determining Single Payment Amounts for Individual Items
- Quality Standards and Accreditation for Suppliers of DMEPOS
- Opportunities for Networks

More specifically, Rotech makes the following recommendations for CMS's consideration:

(1) For certain categories of DMEPOS, CMS should require all suppliers to be accredited prior to submitting bids and should reject a grace period for unaccredited suppliers. If CMS goes forward with the proposed grace period for all DMEPOS, however, CMS should account for suppliers' accreditation status when evaluating bids.

(2) CMS should finalize its proposal permitting suppliers to participate in the program in specific competitive bidding areas regardless of their physical presence in those areas.

(3) CMS should modify its change in ownership proposal to limit the prior approval requirement to those situations in which a change in ownership results in a change in legal identity.

(4) CMS should consider excluding oxygen and oxygen supplies from the list of competitively bid products, because oxygen equipment recently has been experiencing a new payment cap. In addition, competitive bidding of oxygen threatens the continuity of supply arrangements with beneficiaries.

(5) CMS should clarify the amount of time between the issuance of a request for bids and the deadline for submitting bids so that suppliers have sufficient time to form networks, if necessary.

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[2] These are the subject headings that CMS requested commenters to use to flag issues. Each subject is noted as a heading in bold and bracketed lettering immediately preceding the relevant discussion. Please note that some subject headings are addressed multiple times throughout the comment letter.

Please also note that throughout this comment letter, we have suggested revisions to the proposed regulations. Changes to the proposed language are *underlined and italicized*.

(6) CMS should reimburse "grandfathered" suppliers of DMEPOS based on the traditional fee schedule amounts and not on the competitively bid single payment amount.

(7) CMS should reiterate that existing Medicare appeal rights for individual claims remain unaffected by the competitive acquisition program.

(8) CMS should not adopt the proposed rebate program, which could result in suppliers submitting unreasonably low bids and providing potentially illegal rebates to beneficiaries.

(9) CMS should ensure that all qualified independent accreditation organizations employ comparable language and standards in evaluating suppliers and should limit the reporting role of such organizations.

(10) CMS should eliminate its ability to terminate supplier contracts under the competitive acquisition program "for convenience."

(11) CMS should adopt the adjustment factor formula used in the prior demonstration projects instead of calculating the median of composite bids (below the pivotal bid) to determine the single payment amount.

Below are detailed explanations of each of the Company's comments.

I. ELIMINATE THE ACCREDITATION GRACE PERIOD FOR CERTAIN DMEPOS.

[Conditions for Awarding Contracts]

A. Proposed Accreditation Provisions and Discussion.

In proposed 42 C.F.R. § 414.414(c), CMS clarifies that under the competitive acquisition program, contracts would only be awarded to entities meeting applicable quality standards. In addition, CMS emphasizes in the proposed rule that the U.S. Department of Health & Human Services ("HHS") is statutorily required to establish quality standards for *all* DMEPOS suppliers in the Medicare program—not simply for those participating in the competitive acquisition program.

Under the proposed rule, these quality standards would be applied by independent accreditation organizations designated by the Secretary of HHS.[3] In turn, to be a contract supplier in the competitive acquisition program, an entity must have been accredited by one of these designated accreditation organizations. Under the proposed rule, these unaccredited suppliers would be afforded a period of time after submitting a bid in which to be accredited and

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3 *See* 71 Fed. Reg. at 25,674-75 (proposed 42 § 414.414(c)).

to meet the proposed quality standards. After this grace period, if a supplier has not then successfully attained accreditation, CMS will suspend or terminate the supplier's contract.[4]

The length of the grace period under the proposed competitive bidding rule, according to the Agency, would be determined by the accrediting organizations and their ability to complete the accrediting process within each competitive bidding area ("CBA"). This suggests some variances depending on the accrediting organization as well as the CBA. The grace period would be specified in the request for bids ("RFB") for each competitive bidding program in each CBA.[5]

Importantly, CMS proposes to "grandfather" a supplier that has received a valid accreditation prior to CMS's designating the accreditation organizations, provided that the supplier's accreditation was granted by an organization ultimately designated by CMS. These "grandfathered" suppliers need not be re-accredited until their next regularly scheduled accreditation.[6]

B. Recommendation: For Certain Categories of DMEPOS Suppliers, CMS Should Eliminate the Accreditation Grace Period.

Rotech supports CMS's efforts to ensure that suppliers participating in the competitive acquisition program operate under good business practices and offer high quality services. The Agency's insistence that all DMEPOS suppliers be accredited (including those not participating in the competitive acquisition program) should serve to benefit the quality of service received by Medicare beneficiaries. Rotech also applauds the Agency's use of a grandfathering process to allow previously accredited suppliers to participate without having to bear the cost of further accreditation.

Rotech, however, strongly takes issue with the proposed grace period for accreditation. Allowing unaccredited suppliers to submit bids could unnecessarily create problems for the competitive acquisition program.

Suppliers that have not been accredited prior to submitting bids could underestimate or fail to account adequately for the costs of accreditation when calculating bids. The resulting bids would be unreasonably low, which could artificially distort the pivotal bid and, consequently, the single payment amount. Several unintended consequences could also ensue. First, accredited suppliers who have submitted bids higher than the artificially depressed pivotal bid could unfairly lose in the bidding process. Suppliers with a demonstrated history of commitment to good operating principles and high quality products would be unable to furnish goods to

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4 *See id.*

5 *See id.*

6 *See id.* (proposed 42 § 414.414(a)).

Medicare beneficiaries. This runs counter to one of the most fundamental principles of the competitive acquisition program—supplying quality services to beneficiaries.[7]

Second, unaccredited suppliers that fail to account for accreditation costs in their bids may find that, post-accreditation, the single payment amount does not provide sufficient reimbursement. These suppliers may then drop out of the program altogether, jeopardizing access and leaving beneficiaries with depleted choices for competitively bid products. Again, this result is contrary to the goal of ensuring beneficiary access to quality goods and services.

For these reasons, the Company urges CMS not to move forward with the grace period for accreditation as proposed. Instead, Rotech believes that CMS should narrow the scope and only apply the grace period to those DMEPOS industries in which accreditation has not previously been the norm. It is a standard, voluntary procedure—not a requirement—in certain DMEPOS industries, such as home oxygen or power wheelchairs, to be accredited. Accreditation is not the norm for other industries, such as orthotics. Because suppliers in this latter category lack experience with accreditation, CMS should offer a grace period to these companies. Companies in DMEPOS industries experienced with accreditation do not require a grace period and, therefore, CMS should not afford them one.

If CMS does provide a grace period for all DMEPOS suppliers, regardless of the industry, the Agency must consider a supplier's ability to meet these standards prior to selecting the pivotal bid. Otherwise, the bidding pool is tainted by the bids of suppliers that are unqualified to provide competitively bid products to beneficiaries. Without considering eligibility requirements from the beginning, the Company is concerned that competitively bid payment amounts will be unreasonably low.

In addition, if CMS decides to move forward with the proposed grace period, Rotech recommends the following changes to proposed 42 C.F.R. § 414.414 to specify that bids will be evaluated only if submitted by suppliers meeting the requirements listed in subsections (b)-(d).

- In a new subsection (e), the proposed regulation should provide that the conditions for awarding contracts are evaluated prior to evaluating bids: "*(e) Timing of conditions for awarding contracts. CMS will determine whether a bidding supplier meets the requirements in paragraphs (b) through (d) of this section prior to evaluating the bids as described in paragraph (f) of this section.*" Lettering of subsequent subsections would be revised to accommodate new subsection (e).

- Proposed paragraph (e)(2), which would become (f)(2) under the Company's revised numbering, should be modified to make clear that CMS would only include bids from qualified suppliers in its comparative evaluation of bid prices. Specifically, CMS evaluates bids submitted for a product category by

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7 *See* 71 Fed. Reg. 26,543, 26,544 (May 5, 2006).

"[e]stablishing a composite bid for each supplier that submitted a bid for the product category *and met the requirements of paragraphs (b) through (d)*."[8]

II. NO PHYSICAL LOCATION PREREQUISITE TO BIDDING IN A GIVEN CBA

[Submission of Bids Under the Competitive Bidding Program/Opportunity for Networks/Conditions For Awarding Contracts]

Rotech firmly supports CMS's proposal not to restrict bidding to those suppliers physically located in a given CBA. Rotech feels that physical location alone cannot determine whether a supplier can serve Medicare beneficiaries in a given CBA. Moreover, such a proposal would actually inhibit the participation of many large, national suppliers.[9] Currently, large suppliers provide a substantial volume of DMEPOS across the country. These suppliers might not necessarily be physically present in each CBA. The unintended consequence of such a rule would be to limit the supply of products availability in a given CBA.

In addition, physical location is not a precise gauge for supplier ability to service a location. Indeed, a more precise measure of supplier capacity is past business to beneficiaries in the area in conjunction with the supplier's plan for business expansion, if any. Rotech supports CMS's proposal to use this information to determine each bidding supplier's capacity to service a CBA.[10] In particular, CMS plans to collect such information through the Form B Bidding Sheet, which suppliers would complete in submitting a bid for each product category in a CBA.[11] Rotech believes that this approach is accurate and should be finalized as written.

Rotech also believes that in some instances, national chain suppliers may have capacity through more than one supplier to offer services in a selected CBA. This might mean that multiple suppliers within a chain could efficiently offer services within the CBA even though not all those suppliers are located within the CBA. In sum, the key to success of competitive bidding is allowing suppliers with capacity to service CBAs to continue to furnish products to beneficiaries in those areas, regardless of physical location.

III. MODIFY THE CHANGE IN OWNERSHIP REQUIREMENTS

[Terms of Contract]

A. Proposed Change in Ownership Requirement.

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8 *See* 71 Fed. Reg. 25,654, 25,700 (proposed 42 C.F.R. § 414.414).

9 *See id.* at 25,672 (concluding that such a requirement would be "too proscriptive").

10 *See id.* at 25,676.

11 Form B solicits data regarding the total revenue collected by the supplier, the total number of customers served in the CBA for the product category in the past year, and the percentages of those numbers attributable to Medicare. *See* 71 Fed. Reg. 26,543 (May 5, 2006).

As proposed, 42 C.F.R. § 414.422(d) limits a contract supplier's participation in the competitive bidding program after it engages in a change of ownership. Specifically, CMS proposes to evaluate a company's ownership information, its compliance with appropriate quality standards, its financial status, and its compliance status with government programs before the Agency will determine that a supplier can qualify as a contract supplier if there is a change in ownership.[12]

Moreover, under the proposed competitive bidding rule, contract suppliers would be required to notify CMS in writing 60 days prior to the finalization of any change in ownership, merger or acquisition. The successor entity could continue to furnish products in the CBA only if (1) there is a need for the successor entity to function as a contractor to assure expected demand for a competitively bid item; (2) the successor entity meets all requirements applicable to contract suppliers; (3) the successor entity assumes the predecessor contract supplier's contract; and (4) the successor entity executes a novation.[13]

B. Recommendation: CMS Must Modify Its Change in Ownership Provision to Reflect Business Realities.

CMS's proposed change in ownership provision is overly inclusive. According to the proposed rule, CMS seeks to prohibit suppliers from engaging in a strategy of gaining contract supplier status through acquisitions of contract suppliers rather than submitting bids.[14] CMS's language, however, does more than sort out this type of scheme to game the system. CMS's language restricts any change in ownership—from a major corporation's acquisition of all of a contract supplier's assets to a single stockholder's decision to sell his or her shares of stock. All scenarios would require CMS's prior approval to complete the transaction. This penalizes business arrangements that may have no impact on a contract supplier's relationship with CMS. It also needlessly devalues the monetary worth of a supplier's business.

The Agency's proposed change in ownership provision is not only overly burdensome, but the prior approval requirement is also inconsistent with current Medicare provisions. Current Medicare supplier standards, as well as the soon-to-be-implemented quality standards, provide the necessary assurances needed to ensure that only high quality services are provided to beneficiaries. The new notice and prior approval requirement adds nothing meaningful to these assurances.

In addition, the proposed change in ownership's 60-day notice requirement is impracticable. Under the proposed rule, a supplier is required to calculate when a merger, acquisition or other transaction would be finalized in order to obtain 60 days' prior approval from CMS. Mergers, acquisitions and other transfers of interests, however, are subject to

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12 *See* 71 Fed. Reg. 25,654, 25,681-82 (proposed 42 C.F.R. § 414.422(d)).

13 *See id.*

14 *See id.*

frequent delay and negotiation and, therefore, the transaction's finalization date may be unknown until fewer than 60 days remain until CMS's notice deadline.

Rotech makes the following recommendations:

- First, CMS should clarify that the proposed regulation applies only when a supply contract would be transferred to an entirely new or different legal entity as a result of a business transaction. More specifically, if a change in ownership occurs and the legal identity of the contract supplier is not changed in the transaction, there is no need for CMS's prior approval. Alternatively, if the legal identity of the contract supplier does change, CMS understandably would seek assurance that any new supplier is capable of meeting all of the former supplier's obligations and of assuming all of the predecessor entity's obligations. CMS can achieve this clarification by incorporating the definition of "change in ownership" from 42 C.F.R. § 489.18(a) in the proposed regulation. In part, section 489.18(a) provides that merger or consolidation of corporations resulting in a new corporation constitutes a change in ownership; transfer of corporate stock or merger of another corporation into the provider corporation does not.[15]

- Second, Rotech also recommends that CMS remove the prior approval requirement altogether. In addition, CMS should adopt a 30-day, post-transaction timeframe for notice, as required by current regulations. Advance notice is not beneficial in this context and would merely serve to burden DMEPOS suppliers. Importantly, CMS recently reaffirmed this approach in newly finalized enrollment regulations, requiring DMEPOS suppliers to report changes of information and changes of ownership or control within 30 days of their occurrence.[16]

To this end, Rotech suggests the following amendment to proposed 42 C.F.R. § 414.422(d)(1): "A contract supplier must notify CMS in writing *within 30 days of* any change of ownership, *as such term is defined in section 489.18(a) and that would trigger completion of an entire new Form CMS-855S*."[17]

IV. EXCLUDE OXYGEN FROM LIST OF COMPETITIVELY BID PRODUCTS

[Criteria for Item Selection]

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), certain types of DMEPOS may be subject to the competitive acquisition program. This could include DME (other than class III devices under the Federal Food, Drug, and

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15 42 C.F.R. § 489.18(a)(3).

16 *See* 42 C.F.R. § 424.530.

17 *See* 71 Fed. Reg. at 25,701.

Cosmetic Act); items used in infusion and drugs (except inhalation drugs), supplies used in conjunction with DME, enteral nutrients, equipment and supplies, and "off-the-shelf" orthotics.[18] In the proposed competitive acquisition rule, CMS does not specify which products it plans to include in the program. Rather, CMS proposes to phase in the program first among the highest cost and highest volume products or those that have the largest savings potential.[19]

Several of the highest cost and highest volume HCPCS codes for 2003 were oxygen-related: E1390 (Oxygen concentrator); E0431 (Portable gaseous oxygen system); and E0439 (Stationary liquid oxygen) among others. In addition, the "Oxygen Suppliers/Equipment" policy group ranked as the policy group with the highest 2003 DMEPOS allowed charges.[20] Therefore, it appears quite likely that CMS will seek to include oxygen on the list of competitively bid items.

Rotech notes that if oxygen does become subject to the competitive bidding process and is reimbursed at the single payment amount, the Federal government will have sought to extract savings from oxygen three times in as many years. Specifically, section 5101(b) of the Deficit Reduction Act of 2005 ("DRA") established a 36-month limit on monthly payments for stationary and portable oxygen equipment furnished on or after January 1, 2006. Payments for affected items terminate after a period of continuous use of 36 months, at which point the supplier transfers title for the stationary and/or portable oxygen equipment to the beneficiary.[21]

In addition, section 302(c) of the MMA reduces the fee schedule amounts of certain items of DME, including oxygen and oxygen equipment.[22] Under the MMA price reduction, Medicare payment amounts for oxygen are decreased by the percentage difference between the amount of payment otherwise determined for 2002 and the median amount of payment under the Federal Employee Health Benefits Program ("FEHBP"), as determined by the U.S. Department of Health & Human Services Office of Inspector General ("OIG").[23] According to an OIG report, in 2002, FEHBP median payments were approximately 12.4% less than Medicare payments for stationary home oxygen equipment and approximately 10.8% less than Medicare payments for portable home oxygen equipment.[24] In other words, oxygen suppliers have already been subject to

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18 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-73 (2003).

19 *See id.* at 25,669.

20 *See id.* at 25,670-71.

21 *See* Deficit Reduction Act of 2005, § 5101(b), Pub. L. No. 109-171 (Jan. 8, 2006)

22 *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Section 302(c).

23 *See id.*

24 *See* U.S. Department of Health & Human Services, Office of Inspector General, *Medicare and FEHB Payment Rates for Home Oxygen Equipment*, Report No. OEI-09-03-00160, at i (March 2005).

substantial price reductions, and, more importantly, the Medicare program has already achieved significant savings based on these reductions.[25]

The government now seeks to extract even further savings by capping the number of months of rental of oxygen and more extensively decreasing oxygen suppliers' monthly payment amount to the competitively bid price. Other types of DMEPOS are not subject to such doubled efforts at savings, and oxygen should not be treated any differently—especially so closely on the heels of the DRA.

Moreover, while CMS is attempting to save money with the competitive bidding program, it has failed to allow sufficient time to pass since the implementation of the DRA's 36-month rental cap or the MMA's FEHBP price reduction to determine whether these initiatives will achieve significant savings for the Federal government. Nor have suppliers been afforded sufficient time to determine the full impact of these changes. Applying competitive bidding to oxygen would simply be premature.

In addition, Rotech is concerned that adding oxygen to the competitive acquisition program would result in a drop-off of willing suppliers, thereby jeopardizing continuity of the supplier-beneficiary relationship. Although non-contract suppliers of oxygen could be grandfathered into the program and continue to supply oxygen under their original contracts,[26] payment for these grandfathered suppliers would not be at the original fee schedule amount but rather at the competitively bid single payment amount. This shift in payment amount for non-contract suppliers unnecessarily turns the competitive bidding program on its head. These non-contract suppliers will be subject to a potentially significant drop in price based on a system of competitive bidding in which they have either elected not to participate or for which they lost their bid. The result is a decrease in price that could potentially hit suppliers in the middle of their service contracts and price them out of the system. The ultimate—and potentially devastating—result would be a plethora of oxygen suppliers discontinuing their contracts with

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25 In the Regulatory Impact Analysis section of the proposed competitive acquisition rule, CMS recognizes that prices have fallen for certain DMEPOS suppliers, specifically pointing out the 2005 reductions in oxygen supplies.

26 *See* 71 Fed. Reg. at 25,662 (proposed 42 C.F.R. § 414.408(k)). In proposed 42 C.F.R. § 414.408(k), the Agency describes its plan to "grandfather" rental agreements for (1) rented DME, such as inexpensive or routinely purchased items, items requiring frequent and substantial servicing, and capped rental items and for (2) supply arrangements with oxygen suppliers entered into before the start of competitive bidding. When these items are included under a competitive bidding program, suppliers that began furnishing such items to beneficiaries who maintain a permanent residence in a CBA prior to the implementation of a competitive bidding program are "grandfathered" and can continue to furnish these items, even if they are not contract suppliers. Specifically, under the proposed rule, beneficiaries choose to continue renting the item from the grandfathered supplier or a new contract supplier. If the grandfathered supplier is unwilling to continue furnishing the item under the competitive bidding terms, a contract supplier assumes responsibility for furnishing the item and is paid based on the competitively bid single payment amount for that item. A beneficiary can switch to a contract supplier at any time, and the contract supplier would be required to accept the beneficiary. Importantly, suppliers that agree to be grandfathered must agree to be a supplier for all beneficiaries who request to continue to use their services for that item.

oxygen-dependent beneficiaries. This raises potential ethical concerns and, moreover, runs counter to the program's goal of ensuring quality service for beneficiaries.

Rotech also notes that including oxygen in the competitive acquisition program would be inequitable to all oxygen suppliers. If oxygen were competitively bid, both contract suppliers and grandfathered non-contract suppliers would be offering services and, potentially, partial services. Under the proposed rule, contract suppliers would be expected to offer services to beneficiaries who have chosen to terminate their relationship with grandfathered suppliers. If a beneficiary opts to switch from a grandfathered supplier to a contract supplier, for instance at the 24th month of his or her 36-month rental period, the contract supplier would be required to take on the additional costs of supplying oxygen to this beneficiary. This involves supplying a different piece of oxygen equipment, training, set-up and delivery. After 12 months, title then passes to the beneficiary and therefore a new contract supplier is only entitled to 12 months of payment; whereas, under current regulations, suppliers receive 36 months of payment for equipment, training, set-up and delivery. The contract supplier, however, cannot refuse this beneficiary and is stuck with the costs of supplying the services without the benefit of sufficient payment. As was noted at the May 2006 Program Advisory & Oversight Committee ("PAOC") meeting, there is no way for suppliers to calculate these inevitable and potentially frequent cost assumptions in their bids.[27] Again, Rotech notes that the unintended consequence of these payment policies is the withdrawal of rental DME and oxygen suppliers from Medicare altogether.

Based on all of these reasons—uncertainty of savings to be garnered from the recently passed rental cap, fairness, continuity of beneficiary supply, and the inability of contract suppliers to calculate costs—Rotech recommends that oxygen not be made subject to the competitive acquisition program. Suppliers should continue to be paid at the fee schedule amounts pursuant to the 36-month rental cap.

V. ESTABLISH A REASONABLE TIMELINE FOR SUBMITTING BIDS AFTER ISSUING AN RFB

[Submission of Bids Under the Competitive Bidding Program/Opportunity for Networks]

Under the proposed rule, after CMS issues an RFB, potential DMEPOS suppliers would then submit bids to furnish products under the competitive acquisition program.[28] Suppliers would bid separately for all items that CMS specifies are in a product category.[29] Under the proposed rule, suppliers would not be made aware of which product categories are subject to competitive bidding until CMS issues an RFB.

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27 In addition, the result is a windfall for beneficiaries, who can obtain title to nearly new equipment simply by dropping grandfathered suppliers midway through their rental periods.

28 *See* 71 Fed. Reg. at 25,672 (proposed 42 C.F.R. §§ 414.404, 412, 414, 422).

29 *See id.*

In addition, the Agency has proposed to allow suppliers to form networks for bidding purposes. These networks, according to CMS, would consist of several suppliers that have joined together in a legal contractual relationship. Specifically, CMS would require that a legal entity be formed for the purpose of acting as a supplier network—for instance, a joint venture, limited partnership or contractor/subcontractor relationship. Among other requirements, CMS would require that all legal contracts be executed and in place before the network entity can submit a bid for the competitive bidding program.[30] This is a highly time-consuming process, and suppliers must be provided with ample time in order to form such networks.

The proposed rule, however, fails to establish a timeline for submitting bids. As currently written, it is unclear whether CMS will allow sufficient time for suppliers to form new legal entities that serve as networks.

To address the timing issues, Rotech suggests that CMS allow for a reasonable period of time after it has issued an RFB and before suppliers are required to submit bids. Rotech believes that 120 days is a reasonable amount of time. This would provide ample time to form and prepare supplier networks as well as to calculate the costs necessary to submit a bid in response to an RFB.

Rotech recommends that the Agency add a new subpart (h) to proposed § 414.412, which should read as follows: "*(h) Deadline for Submission of Bids. Suppliers or networks of suppliers that submit bids under a competitive bidding program must do so within 120 days following the issuance of a request for bids by CMS.*"[31]

VI. REJECT THE SINGLE PAYMENT AMOUNT FOR GRANDFATHERED SUPPLIERS

[Payment Basis]

A. Proposed Grandfathering Process.

In proposed 42 C.F.R. § 414.408(k), the Agency describes its plan to "grandfather" rental agreements for (1) rented DME, such as inexpensive or routinely purchased items, items requiring frequent and substantial servicing, and capped rental items, and (2) supply arrangements with oxygen suppliers entered into before the start of competitive bidding. When these items are included under a competitive bidding program, suppliers that began furnishing such items to beneficiaries who maintain a permanent residence in a CBA prior to the implementation of a competitive bidding program are grandfathered and can continue to furnish these items, even if they are not contract suppliers.[32] Importantly, suppliers that agree to be

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30 *See id.* at 25,683 (proposed 42 C.F.R. § 414.418).

31 *See id.* at 25,700.

32 *See id.* at 25,662 (proposed 42 C.F.R. § 414.408(k)).

grandfathered must agree to be a supplier for all beneficiaries who request to continue to use their services for that item.[33]

The proposed rule offers beneficiaries the choice to continue renting the item from the grandfathered supplier or to receive services from a new contract supplier. If the grandfathered supplier is unwilling to continue furnishing the item under the competitive bidding terms, a contract supplier is to assume responsibility for furnishing the item. The contracted supplier would be paid based on the competitively bid single payment amount for that item. A beneficiary can switch to a contract supplier at any time, and the contract supplier would be required to accept the beneficiary.[34]

B. Proposed Payment Amounts to Grandfathered Suppliers.

The Agency proposes that grandfathered suppliers who furnish items requiring frequent and substantial servicing and oxygen and oxygen equipment continue furnishing these items in accordance with existing rental agreements or supply arrangements. However, CMS also proposes that grandfathered suppliers be paid the competitively bid single payment amount determined for these items. CMS asserts that payment at competitively determined rates—as opposed to the traditional fee schedule—comports with the overarching goal of competitive bidding to achieve savings for Medicare.[35]

In addition, the Agency proposes to grandfather contract suppliers of rental items or oxygen and oxygen equipment that lose their contract status in a subsequent competitive bidding cycle. This means that the contract supplier who loses its contract in a later bidding cycle will be paid on the basis of the newly established single payment amount. The purpose of this proposal, according to CMS, is to avoid a disruption in beneficiary service of medically necessary items.[36]

C. Recommendation: CMS Must Maintain the Fee Schedule Amount for Grandfathered Suppliers.

Rotech believes that the grandfathering provisions are unworkable as proposed. Practically speaking, permitting non-contract suppliers to continue furnishing their items to beneficiaries likely is a preferable course for most beneficiaries. The payment levels using a competitively bid single payment amount, however, subjects non-participants in the competitive bidding process to competitively bid prices that may be below margins. In addition, this could depress reimbursement to the point of pricing non-contract suppliers out of the Medicare program altogether. This is yet another reason why Rotech strongly urges CMS not to include oxygen in the competitive acquisition program (see discussion in Section IV, above).

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33 *See id.*

34 *See id.*

35 *See id.* 25,663.

36 *See id.*

If CMS opts nonetheless to include oxygen in competitive bidding, Rotech would agree that grandfathering suppliers and allowing them to continue to furnish their items to beneficiaries is the best course of action. Continuity of the supplier-beneficiary relationship is imperative, especially with respect to the provision of vital medical services such as oxygen. The Agency's grandfathering of suppliers should allow beneficiaries to continue their home oxygen service without disruption. Moreover, permitting grandfathered suppliers to continue furnishing DMEPOS does not have the unintended consequence of voiding supply arrangements that grandfathered suppliers have taken care to negotiate and execute.

Although grandfathering is the most logical course here, the payment process for grandfathered non-contract suppliers will unnecessarily burden the competitive acquisition program. Grandfathered suppliers will be subject to a drop in price based on a system of competitive bidding in which they have either elected not to participate or for which they lost their bid. The result is a decrease in price that could potentially adversely hit suppliers in the middle of their service contracts in a way that prices them out of the system. This problem also would occur in the situation where CMS would pay competitively bid prices to contract suppliers who lost their contracts. To avoid these problems, Rotech urges CMS to continue to pay grandfathered suppliers at the fee schedule amount and not to shift reimbursement to the single payment amount.

D. Recommendation: CMS Must Restrict the Ability of Beneficiaries to Drop Grandfathered Suppliers.

Rotech would also like to reiterate that the policy of applying the single payment amount to grandfathered suppliers is equally unfair to contract suppliers. As we mentioned in Section IV above, contract suppliers will be expected to pick up additional contracts from beneficiaries who have chosen to terminate their relationship with grandfathered suppliers. By way of the example we cite in Section IV above, if a beneficiary opts to switch from a grandfathered oxygen supplier to a contract supplier at the 24th month of his or her 36-month rental period, the contract supplier would be required to take on the additional costs of supplying oxygen to this beneficiary such as delivery, set-up, training, and maintenance, among others for the remaining 12 months of the contract. At 12 months, the new equipment passes to the beneficiary.

Rotech makes the following observations:

- This is inequitable. As we noted previously, contract suppliers will have 12 months of payment to offset costs. Under the current system, suppliers receive 36 months of payment to offset costs.

- In addition, suppliers cannot calculate when they will be forced to assume these costs or how much the costs will be when suppliers calculate their bids. Again, the unintended consequence of these payment policies is the withdrawal of rental DME and oxygen suppliers from Medicare altogether.

For these reasons, Rotech recommends that CMS revise its policy so that a beneficiary

remains with the initial supplier for a set, minimum period of months. We recommend that after a period of 6 months of equipment rental, a beneficiary cannot switch suppliers. Under this method, a beneficiary would not be able to drop a grandfathered supplier and contract suppliers would not be required to bear the costs of furnishing equipment without reaping the benefit of full payment.

VII. MAINTAIN AVAILABLE APPEAL RIGHTS

[Administrative or Judicial Review]

Proposed 42 C.F.R. § 414.424 prohibits appeals on most competitive bidding decisions. This would include the awarding of contracts, the establishment of payment amounts, the selection of items to be competitively bid, the selection of CBAs, the establishment of a bidding structure or the number and selection of winning bidders.[37]

Although the preamble to the proposed rule acknowledges that existing rights are not disturbed by competitive bidding, Rotech asks that the proposed regulation specifically preserve existing appeal rights for beneficiaries and suppliers regarding denied claims. To this end, Rotech suggests adding subsection (c) to 414.424, which would read: "*All existing rights to appeal regarding denied claims are unaffected by this provision.*"

Moreover, Rotech suggests clarifying the vague statement in the regulation that "[a] denied claim is not appealable if CMS determines that a competitively bid item was furnished in a competitive bidding area in a manner not authorized by this subpart."[38] It appears that CMS intends that denied claims cannot be appealed if the denial is based upon items being furnished in a CBA in a way that is unauthorized by the proposed competitive bidding rule. If so, CMS should consider changing proposed section 414.424(b) to read as follows: "A claim is not appealable if the denial *is based on a determination by CMS* that a competitively bid item was furnished in a competitive bidding area in a manner not authorized by this subpart."

VIII. REJECT THE PROPOSED REBATE PROGRAM

[Determining Single Payment Amounts For Individual Items]

Under proposed 42 C.F.R. § 414.416(c), CMS would allow a contract supplier that submitted a bid for an individual item below the single payment amount to provide a rebate to beneficiaries equal to the difference between the supplier's bid and the single payment amount.[39] Rotech raises several concerns with respect to the proposed rebate program and urges the Agency to reject the proposal. Specifically:

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37 71 Fed. Reg. at 25,682 (proposed 42 C.F.R. § 414.424).

38 *See id.* at 25,704 (proposed 42 C.F.R. § 414.424(b)).

39 *See id.* at 25,680 (proposed 42 C.F.R. § 414.416(c)).

- Rotech is concerned that this proposal implicates the Federal Anti-Kickback Statute[40] ("AKS"). Under the AKS, any remuneration—including a rebate—intended to induce beneficiaries to purchase a particular Medicare-covered item is generally prohibited. Rotech is concerned that adoption of such a rebate program could result in industry confusion as to what is permissible under the AKS.

- Rotech believes that some suppliers might take advantage of the proposed rebate program to set its rates too low as a "loss leader" of sorts, attracting beneficiaries to the low cost and growing its customer base in this way. This could also encourage the makers of low quality, inexpensive products to inundate the market. A rebate incentive would allow manufacturers of low quality products to offer such low prices in addition to cash-back rebates.

- Rotech is concerned that the practice of giving a rebate to a beneficiary is tantamount to predatory pricing and should not be a part of the competitive acquisition process.

- Rotech is also concerned that the rebate program could have the perverse result of potentially allowing Medicare beneficiaries to make money. By way of example, if the single payment amount for a product is $100 and the supplier's bid amount were $75, the supplier can offer a cash rebate of $25 to a beneficiary. Assuming that the beneficiary's copayment for the product is 20% or $20, the beneficiary has pocketed $5.

For these reasons, Rotech recommends rejecting the rebate program altogether.

IX. ADJUST THE ACCREDITATION REQUIREMENTS TO REFLECT COMPARABLE STANDARDS AND USABLE REPORTING REQUIREMENTS.

[Quality Standards and Accreditation for Suppliers of DMEPOS/Conditions for Awarding Contracts]

Rotech urges CMS to ensure that designated accreditation organizations employ comparable language for describing events, comparable standards for submitting reports to CMS, and comparable review processes. Currently, the various key accreditation organizations apply differing standards and define events differently. The result of such discrepancies could be disparate treatment of suppliers depending upon which entity accredits them. Such a result would not be appropriate in a Federal program.

As mentioned above, CMS is proposing to require all DMEPOS suppliers to maintain accreditation by recognized independent organizations designated by the Secretary of HHS,

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[40] 42 U.S.C. § 1320a-7b(b)(2).

regardless of participation in the competitive acquisition program.[41] Pursuant to the proposed rule, a DMEPOS independent accreditation organization approved by CMS would be required to provide to CMS on a monthly basis (1) a notice of all accreditation decisions; (2) notice of all complaints related to suppliers of DMEPOS and other items; and (3) information about any suppliers of DMEPOS and other items for which the accrediting organization has denied the supplier's accreditation status.[42] To offer uniform application, CMS appears to have begun to address this issue. Specifically, CMS makes the following assertions in the proposed rule:

- CMS plans to promote "consistency" in accrediting providers by using existing procedures for the application, reapplication, selection, and oversight of accreditation organizations and apply them to organizations accrediting DMEPOS suppliers.[43]

- CMS notes that under the proposed rule it would require the submission of detailed comparisons of the organization's accreditation requirements and standards with applicable Medicare quality standards.

- CMS proposes to require accreditation organization applicants to provide a detailed description of the organization's survey processes, including procedures for performing unannounced surveys, frequency of the surveys performed, copies of the organization's survey forms, guidelines and instructions to surveyors, quality review processes for deficiencies identified with accreditation requirements.

- CMS proposes to require the submission of an accreditation organization's decision-making processes and a description of procedures used to notify suppliers of compliance or non-compliance with the accreditation requirements.

- CMS notes that it might require a description of the accreditation organization's procedures for responding to and investigating complaints against accredited facilities, including policies and procedures regarding coordination with appropriate licensing bodies, the National Supplier Clearinghouse and with CMS. In addition, CMS may require that accreditation organization provide descriptions of its policies and procedures for notifying CMS of facilities that fail to meet the accreditation requirements.[44]

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41 *See* 71 Fed. Reg. at 25,675.

42 *See id.* at 25,703 (proposed 42 C.F.R. § 424.58).

43 *See id.* at 25,685 (citing 42. C.F.R. § 488.4, which contains detailed application standards for hospital accreditation organizations).

44 *See id.*

Although these requests are positive steps toward ensuring uniform—or at least comparable—processes among accreditation organizations, Rotech believes that a more fulsome list of defined terms is needed. Also needed is an extensive list of accreditation standards that these organizations should apply when surveying DMEPOS suppliers. As it is currently written, the proposed rule allows CMS to compare and contrast the language and standards used by accreditation organizations. This would not appear to go far enough. Rotech urges CMS to take the next step and define its own accreditation standards.

Rotech also urges CMS to develop standards on how and when to report certain events. As currently proposed, accreditation organizations would make monthly reports of all complaints related to DMEPOS suppliers.[45] A complaint could cover something as *de minimis* as a late delivery or as significant as a death caused by supplier's faulty equipment. Rotech proposes that only material complaints should be reported by the accreditation organizations. Anything less than material should be self-reported by the suppliers themselves; there is no value or usefulness to CMS in having the accreditation organizations report immaterial complaints. To be sure, requiring the reporting of *all* complaints would create an administrative burden on CMS that could overwhelm the competitive acquisition program altogether.

Therefore, Rotech recommends the following changes to proposed 42 C.F.R. § 424.58(c)(iii): An accreditation organization approved by CMS must provide to CMS on a monthly basis "[n]otice of all *material* complaints related to suppliers of DMEPOS and other items and services."[46]

X. ELIMINATE THE PROVISION ALLOWING CMS TO TERMINATE CONTRACTS FOR CONVENIENCE.

[Terms of Contracts]

Under the proposed competitive acquisition rule, CMS allows itself to terminate supplier contracts for cause—for instance, if the contract supplier deviates from contract requirements. CMS also permits itself to terminate supplier contracts "for convenience."[47] Rotech strongly urges CMS to create specific standards dictating how and when CMS is permitted to terminate for convenience.

The proposed regulatory language reads, "CMS has the right to terminate performance under the contract in whole or in part when termination would be in CMS' interest."[48] It would be seriously inequitable for a supplier's competitively won contract to be terminated without cause. Invariably, the supplier will have invested a significant amount of resources into ensuring

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45 *See id.* at 25,703 (proposed rule 42 C.F.R. § 424.58(c)(1)(iii)).

46 *See id.*

47 *See* 71 Fed. Reg. at 25,682.

48 *See id.* at 25,702 (proposed 42 C.F.R. § 414.422(g)).

that it has the capacity to serve the CBA, that it has accurately calculated its bid amount, and that it has formed, if necessary, a strategic network of suppliers. In addition, under the proposed rule, suppliers that have entered into networks will be bound by legal agreements with other suppliers.

As proposed, there is no certainty that any supplier will have the benefit of a full three-year contract term. This lack of continuity could deter suppliers from entering the bidding process. Additionally, if CMS were to terminate a contract for convenience, without cause and without notice, this would cut off supply of the service to beneficiaries, surely an unintended result. For these reasons, Rotech strongly urges CMS to remove the termination for convenience provision. Should CMS determine otherwise, Rotech urges the Agency to create time limits for terminating without cause (i.e., only within the last year of the contract) as well as a notice requirement (i.e., CMS can terminate without cause on 60 days notice).

Rotech also recommends that CMS allow for an appeal or administrative review of any termination for convenience. Such an opportunity for appeal would be consistent with current § 405.874 and more recent pronouncements on the availability of appeal rights for revocation of supplier numbers.[49] Although the proposed rule and the Social Security Act limit a supplier's available appeals with respect to competitive bidding, neither the proposed regulation nor the statute indicate that a supplier cannot appeal a contract termination.[50]

To this end, subsection (g) of proposed § 414.422 should be amended to read as follows:

> (g) *Termination for Convenience. (1)* CMS has the right to terminate performance under the contract in whole or in part when termination would be in CMS' interest. *Termination under this subsection (g) requires CMS to provide 60 days written notice to the affected supplier. CMS cannot terminate under this subsection (g) during the first two years of a contract.*"
>
> *(2) In the event CMS terminates a contract under this subsection (g), the supplier has the right to appeal such determination under the procedures described in § 424.545 and part 405, subpart H of this chapter.*

XI. REJECT SINGLE PAYMENT AMOUNTS BASED ON THE MEDIAN BID

[Determining Single Payment Amounts for Individual Items]

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49 *See* 42 C.F.R. § 424.545. CMS has indicated that more specific appeals regulations are being drafted. *See* 71 Fed. Reg. 20, 754, 20,762 (April 21, 2006).

50 Specifically, the Social Security Act notes that there is no administrative or judicial review under the competitive bidding program of (A) the establishment of payment amounts; (B) the awarding of contracts; (C) the designation of competitive acquisition areas; (D) the phased-in implementation of the program; (E) the selection of items and services for competitive acquisition; or (F) the bidding structure and number of contractors selected. *See* 42 U.S.C. § 1395w-3(b)(10). The proposed rule places identical limits on a supplier's available appeals. *See* 71 Fed. Reg. 25,654, 25,682.

A. Proposed Methodology—Median Bid.

In proposed rule 42 C.F.R. § 414.416, CMS describes its proposed approach for setting the single payment amount. The Agency notes that once contract suppliers are selected for a product category based on their composite bid and the pivotal bid, single payment amounts for individual items in each product category must be determined. CMS proposes to use the median of the supplier bids that are at or below the pivotal bid for each individual item within each product category. This median amount would then become the single payment amount that CMS would establish under the competitive bidding program for the HCPCS code that describes a particular item.

CMS asserts that using the median of bids at or below the pivotal bid will result in a single payment that represents the winning bids for a particular item and has the advantage of being "easily understood" by suppliers and implemented by contractors. CMS also asserts that the median method results in a reasonable payment amount based on market prices.

B. Recommendation: CMS Adopt the Adjustment Factor Approach In Lieu of the Median Bid Approach.

Rotech strongly disagrees that the median payment amount is reasonable. The Company believes that the proposed use of the median of winning suppliers' bids will substantially inhibit suppliers' ability to provide products in CBAs.[51] The proposed method inherently results in half of the winning contract suppliers receiving payment that is less than their original bids. Consequently, this half of the winning suppliers could be priced out of the competitive bidding program altogether. If these suppliers are priced out of the competitive bidding program, beneficiaries would have fewer product alternatives; and therefore, at least one goal of the proposed program would be unmet.

Rotech suggests that CMS adopt the adjustment factor approach used during the demonstration projects for competitive bidding, which is discussed in the preamble of the proposed regulations.[52] This approach requires four steps. First, CMS calculates the average of the winning bids per individual items. Second, CMS calculates the average of the composite bids by taking the sum of the composite bids for all contract suppliers in the applicable CBA and dividing that number by the number of contract suppliers. Third, CMS determines an adjustment factor to bring every winner's overall bids for a product category up to the pivotal bidder's composite bid. Fourth, CMS would then take the average of the winning bids per item and multiply that amount by the adjustment factor to adjust all bids up to the point of the pivotal bid. In this way, winners would be paid by Medicare as much for the total product category as the pivotal bidder. More importantly, under this method suppliers receive their bid prices at a minimum.

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51 *See id.*

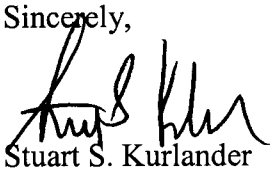
52 *See* 71 Fed. Reg. at 25,679-80.

Using an adjustment factor also guarantees payment rates to be sufficient, because suppliers, for the most part, would have submitted a bid price close to their margins. Ultimately, by using the adjustment factor approach, success of the competitive bidding program can be better assured.

Rotech thus recommends that CMS modify 42 C.F.R. § 414.416 to incorporate the adjustment factor methodology in lieu of the proposed median approach.

Thank you for your considerable efforts to date in implementing the program and for considering Rotech's comments regarding the proposed regulations. Should you have any questions or comments, we can be reached at (202) 637-2200.

Sincerely,



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File No. 026795-0004

June 30, 2006

BY HAND DELIVERY

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445—G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments Regarding CMS—1270—P: "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues"

Dear Administrator McClellan:

On behalf of our client, DJO Incorporated ("DJO" or the "Company"), we submit these comments on the above-referenced proposed regulations, which implement the Medicare Part B DMEPOS Competitive Bidding Program and revise the gap-filling payment methodology used to set fee schedule rates for new codes for DMEPOS items and services.[1] As the world's largest manufacturer of orthotics, as well as a large Medicare supplier of orthotic products and manufactured bone growth stimulators, DJO expects to continue its participation in the Medicare program after the launch of competitive bidding. For this reason, the Company appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services ("CMS") as to the impact of these proposals on the Company and the continued access to orthotics and the DME industries generally.

The competitive bidding program will radically change how Medicare pays for DMEPOS items used by beneficiaries in the home. Payment rates that previously were set based on fee schedule amounts will instead be determined by bid amounts submitted by DMEPOS suppliers for competitive bidding areas. The success of this program depends on the ability of suppliers to submit accurate bids for products (and on CMS's ability to evaluate them appropriately and fulsomely). Of paramount concern to DJO is CMS's ability to accurately and appropriately evaluate the bid submissions for orthotic products. With the vast number of orthotic products

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[1] 71 Fed. Reg. 25654 (May 1, 2006).

and the large number of HCPCS codes describing these products, there is tremendous variability in the industry as to which products belong in which codes. Without more clarity in this area, suppliers will have difficulty determining appropriate products and bids for each HCPCS code and, as a result, the bid submission process (as well as CMS's evaluation process) will be extremely difficult, if not impossible. The resulting competitive bid payment amounts are likely to be irrational. DJO asks CMS to avoid premature inclusion of orthotic products in the competitive bidding program until such time as a satisfactory resolution can been devised. In addition, DJO has serious concerns with the proposed expansion of the statutory definition of off-the-shelf ("OTS") orthotics—which are the only orthotic products that may be competitively bid. The agency should and must hew to the line already drawn by Congress regarding which products are to be included.

DJO's concerns with the proposed regulations cover a number of areas:[2]

- Criteria for Item Selection
- Submission of Bids Under the Competitive Bidding Program
- Conditions for Awarding Contracts
- Determining Single Payment Amounts for Individual Items
- Terms of Contract
- Physician Authorization/Treating Practitioner
- Payment Basis
- Gap-filling
- Administrative or Judicial Review

Summary of Comments

If CMS decides to move forward with competitive bidding for orthotic products, DJO recommends that the following measures be taken:

(1) ***Define OTS Orthotics As Required By the Medicare Statute:*** DJO strenuously disagrees with CMS's proposed definition of OTS orthotics for competitive bidding. The proposed interpretation would broaden impermissibly the statutory definition of OTS orthotics to include all orthotics that do not require assistance of a certified orthotist. This proposal is an impermissible departure from congressional language. Perhaps more critically, the proposal directly conflicts with the existing Federal definition of "qualified practitioners" who possess expertise to furnish certain orthotics to Medicare beneficiaries. This over-broad definition, therefore, must not be finalized. DJO seeks inclusion of the statutory definition in the regulation. The Company also urges CMS to consult with the orthotic industry to determine which HCPCS codes describe OTS orthotics and, of those, which should be included in the initial phase of the program.

(2) ***Ensure Participation of Suppliers With Sufficient Capacity Regardless of Physical***

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[2] These are the subject headings that CMS requested commenters use to flag issues for the agency. Each of these subjects is noted as a heading in bold language and bracketed immediately preceding the relevant discussion. Please note that some subjects are addressed multiple times in this comment letter.

Location in the Service Area: DJO strongly supports CMS's proposal to allow suppliers to participate even if they do not necessarily have a separate physical location in a competitive bidding area ("CBA"), provided that they (a) offer services in the geographic area and (b) have a demonstrated ability to do so. CMS appropriately recognizes that more meaningful indicia than physical location should be determinative of capacity to serve a particular CBA.

(3) ***Categorize Competitively Bid Products Using Existing SADMERC Policy Groups and Use Sub-Groupings for Bidding Purposes:*** Under CMS's proposal, bidding for products would be conducted based on groupings of products into "product categories" and a supplier would need to submit a separate bid for each HCPCS code within a given category. DJO believes that there is no need to "re-invent the wheel" and existing Statistical Analysis Durable Medical Equipment Regional Carrier ("SADMERC") policy groups should be considered. A few of the SADMERC policy groups for orthotics correspond to existing medical policies, with meaningful relationships among grouped codes, while others group codes according to the body part treated. Suppliers who specialize in serving beneficiaries with certain medical conditions (*e.g.*, patients who need a knee orthosis, but not a spinal orthosis) may continue to do so. If broader categories are used, suppliers with specialization for particular parts of the body will not be able to offer competitively bid items and services.

Even if CMS were to use the SADMERC policy groups for orthotics, it would be difficult, if not impossible, to provide a bid amount for each HCPCS code. Most suppliers are unlikely to have a product for each code. In addition, as mentioned above, there is considerable uncertainty as to the appropriate HCPCS code for individual products, and this will make it nearly impossible for suppliers to submit bids on a code-by-code basis. If CMS includes OTS orthotics in the initial phase of competitive bidding, DJO recommends sub-groupings for which a single bid amount could be offered. This recommended methodology is described in further detail below.

(4) ***Ensure the Integrity of Bid Evaluations by Requiring Uniform Financial Standards & Accreditation, Allowing for an Extended Grace Period for Orthotics Suppliers:*** CMS must take steps to safeguard the integrity of the bid evaluation process so that payment rates are realistic. Such steps should include publishing final quality and financial standards that must be met regardless of the size or type of organization. DJO applauds CMS for its recognition that, in the initial phase of competitive bidding, a grace period is needed so that suppliers can come into compliance with the quality standards. An extended grace period is particularly essential for industries such as orthotics in which accreditation is not currently the norm.

(5) ***Recognize That Suppliers Are Only Equipped to Provide Items From Their Own Inventories:*** DJO asks that CMS revise two of its proposals so that they address practical realities and limitations of the DMEPOS industry. First, proposed 42 C.F.R. § 414.422(c) places the onus for repairing and maintaining items previously furnished by non-contract suppliers on contract suppliers. This provision should not be adopted. In most instances suppliers are not equipped to handle such work for products not in their inventories. This is particularly the case for manufacturer/suppliers that typically only or predominantly sell the products they make. Second, proposed 42 C.F.R. § 414.420 would require contract suppliers to make a reasonable effort to furnish a particular brand

or mode of delivery of an item, as prescribed by the physician or treating practitioner. This provision should be revised so that contract suppliers do not need to offer the item if it is not in their inventory.

(6) ***Revise Change in Ownership Rules So That They Are Consistent With Existing Requirements For DMEPOS Suppliers:*** Proposed 42 C.F.R. § 414.422(d) would limit a contract supplier's ability to continue to participate in competitive bidding upon a change in ownership. Among other things, approvals are required. This provision should be revised to allow the supplier to continue to participate in the program, provided that the legal entity enrolled in the Medicare program does not change (*e.g.*, there has been only a change in stock or other equitable ownership). Furthermore, the timeframe for the notice requirement should conform to the existing regulation governing supplier notice of changes in ownership.

(7) ***Set Payment Amounts So That They Reasonably Reflect Actual Bids:*** CMS proposes to use the median of the winning bids (*i.e.*, those at or below the pivotal bid) to set the competitive bidding payment amount for each product. This may force contract suppliers either to furnish products at prices far below their submitted bids or to exit the Medicare program. DJO asks CMS to adopt a payment methodology for competitive bidding that does not artificially depress rates below the bid prices of a substantial number of the winning bidders. The Company asks that the methodology used in the competitive bidding demonstration projects, which was an alternative proposal discussed in the preamble to the proposed regulations, be adopted instead.

(8) ***Retain Competitive Bidding Payment Amounts Throughout A Bidding Cycle When Multiple HCPCS Codes Are Merged Into a Single Code:*** CMS proposes special payment rules to be used when HCPCS codes are revised in the middle of a competitive bidding cycle. DJO generally supports the proposed rules, with one exception. The Company believes that, where multiple codes describing similar products are combined into a single code, the prior codes and their competitive bid payment amounts should continue to be used until the end of the current contract. This would maintain stability in pricing for the products in the CBAs and not upset suppliers' expectations. The payment rates for a given product should not change in the midst of a contract.

(9) ***Refrain From Creating An "Any Willing Provider" Model If CMS Uses Competitive Bidding Rates to Adjust Payment Amounts in Non-competitive Bidding Areas:*** DJO asks that CMS proceed cautiously in implementing its authority beginning in 2009 to adjust payment in non-competitive bidding areas based on payment information determined under the competitive bidding program. This authority could result in a *de facto* "any willing provider" model, in which competitive bidding rates are used nationwide and any supplier that is able to provide services may do so (for reimbursement at those rates). Competitive bidding rates are set with the expectation of a significant increase in volume to offset lower prices. This will not exist in non-competitive bidding areas.

(10) ***Do Not Finalize the Proposed Rebate Program:*** DJO objects to CMS's proposal to allow suppliers to give rebates to beneficiaries for products provided through the competitive bidding program. This ill-advised proposal implicates and may run afoul of the Federal Anti-Kickback Statute and blurs the line between permissible and

impermissible rebates.

(11) ***Protect Existing Medicare Appeal Rights:*** Existing rights of beneficiaries and suppliers to appeal denied claims should not be affected by competitive bidding. DJO requests that proposed 42 C.F.R. § 414.424 be revised to clarify that the prohibition on appealing certain determinations made in the course of conducting the competitive bidding program in no way circumscribes or otherwise affects existing appeal rights.

(12) ***Revise the Proposed Gap-Filling Replacement to Follow Statutorily-Required Procedures & Ensure Fair Pricing:*** CMS's proposal in 42 C.F.R. § 414.210(g) to jettison the current gap-filling methodology for new DMEPOS items in favor of consideration of a variety of pricing data sources must not be adopted without significant revisions. As written, the proposed regulation is vague and impermissibly circumvents the procedural and substantive requirements to be used in any exercise of CMS's inherent reasonableness ("IR") authority. It is essential that any formula adopted here follow a transparent process for establishing reasonable, appropriate fee schedule rates for non-competitively bid products. DJO believes that this new regulation deserves considerable attention that it likely will not receive because it has been appended to the proposed regulations for competitive bidding. DJO therefore asks that CMS postpone publication of a final regulation on this topic to provide time for suppliers to submit additional comments and/or to meet with the agency to discuss alternatives.

Finally, as to appropriate 2007 and 2008 payment updates for Class III devices paid under the DMEPOS fee schedule, DJO asks that CMS consider the comments of the Electrical Bone Growth Stimulators ("EBGS") Coalition, which are provided under separate cover. These comments urge the agency to adopt a specific fee schedule payment update for Class III devices based upon factors unique to Class III devices, and to provide a full CPI-U payment update for both years.

I. DEFINE OTS ORTHOTICS AS REQUIRED BY THE MEDICARE STATUTE

[Criteria For Item Selection]

Under the Medicare statute, OTS orthotics are among the categories of DMEPOS products that may be competitively bid.[3] CMS proposes to broaden the statutory definition of OTS orthotics to include all orthotics that do not require assistance of a certified orthotist. This is an impermissible departure from the definition prescribed by Congress. Not only that, the proposed definition *directly conflicts* with an existing statutory payment provision that defines the types of practitioners who are qualified to furnish certain orthotics to Medicare beneficiaries. DJO strenuously objects to CMS's proposal to put in place a sweeping interpretation of the statutory definition of OTS orthotics. We submit that CMS may not adopt an interpretation that goes well beyond the statutory language and certainly may not do so in a manner that contradicts existing statutory requirements regarding practitioner qualifications. There are practical concerns with the proposed definition as well. Rather than bringing clarity to which orthotics are considered off-the-shelf, the proposal would inject an additional layer of uncertainty by tying the definition to an amorphous standard (*i.e.*, necessary involvement of a certified orthotist).

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[3] 42 U.S.C. § 1395w-3(a)(2)(C).

DJO asks rather that the statutory definition be imported into the regulation, as written, and that CMS work with industry stakeholders including the National Orthotics Manufacturers Assocation (NOMA) to determine which HCPCS codes describe OTS products (and, of those, which should be included in the initial phases of competitive bidding).

CMS May Not Contravene Existing Medicare Requirements Regarding Qualified Practitioners

The Medicare statute defines OTS orthotics as those that "require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual."[4] The proposed regulatory language at 42 C.F.R § 414.402 mirrors that language. Yet, CMS takes this definition multiple steps further in its discussions in the preamble. There, the agency states that the sole reference point for the definition is *whether needed adjustments would require the expertise of an orthotist.* CMS suggests that OTS orthotics are those that:

(1) can be adjusted by a beneficiary, caretaker, or orthotic supplier without the assistance of an orthotist certified by the American Board for Certification in Orthotics and Prosthetics, Inc. ("ABC") or the Board for Orthotist/Prosthetist Certification ("BOC"); and

(2) do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual, which, CMS states, are activities that can only be performed by certified orthotists.[5]

DJO contends that CMS must revise the proposal explained in the preamble because it is inconsistent with existing orthotics payment provisions in the Medicare statute. Indeed, the fact that the proposal is not included in the regulation itself raises questions about the extent to which the agency believes that the additional language is a permissible construction of the statute. It is problematic to hinge the definition of OTS orthotics on involvement of a certified orthotist because the Medicare statute already identifies a more expansive list of practitioners who are qualified to furnish certain custom-fabricated orthotic products to beneficiaries. Of note, this provision includes physicians and qualified physical and occupational therapists as qualified practitioners as well. CMS may not cherry-pick certain types of practitioners with expertise to provide orthotics fitting and adjustment services to beneficiaries. The move to exclude these practitioners is particularly troublesome given that the agency has not yet promulgated regulations to implement the existing statutory language (as was explicitly required by Congress).

By way of background, the Medicare statute contains special payment rules for certain custom-fabricated orthotics, which include a definition of "qualified practitioners" that possess

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4 *See* 42 U.S.C. § 1395w-3(a)(2)(C).

5 71 Fed. Reg. at 25669-70.

expertise to furnish such products to beneficiaries (the "BIPA provision").[6] Under the BIPA provision, Medicare payment for an item on a list of certain custom-fabricated orthotics is only to be made if it is (1) furnished by a qualified practitioner; and (2) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the HHS Secretary determines appropriate.[7] "Qualified practitioner" is defined to include physicians, qualified physical and occupational therapists, licensed orthotists (in states requiring orthotist licensure), and other individuals who are specially trained or educated in the area and certified by ABC, BOC or other approved credentialing programs (in states without orthotist licensure requirements).[8]

As mentioned above, the BIPA provision has yet to be implemented through regulation, as Congress required. However, the statute itself specifies the types of individuals that Congress believes possess the skills and experience needed to provide certain custom-fabricated orthotics to beneficiaries. This definition may not be ignored. A fundamental canon of statutory interpretation provides that "effect must be given, if possible, to every word, clause and sentence of a statute," and that "[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.[9] The BIPA provision clearly acknowledges that more classes of practitioners than only ABC- and BOC-certified orthotists possess expertise to trim, bend, mold, assemble, or customize certain orthotics to fit them to an individual. The list of products to which BIPA applies has yet to be determined, but the statute requires that it consist of a *sub-set of all custom-fabricated orthotics*, which means that it clearly excludes OTS orthotics. For CMS to include only ABC- and BOC-certified orthotists as practitioners with the expertise to fit non-OTS orthotics ignores the other practitioners that are congressionally-approved as having expertise to provide some custom-fabricated orthotics. CMS may not read the words "physician," "qualified physical therapist," and "qualified occupational therapist" out of the statute, and should not be circumventing implementation of the BIPA provision in this manner to begin with. Limiting the definition of OTS orthotics to those not requiring the expertise of an ABC- or BOC-certified orthotist directly contravenes Congress's definition of qualified practitioner and illogically treats their inclusion as

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6 42 U.S.C. § 1395m(h)(1)(F) (as added by Section 427 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA")).

7 The devices falling under the ambit of the special payment rules are to be identified by CMS in a published list and are defined as that subset of custom-fabricated orthotics that are "individually fabricated for the patient over a positive model of the patient."

8 42 U.S.C. § 1395m(h)(1)(F)(iii).

9 NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION, § 46:06, 181-86 (6th ed. 2000); *See also Washington Hosp. Center v. Bowen,* 795 F.2d 139 (D.C. Cir. 1986) (concluding that, in order to fulfill "our obligation to construe a statute so as 'to give effect, if possible, to every word Congress uses,'" it must strike down the Secretary's regulation requiring hospitals to wait until completion of the cost year before appealing prospective payment amounts to the Provider Reimbursement Review Board because the regulation ignored the provision of the Medicare statute permitting such appeals prior to filing a cost report).

surplusage. In short, borrowing or importing some, but not all, of the BIPA provision to define OTS orthotics is ill-advised and impermissible.[10]

CMS Is Bound By The Congressional Definition of OTS Orthotics

Not only does the proposed definition of OTS orthotics contravene the BIPA provision, but also it exceeds the congressional mandate as to which products are to be included in competitive bidding. Congress provided a specific and narrow definition of OTS orthotics that may be competitively bid. The language clearly limits OTS orthotics to those that do not require much, if any, adjustment in order to be used appropriately and that do not require fitting and adjustment expertise in order to be fit to the patient. CMS's proposed definition linking OTS orthotics to the work of a certified orthotist would dramatically *expand* the list of products that are considered OTS and that are subject to competitive bidding. Such an approach may also result in quality of care issues for Medicare beneficiaries. This is because products furnished through the competitive bidding process that require more than minimal self-adjustment may result in a poor fit, product ineffectiveness or even potential injury.

CMS may not implement the OTS definition in a manner that exceeds the congressional mandate, as would the proposal here. In the seminal case concerning agency interpretation of congressional language, the U.S. Supreme Court held that "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."[11] In effect, CMS's proposal discards the statutory definition, replacing the task-related criteria (*i.e.*, minimal self-adjustment for appropriate use and no expertise in trimming, bending, molding, assembling, or customizing to fit to the individual) with a wholly different benchmark for determining when a product ought to be included in competitive bidding: the need for a certified orthotist's involvement. This benchmark differs from and is inconsistent with the statutory criteria, as evidenced by the fact that it would result in a much more expansive list of orthotic products being competitively bid than Congress intended. Indeed, a CMS official[12] speaking at the May 2006 Program Advisory & Oversight Committee ("PAOC") meeting even acknowledged that this proposal goes *far beyond that* specified by Congress.

An elementary canon of statutory interpretation provides that words in statutes are to be accorded their "plain and obvious meaning" because "one must assume that the legislature knew

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10 We note that, through the BIPA provision, Congress intended only to *mandate* involvement of qualified practitioners for a small sub-set of custom-fabricated orthotics. What is important for this discussion of competitive bidding regulations, however, is that the BIPA provision recognizes that such practitioners *have the experience to adjust and fit non-OTS orthotics*. Thus, CMS may not define OTS products by reference only to certified orthotists.

11 *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-3 (1984); *see also* NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION, § 46:01, 121-22 (6th ed. 2000) (stating that "[t]here is no safer nor better settled canon of interpretation that that when language is clear and unambiguous it must be held to mean what it plainly expresses").

12 Joel Kaiser, who presented on this topic at the PAOC meeting, commented that this proposed definition goes beyond the definition in the Medicare statute.

the plain and ordinary meanings of the words it chose to include in the statute."[13] The OTS definition was heavily negotiated at the time that the MMA was enacted, and Congress chose carefully the language it used. If Congress had intended that CMS use a broader definition, or one that used the qualifications of individuals furnishing the products as a proxy, it surely would have done so. Indeed, Congress used orthotist certification as a limiting requirement in the BIPA provision, indicating that, when the legislature wants to use this indicator, it does so. CMS may not go far beyond the statutory language in determining orthotic products that may be competitively bid.

CMS's Proposed Benchmark Is Impracticable

In addition to concerns that the proposed definition of OTS orthotics is not a reasonable construction of the statutory language, there are practical concerns with the proposal. It all together fails to bring clarity to which orthotics are considered off-the-shelf. In fact, DJO believes that tying the definition to whether the involvement of a certified orthotist is needed muddies the waters as to which products would be included. There is no Federal definition of orthotists or their scope of practice. A limited number of states have orthotist licensure or certification laws and, among those that do, the scope of practice varies considerably. Thus, there is no resource—beyond anecdotal evidence through discussions with certified orthotists—that CMS could use to understand what the proposed definition actually means. Involvement of a certified orthotist is not a meaningful, clear benchmark; rather, it is an amorphous, highly contentious standard that will not provide CMS with clear direction as to the orthotic products that could be competitively bid.

For these reasons, DJO believes that the proposed interpretation of OTS should not and may not be finalized. DJO recommends that the regulation tracking closely to the statutory language be finalized as written, but that the gloss added in the preamble not be used. If, however, CMS does seek to enhance the definition, the agency must recognize all other practitioners with expertise to provide orthotic products who are currently recognized under Federal law. Under this alternate approach, any orthotic that requires the assistance of a qualified practitioner (as defined under the BIPA provision) would not be considered OTS.

As to the codes to be included, DJO suggests that CMS consult with stakeholders, including the National Orthotic Manufacturers Association ("NOMA"), to determine the appropriate OTS orthotics codes. NOMA would be pleased to provide a list of OTS orthotics codes to the agency for its consideration upon request.

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[13] NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION, § 46:01, 124 (6th ed. 2000).

II. ENSURE PARTICIPATION OF SUPPLIERS WITH SUFFICIENT CAPACITY REGARDLESS OF PHYSICAL LOCATION IN THE SERVICE AREA

[Submission of Bids Under the Competitive Bidding Program]

DJO believes that large capacity suppliers currently provide a significant volume of DMEPOS items to beneficiaries and asserts that, unless they are included in competitive bidding, there will be a shortage or total lack of certain competitively bid items in the CBAs. Many of these large suppliers operate through central headquarters, yet offer services nation-wide. DJO thus supports CMS's proposal not to require that bidding suppliers be physically located in the CBAs in which they submit bids.

As CMS recognizes, location is an imprecise measure as to whether a supplier would be willing and able to serve Medicare beneficiaries in a given CBA.[14] Further, CMS's proposal accords with longstanding Medicare supplier standards. Many large capacity suppliers, including DJO, use a centralized operation (at which billing, patient contact, complaint and other matters are addressed), with sales representatives operating in locations throughout the country. Often, based on a prescription, orthotic products are shipped from the manufacturing plant or headquarters of a supplier to a patient's home or to a physician's office, the location at which they are provided to the patient. Under this longstanding physician's office model, the supplier does not maintain physical locations in all 50 states, but still ably serves locations across the country.

Medicare has a longstanding policy of accommodating such organizational structures. The Medicare statute provides that all suppliers furnishing medical equipment and supplies to beneficiaries must obtain a supplier number, showing that they meet supplier standards. The statute calls for CMS to create a supplier standard requiring the supplier to "maintain a physical facility on an appropriate site."[15] Through Medicare Supplier Standard #7, CMS implements this requirement and recognizes that some suppliers will be operating in various geographic areas but that it can be organized using a centralized location.[16] In addition, DJO believes that centralized operations enable the Company to interact effectively and in a uniform manner with Medicare contractors and to provide consistent, high quality services to Medicare beneficiaries.

In short, physical location is an inappropriate gauge for supplier interest and ability to service a CBA. DJO supports the approach that CMS proposes to use, which combines review of the supplier's past business to beneficiaries in the CBA, with reference to the supplier's

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14 71 Fed. Reg. at 25672.

15 42 U.S.C. § 1395m(j).

16 *See* 42 C.F.R. § 424.57(c)(7). Supplier Standard #7 states that a supplier must certify that it: "Maintains a physical facility on an appropriate site. The physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communication records. For purposes of this standard, a post office box or commercial mailbox is not considered a physical facility. In the case of a multi-site supplier, records may be maintained at a centralized location."

detailed business plan for expansion.[17] These indicia will enable CMS to more accurately measure supplier capacity than would an imprecise focus on the supplier's physical location. CMS proposes to collect this information through draft Form B (Bidding Sheet)—the form that bidding suppliers would complete in submitting a bid for each product category in a CBA. On this form, CMS solicits data regarding the total revenue collected by the supplier, the total number of customers served in the CBA for the product category in the past year, and the percentages of those numbers attributable to Medicare. This form also asks bidding suppliers to describe their expansion plans for the CBA, if they plan to do so.[18] DJO believes that this approach is sound, accurate and should be finalized as written.

III. CATEGORIZE COMPETITIVELY BID PRODUCTS USING EXISTING SADMERC POLICY GROUPS AND USE SUB-GROUPINGS FOR BIDDING PURPOSES

[Submission of Bids Under the Competitive Bidding Program]

CMS proposes to conduct bidding for products grouped into "product categories," defined as groups of similar items used in the treatment of a related medical condition. Each group would be comprised of items defined by HCPCS codes. To bid on a product, a supplier would need to submit bids on the full spectrum of HCPCS codes contained in that product category, with a separate bid amount for each HCPCS code. CMS also proposes that the composition of the product categories may differ from one CBA to another, depending on whether the agency believes it will be able to realize savings for a particular product in a particular CBA.[19]

It makes sense for CMS to use the existing SADMERC policy groups as the product categories for competitive bidding, rather than inventing new and broader categories. Some of the SADMERC policy groups for orthotics classify HCPCS codes according to the medical policy to which they belong, making them rational groupings from a clinical perspective. Other policy groups for orthotics reflect different areas of the body for which the products may be used. These groupings provide ready categories, with sound clinical bases and with which both CMS and suppliers are familiar, for use in competitive bidding.

Even if the SADMERC policy groups are used, DJO believes that it will be incredibly difficult from a practical perspective to implement competitive bidding for OTS orthotic products unless the categories are narrowly described. There are a significant number of HCPCS codes and considerable variation in the industry as to how the codes are interpreted. In addition, most suppliers are unlikely to have a product for each code. DJO is among the largest, if not the largest, suppliers of orthotic products in the U.S., and the Company believes that it might not have a product that fits into each code in a policy group. DJO therefore suggests that CMS not implement competitive bidding for orthotic products without also providing clarification of the

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17 71 Fed. Reg. at 25676.

18 *See* http://www.cms.hhs.gov/PaperworkReductionActof1995/PRAL/itemdetail.asp?filterType=none&filterbyDID=-99&sortByDID=2&sortOrder=descending&itemID=CMS063052.

19 71 Fed. Reg. at 25672-73.

products to be bid under the codes selected. Unless this first step is undertaken, there would be such drastic variability in the bidding that the entire process would be tainted.

DJO also recommends that each OTS product category be further divided into sub-groupings. These sub-categories, or sub-groupings, could represent families of similar codes that would be reflective of the multiple functionalities of the various products, as well as the multitude of coding, coverage and reimbursement complexities necessary to support providing products to beneficiaries in the CBA. For instance, a select, small number of knee brace codes with products that perform the same clinical function could be grouped together. Rather than submitting a separate bid for each HCPCS code within a product category, the supplier would offer a single bid amount for the sub-grouping. Without such a mechanism, DJO is concerned that most suppliers, even large capacity suppliers that operate on a national basis, might be precluded from bidding.

To effect these changes, DJO asks that the applicable proposed regulations be revised as follows:

- 42 C.F.R. § 414.412 should be revised so that subsection (c) reads (with proposed language in italics): "Product categories include items that are used to treat a related medical condition. The list of product categories, and the items included in each product category that is included in a particular competitive bidding program, are identified in the request for bids for that competitive bidding program *and will correspond to the policy groups of the Statistical Analysis Durable Medical Equipment Regional Carrier, unless CMS determines that there is good cause to align items differently for a particular competitive bidding program*."

- 42 C.F.R. § 414.412 should be revised so that subsection (d) reads: "Suppliers must submit a separate bid for every item included in each product category that they are seeking to furnish under a competitive bidding program, *unless CMS permits a bid for a sub-category for bidding purposes.*"

IV. ENSURE THE INTEGRITY OF BID EVALUATIONS BY REQUIRING UNIFORM FINANCIAL STANDARDS & ACCREDITATION, ALLOWING FOR AN EXTENDED GRACE PERIOD FOR ORTHOTICS SUPPLIERS

[Conditions For Awarding Contracts]

CMS must take steps to safeguard the integrity of the bid evaluation process so that payment rates are realistic. DJO strongly supports CMS's proposal to require suppliers to meet quality and financial standards in order to be awarded bids. This should include the requirements that suppliers be subject to a uniform set of financial standards, regardless of the size or type of organization, and that they meet quality standards and be accredited in order to participate in the program.

For bid evaluation, CMS proposes a three-step process: (1) establish a single composite bid for each supplier for a particular product category; (2) array these composite bids from lowest to highest; and (3) select a pivotal bid (based on estimated beneficiary demand), with winning bidders being those at or below the pivotal bid.[20] In addition, under proposed 42 C.F.R. 414.414, CMS would require that each supplier meet basic eligibility requirements (such as complying with existing Medicare supplier standards), comply with DMEPOS quality standards and be accredited by a CMS-approved accrediting organization, and meet applicable financial standards. CMS does not clarify at what point in the bid evaluation process it would confirm that such standards have been met.

DJO notes that, as a practical matter, for this initial phase of competitive bidding, a large number of suppliers may be in the process of obtaining accreditation and coming into compliance with the quality standards. To address the initial phase, therefore, CMS proposes to allow a grace period for compliance with the quality standards.[21] DJO applauds CMS's recognition that a grace period is needed to assist many suppliers in becoming accredited, particularly given that the finalized standards have not yet been released. An extended grace period should be afforded to suppliers in industries like orthotics in which accreditation is not currently the norm. Suppliers in such industries lack experience with accreditation, and it will take additional time for them to become accredited. DJO strongly urges CMS to provide an extended grace period for orthotics suppliers.

V. RECOGNIZE THAT SUPPLIERS ARE ONLY EQUIPPED TO PROVIDE ITEMS FROM THEIR OWN INVENTORIES

[Terms of Contract; Physician Authorization/Treating Practitioner]

DJO asks that CMS revise two of its proposals so that they address practical realities and limitations of the DMEPOS industry. Without the below-discussed changes to the proposed regulations, suppliers may face difficulties operating in a manner that makes good business sense and could be disincentivized from participating in the program. If existing large-capacity suppliers exit the Medicare program, this, of course, would have a devastating impact on beneficiaries' ability to obtain needed items and would jeopardize the success of competitive bidding.

Responsibility for Repairs/Maintenance of Items Furnished By Non-Contract Suppliers

CMS proposes to oblige contract suppliers to bear responsibility for repairs and maintenance of items that were previously furnished by non-contract suppliers. In many, if not most, instances, suppliers have no experience in repairing or performing maintenance on items that were supplied by other suppliers and would not be able to perform such work themselves.

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20 *See* 71 Fed. Reg. at 25674-75.

21 *See* 71 Fed. Reg. at 25675.

Contract suppliers would, in effect, be forced to pay for a sub-contractor to perform the service—a result that would impose significant costs on winning suppliers. It is difficult to determine what these costs will be in advance of bid submission and, as a result, short of CMS providing the information as part of the Requests for Bids, there is no way for suppliers to weigh this cost in determining bid prices. Even if CMS is able to offer this information prior to bid submission, the proposal is particularly onerous for manufacturer-suppliers that only carry and sell their own products. Thus, DJO asks that CMS continue to pay for repair and maintenance of DMEPOS items performed by non-contract suppliers, as has been the agency's practice in the past. There is no reason to shift this burden to another supplier, particularly one who is likely to be unequipped to perform the services itself.

DJO suggests that 42 C.F.R. § 414.422(c) be revised to add a new subsection (3) which states: "*Contract suppliers that are FDA-approved manufacturers and that only furnish their own products to beneficiaries in the competitive bidding area are exempt from the requirement in paragraph (1) for purposes of items furnished by other suppliers*."

Physician Authorization of Product Brand

DJO believes that revision is also warranted for proposed 42 C.F.R. § 414.420 to acknowledge business considerations for manufacturer/suppliers. Under this provision, contract suppliers would be required to make a reasonable effort to furnish a physician-specified brand (or mode of delivery). CMS notes that physicians and other treating practitioners could prescribe a particular product brand if they determine that it would avoid an adverse medical outcome for the beneficiary. If a treating practitioner specifies a particular product under these circumstances, the contract supplier would be required to "make a reasonable effort to furnish the particular brand." If the supplier is unable to furnish the designated product, it would need to work with the practitioner to find an alternate item that is appropriate and obtain a revised order.[22]

Manufacturer/suppliers maintain inventories that contain predominantly their own products and could have difficulty furnishing a brand other than their own. DJO believes that the regulation should be revised to make clear that the contract supplier need not be able to offer the item if it is not part of its inventory. This could be accomplished by adding a new subsection (b)(4) to 414.420, stating: "*The contract supplier is not required to furnish the particular brand or mode of delivery itself if such brand or mode of delivery is not in its inventory in order to be deemed to have made a reasonable effort under this paragraph (b)*."

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22 *See* 71 Fed. Reg. at 25684.

VI. REVISE CHANGE IN OWNERSHIP RULES SO THAT THEY ARE CONSISTENT WITH EXISTING REQUIREMENTS FOR DMEPOS SUPPLIERS

[Terms of Contract]

Proposed 42 C.F.R. § 414.422(d) would limit a contract supplier's ability to continue to participate in competitive bidding upon a change in ownership of its business. CMS proposes to require contract suppliers to notify CMS in writing 60 days prior to any changes of ownership, mergers or acquisitions being finalized. CMS would only allow the successor entity to continue to furnish products in the competitive bidding area if (1) there is a need for the successor entity to function as a contractor in order to assure expected demand for a competitively bid item; (2) the successor entity meets all requirements applicable to contract suppliers; (3) the successor entity assumes the contract supplier's contract, including all obligations and liabilities; and (4) the successor entity executes a novation agreement.

This proposal is over-broad and would needlessly penalize business arrangements that may have no impact on the contract supplier's relationship with CMS. Furthermore, it would devalue contract suppliers' businesses. Existing standards—including the Medicare supplier standards and the forthcoming quality standards—already provide sufficient assurances to ensure that high quality services are provided to beneficiaries. This proposed notice requirement would not add to these assurances in any meaningful way.

DJO believes that the proposed regulation should be modified to clarify that the notification obligation and the limitations on continuing as a contract supplier apply only where the contract is being transferred to a new or different legal entity. The test would be the same as currently used to determine whether a new supplier enrollment application is needed under the instructions for Form CMS-855S. In those circumstances in which the legal identity of the contract supplier is not altered, by way of example, there may be no need to obtain the prior approvals. In contrast, where the legal identity of the acquired contract supplier would occur as a result of the change in ownership, CMS may want assurances that the new supplier will be able to meet all obligations of the former supplier and will assume all of its liabilities under the existing contract.

CMS could also borrow (as it has in the past) from the definition of "change of ownership" in the provider context under 42 C.F.R. § 489.18(a). With respect to corporations, by way of example, this regulation provides that:

> The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.[23]

DJO thus suggests adopting this definition in the proposed regulation. This would notify

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[23] 42 C.F.R. § 489.18(a)(3).

contract suppliers of the types of transactions that would trigger the completion of a new Form CMS-855S, as well as the change that would trigger the examination by CMS that a contract supplier can continue to meet the obligations under the existing contract.

In addition, DJO believes that there is no reason to depart from the existing 30-day post-change timeframe provided for suppliers to alert CMS as to changes of information, ownership or control. The current regulations do not require notice to CMS until *after the change has occurred*, and there is no reason why prior notice would be needed in this context. CMS recently re-affirmed this approach in newly finalized supplier enrollment regulations. Under 42 C.F.R. § 424.530, DMEPOS suppliers are required to report changes of information and changes of ownership or control within 30 days of their occurrence.

DJO thus suggests the following revisions to 414.422(d)(1): "A contract supplier must notify CMS in writing *within 30 days of* any change of ownership *(as such term is defined in section 489.18(a)) that would trigger completion of an entire new Form CMS-855S*."

VII. SET PAYMENT AMOUNTS SO THAT THEY REASONABLY REFLECT ACTUAL BIDS

[Determining Single Payment Amounts for Individual Items]

CMS's proposed methodology for setting competitive bidding payment amounts may not reasonably reflect actual bid amounts. Under proposed 42 C.F.R. § 414.416, CMS would use the median of winning suppliers' bids as the payment amount. This approach will by its nature result in a rate that is lower than the bid prices of half of the winning bidders. Many suppliers, including DJO, fear that they will not be able to continue to provide products to beneficiaries in the CBAs if the established rates are far below their bid prices. In order to raise the chances that they will be selected to participate in competitive bidding, suppliers are likely to submit bids at or near their margins. Thus, if CMS sets the payment rates at the median of winning bidders' bid prices, up to half of the winning bidders may consider these rates unacceptable and may not be able to continue to provide products to beneficiaries in those areas.

There are alternative approaches open to CMS that would lead to reasonable payment rates. These include the adjustment factor approach that was used in the demonstration projects, which is discussed in the preamble to the proposed regulations.[24] DJO urges CMS to adopt a methodology that ensures that contract suppliers are not being reimbursed at payment rates below their bid amounts on an overall basis. Contract suppliers should receive payment amounts that are at least as much as their bid prices. Suppliers may be less likely to leave the Medicare program if there is some assurance that payment rates will be sufficient.[25] DJO thus recommends that the median approach not be finalized and that an alternative approach resulting in reasonable payment rates be adopted.

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24 *See* 71 Fed. Reg. at 25679-80.

25 DJO also suggests that CMS consider re-competing a product category in a CBA if a contract supplier with significant capacity exits the program mid-cycle.

VIII. RETAIN COMPETITIVE BIDDING PAYMENT AMOUNTS THROUGHOUT BIDDING CYCLE WHEN MULTIPLE HCPCS CODES ARE MERGED INTO A SINGLE CODE

[Gap-filling]

CMS proposes special payment rules in 42 C.F.R. § 414.426 for competitively bid HCPCS codes that are revised in the middle of a competitive bidding cycle. The Company believes that, for the most part, these proposed rules strike the right balance. However, revision is needed for the proposal addressing the situation in which multiple codes describing similar products are combined into a single code. DJO asks that, in such situations, CMS maintain the status quo for until the contract ends to avoid significant decreases in payment rates that would upset suppliers' expectations as to the amounts they will receive for furnishing items to beneficiaries in the CBAs.

CMS proposes to calculate rates differently based on the nature of the coding change, so that:

(1) If a single code is split into multiple codes, the supplier would be paid the payment amount for the former code.[26] Therefore, the split into new codes would not impact payment. During the subsequent bidding cycle, suppliers would bid on the new separate and distinct codes.

(2) For codes for several components that are merged into a single new code, the payment policy would differ depending on whether the former codes described (a) components of a single product or (b) multiple products. If the former codes described components of a single product (scenario (a)), the supplier would be paid a rate equal to the total of the payment amounts under the former codes. If the former codes described multiple products (scenario (b)), the new payment amount would be the average (arithmetic mean) of the former payment amounts weighted by the frequency of payments for the former separate codes. For each of the two scenarios, during the subsequent bidding cycle, suppliers will bid on the new single code.[27]

DJO asks CMS not to finalize scenario (b) in the second point above. This formula could result in significantly different pricing for a product or products in the middle of a bidding cycle. Using the new code would up-end suppliers' expectations as to the payment that they would receive for furnishing products to beneficiaries in the CBA. It could also result in unfair payment changes mid-cycle that would be a disincentive to supplier participation. More significantly, adopting this proposal could cause contract suppliers to exit the program mid-cycle—which, in turn, could result in product supply issues for beneficiaries in the CBAs. If

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26 This applies both to the circumstance in which the former code was for a single product and is split into codes for its components and that in which the former code was for two or more similar products and is split up.

27 *See* 71 Fed. Reg. at 25688-89.

CMS decides to adopt this proposal despite these concerns, the agency should clarify how the weighting would occur (for instance, whether CMS would review payments for all suppliers in all jurisdictions or only contract suppliers in CBAs).

DJO thus suggests that, where multiple codes for similar items are merged to a single new code, CMS continue to use the former codes and payment rates for the remainder of the bidding cycle. The proposal in 42 C.F.R. § 414.426(d) would need to be revised as follows: "If multiple codes for similar items are merged into a single code, *the codes that were competitively bid and the established payment amounts for those codes, with any adjustments provided under § 414.408(b), will remain in effect for the remainder of the competitive bidding program*."

IX. REFRAIN FROM CREATING AN "ANY WILLING PROVIDER" MODEL IF CMS USES COMPETITIVE BIDDING RATES TO ADJUST PAYMENT AMOUNTS IN NON-COMPETITIVE BIDDING AREAS

[Payment Basis]

In 2009 or subsequent years, CMS proposes to use its statutory authority to adjust payment in other areas based on payment information determined under the competitive bidding program. CMS should implement this authority carefully. DJO asks that CMS provide industry stakeholders another opportunity to comment on how to implement this provision at a later date once CMS develops a particular proposal.

DJO fears that CMS may use this authority in a manner that would move the Part B DMEPOS benefit toward a *de facto* "any willing provider" model in which competitive bidding rates are used nationwide and any supplier that is able to provide services may do so (for reimbursement at those rates). Congress did not intend for competitive bidding to result in such a model. Because competitive bidding rates will be based on bid amounts that are calculated using an assumed increase in volume, suppliers' expectations are different than for non-competitive biding areas. The expectation is that there will be few suppliers in each CBA for competitively bid products and, accordingly, that the winning suppliers can offer lower prices because these prices will be offset by the higher volume of products they will furnish. In non-competitive bidding areas, this increase in volume would not necessarily exist to balance out decline in payment rates. Thus, competitive bidding payment rates do not translate to other areas and should not be applied there. DJO asks CMS to take this into account if it uses competitive bidding rates to set fee schedule amounts.

X. DO NOT FINALIZE THE PROPOSED REBATE PROGRAM

[Determining Single Payment Amounts For Individual Items]

CMS proposes to permit contract suppliers that submitted bids for an item below the competitive bidding payment amount to provide voluntary rebates to beneficiaries. This rebate would be the difference between the supplier's bid amount and the competitive bidding payment amount for the product. As was evident based on the many PAOC committee members and industry representatives who objected to this proposal at the PAOC meeting, the industry is vehemently opposed to this proposal. DJO shares their concerns that this proposal implicates and may violate the Federal Anti-Kickback Statute (the "AKS") and, for that reason, strongly

urges that proposed 42 C.F.R. § 414.416(c), which describes the rebate program, not be finalized.

The AKS is a criminal prohibition that provides punishment for any person who "knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person ... to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program."[28] Rebates intended to induce beneficiaries to purchase a particular Medicare-covered item are generally prohibited under the AKS. DJO is concerned that adoption of the rebate program would generate significant confusion in the industry as to what is permissible under the AKS and what continues to be prohibited. DJO asks that the proposed regulation be deleted.

XI. PROTECT EXISTING APPEAL RIGHTS

[Administrative or Judicial Review]

Under proposed 42 C.F.R. § 414.424, CMS prohibits appeals on most decisions made regarding competitive bidding, in line with the relevant statutory provision. For instance, decisions as to which suppliers are awarded contracts, the payment amounts established, and selection of items to be competitively bid are all not appealable.[29] DJO is concerned, however, that, as written, the proposed regulation does not make clear that existing rights of beneficiaries and suppliers to appeal denied claims are preserved.

In the preamble to the proposed regulations, CMS acknowledges that existing rights are undisturbed by competitive bidding. DJO requests that this be explicitly stated in the regulation itself so that appeal rights are safeguarded. This could be accomplished by adding the following subsection (c) to 414.424: "*All existing rights to appeal individual claims are unaffected by this provision.*" DJO also believes that the statement in the regulation that "[a] denied claim is not appealable if CMS determines that a competitively bid item was furnished in a competitive bidding area in a manner not authorized by this subpart" is vague as written and could benefit from clarification (or should be removed).

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28 42 U.S.C. § 1320a-7b(b)(2).

29 71 Fed. Reg. at 25682.

XII. REVISE THE PROPOSED GAP-FILLING METHODOLOGY REPLACEMENT TO FOLLOW STATUTORILY-REQUIRED PROCEDURES & ENSURE FAIR PRICING

[Gap-filling]

[Gap-filling]

DJO applauds CMS for its recognition of the inherent flaws in the current gap-filling methodology and the agency's decision to replace the current formula with a new methodology that reflects the true prices for new technology. Portions of the proposal in 42 C.F.R. § 414.210(g), however, are so vague as to be unworkable. In addition, the effort to use a functional technology assessment without any procedural safeguards impermissibly circumvents CMS's IR authority. This is particularly troubling given that the IR regulations only recently became final and already are being treated as obsolete. It is essential that any formula adopted here be grounded in both substantive and procedural safeguards and follow a transparent process for establishing reasonable, appropriate fee schedule rates for non-competitively bid products.

At the outset, DJO notes that many in the industry have urged CMS to devote considerable attention to this new regulation and specifically have requested that it be considered separate and apart from the proposed regulations for competitive bidding. DJO reiterates this request here, and asks that CMS postpone publication of a final rule to provide time for suppliers to submit additional comments and/or meet with the agency to discuss alternatives. The additional time is needed to give due consideration in separate comments. By including the proposal in the context of the competitive bidding rulemaking—a rule that CMS officials have publicly recognized is only tangentially related to gap-filling—CMS has created needless timing conflicts. Given the resources that need to be expended to comment fully on the competitive bidding rule, suppliers (and CMS, for that matter, since the same individuals are responsible for both competitive bidding and gap-filling) are being pressed to stretch those limited resources. Both rules are simply too important to risk presentation of rushed comments (and/or rushed review of those comments). DJO, therefore, requests an additional period of 60 days to comment on the gap-filling methodology.

In the absence of additional time, and to meet the current time line, DJO submits the following comments concerning the proposal.

Substantive Criteria

Under the gap-filling proposal, where a new HCPCS code is created and no price information is available from the base period, the fee schedule amount for the code would be calculated by taking into account one or more of the following three data sources: (1) median retail prices (from supplier price lists, manufacturer suggested retail prices, or wholesale prices, plus an appropriate mark-up), (2) existing fee schedule amounts for comparable codes, and/or (3) results of a functional technology assessment ("FTA") of products in the new code. DJO supports the move away from the current gap-filling methodology because it relies on deflation

factors that often result in drastic under-compensation for new products.[30] DJO believes, however, that the proposed criteria lack specificity sufficient to inform stakeholders as to the formula to be used.

A lack of specificity without proper safeguards offers the public inadequate notice of how the formula would be used. Two examples are illustrative: First, the proposal suggests that pricing for comparable codes could be used as a proxy for the rates applicable for the new code. How would CMS determine which codes are "comparable"? Would significant functional and clinical differences in the products categorized in these codes be considered? How would CMS account for and quantify these differences?

Second, CMS proposes to use median retail prices to set pricing. How will CMS identify retail prices and how will the agency weight the prices? Regardless of the source for the prices, DJO suggests that CMS use a *weighted median* so that pricing by outlier suppliers that do not provide a significant volume of items to the Medicare program is not given undue importance in setting pricing.

As to the FTA, the notice states that there were three main areas studied in the FTA conducted in CMS's pilot study: (1) Functional Assessment, which evaluated the device's operations, safety and user documentation relative to the Medicare population; (2) Price Comparison Analysis, which involved a cost analysis comparing the product to similar products or alternative treatment modalities; and (3) Medical Benefit Assessment, which focused on the effectiveness of the product using scientific literature and interviews of providers to determine if the product does what it purports to do. Not only is this vague explanation insufficient information for meaningful comments, the FTA analysis oversteps congressional mandates on when the agency can adjust fee schedule amounts and identify alternative "realistic and equitable" amounts. It is improper for CMS to cast aside Congress's grant of IR authority. Further, CMS should not resort to incorporating a coverage analysis to establish pricing. Here, as well, Congress has proscribed how to evaluate coverage. Simply, CMS cannot exercise powers that contradict Congress's specific language in specific statutory grants of authority.[31]

Pricing should be established using objective criteria that can be applied to all products in the same way. A transparent formula, capable of being reproduced for all products must be used. One approach might be to develop an algorithm with a sequential analysis. The FTA should be discarded all together as inappropriate and already addressed through CMS's IR authority.

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30 Gap-filling uses current pricing information, which is then deflated back to a base period to be in line with statutory payment methodology for DME and then inflated based on statutorily-prescribed update factors. CMS has traditionally used the percentage increase in the CPI-U to deflate current pricing—which can be an inappropriate deflationary factor if it is not in line with price increases (or lack thereof) over time in the industry.

31 *See, e.g., Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-3 (1984) (holding that "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress"); *see also United States v. Haggar Apparel Co.*, 526 U.S. 380, 393 (1999) (confirming that "rules as to instances not covered by the statute should be parallel, to the extent possible, with the specific cases Congress did address").

Procedural Requirements

In addition to the substantive revisions that are needed, CMS's proposal to use an FTA also suffers from a complete lack of procedural safeguards to ensure that appropriate pricing results. Even though this proposal seeks to achieve the results of a coverage a coverage and IR analysis, it fails completely to offer any of the procedural safeguards of these latter processes. Particularly where, as here, CMS is moving away from its current objective gap-filling methodology to a vague, subjective set of criteria, procedural safeguards are even more critically needed.

As CMS describes in the preamble to the proposed regulations, the two FTAs that have previously been undertaken in its pilot study (the results of which have not been shared with stakeholders) involved evaluation of the device's safety and effectiveness in improving clinical outcomes. Both of these elements are considered in determining whether an item meets the Medicare statute's "reasonable and necessary" standard and will be covered under the Medicare program.[32] It is significant that over the years the coverage process has become more open. To that end, Congress recently mandated that CMS follow a defined process for making NCDs, including providing an opportunity to appeal the decisions.[33] There is now a fulsome appeals process available for aggrieved parties who believe an NCD provision is unreasonable.[34] Similar processes are available for challenges to local coverage determinations.[35] CMS must not and may not circumvent these procedural requirements by folding a coverage decision into the payment calculation process.

Perhaps most importantly, payment adjustments like those being proposed here are *statutorily required to undergo a notice and comment process* as well. Under the IR provisions, CMS must analyze a variety of factors and adjust pricing for an item or service upon a determination that the otherwise applicable payment amount is grossly excessive or grossly deficient, which is defined by its own regulations to include a threshold variance of fifteen

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32 42 U.S.C. § 1395y(a)(1)(A); *see also* Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapt. 15, § 110.1 (stating that the necessity of equipment is determined based on "when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member" and that reasonableness is determined based on considerations such as whether the expense of the equipment would not be clearly disproportionate to the therapeutic benefits that could ordinarily be derived from it).

33 Congress revised the Medicare statute to require CMS to issue a proposed decision on a request for an NCD within 6 months of the request for coverage (9 months for requests that require outside technology assessments or Medicare Coverage Advisory Committee deliberation). There is to be a 30-day public comment period from the date of release of the proposed decision and CMS is required to publish a final decision (including responses to comments received) within 60 days of the conclusion of this comment period. *See* 42 U.S.C. § 1395y(l).

34 NCDs can be reviewed by the HHS Departmental Appeals Board ("DAB"). To determine whether the NCD was reasonable, the DAB will review the record, may permit discovery and taking of evidence if it is lacking information, and may consult with scientific and clinical experts. *See* 42 USC § 1395ff(f)(1).

35 *See* Medicare Program Integrity Manual (CMS Pub. 100-08), Chapt. 13, § 13.13.

percent.[36] Once CMS has determined that a payment amount is grossly excessive or deficient, it may establish a payment amount only by considering certain factors, including pricing information and the resources required to produce the products. There is no reason to use an FTA when the robust IR authority exists. Significantly, CMS may not use its IR authority without first following the required procedural steps:

- For payment adjustments of 15%, CMS must provide notice and opportunity to comment by publishing the proposed and finalized payment adjustment in the Federal Register.

- For payment adjustments of greater than 15% in a single year, more rigorous reviews and procedures are to be undertaken. As to the procedures, CMS must consult with supplier representatives from the industry likely to be affected by the payment change. Notice of the proposed determination must also be published in the Federal Register, with a 60-day public comment period. The Federal Register Notice with the proposed determination must contain an explanation of the factors and data considered in determining that the payment amount is grossly excessive or deficient, list the proposed payment amount, and describe the factors and data used to set this adjusted rate. CMS is to consider any comments submitted prior to publication of a final determination, and discussion responsive to these comments is to be included in the Federal Register Notice announcing the finalized payment determination.[37]

Here, CMS would give itself authority to use the results of an FTA *at any time* to adjust previously-established prices and without identifying any standards. The agency would need only to determine that the pricing methods that were used resulted in payment amounts that do not reflect the cost of furnishing the product. This aspect of the regulation directly conflicts with and circumvents CMS's IR authority, and DJO strongly opposes finalization of this proposal. FTAs should not be used to determine pricing.

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36 IR authority is implicated only where the overall payment adjustment needed to produce a realistic and equitable payment amount is 15% or more. CMS can make an adjustment of less than 15% in a given year under its IR authority, provided that it has been determined that an overall adjustment of 15% or more is warranted. *See* 42 C.F.R. § 405.502(g); 70 Fed. Reg. 73623, 73626 (Dec. 13, 2005).

37 42 USC § 1395u(b)(8)-(9); 42 C.F.R. § 405.502(g)-(h).

Thank you for your considerable efforts to date in implementing the program and for considering DJO's comments regarding the proposed regulations. Should you have any questions or comments, we can be reached at (202) 637-2200.

Truly yours,

Stuart S. Kurlander
Esther R. Scherb
Of LATHAM & WATKINS LLP

Cc: DJO Corporation
Rebecca L. Spain, Latham & Watkins LLP

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DACC

Diabetes Access to Care Coalition

June 29, 2006

Centers for Medicare and Medicaid Services
Attention: CMS-1270-P
Mail Stop: C4-261-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Proposed Rule on Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues (Docket Number CMS-1270-P)

Dear Dr. McClellan:

The Diabetes Access to Care Coalition ("DACC")[1] respectfully submits these comments to the Centers for Medicare and Medicaid Services' ("CMS") regarding the Proposed Rule on *Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues* published on May 1, 2006 (71 Fed. Reg. 25654 (May 1, 2006)) (the "Proposed Rule").

The DACC includes the leading manufacturers of blood glucose monitoring systems distributed in the United States.[2] Thus, we offer our comments with a special focus on the needs of people with diabetes. We recognize that Congress intended the competitive bidding program to provide additional cost-savings for the Medicare program – and we support that goal. However, we also believe that Congress did not intend for the competitive bidding process to create barriers to access for blood glucose monitoring systems, thereby threatening the ability of people with diabetes to self monitor, which is so critical in diabetes disease management. We are committed to working closely with CMS on this important program.

We offer these comments on both broad and specific issues raised in the Proposed Rule. First, as context for our comments, we provide some background information supporting our position that the Medicare beneficiaries who use blood glucose monitoring systems are a unique

[1] Please note that DACC is distinct from a similarly named coalition, the Diabetes Care Coalition.
[2] Members of DACC are Abbott; Bayer HealthCare; BD (Becton, Dickinson and Company); LifeScan, Inc.; and Roche Diagnostics.

population. They merit special consideration with respect to the impact that competitive bidding of these systems will have on their health because of the potential reductions in access to care and choice they could suffer. Second, we offer our general comments, and in particular we urge CMS to further study the impact that competitive bidding of blood glucose monitors and related supplies will have on these beneficiaries before deciding whether to subject these products to a competitive bidding program. Third, we comment on specific provisions of the Proposed Rule.

I. Introduction

Diabetes – A Significant and Growing Concern

Diabetes is a significant and growing health and financial concern facing older Americans and the Medicare program. According to the Centers for Disease Control ("CDC"), based on 2002 data 10.3 million people or 20.9% of persons 60 years or older have diabetes.[3] From 1996 through 2004, the incidence of diagnosed diabetes increased 55% among persons aged 65-74 years (from 11.7 to 18.1 per 100 population).[4] Additionally, approximately 40 percent of U.S. adults ages 40 to 74 – or 41 million people – currently have "pre-diabetes," a condition that raises a person's risk of developing type 2 diabetes, heart disease, and stroke.[5] Furthermore:

- Diabetes was the sixth leading cause of death listed on U.S. death certificates in 2000.[6]
- Adults with diabetes have heart disease death rates and risk for stroke about 200 to 400 percent higher than adults without diabetes.[7]
- Diabetes is the leading cause of end-stage renal disease, accounting for 44 percent of new cases. In 2001, a total of 142,963 people with end-stage renal disease due to diabetes were living on chronic dialysis or with a kidney transplant.[8]
- Diabetes is the leading cause of new cases of blindness among adults aged 20-74 years. Diabetes retinopathy causes 12,000 to 24,000 new cases of blindness each year.[9]
- About 60% to 70% of people with diabetes have mild to severe forms of nervous system damage. Severe forms of diabetes nerve disease are a major contributing cause of lower-extremity amputations. More than 60% of non-traumatic lower-limb amputations occur among people with diabetes.[10]

In sum, diabetes exists in epidemic proportions in the United States and has profound effects on overall patient health.

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[3] Centers for Disease Control, National Diabetes Fact Sheet (2005), *available at* http://www.cms.hhs.gov/SpecialNeedsPlans/Downloads/finalSNPfactsheetsum2-14-06.pdf.

[4] Centers for Disease Control, National Diabetes Surveillance System, Prevalence of Diabetes, http://www.cdc.gov/diabetes/statistics/prev/national/tablebyage.htm

[5] News Release Department of Health and Human Services, Revised Definition Means Millions More Have Pre-Diabetes (April 29, 2004), *available at* http://www.hhs.gov/news/press/2004pres/20040429.html.

[6] National Diabetes Fact Sheet, *supra* note 3.

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *Id.*

Value of Self-Monitoring and Compliance

Researchers have consistently shown the value of tight glycemic control in mitigating complications arising from diabetes.[11] Improved glycemic control benefits patients with either type 1 or type 2 diabetes.[12] Generally, for example, for every 1% reduction in the results of A1c blood tests (e.g., from 8.0% to 7.0%), the risk of developing microvascular diabetes complications (eye, kidney, and nerve disease) is reduced by 40%.[13] A key component to achieving tight glycemic control is a patient's ability to self-monitor.[14] A patient's reduction in compliance, for whatever reason, with his or her diabetes care plan, including self testing, can cause devastating health consequences.

We are very concerned that implementation of the Proposed Rule will disrupt the self-monitoring testing regimen and put at risk the compliance and health of people with diabetes. Furthermore, a substantial number of Medicare beneficiaries with diabetes who are also members of minority populations and persons with low incomes already face substantial access to care issues and new barriers, such as limiting the availability of local suppliers of diabetes care systems, should be avoided. To that end, CMS and the Proposed Rule should ensure that beneficiaries will continue to have access to the blood glucose monitoring equipment systems required to maintain safe blood sugar levels and comply with their physician-recommended testing regimens. The care and self-monitoring made possible by these systems – which include meters, lancets, blood glucose test strips and other diabetes testing supplies – maintain the health of persons with diabetes each day.

Costs of Noncompliance

Medicare beneficiaries who are diagnosed with diabetes account for nearly one-third of overall Medicare program costs.[15] Those costs are best controlled through a system of careful self monitoring and coordinated provider care.[16] Specifically, for example, nephropathy can lead to end-stage renal disease and kidney dialysis, which we know costs the Medicare program $ 832 million in annual costs. The costs of non-compliance can include increased frequency of emergency room visits and subsequent hospitalizations, expensive dialysis, and amputations. In 2002, the estimated cost of treating diabetes and its complications, direct and indirect, was $132 billion for the US, a 32% increase from the prior year.[17] Direct medical costs were $92 billion,

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[11] *See* McCulloch, David, *Managing Diabetes for Improved Health and Economic Outcomes*, 6 Am. J. of Managed Care S1089, S1095 (2000).

[12] National Diabetes Fact Sheet, *supra* note 3.

[13] *Id.*

[14] HealthPolicy R&D, Medicare's New Competitive Acquisition Program for Durable Medical Equipment: Policy Considerations Involving Beneficiaries with Diabetes, Community-Based Retail Pharmacies and Blood Glucose Monitoring 9 (January 2006) (citing The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Study Research Group, *Intensive Diabetes Treatment and Cardiovascular Disease in Patients with Type 1 Diabetes*, 329 New Eng. J. Med. 977-986 (1993).

[15] Centers for Medicare & Medicaid Services, Medicare Health Support program Overview, *available at* http://www.cms.hhs.gov/CCIP/01_Overview.asp#TopOfPage.

[16] *See* McCulloch, *supra* note 11.

[17] Paul Hogan et al., Am. Diabetes Ass'n, *Economic Costs of Diabetes in the U.S. in 2002*, 26 Diabetes Care 917, 917-918 (2003).

and had doubled over the past 5 years.[18] On average, the nation spends $13,243 on each person with diabetes, compared to $2,560 for persons who do not have diabetes.[19] At the same time, we also know that the appropriate primary and preventative care for persons with diabetes could save Medicare $1.3 billion annually, attributable just to the reduction in hospital admissions due to diabetes complications.[20] To avoid tremendous costs to the Medicare program, CMS should proceed cautiously to avoid damaging one of the first and most important lines of defense against greater health problems for people with diabetes. We know self-monitoring works.

Key Principles

We urge that CMS keep five (5) principles in mind as it finalizes the Proposed Rule:

(1) **The Rule Must Continue Beneficiary Access to Care**: The Final Rule should safeguard beneficiary access to needed products and services within their local communities, including access to pharmacists and neighborhood suppliers. Pharmacists in more than 55,000 community-based retail pharmacies continue to provide a large part of the necessary education and training to people with diabetes on the use of blood glucose monitoring systems. Access to these health care professionals and other local care givers must be maintained so that the continuum of care for this chronic condition is not disrupted.

(2) **The Rule Must Protect Beneficiary Choice—Clinical Use of Appropriate Technology Is Critical**: Medicare must preserve access to the full range of available blood glucose monitoring products and related services. No one meter can serve the diverse needs of the diabetes patient population. Medicare beneficiaries have special needs related to dexterity, vision and cognitive status that require careful consideration by the health care professional when selecting products designed to meet a beneficiary's particular needs. Ensuring beneficiary access to appropriate technology is vital to ongoing disease management efforts. For example, for those living with diabetes, electronic connectivity is an important feature that enables intervention by a health care provider, thus serving as an integral part of disease management efforts.

The Medicare Modernization Act ("MMA") authorized the development of chronic care improvement programs, called Medicare Health Support programs, to improve the health and quality of life of Medicare beneficiaries living with chronic illnesses. These programs are designed to help participants adhere to their physicians' plans of care and obtain the medical care necessary to reduce health risks. As evidenced by CMS's development of those programs, the agency has endeavored to make disease management the hallmark of care for Medicare beneficiaries with chronic conditions, such as diabetes. We urge CMS to safeguard the strides that have been made by permitting the full range of appropriate technology to continue to be available to individuals.

(3) **The Rule Should Promote Innovation**: This rulemaking should not remove incentives for continued innovation in the area of blood glucose monitoring systems. The

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[18] *Id.*
[19] *Id.*
[20] Agency for Healthcare Research and Quality, 2005.

development of new technologies supports self-care and greater compliance with a difficult daily regimen of testing and appropriate medication by seeking to make testing easier, less painful and more integrated with care decisions. Such product innovation creates long term cost-savings to the Medicare program in the form of decreased disease complications and costs as outlined above.

(4) **The Rule Should Ensure Transparent Bidding Processes and Must Be Clear**: The DMEPOS competitive acquisition rules and policies issued by CMS should be clear, consistent and not subject to varying interpretation. Specifically, the process for submitting, selecting and finalizing bids should be clear to both suppliers and beneficiaries for every item bid. Furthermore, the resulting competitive bidding program must be transparent to all those involved, so that fairness is never in doubt.

(5) **Lower Supply Prices in the Part B DME Benefit Does Not Necessarily Produce Overall Medicare Expenditure Savings**: The MMA requires that the Secretary apply competitive bidding to DMEPOS in order to achieve savings in the Medicare program. The MMA further authorizes the Secretary to exempt from competitive bidding those "items and services for which application of competitive acquisition is not likely to result in significant savings." CMS should of course include in any analysis of cost savings the administrative costs associated with implementation and operation of the bidding program. However, DACC does not believe that the calculation of those cost-savings looks exclusively to the competitive bidding program as a discrete component of Medicare Part B. The law simply does not say this.[21]

The DACC believes that the MMA requires the Secretary to take a broader view of "cost savings" related to potential bid items. In order to obtain true cost savings, CMS's should consider total savings under the Medicare program incorporating a disease management approach. As CMS analyzes these issues, and as it implements the competitive bidding program, CMS should look beyond an individual item of DME – such as lancets or test strips – in its evaluation and consider whether overall Medicare cost savings will in fact be realized. For example, persons with diabetes commonly face co-morbidities, including heart disease and circulatory problems (e.g., high blood pressure). Successful disease management programs for chronic conditions such as diabetes require ongoing, consistent self-monitoring and collaboration between the patient and his or her health care providers on multiple fronts. And, when successful, those programs mitigate or avoid the onset of related complications that often require intensive and repeated care in much more expensive emergency room or acute care in-patient settings.[22]

The DACC is concerned that changes to how patients access the full spectrum of needed diabetes care systems, such as requiring beneficiaries to visit multiple locations for their pharmaceuticals and supplies, could have a costly impact on the Medicare program overall

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[21] Indeed, when the law means to calculate economies on a competitive bidding specific-basis, it says so directly. Social Security Act section 1847(b)(2)(A)(iii), for example, specifies that "total amounts paid to contractors *in a competitive acquisition area*" must be "less than the total amounts that would otherwise be paid." (emphasis supplied). In contrast, the law's authority to exempt items and services contains no such language restricting the calculation of "significant savings" to competitive bidding or Part B's DME benefit.

[22] *See* McCulloch, *supra* note 11.

because the system will be working against patients' attempts to be compliant with their care regimens. Any material increase in noncompliance of Medicare beneficiaries who fail to adequately monitor their blood glucose because of a disruption in their access to care could produce significant increased costs to the Medicare program as a whole (including the Part A hospital benefit). The link between compliance with diabetes testing and Part A costs is well known. As the AHRQ points out, adequate monitoring and primary care for diabetes could save $1.3 billion annually in Medicare hospital costs under Part A. The DACC recommends that CMS take a more holistic view of "cost-savings" and consider the impact of changes on not only Part B, but also Part A, in deciding whether to implement a competitive bidding program applicable to blood glucose monitoring systems.

In addition, we believe that CMS must look beyond the simple costs to Medicare associated with blood glucose monitoring systems and consider that those costs are not necessarily driven by high supply costs but rather by the diabetes epidemic. CMS should regard diabetes care systems as an investment in preventing future poor health outcomes and resulting higher costs. At a time when diabetes has reached epidemic proportions, we believe that the opportunities for comprehensive Medicare program savings in diabetes care expenditures are to be found in increasing prevention strategies such as ensuring patients' access to self monitoring care and diabetes care plan compliance and should not be focused on potential short-term cost-reductions that might be exacted from the Part B DME benefit.

II. General Comments

1. CMS Should Exclude Blood Glucose Monitoring Systems from Competitive Bidding or, at a Minimum, Delay Bidding for Such Systems Until Further Studies Are Completed

CMS excluded blood glucose monitors and supplies from the two competitive bidding demonstration projects because of the additional complexity of ensuring that glucose monitors were matched with the appropriate testing supplies.[23] Thus, the impact that competitive bidding would have on beneficiaries and suppliers is unknown for these particular products. Furthermore, the Proposed Rule includes several untested features and methodologies – particularly in the establishment of prices. *We therefore respectfully request that CMS exclude diabetes care from competitive bidding. At a minimum, CMS should not implement competitive bidding on diabetes care items unless (1) CMS has established the key components of the competitive bidding program based on proven methods and (2) has evaluated the use of such a competitive bidding program in a limited population of people with diabetes.* We do not believe that implementation of the Proposed Rule in 10 MSAs in 2007 should serve as the evaluation of what works and what does not work either in general or with people with diabetes. The stakes are simply too high, particularly for the large and growing population of Medicare beneficiaries who are living with diabetes and who require medically complex treatment on a day-to-day basis.

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[23] U.S. Gov't Accountability Office, Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies 10 (2004).

CMS has the time to provide adequate consideration of the best approach to competitive bidding as applied to diabetes care and we suggest taking the time to do so. We have learned lessons in other contexts – particularly under the Medicare Part D Program—that suggest the agency should take the time required in the beginning to ensure that competitive bidding of DMEPOS does not have a negative impact on persons with diabetes whose daily care depends on having uninterrupted access to blood glucose monitoring equipment systems and related supplies.

Furthermore, CMS has the authority to phase-in the competitive bidding program based on which items and services have the largest savings potential.[24] Thus, if it is uncertain at this time whether diabetes care qualifies for an exemption from competitive bidding, CMS could implement the program narrowly, carefully evaluating the impact that the program has on persons with diabetes and quantifying the associated costs and cost-savings to determine whether indeed there are likely to be significant savings to the Medicare program as a whole. Such an approach could avoid costly mistakes that would hurt beneficiaries and waste precious Medicare Program resources.

2. If Blood Glucose Monitoring Systems are Included, the Competitive Bidding Program Must Ensure Beneficiary Access.

Beneficiary Access to Care

The final rule should seek to provide beneficiaries with necessary access to products and supportive services within their local communities, including access to pharmacists and neighborhood suppliers. Community-based retail pharmacies are the main source of diabetes supplies for the elderly.[25] Pharmacists in the more than 55,000 community-based retail pharmacies also provide valuable education and training to people with diabetes on the use of blood glucose monitoring systems.

Limiting the number of local pharmacies that may provide blood glucose monitoring equipment and related supplies to Medicare beneficiaries could interfere with the ability of beneficiaries to obtain their diabetes-related medications and other diabetes care items at a single location. This would be inconsistent with the protections for access to pharmacies that were established under the Medicare Part D drug benefit.

Under Medicare Part D, safeguards are in place to ensure beneficiary access to community-based retail pharmacies. Part D plans must permit any pharmacy that is willing to accept the plans' terms and conditions to participate in the plan's network.[26] Additionally, CMS established retail pharmacy network standards, adopting the TRICARE Pharmacy Access

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[24] Social Security Act §1847(a)(1)(B)(ii) ("[The competitive acquisition programs] may be phased in first among the highest cost and highest value items and services or those items and services that the Secretary determines have the largest savings potential.").

[25] HealthPolicy R&D, *supra* note 14, at 11 (citing IMS Health, Inc. data on file with HealthPolicy R&D and Katherine Knapp et al., California HealthCare Foundation, *The Role of Community Pharmacies in Diabetes Care: Eight Case Studies* (July 2005)).

[26] Social Security Act §1860D-4(b)(1)(A) (42 U.S.C. §1395w-104(b)(1)(A)) provides that "[a] prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan."

Standards.[27] These standards require that in every state in which the plan operates, 90% of Medicare beneficiaries in urban areas have access to a retail pharmacy within two miles, 90% of beneficiaries in suburban areas have access within five miles, and 70% of beneficiaries in rural areas have access within 15 miles.[28]

No one is immune from diabetes; however, there is greater incidence of the disease in certain ethnic[29] and lower-income populations.[30] People who fall within these populations often lack access to appropriate care.[31] CMS should consider these factors and establish supplier access standards similar to the pharmacy access standards promulgated in Medicare Part D.[32] Requiring an indigent patient living in an urban center, for example, to obtain supplies from an distant suburban neighborhood should not be considered adequate access to care. Additionally, if CMS does not take appropriate precautions to ensure supplier participation and geographic distribution, then those individuals with diabetes living within minority communities may find that their neighborhood suppliers, who were best equipped with the communication skills needed to provide appropriate education, are no longer available as suppliers.

Beneficiary Access to Choice

Medicare beneficiaries also should have access to an array of blood glucose testing equipment within a reasonable travel distance to improve the likely clinical outcomes. Diabetes requires long term medical attention and plagues patients with numerous complications.[33] Consequently, access to a wide selection of testing equipment is critical to improving the likely outcomes for patients with diabetes and may prevent or delay more serious complications associated with diabetes. In light of the MMA's purpose to improve coverage and choices available to Medicare beneficiaries,[34] CMS should implement policies that cover a reasonable array of diabetes supply options to improve outcomes and ensure patient choice.

3. We have Learned Important Lessons from Part D Implementation

CMS should not underestimate the communications challenges it and its contractors will face in making beneficiaries with diabetes aware of the new procedures for procuring their blood glucose monitoring supplies. We fear that changes of this magnitude and complexity will not be intuitively grasped by the large number of beneficiaries affected. For example, in opening enrollment for the new Part D Medicare benefit – including transitioning large numbers

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[27] 42 C.F.R. §423.120(a)(1).

[28] *Id.*

[29] Centers for Disease Control, Diabetes: Disabling, Deadly, and on the Rise 2006, *available at* http://www.cdc.gov/nccdphp/publications/aag/pdf/aag_ddt2006.pdf.

[30] Centers for Disease Control, Morbidity and Mortality Weekly Report: Socioeconomic Status of Women with Diabetes, 51(07), 148-49 (2002), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5107a3.htm.

[31] *Id.*

[32] *See* Social Security Act §1860D-4(b)(1)(C)(i)-(iii) (42 U.S.C. §1395w-104(b)(1)(C)(i)-(iii)) (requiring sufficient number of retail pharmacies to ensure "convenient access").

[33] National Institute of Diabetes and Digestive and Kidney Disease, Diabetes Overview, NIH Pub. No. 06–3873 (2006), *available at* http://diabetes.niddk.nih.gov/dm/pubs/overview/index.htm.

[34] *See, e.g.,* Social Security Act §1860D-3 (42 U.S.C. §1395w-103)) (assuring access of beneficiaries to a choice of qualified prescription drug coverage).

Medicare-Medicaid "dual eligibles" – it became apparent that the messages and instructions CMS sought to communicate were not always received, despite the agency's substantial and creative efforts. Here, inserting a new supplier distribution network into the middle of a fast-growing epidemic will raise similar confusion and misunderstanding – and put in jeopardy beneficiaries' compliance with their diabetes-testing regimens.

Specifically, CMS needs to apply the lessons learned from the process of educating beneficiaries with regard to the Part D benefit. For example, as MedPAC noted in the October 4, 2004 letter to Dr. McClellan "research consistently has shown that web-based resources are not sufficient to explain to some beneficiaries the complex choices they will face. Many beneficiaries require individual counseling."[35] In the same letter, the point was made that "it would be useful to devote some resources to developing education materials for pharmacists and physician on the Part D drug benefit."[36] MedPAC found that pharmacists play an important role during the transition period and that information should be sent to the local pharmacies as well as to the corporate headquarters of the major pharmacy chains.[37] Because of the unique retail aspect of diabetes supplies, it will be important to communicate with these providers as part of any transition planning for the competitive acquisition program.

As we have stated earlier in this letter, persons with diabetes rely extensively on the pharmacists for all of their diabetes medication and supplies and rely on their physician for obtaining the necessary prescription. Given the major disruption that competitive bidding could have on Medicare beneficiaries, it is imperative that all suppliers and physicians have the information needed to help educate the Medicare beneficiary about the changes before they occur and in the first several months after the change has taken place.

Specific Comments on the Proposed Rule:

For the agency's convenience and for clarity, we are reproducing the outline of the entire Proposed Rule, and we are placing our comments following the sections to which they relate.

A. Purpose and Definitions (Proposed § 414.400 and § 414.402)

B. Implementation Contractor (Proposed § 414.406)

DACC Comment: We believe that CMS will have trouble applying its current criteria for selecting MSAs because the agency will not be able to properly ascertain whether it has ensured that, at least, one MSA is chosen in each DMERC region. This is in part because three of the four regions will have new boundaries under the DME MAC transition scheduled for July 1. More importantly, there is uncertainty regarding whether the new DME MACs will be phased in on July 1, given current bid protests with respect to two of the four regions and GAO's recent ruling in favor of the protestor in one of the two contested regions.

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[35] MedPAC, Letter to Mark McClellan, *available at* http://www.medpac.gov/publications/other_reports/100404_ptd_RS_comment.pdf.pdf (October 4, 2004).

[36] *Id.*

[37] MedPAC Report to the Congress, *New Approaches in Medicare* 22 (June 2004).

C. Payment Basis (Proposed § 414.408)

1. Payment Basis (Proposed § 414.408(a))

2. General Payment Rules (Proposed § 414.408(c)–(j))

3. Special Rules for Certain Rented Items of DME and Oxygen (Grandfathering of Suppliers) (Proposed § 414.408(k))

DACC Comment: While diabetes care systems are not generally rental items, a similar type of phase-in period should apply to diabetes supplies. See further discussion under section 6, "Requirement to Obtain Competitively Bid Items From a Contract Supplier ."

a. Process for Grandfathering Suppliers

b. Payment Amounts to Grandfathered Suppliers

(1) Grandfathering of Suppliers Furnishing Items Prior to the First Competitive Bidding Program in an Area (Proposed § 414.408(k))

(2) Suppliers That Lose Their Contract Status in a Subsequent Competitive Bidding Program

c. Payment for Accessories for Items Subject to Grandfathering

4. Payment Adjustment to Account for Inflation (Proposed § 414.408(b))

DACC Comment: The DACC commends CMS for assuring that Contract Suppliers can rely on increased pricing based on corresponding increases in the CPI-U during the period that the Contract Supplier has a written agreement with CMS. We urge CMS to include explicit language on these CPI-based payment adjustments in the written agreement with the Contract Suppliers.

5. Authority to Adjust Payments in Other Areas (Proposed § 414.408(e))

DACC Comment:

First, CMS has not provided sufficient detail in this section, which precludes us from commenting effectively.

Second, when CMS does propose a process for this authority, while the agency does have the power to apply competitively bid prices to other regions, CMS should develop an open process for that decision-making, similar to the process which exists for coverage decisions. Numerous factors contribute to the variances in the cost of providing products and services in different areas of the United States. Many of these factors vary based on location specific

differences. Due to the potential impact on large numbers of beneficiaries and suppliers, as a matter of policy CMS should give potentially impacted stakeholders the opportunity to comment on the methodology CMS plans to use in applying this power once the competitive bidding program has been implemented.

6. Requirement to Obtain Competitively Bid Items From a Contract Supplier (Proposed § 414.408(f))

DACC Comment:

First, we believe that imposing the requirement to obtain competitively bid items from a contract supplier could create significant market disruptions that would result in barriers to access for beneficiaries. We recommend that CMS provide a phase-in period for transitioning Medicare beneficiaries to the successful contract suppliers for all types of DMEPOS, not just the rental items listed in the Proposed Rule.

When considering the need for a transition period, we urge CMS specifically to examine where Medicare beneficiaries with diabetes obtain the full range of their care and analyze specifically where within an MSA contracted suppliers are distributed in relation to these beneficiaries. As the supply system currently exists, the majority of people with diabetes obtain glucose monitors and test strips from local neighborhood pharmacies. There are over 55,000 retail pharmacy outlets that currently supply self-monitoring blood glucose supplies.[38] On average, beneficiaries visit their pharmacy about once per month to obtain a range of diabetes supplies and care advice from their pharmacist.[39] The continuum of care provided by health care professionals, such as a retail pharmacist, is key to the care of persons with diabetes. This purchase pattern is different than for most other DME, where the supplier is a traditional DME supplier and not the local neighborhood pharmacy.

Under the Proposed Rule, if they can not afford to create a network just for this process, the vast majority of those neighborhood pharmacy outlets may well have to bid individually to become contracted suppliers, which will likely be an onerous and costly process for those small operations. We believe those obstacles will limit beneficiary access by severely limiting the number of neighborhood pharmacies becoming contracted suppliers. Unfortunately, those same excluded neighborhood pharmacies will likely be located in the areas where they are most needed to ensure beneficiary access, such as low income neighborhoods. As a result, there could be huge geographic gaps within a given metropolitan statistical area. Although these gaps could apply to all Medicare beneficiaries, they could be particularly burdensome, for example, to disadvantaged center-city populations, which would be required to travel great distances outside of their neighborhoods to obtain competitively bid supplies from a contract supplier, and to minority populations, which would be required to obtain their care systems from suppliers ill-equipped to overcome potential communication barriers. Many of those beneficiaries may lack personal transportation or access to suitable public transportation that could take them to the required area outside of their neighborhood.

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[38] Katherine Knapp, et al., California HealthCare Foundation, *The Role of Community Pharmacies in Diabetes Care: Eight Case Studies* 5 (July 2005).
[39] *Id.*

The effects of even a slight increase in the difficulty of physically obtaining supplies should not be underestimated, especially in a population that faces substantial socioeconomic disadvantages at the outset. In the Medicare Part D implementation process, CMS recognized the importance of the retail pharmacy relationship with Medicare beneficiaries, and this aspect of beneficiary access and education also should be protected in the final rule. We believe that not recognizing the key role of small neighborhood suppliers, such as retail pharmacies, could result in negative health and economic outcomes by:

- Reducing local suppliers below a level sufficient to meet beneficiary needs for glucose monitoring equipment;
- Reducing beneficiaries' ability to conveniently obtain supplies from a local supplier;
- Breaking beneficiary relationships with local pharmacists and suppliers
- Denying beneficiary choice by precluding access to the full range of available glucose monitoring products and related services
- Lessening beneficiaries' ability to comply with diabetes self-monitoring regimens thereby increasing overall use of expensive health care services
- Working at cross-purposes to Medicare and other proven disease management efforts

Before inclusion of diabetes supplies in competitive bidding categories, CMS should ensure that imposing this requirement will not compromise beneficiary access and will preserve important aspects of customary care access routes, including smaller suppliers and geographic distribution. At a minimum, providing for a phase-in period will give CMS an opportunity to observe the impact of this requirement on beneficiaries.

Second, we are concerned about the potential for disruptions in Medicare beneficiaries' ability to access needed supplies in a single location either at home, while away from home either during an emergency (e.g., death in the family) or while on a planned vacation or extended stay in an area where they are not a permanent resident. As the agency knows, it will need to educate Medicare beneficiaries on access to available care and the agency also will need to ensure that contract suppliers also communicate in an effective manner with beneficiaries on these issues.

For persons with diabetes, taking these steps is essential to safeguard against the potential for disruption in the continuum of self-care and monitoring, which is critical for persons with diabetes. In particular, it is essential for diabetes beneficiaries who rely on particular blood glucose monitoring systems to meet their individualized needs to understand that having access to certain supplies in their area of residence does not mean that they will have access to the same supplies when they are in other locations. These pharmacies may also have a difficult time explaining to beneficiaries that "I can provide all your medications but not your supplies." If the brand or model of product the beneficiary needs is not accessible in an area where the person has traveled, a serious disruption in care could result. For example, a beneficiary may travel to Florida from her home in Maryland and find that she cannot access her brand of test strips because these strips are not available in Florida. CMS should ensure processes that do not provide barriers to access for beneficiaries traveling outside of their competitive bidding area.

DACC recommends that CMS allow beneficiaries to obtain their supplies from any Medicare supplier.

Third, Medicare beneficiaries who are accustomed to having access to their blood glucose monitoring systems and related supplies as well as the multitude of pharmaceuticals that compose their daily care routine could easily fall out of compliance with that routine if the appropriate drugs and supplies are not readily accessible. For example, a beneficiary is likely to obtain his diabetes care items and medications as well as his heart and high blood pressure medications from a single pharmacy or local supplier. If that pharmacy is not a contract supplier, then the beneficiary will have to obtain some or all of his needed medical care from a second – or even a third – supplier.

CMS has not addressed these individual-level issues in the Proposed Rule and we believe this level of detail is essential to ensuring that competitive bidding does not create barriers to access to care. Coordination of benefits available to each beneficiary in real-time at each contract supplier should be addressed in the final rule. These logistical problems present potentially onerous barriers to care and/or disruptions in care and can cause beneficiary frustration.

We strongly recommend that CMS consider geographic proximity rules similar to those under Medicare Part D and TRICARE discussed below. In addition, CMS should provide for extensive education and training of Medicare beneficiaries as well as contract and non-contract suppliers.

Fourth, we highlight again the importance of the continuum of daily self-monitoring and care to people with diabetes – and the possibility that drastic changes in access to needed supplies could have a disruptive impact on patient care. We note that Medicare currently lacks any sort of real-time information management system that would allow suppliers and beneficiaries to identify the appropriate choices and reimbursement levels for their supplies. If a Medicare beneficiary walks into a pharmacy that offers the very supplies the beneficiary needs, but that particular pharmacy is not a contracted supplier, the pharmacy will have to deny the beneficiary access to the product that sits on its shelf. In a similar vein, if a Medicare beneficiary is visiting another location outside of his or her MSA, and wants to purchase products that are available on the shelf, the pharmacy may not know which products are covered and what the appropriate reimbursement is for that particular beneficiary. Each beneficiary will have to learn how to coordinate a more complex system of care based on whether or not his or her local pharmacy or supplier submits a bid and whether or not they are successful.

7. Limitation on Beneficiary Liability for Items Furnished by Non Contract Suppliers (Proposed § 414.408(f))

D. Competitive Bidding Areas

DACC Comment:

First, we are concerned that the Proposed Rule does not adequately address access to care for persons with diabetes. As discussed in Section C.6. "Requirement to Obtain Competitively Bid Items From a Contract Supplier," the Proposed Rule creates the potential for large geographic gaps to arise within an MSA. The short and long-term impact of any gaps in access to care in local neighborhoods within MSAs could be devastating.

There are several factors related to the competitive bidding of blood glucose monitoring equipment and supplies that raise concerns that differ from the concerns related to other types of DME. Beneficiary purchase patterns and educational needs and the potential for interaction with Part D are all unique concerns that arise in relation to the competitive bidding of blood glucose monitoring systems. As previously discussed, Medicare beneficiaries with diabetes currently obtain their blood glucose monitoring systems through local suppliers located within their communities. This is in contrast to consumers of many other types of DME who may often have their necessary equipment and supplies delivered to them. Additionally, during the visits to their local suppliers, Medicare beneficiaries with diabetes receive valuable education and training that is essential to their self-monitoring care plans. Moreover, many patients with diabetes have strict medication regimens directly and indirectly related to their diabetes. Not providing measures to ensure that local suppliers are appropriately dispersed and sufficiently numbered within a competitive bidding area could mean that a beneficiary will be forced to visit multiple and distant locations to obtain the medications and supplies necessary for remaining compliant with his or her care plan.

To be more specific, under the current system, there are a large number of suppliers for blood glucose monitoring equipment and supplies that are distributed throughout the United States. Compare the roughly 56,000 suppliers of blood glucose monitoring equipment in the United States to only about 12,000 suppliers of oxygen and related supplies.[40] The same proportion holds true within MSAs. In New York City alone, for example, there are over 1,300 suppliers of glucose monitoring equipment and only about 345 suppliers of oxygen.[41] Implementing a competitive bidding program without providing safeguards to ensure reasonable access to suppliers within a competitive bidding area could result in the elimination of hundreds of suppliers within an MSA, almost certainly creating large geographic gaps in access to care.

CMS should adopt the "convenient access" standard already in place for beneficiaries with drug benefits under Medicare Part D.[42] Like these Part D enrollees, beneficiaries with diabetes must usually *go to* suppliers to secure the products they need; the products do not generally come to them. As such, geographic distance becomes a clear measure of access: the

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[40] Centers for Medicare and Medicaid Services, National Supplier Clearinghouse, http://www.medicare.gov/supplier.

[41] *Id.*

[42] Social Security Act §1860D-4(b)(1)(C)(i)-(iii) (42 U.S.C. §1395w-104(b)(1)(C)(i)-(iii)). *See also* 42 C.F.R. §423.120(a)(1).

further a beneficiary is from a supplier, the more difficult it will be to secure the diabetes testing supplies needed to maintain compliance with their testing regimens. The Part D "convenient access" standards, themselves based on TRICARE standards, offer an established benchmark for how far an elderly beneficiary should have to travel to secure a needed product. Indeed, the very existence of the Part D benchmark means that any lesser standard is *per se* injurious to beneficiary access.

Second, we are concerned that the MSAs that are likely to be selected by CMS (e.g., Miami and Houston) are among those MSAs with the highest prevalence of diabetes and its co-morbidities. The large number of persons with diabetes in these areas and the intensity and amount of need required by these beneficiaries could be overwhelming to CMS, its contractors and suppliers. We recommend that CMS consider delaying competitive bidding for blood glucose monitoring systems and related supplies until CMS has first implemented the competitive bidding program for other types of DMEPOS and has refined the program based on that experience.

1. Proposed Methodology for MSA Selection for 2007 and 2009 Competitive Bidding Programs (Proposed § 414.410)

   a. MSAs for 2007

DACC Comment: The DACC commends CMS on both the detail provided in the Proposed Rule regarding the selection of MSAs for 2007 regarding both the substantive criteria to be used and the process for making the selection. That level of detail helps us tremendously as we develop our comments. Indeed, we have no questions about this section. Frankly, we would like to see that same level of detail in the other portions of the Proposed Rule.

   b. MSAs for 2009

DACC Comment: The DACC believes CMS should not be planning currently to implement a change in the selection criteria during the second round of selecting MSAs. CMS does not yet have the benefit of the learning from the first round of competitive bidding, and thus cannot yet know what will or will not need to change for subsequent bidding rounds. CMS should take the time necessary to carefully evaluate the overall impact that the competitive bidding program will have on beneficiary access to care, access to choice, and quality of care before considering modifications to the program criteria for MSA selection. CMS should not already be planning to modify the 2007 MSA selection criteria in 2009. As yet, CMS offers no compelling reason for treating the two periods differently.

2. Establishing Competitive Bidding Areas (Proposed § 414.410)

   a. Authority to Exempt Rural Areas and Areas With Low Population Density Within Urban Areas (Proposed § 414.410(c))

   b. Establishing the Competitive Bidding Areas for 2007 and 2009 (Proposed § 414.410(b))

DACC Comment:

First, the Coalition is concerned about the scope of CMS' statement that it has the authority to expand competitive bidding beyond the boundary of MSA. While an MSA may represent an imprecise proxy for a service area, it should not be expanded and CMS should not go beyond that limitation on the scope of competitive bidding. Section 1834(a)(1)(F)(ii) represents exclusive means for dealing with areas outside the selected MSAs. Congress would not have included this provision in the statute if Congress intended CMS to apply competitive bidding beyond the selected MSAs in these early stages. We understand the CMS analysis of natural markets, and if CMS is worried about natural markets, it would seem to be a natural solution for CMS to contract, not expand, the competitive bidding areas.

Second, CMS proposes that an area outside the boundaries of an MSA be considered for inclusion in a competitive bidding area based on multiple criteria, including that the area is part of the "normal service area or market" for suppliers who serve the MSA or areas within the boundaries of an MSA. How does CMS propose to define the concept of "normal service area" when extending a competitive bidding area beyond the boundaries of an MSA? This lack of specificity precludes us from commenting effectively on this proposal.

c. Nationwide or Regional Mail Order Competitive Bidding Program (Proposed § 414.410(d)(2))

DACC Comment:

First, CMS should ensure that beneficiary choice is protected. Beneficiaries have different clinical needs and should be allowed to satisfy those needs by choosing the distribution channels tailored most closely to their individual circumstances. We strongly oppose any requirement that forces or coerces people with diabetes to obtain their supplies from one particular type of outlet. At the May 22, 2006 meeting of the Program Advisory and Oversight Committee ("PAOC"), CMS conceded that face-to-face contact between beneficiaries may be required and that a mail order program may require a tailored approach based on the type of DMEPOS being supplied. We also understood CMS at that meeting to say that all mail order programs should be voluntary on the part of beneficiaries. For example, the Proposed Rule differentiates between original procurement and replacement of blood glucose monitoring systems and related supplies. Contrary to the PAOC statements, however, the language in the Proposed Rule explains that CMS is considering making the use of mail order mandatory for the purchase of blood glucose monitoring test strips.[43] We reiterate that CMS's focus should be to protect beneficiary choice among channels and should not force beneficiaries to obtain supplies through a particular channel. Instead, beneficiaries should be able to choose the channel that best fits their needs. Such a focus would be consistent with Medicare's broader efforts to protect patient choice.

Second, competitive bidding is largely about getting the best price for the government through supplier competition. The various distribution channels are facets of the same market

[43] Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues, 71 Fed. Reg. 25,654, 25,669 (May 1, 2006).

and compete for the same customer. Therefore, we believe that there is no need to have a separate program devoted to national mail order or to any other individual distribution channel. Doing so would not only be redundant and pose a greater administrative burden, but it would also result in reduced competition.

Third, CMS suggests throughout the Proposed Rule that more suppliers mean increased competition on a local basis, and therefore increased savings for the program. However, CMS appears to abandon this argument with respect to the creation of a national mail order program. We are concerned that the agency's inconsistent policy rationale does not comport with the overall goals of competitive bidding and urge CMS to re-evaluate its national mail order program in light of these market concerns.

Fourth, the impact of a national or regional mail order program on beneficiary compliance with day-to-day care requirements is unknown and is likely to be negative on patients who are elderly who may not adapt well to the use (exclusively or otherwise) of a mail order service. It seems relatively well known that elderly populations adapt to change poorly, and that some of them require more direct care than mail-order can provide. Certainly this is not universally true, but we suspect those who are comfortable with a mail order service already use it. Forcing those who have not voluntarily elected to use mail-order to do so is risky indeed. Currently, approximately two-thirds[44] of Medicare beneficiaries obtain their blood glucose strips at a retail outlet. For a person with diabetes to fall out of compliance with his or her health care regimen – including consistent monitoring of blood glucose levels – would jeopardize that person's health as well as increase the cost to the health care system overall. Given the fact that one-third of Medicare costs are attributable to services for individuals with diabetes, this cost could be staggering.

Fifth, CMS should analyze annualized cost to serve variability between different supplier channels. The justification for such an analysis is to address the fact that different channels of distribution may produce different patterns of use. For example, mail order has its own costs that need to be fully accounted for. If the increased cost of providing DMEPOS to Medicare beneficiaries, including the ancillary customer support services, are higher, Medicare may not realize expected cost savings.

Sixth, how would a national mail order program supply the disease management services currently provided by local pharmacists and suppliers– including addressing the cognitive disorders, language barriers and hearing issues that many Medicare beneficiaries have?

Seventh, DACC is concerned about the impact that a mail order program may have on small suppliers who may not be able to compete on the basis of price alone with large suppliers. With fewer suppliers able to compete to be a contract supplier, the impact would be anti-competitive because: (a) it would reduce consumer choice; (b) it would remove access at the local level; and (c) it would disrupt the marketplace by reducing the number of suppliers available to offer services to beneficiaries. CMS appears to be taking an inconsistent position with respect to small suppliers because the agency states in the notice that it supports the

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[44] HealthPolicy R&D, *supra* note 25, at 11.

inclusion of these suppliers; however, this procedure is likely to result in fewer small suppliers in the marketplace.

Eighth, at this time, the ratio of suppliers to persons with diabetes may be relatively high. However, the selection of contract suppliers in the Proposed Rule seems likely to make that ratio more concentrated as the program drives companies out of the market by concentrating market share in the winners. We believe that in order to achieve the benefits of a competitive marketplace (e.g., innovation and lower prices in the future), it is good to have a higher ratio of suppliers to beneficiaries. If a fewer number of suppliers is making available blood glucose monitoring systems and related supplies, we are concerned that it will reduce the number of local suppliers available for advice and day-to-day counsel. Moreover, elsewhere in this comment letter we explain that driving too many suppliers out of business will ultimately reduce competition available for subsequent competitive bidding processes. We urge CMS to preserve the number of suppliers in the marketplace – particularly by establishing supplier access requirements analogous to the pharmacy access standards established under Medicare Part D and TRICARE. See discussion above at II.2..

Ninth, there is no provision to require "quick" (e.g., less than 24-hour) access to supplies in an area where a mail order supplier is a contract supplier.

Tenth, in the alternative, we recommend that any proposal by CMS to implement a mail order program be subject to a separate rulemaking and that, under any circumstance, this program be voluntary for beneficiaries, consistent with the typical practice in Medicare Part D and among commercial payors.

d. Additional Competitive Bidding Areas After 2009 (Proposed § 414.410(d))

E. Criteria for Item Selection

DACC Comment:

CMS states that they "may elect to phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding." We agree that this approach would be appropriate for certain product categories to ensure appropriate learning before implementation. We believe that CMS should apply this approach to diabetes care supplies because they comprise a system of care and should not be viewed as independent parts.

Second, we are concerned that the bidding system in its proposed form does not recognize the diversity that may exist within the full range of an "item" in each product category, particularly those related to blood glucose monitoring systems. Blood glucose monitoring systems and related supplies are not fungible. There is a significant amount of innovation and differentiation among these systems that corresponds to quality of care and varying patient needs. We urge CMS not to overlook the importance of ensuring diversity of products.

Third, we are further troubled by the lack of standards related to item selection and bid selection that would assure the quality of those items. Under the Proposed Rule, a bidder must bid on each item within a category. A particular supplier may be capable of supplying more than one brand or model of a particular "item." If a particular brand or model of an item is a fundamentally better product for Medicare beneficiaries but within a HCPCS code more "expensive" for a supplier to supply, under the Proposed Rule there is an incentive to bid with the intent of providing a lesser quality brand or model of the item in order to achieve a greater profit margin by the supplier. There is currently no provision that requires a supplier to specify which brand or model of a particular item the supplier intends to provide.

The importance of standards for item selection is particularly pronounced in the case blood glucose monitoring systems. In contrast to other DMEPOS industry segments, it is more appropriate for the blood glucose monitoring system *manufacturer* – not the supplier – to provide multi-lingual technical support for the patients who use these systems. It is simply infeasible for a supplier to understand the intricacies of each of the diverse collection of monitoring systems in use within the Medicare beneficiary population. As such, the quality and continuous availability of manufacturer-provided technical support are critical to ensuring that beneficiaries with diabetes do not misinterpret test results, which, in turn, can lead to adverse health consequences and even death. We therefore recommend that should CMS implement competitive bidding for blood glucose monitoring systems, it apply minimum manufacturer quality standards with respect to suppliers' bids on those products. Specifically, we recommend that supplier bids on any category or sub-category of monitors or test strips not be eligible for consideration or acceptance unless the products proposed to be bid are accompanied by an assurance of 24-hours-per-day, 7-days-per-week manufacturer technical support. This type of beneficiary-protection assurance may be implemented under the Secretary's statutory authority to consider whether "specific items within codes . . . have a greater therapeutic advantage to individuals."[45]

Fourth, we are concerned that CMS does not have any qualitative or quantitative data on the impact of competitive bidding on blood glucose monitoring systems from its demonstration projects in Polk County and San Antonio. We urge CMS to limit the implementation of competitive bidding for diabetes supplies until CMS has an opportunity to further evaluate the impact on beneficiaries and suppliers. See discussion above under General Comments.

Fifth, CMS has not provided sufficient detail as to what "reports and studies" CMS would rely upon in making the determination whether to include diabetes-related DME in the range of items to be bid upon by contract suppliers. This lack of specificity precludes us from commenting effectively on this aspect of the section.

F. Submission of Bids Under the Competitive Bidding Program (Proposed § 414.412)

1. Providers (Proposed § 414.404 and 414.422)

2. Physicians (Proposed § 414.422)

[45] Social Security Act §1847(b)(7) (42 U.S.C. §1395w-3(b)(7)).

3. Product Categories for Bidding Purposes (Proposed § 414.412)

DACC Comment: The Proposed Rule allows a bidding supplier to bid for the product categories that they are seeking to furnish under the competitive bidding program. However, submitted bids must include a bid for each item within a particular product category. Such a requirement may pose problems, particularly for small or specialized suppliers. Although CMS has provided an option for forming networks, it is unclear whether this would be a feasible solution for these suppliers. In fact, although networking was included as an option during the demonstration projects, no networks actually submitted bids. See further discussion of issues related to networks under Section L. Opportunity for Networks.

4. Bidding Requirements (Proposed § 414.408)

a. Inexpensive or Other Routinely Purchased DME Items

b. DME Items Requiring Frequent and Substantial Servicing

c. Oxygen and Oxygen Equipment

d. Capped Rental Items

e. Enteral Equipment and Supplies

f. Maintenance and Servicing of Enteral Infusion Pumps

g. Supplies Used in Conjunction With DME

h. OTS Orthotics

G. Conditions for Awarding Contracts (Proposed § 414.414)

DACC Comment: To mitigate the impact of disruption in access to care, we recommend that CMS consider a phase-in period for transitioning Medicare beneficiaries to the successful contract suppliers for all types of DMEPOS, not just those rental items listed in the Proposed Rule. CMS has proposed a very aggressive timeline that provides inadequate opportunity for the agency to invest the significant number of months that will be required to educate beneficiaries and suppliers before competitive bidding is implemented. Because beneficiary education is a critical step in securing meaningful access to integrated blood glucose monitoring systems, any CMS action to move forward without such education would be extremely disruptive to the current system of beneficiary care. CMS should consider a transition plan, or, at a minimum, should develop contingency plans to minimize the negative effects of such a disruption. See detailed discussion under Section C.6. "Requirement to Obtain Competitively Bid Items From a Contract Supplier."

1. Quality Standards and Accreditation (Proposed § 414.414(c))

DACC Comment: As CMS is aware, under the Proposed Rule a winning contract supplier must meet the quality standards, which are still in draft form at this time. Furthermore, the MMA requires the Secretary to select and approve accreditation organizations to apply the quality standards. Because CMS has not yet designated the accreditation organizations, it is unclear how CMS will be able to determine whether the selected suppliers meet the quality standards in time for the bidding to commence in 2007. We believe that to assure quality of care, the quality standards and the related accreditation processes must be completed *before* competitive bidding is implemented. Poor performance by a contract supplier could have an immediate impact on thousands of Medicare beneficiaries, and this should be avoided even if it means a delay in implementation of competitive bidding.

While it is important for every supplier to meet quality criteria to ensure that products and services are provided in a manner that meets the needs of each Medicare beneficiary, it is imperative that each contracted supplier providing diabetes care systems understands the unique needs of those persons with diabetes, and that each of these suppliers provides the necessary support services in a manner that addresses those needs. CMS has stated that the quality standards will increase quality of care, and not allow it to decline. We agree that the accreditation process is an integral element of ensuring quality of care. Thus, we strongly urge CMS to delay implementation of any competitive bidding applicable to diabetes care until such time as each supplier that intends to bid to supply blood glucose monitoring systems and supplies has demonstrated achievement of the quality standards through the accreditation process.

2. Eligibility (Proposed § 414.414(b))

3. Financial Standards (Proposed § 414.414(d))

4. Evaluation of Bids (Proposed § 414.414(e))

   a. Market Demand and Supplier Capacity (Proposed § 414.414(e))

DACC Comment: One of CMS's stated objectives for the Medicare DMEPOS Competitive Bidding Program is "[t]o assure beneficiary access to quality DMEPOS as a result of the program,"[46] and to save money. We believe that preserving a large number of suppliers would both have a positive impact on ensuring competition in future competitive biddings, and would better help to ensure an adequate supply of the articles of DME. If CMS drives too many suppliers out of a market, the next time it conducts a competitive bid in that location, the savings may dry up and indeed the prices may go up. CMS makes no mention of this consideration, or what it will do to ensure an adequate future supply of suppliers for future bidding. To this end, CMS should identify what it will do to maintain a large enough number of suppliers within MSAs. It would seem that awarding enough contracts to ensure that future pool of suppliers would be an element of that plan.

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[46] Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues, 71 Fed. Reg. at 25657.

b. Composite Bids (Proposed § 414.414(e))

DACC Comment:

First, we are concerned that the composite bid process creates incentives for a provider to game the system by submitting artificially low bids on certain items and artificially high bids on others in order to manipulate the bidding supplier's composite score. This is a significant defect, since there is nothing in the Proposed Rule that says the quantities a bidder offers for each article in a group have to be proportionate. So, a bidder could dramatically under price an item they don't expect to sell many of, and overprice the item they expect to sell a lot of. After they win the bid, they conveniently run out of the low priced item well before they run out of the more expensive one.

Moreover, the Proposed Rule does not provide adequate methods for reevaluating composite bids if a successful bidder is unable to continue participating in the program. For example, a bidder that submits an artificially low bid in order to "win" may not be able to sustain its business, thereby not only forcing its own exit from the program, but saddling other Medicare suppliers with an unfair and artificially low payment amount. In addition, a winning bidder may need to leave the program because it cannot maintain compliance with quality standards.. When a winning bidder drops out of the program for whatever reason, CMS should reevaluate the composite bids for the remaining winning bidders – as well as those of any additional bidders that need to be offered contracts to ensure adequate supply -- and adjust the payment amount accordingly.

Second, we are also concerned that the proposed composite bid methodology currently provides for no way to account for differentiation among bidding suppliers based on quality. We recommend that CMS add a proxy for quality considerations in its selection of bids.

c. Determine the Pivotal Bid (Proposed § 414.414(e))

DACC Comment:

First, we are concerned that after the selection of the pivotal bid at the composite bid price, which is an aggregate price, in each product category, CMS proposes to disaggregate items within the category and to identify a single payment amount for an item based on the median of the contract suppliers' bid prices. The "disconnect" caused by selecting winning bidders based on aggregate prices and determining payment amounts based on disaggregated prices ensures that at least half of the "winning" bidders will be required to sell items at a price lower than their bid price. See similar discussion under Section H. Determining Single Payment Amounts for Individual Items.

Second, CMS should strongly encourage and create incentives for suppliers to include quality considerations, such as costs related to providing customer service, in determining their bids, while simultaneously limiting pressures to lower bid prices at the expense of sacrificing quality. Elimination or reduction of customer services to persons with diabetes would have a devastating impact on the continuum of care. To this end, CMS should establish a process by

which contract suppliers are not forced to supply items at a price lower than their bid price, which should represent the lowest price at which a supplier is able to provide the range of services required to supply an item of DMEPOS.

Third, while the methodology used to identify the pivotal bid is intended to ensure that projected demand within a competitive bid area is met, how does selection of the Pivotal Bid assure access to care? CMS should implement measures to ensure not only that demand is met but that access is not compromised. See discussion under D. Competitive Bidding Areas.

d. Assurance of Savings (Proposed § 414.414(f))

DACC Comment:

First, we are concerned that the Proposed Rule focuses on disproportionately on savings and not on quality, particularly given the fact that the quality standards are not yet finalized. CMS states that the bid price should reflect the cost of providing quality products and services; however, there is a clear disincentive to submit too high of a bid for risk of losing. Notwithstanding the finalization of the quality standards, CMS should emphasize quality by developing incentives to encourage successful contract suppliers to provide quality service. Similarly, CMS should make clear the consequences of providing poor quality and customer service.

Second, while CMS states that it will evaluate savings at the item level, we strongly urge CMS to take a broader view and evaluate savings in a more holistic manner, including, but not limited to, a consideration of savings at an overall Medicare program level. See detailed discussion under Introduction – Key Principles.

e. Assurance of Multiple Contractors (Proposed § 414.414(g))

DACC Comment:

First, CMS has not proposed enough safeguards to ensure there will be an adequate supply for each item. For example, CMS should acknowledge the inherent uncertainty associated with a bidding process by incorporating an appropriate margin for error in its calculations.

Second, the concept of the pivotal bid is based on an assumption that an accurate prediction of demand is possible. Predicting the demand and in turn determining the pivotal bid for diabetes care systems is fundamentally different than for other DME. Diabetes is a quickly-rising epidemic involving a much larger scale of afflicted patients and suppliers than for other DMEPOS consumer populations. Thus, an accurate prediction of adequate supply in the category of blood glucose monitoring systems is riskier and more complicated than for other types of DMEPOS.

Third, CMS has not proposed a requirement that geographic diversity be a consideration in the selection of successful contract suppliers. We believe that it is necessary to have successful contract suppliers from both storefront and mail order distribution channels.

Fourth, we believe that an essential element of meeting CMS's objective to assure beneficiary access to quality DMEPOS includes maintaining a large number of suppliers within a competitive bidding area. Ironically, the competitive bidding program will likely have the effect of driving suppliers out of the market, thereby reducing the number of suppliers available to bid on supplies in subsequent bidding years, and reducing competition.

Fifth, we also believe that CMS should make efforts to maintain a large number of suppliers within a marketplace to assure beneficiary access to care and choice. See discussion above under General Comments.

f. Selection of New Suppliers After Bidding (Proposed § 414.414(h))

H. Determining Single Payment Amounts for Individual Items (Proposed § 414.416)

1. Setting Single Payment Amounts for Individual Items (Proposed § 414.416(b))

DACC Comment: CMS's proposed methodology for establishing the Single Payment Amount is not based on past experience (e.g., a demonstration project such as those conducted in Polk County, Florida and San Antonio, Texas). We recommend using only proven methodologies at this time and use of the median bid as the Single Payment Amount has not been tested. In particular, we are concerned about the use of the median price as the single payment amount for several reasons:

First, based on the knowledge that CMS will use the median price as the single payment amount for an item, suppliers may submit lower bids resulting in a distortion from the actual range of bids suppliers believe is appropriate for the items and related services.

Second, there is a fundamental question about both fairness and feasibility in terms of imposing a single price that is lower than what half of the successful bidders bid. For example, if a supplier is among the upper half of bidders, and the median price is selected, that "successful" bidder will be forced to supply the product at a price lower than its bid. This methodology for determining the single payment amount calls into question whether those "successful" bidders will be likely to cooperate and sell product at that lower price. If any of those "successful" bidders are not willing to supply products at the lower price, then the actual available supply of a particular item may not meet the projected demand thought to be satisfied in identifying the Pivotal Bid.

Third, we do not believe that using the median price as the single payment will allow CMS to satisfy the Social Security Act's requirement that CMS select the number of contract suppliers necessary to ensure adequate supply for each item. Under the Proposed Rule, CMS will attempt to guarantee adequate supply through an assessment of a supplier's ability to assure

delivery of a certain quantity of supplies as well as that supplier's bid price. Based on a supplier's composite bid, bidders will be included as winning bidders until the projected demand is satisfied. The last winning bidder's composite bid price is the resulting "pivotal bid." Because the composite bid is based on the supplier's bid for an item and the item's weight within the product category, it is an aggregate price. By proposing to then disaggregate the items within a product category to determine the single payment amount, CMS can no longer ensure that there is adequate supply to meet the projected demand unless all winning bidders can supply the bid upon supplies at the single payment amount, which will be lower than bid price for half of the suppliers. If projected demand cannot be met, beneficiary access will be harmed. That violates the Social Security Act, for CMS to adopt a system not designed to provide for adequate supply.

2. Rebate Program (Proposed § 414.416(c))

DACC Comment:

First, the rebate program, as currently proposed, raises inducement and anti-kickback concerns. The Proposed Rule is ambiguous as to how a provider can avoid liability under the Federal Anti-kickback statute for a disclosure of the rebate to a beneficiary. We urge CMS to harmonize these two conflicting regulatory schemes, particularly by explicitly stating when a supplier may disclose the fact and amount of a rebate to a beneficiary. At this time, it appears that the disclosure may only be made after a demonstrable decision has been made to purchase an item, but before the purchase is consummated. The ambiguity in the Proposed Rule makes it difficult for suppliers know whether they are in compliance and exacerbates the potential for fraud and abuse.

Second, we are also concerned that the rebate program provides an incentive for suppliers to offer only the lowest cost products to beneficiaries. While incentivizing low bids through the rebate program may achieve CMS's goal of allowing beneficiaries to realize additional savings, such a result is likely to be at the price of sacrificing quality and beneficiary choice.

I. Terms of Contract (Proposed § 414.422)

1. Terms and Conditions of Contracts

2. Furnishing of Items (Proposed § 414.422(c))

3. Repairs and Replacements of Patient Owned Items Subject to Competitive Bidding (Proposed § 414.422(c))

4. Furnishing Items to Beneficiaries Whose Permanent Residence Is Within a CBA

5. Furnishing Items to Beneficiaries Whose Permanent Residence Is Outside a CBA

6. Information Collection from the Supplier

7. Change in Ownership (Proposed § 414.422(d))

8. Suspension or Termination of a Contract (Proposed § 414.422(f))

J. Administrative or Judicial Review (Proposed § 414.424)

K. Opportunity for Participation by Small Suppliers

DACC Comment:

First, many small companies sell blood glucose monitoring supplies (e.g., test strips) both through mail order and through pharmacies. However, due to the requirement that a submitted bid include a bid for each item within a particular product category, these companies will not be able to bid unless they can successfully form a network. For many of these small "Mom & Pop" shops it seems unrealistic to expect that they will have the resources to form networks that are able to efficiently and effectively compete with larger suppliers. To this end, we urge CMS to, establish a technical assistance program, which should include provision of a forum for the establishment of networks, to assist small providers in participating in the competitive bidding processes.

Second, while it appears that CMS is trying to ensure that small suppliers can bid, it is unclear what CMS is doing to ensure that small suppliers can win. Many small suppliers are neighborhood businesses that serve their local communities and are integral in ensuring convenient access to care for many beneficiaries. For this and other reasons, CMS should take action to ensure actual participation by small suppliers, not just a meaningless opportunity to bid.

L. Opportunity for Networks (Proposed § 414.418)

DACC Comment: Other than the proposed 20% rule, the Proposed Rule does not provide for safety measures to ensure that collusion among competitors would be avoided in the formation of networks. Have the Department of Justice and the Federal Trade Commission expressed an opinion on the appropriateness of the 20% rule?

M. Education and Outreach

1. Supplier Education

DACC Comment: CMS's aggressive timeline for implementation requires that CMS take the necessary time before implementation to educate all parties involved. In addition to beneficiary and bidding supplier education efforts, CMS should make a concerted effort to educate non-contract suppliers in an MSA and suppliers in non-competitively bid areas. It is certain that these suppliers will play an important role in beneficiary education. For example, many beneficiaries will likely attempt to obtain supplies from their current suppliers regardless of whether or not their current supplier is a winning bidder. Thus, those non-contract suppliers will need to provide key information to their former customers. The value of this educational effort

on the part of CMS emphasizes the need for a phased-in transition process or other contingency plans. See discussion above under G. Conditions for Awarding Contracts.

2. Beneficiary Education

DACC Comment:

First, as part of CMS's commitment to educate beneficiaries, CMS should publish supplier customer satisfaction survey results and/or statistics on quality measures to assist beneficiaries in making informed decisions. This would be consistent with the steps CMS took to facilitate beneficiary decision making within the Medicare Part D benefit.

Second, CMS states that one focus of CMS's education efforts toward beneficiaries will be the increased quality of products beneficiaries will be receiving as a result of the competitive bidding process. We believe that this statement is unsupported, and that, in fact, the opposite may be true. The statement wrongly suggests that suppliers that do not choose to bid or are not chosen solely on the basis of price do not supply high quality products. Indeed, it may be that the cost of developing a higher quality product prevents a supplier from bidding low enough to be selected for participation in the program. CMS should not use this misleading statement as part of their effort to educate beneficiaries on the competitive bidding program.

N. Monitoring and Complaint Services for the Competitive Bidding Program

O. Physician Authorization/Treating Practitioner and Consideration of Clinical Efficiency and Value of Items in Determining Categories for Bids (Proposed § 414.420)

DACC Comments:

See discussion under E. Criteria for Item Selection.

First, we are concerned about the clinical comparability of items within a particular HCPCS code. While HCPCS codes are assigned to multiple versions of a similar item, it is possible that there is wide variance in the brands or models available within a HCPCS code. Under the Proposed Rule, if the suppliers chosen as the successful contract suppliers in a particular MSA offer some but not all of the brands of an item, then the patient must overcome hurdles to get access to the "right" brand, which has been determined by a health care professional to best serve the patient's individualized needs.

Second, not offering an appropriate array of items may create significant, unnecessary barriers to quality care. Presumably, if a physician orders a particular brand or model, the physician has exercised his or her clinical judgment that the item is the best item for the patient. When selecting a self-monitoring blood glucose system for a patient, the health care professional makes a choice based on many factors, including, but not limited to: (a) strip size and ability of the patient to handle the strip (e.g., dexterity issues, tremor, vision problems, ability to touch reagent pad without affecting the result); (b) the impact on a blood test due to the patient's other

conditions, such as anemia, gout or congestive heart failure, and the monitoring system's ability to screen out interfering substances; (c) the ability of the patient to read the results from the display; (d) the sample size (i.e., whether patient has issues related to bleeding, such as warfarin therapy, skin thickness); (e) monitoring glycemic levels (e.g., data storage and/or connectivity to assist patients and clinicians with overall management); (f) ease of calibration; and (g) auto on/off features.

CMS should work to preserve a physician's recommendations. By permitting access to items based solely on the availability of brands or models from the winning bidders, the Proposed Rule potentially disrupts physician judgment exercised when ordering a specific brand or model item of DMEPOS. This could be true even if the item is currently a covered item under the Medicare HCPCS system. For example, certain blood glucose meters may require a large amount of blood to establish an accurate reading while another meter within the same HCPCS code may require only a small drop of blood. Unsurprisingly, this difference can have a major impact on patient compliance. If a winning bidder does not supply the meter requiring only a small amount of blood, then it is entirely possible that the patient who is forced to use the meter requiring a large amount of blood will fall out of compliance with their care plan. The decision a health care provider makes based on an patient's specific needs should not be denied merely because of the supplies available under the competitive bidding program. DACC recommends that physicians be allowed to state on a prescription that the prescription needs to be "dispensed as written," consistent with the practice permitted under the current system.

MMA also provides for a grievance, coverage, reconsideration and appeals process for non-formulary or non-preferred drugs. CMS should ensure that a similar process is available to allow beneficiaries to access the appropriate diabetes supply given their specific clinical needs. The bidding organizations should define the specific processes that they will use to address beneficiary requests and CMS should address the procedures as part of their outreach to beneficiaries, pharmacies and physicians.

In addition, the grievance and appeals procedures covering Part B benefits should be applied to the competitive acquisition program and the process should be communicated to the beneficiaries, as well as the pharmacies and physicians who interact with them.

P. Quality Standards and Accreditation for Suppliers of DMEPOS

DACC Comment: We agree that the quality standards and the related accreditation process are vital to ensuring quality of care. To this end, we believe the quality standards and accreditation processes must be completed *before* competitive bidding is implemented. Please see additional comments in Section G "Conditions for Awarding Contracts – Quality Standards and Accreditation."

1. Special Payment Rules for Items Furnished by DMEPOS Suppliers and Issuance of DMEPOS Supplier Billing Privileges (Proposed § 424.57)

2. Accreditation (Proposed § 424.58)

3. Ongoing Responsibilities of CMS Approved Accreditation Organizations

4. Continuing Federal Oversight of Approved Accreditation Organizations

   a. Equivalency Review

   b. Validation Review

   c. Notice of Intent To Withdraw Approval for Deeming Authority

   d. Withdrawal of Approval for Deeming Authority

   e. Reconsideration

Q. Low Vision Aid Exclusion (Proposed § 414.15)

R. Establishing Payment Amounts for New DMEPOS (Gap-filling) (Proposed § 414.210(g))

DACC Comment:

First, we are concerned that the Proposed Rule addresses tremendously important gap-filling and HCPCS coding procedures for new DMEPOS in a relatively cursory way. While we may agree that the existing gap-filling methodology used for new DME could be improved, we are concerned about CMS's proposal to use a technology assessment process to determine whether to establish new HCPCS codes and their payment amounts. The proposed gap-filling methodology has broad implications and should be given the consideration and detail that this complex issue requires.

Second, we urge CMS to defer these subjects, which are separate and distinct issues from competitive bidding, for separate notice and comment period. We explain, below, why we think the notice violates the APA by grouping these disparate subjects together in one document, with a title that does not capture the breadth of the topics. It is revealing to look at the different places at which these rules need to be codified.

Third, in addition to our concerns about the proposed methodology for determining prices for new technology, we are concerned that if prices are subject only to the CMS's discretion, the prices established may be unreasonably low, which will have a negative impact on innovation by the manufacturing industry. Another adverse consequence of setting the payment level too low is that there will not be enough companies either willing or able to supply the needed product, and beneficiaries will suffer. These unreasonably low prices may discourage development of new technologies that could have a positive impact on the care of Medicare beneficiaries, including those living with diabetes.

Fourth, we believe it is imperative that CMS include the due process protections of the kind that CMS employs in making coverage decisions. These necessary protections are designed

to ensure transparency and appropriate decision-making for such important subjects. In the courts, there is a rule of thumb that the level of procedural protections due is proportionate to the importance of the decision. Setting the payment level for new technology is likely the single most important determinant of the supply, both current and future. Further, the complexities associated with setting the payment level bode for a public process, to better insure that the decision is correctly made. A public process also leads to a certain sense of fairness, because it allows for participation by stakeholders. Without such a process, it leaves stakeholders no avenue to offer their insights, other than complaining to members of Congress. Creating an administrative process for the decision-making creates an outlet for stakeholder concerns, so they do not need to bubble over into other forums.

Fifth, CMS has not yet provided important details on the proposed technology assessment process. This process includes functional assessments, price comparison analysis, and medical benefit assessments, each of which are likely to be best performed by a different experts. However, CMS has yet to provide any details on where these different experts are to be found within the agency. Coverage decisions and payment decisions ordinarily are separate decisions in part because they call upon completely different sets of expertise. Due to the lack of specificity in these and other areas related to the proposed gap-filling and establishment of new HCPCS code methodologies, we are unable to comment effectively on these issues. Moreover, the detail that *is* provided is concerning, for it leads us to believe that the proposed new process will duplicate existing coverage and payment procedures, requiring additional steps, but providing no additional benefit.

S. Fee Schedules for Home Dialysis Supplies and Equipment (Proposed § 414.107)

T. Fee Schedules for Therapeutic Shoes (Proposed § 414.228(c))

III. Collection of Information Requirements

IV. Response to Comments

V. Regulatory Impact Analysis

A. Overall Impact
B. Anticipated Affects
C. Implementation Costs
D. Program Savings
E. Effect on Beneficiaries
F. Effect on Suppliers
   1. Affected Suppliers
   2. Small Suppliers
G. Accounting Statement

***

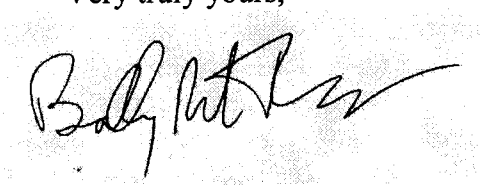
We conclude with two overall points.

First, CMS should provide more specificity in the Proposed Rule. In our section by section comments, above, we pointed out some of the places where crucial detail is lacking. **See Sections II.C.5., II.D.2.b., II.E. and II.R. under the Specific Comments section of this document.** We believe that this lack of specificity prevents us from commenting effectively, and therefore violates the Administrative Procedures Act ("APA"). The whole purpose of a proposed rule is to put the public on notice regarding the important contemplated features of the rule so that the public has enough information to be able to comment on the possible consequences of the rule. Unfortunately, we do not know enough about what CMS plans to do in those areas to be able to forecast the possible consequences.

In addition, the notice is defective in that it combines unrelated proposals. We are very concerned that the Proposed Rule addresses a variety of topics that are far afield from competitive bidding [see section II.D.2.c on a national mail order program and section II.R. "Establishing Payment Amounts for New DMEPOS" discussing gap filling measures] that require consideration as separate and distinct programmatic changes. We strongly urge CMS to limit the Proposed Rule to those issues that are directly related to competitive bidding and to remove all other issues so that these areas may receive the separate rulemaking they deserve. We believe that parties who would otherwise be stakeholders and therefore interested in commenting on these other aspects of the Proposed Rule have not received proper notice of the proposed changes because the title of the Proposed Rule has not given notice of those other changes. As such, those parties are being denied their right to comment as specified by the APA's requirement that notice of proposed rulemaking be published in the Federal Register, including a statement of the time, place, and nature of public rulemaking proceedings; reference to the legal authority under which the rule is proposed; and either the terms or substance of the proposed rule or a description of the subjects and issues involved. The only remedy is for the agency to republish these other topics in separate rulemaking with appropriate titles that capture the full scope of the contemplated changes.

We look forward to working with CMS on implementation of the Proposed Rule. If you would like to discuss this issue further, please contact me at Epstein Becker & Green at 202-861-0900.

Very truly yours,



Bradley Merrill Thompson,
For the Diabetes Access to Care Coalition

cc: Herb Kuhn
Laurence Wilson
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SUPLIDORES DE EQUIPO MÉDICO ASOCIADOS, INC.

May 25, 2006

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Re: Competitive Bidding Areas (Comments)
Federal Register Vol. 71, No. 83 – Monday, May 1, 2006 – Proposed Rules

Dear Distinguished Members of the PAOC and CMS Evaluators,

In my capacity as President of SEMA (Suplidores de Equipo Médico Asociados, Inc.), a Puerto Rico DMEPOS association that for the past 13 years has been representing and providing orientation to DME suppliers in Puerto Rico, it has been brought to my attention by our internal committee in charge of studying the impact of the Competitive Bidding Program on the island, local DME members, patient advocates and practitioners in Puerto Rico's health care system, their concerns regarding the methodology proposed by CMS and the possibility of Puerto Rico being selected for the initial phase of the Competitive Bidding Program in 2007.

Under section 302 of the Medicare Modernization Act of 2003, the law requires Medicare to replace the current durable medical equipment payment methodology for certain items with a competitive acquisition process to improve the effectiveness of its methodology for setting DME payment amounts. According to CMS this new bidding process will harness marketplace

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dynamics and will create incentives for suppliers to provide quality items and services in an efficient manner and at reasonable costs.

According to section 1847(a)(1)(B) of the Social Security Act, CMS has the authority to phase-in Competitive Bidding Programs so that the bidding under the program occurs in 10 of the largest metropolitan statistical areas (MSA's) in 2007. Within their proposal CMS presents a methodology for selecting the initial Competitive Bidding areas for 2007 by selecting 10 areas from a pool of the top 50 MSA's using Census Bureau population data and excludes the top three major metropolitan areas that included New York, Los Angeles and Chicago. They propose to eliminate the 25 MSA's that had the fewest DMEPOS allowed charges for items furnished in 2004 and scored the remaining 25 MSA's on combined rankings based on DMEPOS allowed charges per fee-for-service beneficiaries and ratio of providers to beneficiaries using DMEPOS in 2004. Based on this ranking formula, Puerto Rico may possibly be selected as one of the ten areas for the initial phase of the Competitive Bidding Program in 2007.

We vehemently oppose the inclusion of Puerto Rico in this 2007 initial phase program and we present the following rationale as to why Puerto Rico should not be included in this initial phase.

The primary objective of the Competitive Bidding Program is to reduce the amount Medicare pays for DMEPOS and bring the reimbursement amount more in line with that of a competitive market. With the implementation of the Medicare Advantage (MA) program in Puerto Rico, this objective has been achieved. According to information provided by the CMS Director of Puerto Rico, Ms. Delia Lasanta, more than 50% of the beneficiaries in Puerto Rico are presently enrolled in an MA program as of May 9, 2006. Currently in Puerto Rico there are eleven Medicare Advantage Organizations providing services to beneficiaries across the island. Geographically, Puerto Rico is a relatively small island, ranging 100 miles east to west and 35 miles north to south, and is composed of 78 municipalities of which the vast majority are rural areas. Two of these municipalities may be considered slight metropolitan areas. The major city and capital, San Juan, is considered the largest metropolitan area in Puerto Rico, however large sections of this city are still rural in nature and does not fully encompass the conceived idea of a major metropolitan city such as Houston, Detroit or Boston, which are cities fully recognized as metropolitan in nature. Therefore, upon considering the total amount of MA Organizations that cover Puerto Rico, the small size of the island, the aggressive marketing and reach-in programs used by these MA Organizations, and the steady increment of enrollment by beneficiaries, it is strongly believed that by 2007 the number of MA enrollees could come close to cover all beneficiaries on the island.

When evaluating Puerto Rico's marketplace one must consider that currently Puerto Rico does not possess any local DMEPOS manufacturers, which forces local suppliers to order supplies from companies in the United States, causing an increase of costs. Only companies that

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can order in large, bulk quantities would have the ability to endure the Puerto Rico market and be competitive within the Competitive Bidding Program. The result would be an economic catastrophe for many small DME supply companies and would eventually lead to possible healthcare anti-trust violations. This outcome has proven to be probable, between 1999 and 2001 a Medicare pilot program was initiated in Polk County, Florida and after only two rounds of bidding, one national company emerged as dominant in the Medicare oxygen market. This is extremely worrisome for the constituents of Puerto Rico healthcare systems having the majority of DME suppliers forced out of the market due to their small business volume, which consists mostly of beneficiaries located in difficult to reach rural areas; therefore the Competitive Bidding Program would inadvertently impact the beneficiaries access to DME supplies that previously were available in their region. This eventual result would defeat one of the main objectives of the program, which consists in the protection of beneficiary access to quality DME supplies. Although CMS through the Competitive Bidding Program contends that standards can protect quality, the government's ability to develop and enforce standards in Puerto Rico has proven to be very poor specifically when enforcing standards against MA Organizations regarding marketing tactics. Relying on government defined and enforced standards are no substitute for the ability for beneficiaries to choose among various suppliers.

In addition, long-standing relationships between beneficiaries and familiar suppliers will be interrupted causing disruption in service and dissatisfaction for patients. Given Puerto Rico's location in the heart of the Caribbean Sea the island is impacted yearly by hurricanes and tropical storms that makes it impossible for distant suppliers to provide the service needed because of sudden flooding in many of the small, rural roads in the vast regions of the island, these common events impacts the beneficiaries access to DME supplies, such as oxygen tanks that are needed on a regular basis. In summary, the result of the implementation of the Competitive Bidding Program would be that small, community-based suppliers would be displaced by larger chain suppliers that can take advantage of economies of scale, but which may not be in the interests of beneficiaries. The Competitive Bidding Program will make it impossible for the beneficiary that decides to continue with Traditional Medicare to do so, because although in essence the beneficiary would be entitled to continue under the label of "Traditional Medicare", they would not have the actual benefits of selecting from an array of suppliers since only one or two suppliers would be available to provide services. It is this freedom of selection that is currently provided by Traditional Medicare that must be vigilantly safeguarded.

Another relevant aspect to consider is that the Allowed Charges used to consider Puerto Rico in the implementation of this initial phase corresponds to the 2004 fee schedule. During 2003 to 2004 CMS allowed charges to Puerto Rico which were higher than in the States due to the recognition of the added costs involved in importing DME supplies, such as local importation taxes, shipment/transportation expenses and freight-insurance charges, but in 2005 this fee-schedule was reduced by CMS and presently the DME suppliers now have to absorb these previous added costs, therefore the use of Allowed Charges of 2004 does not reflect the current

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reality of Allowed Charges in Puerto Rico, which the PAOC is using to select the MSA's that are to be included in the initial phase of the program in 2007.

Another important factor that needs to be addressed is the language barrier that currently exists between Puerto Rico and the United States, given that the majority of the islanders are native Spanish speakers. The implementation of this program will be at a high cost for many suppliers and will cause a decrease in supplier access to beneficiaries, resulting in a less competitive market.

Since Puerto Rico is composed of almost 100% Hispanic communities, there is a high predisposition to certain health conditions, such as Diabetes and Heart Diseases, which have a direct impact in the Allowed Charges made to Medicare. Based on studies performed by the Department of Health of Puerto Rico, statistics showed that 18 out of every 100 women 65 years of age or older were diagnosed with chronic heart conditions and 22 out of every 100 men 65 years of age or older were also diagnosed with chronic heart conditions. Regarding diabetes, statistics demonstrated that 20 out of every 100 women 65 years of age or older were diagnosed with diabetes and 22 out of every 100 men 65 years of age or older were also diagnosed with diabetes. This data demonstrates a steady increment in the diagnosis of these chronic conditions on the island, therefore it is important that when analyzing the Allowed Charges one has to consider the reality that many beneficiaries in Puerto Rico possess these serious and chronic illnesses. In fact, the supply costs in Puerto Rico are currently competitive and even though the Allowed Charges numbers are high, one cannot conclude that the high Allowed Charges is a result of suppliers not being competitive.

Another CMS objective for the implementation of the Competitive Bidding Program is to limit the burden on beneficiaries by reducing their out-of-pocket expenses, it is SEMA's belief that MA Organizations have already achieved this goal by providing their enrollees with no out-of-pocket expenses or low out-of-pocket expenses.

Based on the rational presented in this letter it is SEMA's understanding that the objective of the Competitive Bidding Program will not be achievable in Puerto Rico and will cause a contrary effect for the implementation will result in attaining the opposite results originally intended. In fact Medicare will incur a larger economic expense to achieve an objective that is already taking place because of the MA Organizations actions and the changes resulting from the Medicare Reform of 2003. It is SEMA's position and request that the Competitive Bidding Program in Puerto Rico not be implemented in 2007 or in 2009, because the current system already provides a way to harness marketplace dynamics that creates incentives for suppliers to provide quality items and services in an efficient manner and at a reasonable cost.

For these reasons, we present these rationales to our distinguished members of the PAOC and CMS Evaluators that have the difficult task of recommending to CMS the methodology to select

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the regions that will be included in the 2007 initial phase. We strongly recommend that the PAOC and CMS Evaluators consider the rationale previously presented when deciding whether to include Puerto Rico in the initial phase or in the program all together.

Sincerely,

Ramon Bonilla
President - SEMA

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File No. 025147-0000

JUN 30 2006

June 30, 2006

BY HAND DELIVERY

Mark B. McClellan, M.D., Ph.D.
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Department of Health & Human Services
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200 Independence Avenue, SW
Washington, D.C. 20201

Re: Comments Regarding CMS—1270—P: "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues"

Dear Administrator McClellan:

On behalf of our client, Hoveround Corporation ("Hoveround" or the "Company"), we submit these comments on the above-referenced proposed regulations, which implement the Medicare Part B DMEPOS Competitive Bidding Program and revise the gap-filling payment methodology used to set fee schedule rates for new codes for DMEPOS items and services.[1] As a manufacturer and Medicare supplier of power mobility products, Hoveround expects to participate in the competitive bidding program and, for this reason, would be directly impacted by the proposals. The Company has concerns about some of the proposed policies and appreciates the opportunity to provide comments on this very significant new program.

With the competitive bidding program, the Centers for Medicare and Medicaid Services ("CMS") is ushering in a new chapter in Medicare history—setting payment for DMEPOS items used by beneficiaries in the home based not on fee schedule amounts, but rather on bid amounts submitted by DMEPOS suppliers. Hoveround's concerns and submitted comments are directed to the following areas in the proposed regulations:[2]

- Submission of Bids Under the Competitive Bidding Program
- Opportunity for Networks

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1 71 Fed. Reg. 25654 (May 1, 2006).

2 These are the subject headings that CMS requested commenters use to flag issues for the agency. Each of these subjects is noted as a heading in bold language and bracketed immediately preceding the relevant discussion. Please note that some subject headings are addressed multiple times in this comment letter.

- Conditions for Awarding Contracts
- Determining Single Payment Amounts for Individual Items
- Terms of Contract
- Physician Authorization/Treating Practitioner
- Payment Basis
- Gap-filling
- Administrative or Judicial Review

Summary of Comments

With this comment letter, Hoveround provides eleven recommendations for CMS's consideration:

(1) ***Secure Participation of Capacity Suppliers that May Not Have a Physical Location in the Service Area:*** Hoveround agrees with CMS's decision to permit suppliers that do not necessarily have a separate physical location in a competitive bidding area ("CBA"), but that offer services in the geographic area and have a demonstrated ability to do so, to participate in competitive bidding for that CBA. CMS should not limit indicia of capacity to having supplier numbers in a CBA, but rather should use meaningful indicia of capacity to serve a CBA.

(2) ***Classify Products Subject to Competitive Bidding Using Existing Medical Policy Categories and Consider Special Circumstances of Using Power Wheelchair Codes for Which There is Limited Experience:*** CMS proposes to conduct bidding for products grouped into "product categories." Hoveround recommends the use of existing Statistical Analysis Durable Medical Equipment Regional Carrier ("SADMERC") policy groups. Because these policy groups correspond to existing medical policies, the codes have a meaningful relationship to each other. Specialty suppliers can offer quality services to beneficiaries with certain medical conditions (*e.g.*, patients who need wheelchairs but not crutches), but—if the categories are not sufficiently narrow—suppliers with specialization in areas such as mobility needs will not be able to offer competitively bid items and services.

In addition, for purposes of competitively bidding power wheelchairs, Hoveround strongly believes that there is insufficient experience with the new HCPCS codes that are to become effective in October 2006. Special consideration should be given for situations where the Medicare program has significantly redefined a medical policy such that little or no information exists as to adequacy of coverage and/or fee schedule payment amounts.

(3) ***Ensure the Integrity of Bid Evaluations by Requiring Accreditation Prior to Bid Submission:*** CMS must take steps to safeguard the integrity of the bid evaluation process so that payment rates are realistic. This should include the requirement that suppliers be accredited prior to submitting bids. Only accredited suppliers can account for the initial and ongoing operational costs of accreditation in their bid proposals. At minimum, CMS should ensure that only the bids of suppliers

that meet the accreditation and quality standards are considered and selected as winning bidders.

(4) ***Cap Estimated Capacity Per Supplier When Selecting Winning Bidders to Preserve Competition and Beneficiary Choice:*** CMS proposes to determine winning bidders by selecting a "pivotal bid" from among the composite bids submitted by suppliers. This pivotal bid would be set at the point where expected combined capacity of bidders is sufficient to meet expected beneficiary demand for items in a product category in the CBA. Hoveround strongly believes that CMS should take steps to ensure that this approach is transparent and, importantly, does not result in selection of a small number of suppliers with large capacity to the detriment of the industry, the agency, and beneficiaries alike. It is in the interest of the program to preserve competition among suppliers so that there are several competing bids in subsequent bidding cycles and so that beneficiaries continue to have a choice in the products furnished to meet their medical needs. Hoveround recommends that CMS cap each supplier's capacity at 20% of anticipated demand to ensure that a small number of very large suppliers do not become the only winning bidders for a CBA.

(5) ***Tailor Program Requirements to Address Business Considerations of the DMEPOS Industry:*** In order to meet with success, the competitive bidding program must incorporate the practical realities and limitations of the DMEPOS industry. This might at first blush appear to be an obvious goal, but the means to accomplish this are not evident. To that end, therefore, Hoveround offers the following recommendations to modify four specific proposals:

(a) Proposed 42 C.F.R. § 414.422(c), which would require contract suppliers to bear responsibility for repairs and maintenance of items that were previously furnished by non-contract suppliers, should be revised to reflect that suppliers in most instances cannot handle such work for products other than those that they sell and thus this proposal should not be finalized;

(b) Proposed 42 C.F.R. § 414.420, which would oblige contract suppliers to make a reasonable effort to furnish a particular brand or mode of delivery of an item, as prescribed by the physician or treating practitioner, should be revised to make clear that the contract supplier need not have the ability to offer it if the item is not part of the supplier's inventory;

(c) Proposed 42 C.F.R. § 414.422(d), which would place limitations on contract suppliers' ability to continue to participate in competitive bidding upon a change in ownership, should be modified to permit contract suppliers to continue to participate as such if the legal entity enrolled in the Medicare program does not change (*e.g.*, there has been only a change in stock or other equitable ownership); and

(d) CMS's preamble to the proposed regulations, which discusses a requirement that contract suppliers of power wheelchairs offer rental items, should be limited to discrete situations, so that suppliers are not

required to float a large volume of loans to subsidize rentals, particularly given that the vast majority (Hoveround's experience shows 99%) of patients requiring power mobility have chronic and progressive conditions that require them to use the equipment for extended periods of time.

(6) ***Adopt an Approach for Setting Payment Amounts that Reasonably Reflects Actual Bids:*** Proposed 42 C.F.R. § 414.416, which would use the median of the winning bids (*i.e.,* those at or below the pivotal bid) to set the competitive bidding payment amount for each product, may force contract suppliers either to furnish products at prices far below their submitted bids or to leave the Medicare program. To avoid such an inevitable result, CMS should adopt a payment methodology for competitive bidding that does not set artificially depressed rates below the bid prices of a substantial number of the winning bidders. The formula used in prior demonstration projects (which was also offered in the proposed rule as an alternative) should be adopted instead.

(7) ***Ensure Payment Rules Used For HCPCS Codes Revised Mid-Cycle Result in Reasonable Payment Amounts:*** Under proposed 42 C.F.R. § 414.426, CMS proposes special payment rules for circumstances in which existing HCPCS codes are revised in the middle of a competitive bidding cycle. In situations where multiple codes describing similar products are merged into a single code, Hoveround seeks modification of the proposal, so that codes that were competitively bid continue to be used, along with their established payment amounts, until the end of the current contract.

(8) ***Consider Sales Volume Assumption Used to Calculate Bids When Using Competitive Bidding Rates to Adjust Payment Amounts in Non-Competitive Bidding Areas:*** CMS should take care in implementing its authority beginning in 2009 to adjust payment in non-competitive bidding areas based on payment information determined under the competitive bidding program. Application of this authority should not result in a de facto "any willing provider" model, with competitive bidding rates being set nationwide. Competitive bidding rates assume a significant increase in volume to offset lower prices that would not exist in non-competitive bidding areas.

(9) ***Discard the Proposed Rebate Program:*** Hoveround joins the objections lodged by the rest of the DMEPOS industry concerning CMS's proposal to allow suppliers to give rebates to beneficiaries for items furnished through the competitive bidding program. This proposal implicates and may run afoul of the Federal Anti-Kickback Statute and blurs the line between permissible and impermissible rebates in an ill-advised manner.

(10) ***Safeguard Existing Medicare Appeal Rights:*** Hoveround requests that proposed 42 C.F.R. § 414.424 be revised to clarify that existing rights of beneficiaries and suppliers to appeal denied claims are unaffected by the prohibition on appealing certain determinations made in the course of conducting the competitive bidding program.

(11) ***Revise the Proposed Gap-Filling Replacement to Follow Statutorily-Required***

Procedures & Ensure Fair Pricing: CMS's proposal in 42 C.F.R. § 414.210(g) to jettison the current gap-filling methodology for new DMEPOS items in favor of consideration of a variety of pricing data sources must not be adopted without significant revisions. As written, the proposed regulation is vague and impermissibly circumvents the procedural and substantive requirements to be used in any exercise of CMS's inherent reasonableness ("IR") authority. It is essential that any formula adopted here follow a transparent process for establishing reasonable, appropriate fee schedule rates for non-competitively bid products. Hoveround believes that this new regulation deserves considerable attention that it likely will not receive because it has been appended to the proposed regulations for competitive bidding. Hoveround therefore asks that CMS postpone publication of a final regulation on this topic to provide time for suppliers to submit additional comments and/or to meet with the agency to discuss alternatives.

I. SECURE PARTICIPATION OF CAPACITY SUPPLIERS THAT MAY NOT HAVE A PHYSICAL LOCATION IN THE SERVICE AREA

[Submission of Bids Under the Competitive Bidding Program/Opportunity for Networks/Conditions For Awarding Contracts]

Hoveround believes that a relatively small number of large-capacity suppliers currently provide a significant volume of DMEPOS items to beneficiaries and that, without their involvement in competitive bidding, there is likely to be a shortage or total lack of availability of certain items in CBAs. Hoveround thus supports CMS's proposal not to require bidding suppliers to be physically located in the CBAs in which they submit bids. In addition, CMS should ensure that large chain suppliers cannot game this system. As written, the proposed regulations do not clearly prevent suppliers with multiple supplier numbers from submitting multiple bids in a single CBA. The regulations should be revised to prevent unfair practices.

Below we address recommendations on these two issues.

CMS Correctly Recognizes that No Physical Location Should Be Required

Hoveround agrees that physical location is an imprecise proxy for whether a supplier would be willing and able to serve Medicare beneficiaries in a given CBA.[3] Relying on physical location would prevent the participation of many suppliers, including several with large capacity that operate on a national scale. This in turn could have the perverse, unintended effect of drastically limiting the supply of products available for beneficiaries in CBAs. Hoveround therefore supports CMS's proposal not to require bidding suppliers to be physically located in the CBAs in which they submit bids.

CMS's proposal is in line with longstanding Medicare supplier standards. As the agency is aware, some large capacity suppliers use a centralized operation (at which billing, patient

[3] 71 Fed. Reg. at 25672 (concluding that such a requirement would be "too proscriptive").

contacts, complaints and other matters are addressed), with warehouse locations across the U.S. from which products are delivered to patients for home use. These satellite warehouse locations do not have their own Medicare DMEPOS supplier numbers; rather, they are part of the national organization and operate under its supplier number. Medicare has a longstanding policy of permitting such organizational structures. The Medicare statute provides that all suppliers furnishing medical equipment and supplies to beneficiaries must obtain a supplier number, showing that they meet supplier standards. The statute calls for CMS to create a supplier standard requiring the supplier to "maintain a physical facility on an appropriate site."[4] Medicare Supplier Standard #7 implements this requirement, stating that a supplier must certify that it:

> Maintains a physical facility on an appropriate site. The physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communication records. For purposes of this standard, a post office box or commercial mailbox is not considered a physical facility. In the case of a multi-site supplier, records may be maintained at a centralized location.[5]

This supplier standard recognizes that some suppliers will be set up with multiple sites and that all of the functions of a Medicare supplier need not be performed at each site. The instructions for completing the enrollment application (Form CMS-855S) further clarify this point; CMS distinguishes between "new business locations"—for which a complete CMS-855S is to be completed and an entirely new supplier number is needed—and sites that are part of an organization with an existing supplier number, for which no reporting obligation exists.[6]

Hoveround has taken the approach of organizing itself with a centralized office and a number of warehouse locations. The Company believes that this approach allows it to more effectively interact with Medicare contractors and to provide consistent, high quality services to Medicare beneficiaries.

In sum, the key to success of competitive bidding is ensuring that suppliers who have the capacity to service CBAs can continue to furnish products to beneficiaries in those areas. Use of physical location as a gauge for supplier interest and ability to service a CBA would create product supply issues. It is also an imprecise method for determining whether a supplier can handle business in the area.

An accurate measure of supplier capacity is past business to beneficiaries in the area (*i.e.*, prior years' total allowed charges for products in the product category), coupled with the supplier's detailed business plan for expansion, if any. Notably, CMS proposes to use such

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4 42 U.S.C. § 1395m(j).

5 42 C.F.R. § 424.57(c)(7).

6 *See* Form CMS-855S (http://www.cms.hhs.gov/cmsforms/downloads/cms855s.pdf).

information in determining the capacity of each bidding supplier[7] and proposes to collect it through proposed Form B (Bidding Sheet)—the form that bidding suppliers would complete in submitting a bid for each product category in a CBA. On this form, CMS solicits data regarding the total revenue collected by the supplier, the total number of customers served in the CBA for the product category in the past year, and the percentages of those numbers attributable to Medicare. This form also asks bidding suppliers to describe their expansion plans for the CBA, if any.[8] Hoveround believes that this approach is sound and accurate and that it should be finalized as written.

CMS Should Limit Bids To One Bid Per Supplier

As described above, under existing Medicare DMEPOS supplier rules, a single organization may have multiple supplier numbers, provided that each location in its own right meets the Medicare supplier standards.[9] Particularly in the early stages of the program's implementation, CMS should be wary of the ability of suppliers with multiple supplier numbers to game the system in ways that could result in less savings and/or jeopardize the success of competitive bidding. Specifically, national chain suppliers with multiple supplier numbers can submit multiple bids for a single CBA in a way that limits competition. CMS should tighten its existing proposal to ensure that a *single organization* may only submit one bid.

Hoveround urges CMS to ensure that organizations with multiple supplier numbers are not incentivized to manipulate the bidding system by submitting an array of bids for a single product category in a CBA as a way of increasing its odds of being selected as a contract supplier. The purpose of competitive bidding is to achieve savings through the lowest competitive bid that can retain Medicare business. Without prohibiting the practice of a single supplier inappropriately submitting multiple bids, there is no way for Medicare to ensure that competition will not be unfairly impeded.

In proposed 42 C.F.R. § 414.418(b)(5), CMS explicitly forbids a supplier to submit a bid both on its own and as part of a network for a particular product category.[10] The reason for this provision is likely that CMS believes it is inappropriate for a supplier to take "two bites at the apple." Hoveround believes that this proposal should be taken a step further. CMS should include a requirement that suppliers with common ownership of 5% may only submit a single bid for each product category in a given CBA.[11] A similar restriction should be put in place for suppliers under control of other suppliers, so that only one bid submission for each product

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7 71 Fed. Reg. at 25676.

8 *See* http://www.cms.hhs.gov/PaperworkReductionActof1995/PRAL/itemdetail.asp?filterType=none&filterbyDID=-99&sortByDID=2&sortOrder=descending&itemID=CMS063052

9 *See* 42 C.F.R. 424.57(c);

10 *See* 71 Fed. Reg. at 25683.

11 In many cases, the requirement that the supplier demonstrate past history of conducting business in the CBA may mitigate against a supplier's ability to game the system in this manner; however, out of an abundance of caution, Hoveround asks that CMS adopt a common ownership restriction.

category is made for each CBA. This could be accomplished by revising 42 C.F.R. § 414.412—the provision describing the rules for bid submission—to add a new subsection (h), stating (italicized language added):

> *A bidding supplier may only submit one bid per product category per competitive bidding area. Bidding suppliers with common ownership of 5% or more, or that are under control of another supplier, shall be deemed a single supplier for purposes of this section.*"

This change would go far toward ensuring that the bidding process is conducted on an even playing field—free from activities that can skew bidding and favor organizations with multiple supplier numbers over other bidders.

II. CLASSIFY PRODUCTS SUBJECT TO COMPETITIVE BIDDING USING EXISTING MEDICAL POLICY CATEGORIES AND CONSIDER SPECIAL CIRCUMSTANCES OF USING POWER WHEELCHAIR CODES FOR WHICH THERE IS LIMITED EXPERIENCE

[Submission of Bids Under the Competitive Bidding Program]

CMS proposes to conduct bidding for products grouped into "product categories," defined as groups of similar items used in the treatment of a related medical condition. Each group would be comprised of items defined by HCPCS codes. To bid on a product, a supplier would need to submit bids on the full spectrum of HCPCS codes contained in that product category—with a separate bid amount for each HCPCS code. CMS also proposes that the composition of the product categories may differ from one CBA to another, depending on whether the agency believes it will be able to realize savings for a particular product in a particular CBA.[12]

Hoveround strongly urges CMS to use the existing SADMERC policy groups as the product categories for competitive bidding, rather than inventing new and broader categories. The SADMERC policy groups are groupings of HCPCS codes that correspond to their assignment to medical policies. Thus, they are a rational grouping from a clinical perspective, in so far as they are likely to include items and services that beneficiaries with certain medical conditions might need. In addition, they are narrow enough to promote specialization among suppliers, which, in turn, may enhance the quality of services provided to beneficiaries.

A single supplier is likely to carry a wide array of products within a medical policy area. CMS must balance the desire to permit beneficiaries to use a single supplier for their DMEPOS needs (the "one-stop shop" structure), with the importance of promoting specialized, effective service. If CMS creates new, broad product categories, many, if not all, suppliers would not be able to provide an item for each HCPCS code. For instance, many power mobility suppliers carry only powered products (such as power wheelchairs and POVs) and do not necessarily carry other mobility equipment (such as canes, walkers, or manual wheelchairs). In opting to conduct

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[12] 71 Fed. Reg. at 25672-73.

bidding at the product category level, CMS highlighted that it favors that approach because it both allows suppliers to be specialized in their product offerings and permits them to take advantage of economies of scale. This rationale holds true for using the existing policy group definitions for the competitive bidding product categories as well. If broader categories are used, there is a greater likelihood that products for which no significant savings can be achieved would nonetheless be included in the competitive bidding program.

As to needed revisions to the applicable proposed regulation, 42 C.F.R. § 414.412, Hoveround asks CMS to revise subsection (c) so that it reads as follows (with proposed language in italics):

> Product categories include items that are used to treat a related medical condition. The list of product categories, and the items included in each product category that is included in a particular competitive bidding program, are identified in the request for bids for that competitive bidding program *and will correspond to the policy groups of the Statistical Analysis Durable Medical Equipment Regional Carrier, unless CMS determines there is good cause to align items differently for a particular competitive bidding program*.

In addition, Hoveround urges CMS to evaluate the impact of changes to policy groups that occur shortly before the bidding process. For example, the power mobility device benefit is in the midst of an extensive overhaul and remains in a state of flux. Most recently, 64 new codes were established, to become effective October 1, 2006. The payment rates have not yet been determined. Nor has a local coverage policy been finalized. In light of the changes here, if any of these new power mobility device codes are selected for a product category, this would add a layer of uncertainty about how to bid the codes for purposes of competitive bidding (and how to select winning bidders). Without weighing these uncertainties, an inappropriate array of codes may be selected for a product category. This may result in a tremendous disservice to Medicare beneficiaries—who would almost certainly be hit hard if capacity and pricing estimations are incorrect and there is a scarcity of certain power wheelchair products in their geographic areas.

Recognizing that there is no easy solution here, Hoveround suggests that CMS weigh carefully the option of using existing codes for competitive bidding purposes only. This would eliminate, or at least minimize, confusion and uncertainties, since both CMS and the supplier community understand historical pricing and capacity information. Bids could be based on informed experiences with the codes and CMS would be in a better position to select winning bidders because there would be available information on supplier capacity and beneficiary need in a specific area. One of the benefits of this approach is that there could be no question that savings could be projected. The new codes, once effective, could be used in all non-competitive bidding areas. After initial phases of the program, suppliers and CMS would have gained experience with the codes in other areas and there would be pricing and capacity data for the new codes.

III. ENSURE THE INTEGRITY OF BID EVALUATIONS BY REQUIRING ACCREDITATION PRIOR TO BID SUBMISSION

[Conditions For Awarding Contracts]

Hoveround strongly supports CMS's proposal to require suppliers to meet quality and financial standards in order to be awarded bids. The Company believes that it is also imperative that suppliers be accredited prior to submitting the bids and, at a minimum, that only the bids of qualified suppliers be considered in selecting winning bidders. Only by doing so can CMS ensure that the integrity of the bid evaluation process is maintained and results in reasonable competitive bidding payment rates.

In proposed 42 C.F.R. 414.414, CMS would require that each supplier meet basic eligibility requirements (such as complying with existing Medicare supplier standards), comply with DMEPOS quality standards and be accredited by a CMS-approved accrediting organization, and meet applicable financial standards. To evaluate the bids themselves, CMS proposes a three-step process: (1) establish a single composite bid for each supplier for a particular product category; (2) array these composite bids from lowest to highest; and (3) select a pivotal bid (based on estimated beneficiary demand), with winning bidders being those at or below the pivotal bid.[13] The timing of CMS's determination as to whether a supplier meets the eligibility standards is key.

CMS proposes to allow a grace period during which bidding suppliers could come into compliance with the quality standards.[14] The agency does not otherwise address the order in which it will evaluate bid submissions. At the May 2006 Program Advisory & Oversight Committee ("PAOC") meeting, CMS officials indicated that the agency has not yet decided how to address this issue. Hoveround recognizes that a grace period would assist certain suppliers in becoming accredited, particularly given the compressed time after the quality standards are finalized in June 2006. Under no circumstances, however, should the grace period be permitted to undermine the integrity of the bidding process. There is a very real danger that, if CMS permits suppliers to submit bids prior to becoming accredited, these suppliers will drastically underestimate the operational costs involved in obtaining and maintaining accreditation.

Hoveround believes that suppliers will not be able to calculate bid amounts accurately unless they have first undertaken and completed the accreditation process. Inaccurate bids—particularly in an industry where accreditation has become the standard—could result in competitive bidding payment amounts that do not account for the recognized cost inputs in maintaining accreditation and that are inappropriately low. This in turn would either lead to beneficiaries receiving poor quality items and services or a complete lack of access to products because suppliers are forced to exit the Medicare program for financial reasons. To avoid such

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13 *See* 71 Fed. Reg. at 25674-75.

14 *See* 71 Fed. Reg. at 25675.

results, Hoveround urges CMS not to permit a grace period.

If, however, CMS decides to offer a grace period notwithstanding these serious concerns, it is absolutely critical that the agency consider the supplier's ability to meet these standards *prior to selecting the pivotal bid.* Otherwise, the bidding pool will be tainted by bids of suppliers that are not qualified to provide competitively bid products to beneficiaries. Without up-front consideration of the eligibility requirements, Hoveround is concerned that competitive bidding payment rates will be artificially depressed and unreasonably low.

If CMS does decide to go forward with its proposal to permit a grace period, Hoveround recommends that the agency revise proposed 42 C.F.R. § 414.414 to specify that bids will be evaluated only if submitted by suppliers meeting the requirements listed in subsections (b)-(d). Specifically, those subsections provide that the supplier must meet basic eligibility requirements, comply with DMEPOS quality standards and be accredited by a CMS-approved accrediting organization, and meet applicable financial standards. The following two changes would accomplish this:

- First, the proposed regulation should provide that the conditions for awarding contracts are evaluated prior to evaluating bids. This order of operations could be explicitly set forth in a separate subsection, for instance, in a new subsection (e), stating: *"(e) Timing of conditions for awarding contracts. CMS will determine whether a bidding supplier meets the requirements in paragraphs (b) through (d) of this section prior to evaluating the bids as described in paragraph (f) of this section."* The lettering of the subsequent subsections would need to be shifted down one alphabetical letter, so that current subsection (e) becomes subsection (f) and so on.

- Second, proposed paragraph (e)(2)—which would be paragraph (f)(2) under the revised numbering suggested in our first point—should be modified accordingly, so it is clear that CMS would only include bids from qualified suppliers in its comparative evaluation of bid prices. The following added language is suggested: "[CMS evaluates bids submitted for a product category by— . . .] Establishing a composite bid for each supplier that submitted a bid for the product category *and met the requirements of paragraphs (b) through (d).*"

IV. CAP ESTIMATED CAPACITY PER SUPPLIER WHEN SELECTING WINNING BIDDERS IN ORDER TO PRESERVE COMPETITION AND BENEFICIARY CHOICE

[Conditions for Awarding Contracts]

Not only is it vitally important that CMS select only from qualified suppliers (as discussed above), but also Hoveround strongly believes that the contract award process must not result in the selection of only a small number of suppliers with large capacity. Hoveround is concerned that, as proposed, the selection process can easily result in only one or two suppliers with a very large capacity servicing a CBA. Such a result, for the most part, does not preserve the goals of a competitive program.

Specifically, under 42 C.F.R. § 414.414, CMS proposes to determine winning bidders by selecting a pivotal bid from among the composite bids submitted. As discussed above, the pivotal bid would be set at the point where the expected combined capacity of bidders is sufficient to meet expected beneficiary demand for items in a product category in the CBA. There is no transparent method to ensure that demand is not satisfied by one or two very large suppliers. At the same time, to preserve competition among suppliers, a reasonable number of low-priced bids should be able to prevail. Only in this way can future bidding cycles and savings continue to result from competitive bidding.

The Medicare statute requires selection of multiple bidders, and Hoveround supports CMS's inclusion of this requirement in the proposed regulations (proposed 42 C.F.R. § 414.414(g)). With only two suppliers retaining Medicare business in a region, however, there may be little to no competitively priced bids in the later phases of the program. Hoveround therefore urges CMS to take the long view in designing and implementing this program, so that it can continue to work and reap benefits beyond the initial phases. Hoveround recommends that CMS incorporate a cap on each supplier's capacity when evaluating demand for any given CBA. This would go a long way to protect beneficiaries' interests and ensure that they continue to enjoy choice in the products furnished to meet their medical needs.

A cap may be structured to evaluate low bids from very large suppliers favorably, yet also to limit each bidding supplier's demand to 20% of anticipated demand. In this way, even if the supplier could provide 50% of the products needed, it would only get credit for 20% for purposes of determining winning bidders. Further, the formula used should incorporate a transparent methodology that can be easily understood and reproduced. To ensure the integrity of such a methodology, CMS should make available the list of all bidding and winning suppliers and should provide an explanation of the methodology used to determine the composite bid, pivotal bid and competitive bidding payment amounts for each product category.

V. TAILOR PROGRAM REQUIREMENTS TO ADDRESS BUSINESS CONSIDERATIONS OF THE DMEPOS INDUSTRY

[Terms of Contract; Physician Authorization/Treating Practitioner]

Hoveround believes that, as proposed, the program does not adequately address business considerations of the DMEPOS industry and that a number of changes should be made to the regulations to ensure that suppliers are able to participate as a practical matter. Together, these provisions could lead many current suppliers to exit the Medicare program—a result that would have a devastating impact on beneficiaries' ability to obtain needed items.

Responsibility for Repairs/Maintenance of Items Furnished By Non-Contract Suppliers

Proposed 42 C.F.R. § 414.422(c) requires contract suppliers to bear responsibility for repairs and maintenance of items that were previously furnished by non-contract suppliers. Hoveround requests that, in recognition of the fact that contract suppliers can only perform such services for products that they sell, CMS refrain from finalizing this proposal.

Hoveround opposes this proposal because it ignores practical realities of the DMEPOS industry. In many, if not most, instances, suppliers have no experience in repairing or performing maintenance on items that were supplied by other suppliers and will be unable to perform such work themselves. This proposal, in effect, will require the contract suppliers to pay for a sub-contractor to perform the service—a result that would impose significant costs on winning suppliers. Otherwise, suppliers will need to seek out manufacturers to obtain parts needed to make repairs and, particularly if the suppliers do not have an ongoing business relationship with particular manufacturers, may not be in a position to obtain favorable prices for these one-off situations. It is difficult to determine what these costs will be in advance of bid submission and, as a result, short of CMS providing the information as part of the Requests for Bids, there is no way for suppliers to weigh this cost in determining bid prices.

Even if CMS is able to offer this information prior to bid submission, the proposal is particularly onerous for manufacturer-suppliers that only carry their own products and suppliers that have arrangements only with certain manufacturers, as is often the case in the DMEPOS industry. It is these very entities (manufacturer-suppliers and suppliers with consolidated purchasing arrangements) that may be able to provide the lowest bid prices because standardization of their product lines enables them to keep costs down. CMS's proposal, then, could inadvertently cause suppliers to increase the bid amounts submitted and, in the aggregate, decrease savings from competitive bidding significantly.

Hoveround therefore recommends that CMS continue to make payments for repair and maintenance of DMEPOS items to the non-contract supplier, as it has done in the past.[15] There is no reason to shift this burden to another supplier, particularly one who is likely to be unequipped to perform the services itself. If, however, CMS decides to proceed with this proposal, at a minimum, the agency should exempt manufacturer-suppliers from the requirement. Under this approach, the following regulatory language would be appropriate. A new subsection (c)(3) may be incorporated into 414.422: "*Contract suppliers that are FDA-approved manufacturers and that only furnish their own products to beneficiaries in the competitive bidding area are exempt from the requirement in paragraph (c)(1) for purposes of items furnished by other suppliers*."

Physician Authorization of Product Brand

Hoveround believes that revision is also warranted for proposed 42 C.F.R. § 414.420. This provision would oblige contract suppliers to make a reasonable effort to furnish a physician-specified brand (or mode of delivery). Under this provision, CMS notes that physicians and other treating practitioners could prescribe a particular product brand if they determine that it would avoid an adverse medical outcome for the beneficiary. If a treating practitioner specifies a particular product under these circumstances, the contract supplier would be required to "make a reasonable effort to furnish the particular brand." If the supplier is unable to furnish the

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15 Under existing Medicare Supplier Standard # 6, suppliers are required to provide maintenance and repairs for items furnished to beneficiaries under warranty at no charge. *See* 42 C.F.R. § 424.57(c)(6). There is no reason to alter this longstanding business requirement.

designated product, it would need to work with the practitioner to find an alternate item that is appropriate and obtain a revised order.[16]

Manufacturer-suppliers only maintain inventory that contains their own products and will never be able to furnish a brand other than their own. Hoveround believes that the regulation should be revised to make clear that the contract supplier need not be able to offer the item if it is not part of its inventory. This could be accomplished by adding a new subsection (b)(4) to 414.420, stating: "*The contract supplier is not required to furnish the particular brand or mode of delivery itself if such brand or mode of delivery is not in its inventory in order to be deemed to have made a reasonable effort under this paragraph (b).*"

Change In Ownership

Under proposed 42 C.F.R. § 414.422(d), CMS would place limitations on contract suppliers' ability to continue to participate in competitive bidding upon a change in ownership of their business. CMS proposes to require contract suppliers to notify CMS in writing 60 days prior to any changes of ownership, mergers or acquisitions being finalized. CMS would only allow the successor entity to continue to furnish products in the competitive bidding area if (1) there is a need for the successor entity to function as a contractor in order to assure expected demand for a competitively bid item; (2) the successor entity meets all requirements applicable to contract suppliers; (3) the successor entity assumes the contract supplier's contract, including all obligations and liabilities; *and* (4) the successor entity executes a novation agreement.

Hoveround believes that this proposal is overly restrictive and penalizes business arrangements that may have no impact on the contract supplier's relationship with CMS. Further, the proposed regulation would needlessly devalue the monetary worth of a supplier. Critically, the existing Medicare supplier standards, as well as the soon-to-be-implemented quality standards, already provide all the necessary assurances needed to ensure that only high quality services are provided to beneficiaries. The new notice requirement does not add to these assurances in any meaningful way.

Hoveround believes that the proposed regulation should be modified to clarify that the notification obligation and the limitations on continuing as a contract supply apply only where the contract is being transferred to new or different legal entity. The test would be the same as currently used to determine whether a new supplier enrollment application is needed under the instructions for Form CMS-855S. In those circumstances in which the legal identity of the contract supplier is not altered, by way of example, there may be no need to obtain the prior approvals. In contrast, if the legal identity of the acquired contract supplier would change as a result of the change in ownership, CMS may want assurances that the new supplier will be able to meet all obligations of the former supplier and will assume all of its liabilities under the existing contract.

CMS could also borrow (as it has in the past) from the definition of "change of

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16 *See* 71 Fed. Reg. at 25684.

ownership" in the provider context under 42 C.F.R. § 489.18(a). With respect to corporations, by way of example, this regulation provides that:

> The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.[17]

Hoveround thus suggests adopting this definition in the proposed regulation. This would notify contract suppliers of the types of transactions that would trigger the completion of a new Form CMS-855S, as well as the change that would trigger the examination by CMS that a contract supplier can continue to meet the obligations under the existing contract.

In addition, Hoveround asks that CMS finalize this proposal so that it is consistent with the existing notice requirements for DMEPOS suppliers. The current regulations do not require notice to CMS until *after a change of information or ownership has occurred* and adopt a 30-day timeframe. There is no reason to require advance notice in this context. CMS recently re-affirmed this approach in newly finalized supplier enrollment regulations, requiring DMEPOS suppliers to report changes of information and changes of ownership or control within 30 days of their occurrence.[18]

For these reasons, Hoveround suggests the following revisions to 414.422(d)(1): "A contract supplier must notify CMS in writing *within 30 days of* any change of ownership *(as such term is defined in section 489.18(a)) that would trigger completion of an entire new Form CMS-855S*."

Furnishing Power Wheelchairs On a Rental Basis

In the preamble, CMS proposes to require contract suppliers of power wheelchairs to agree to give the beneficiary (or caregiver) the choice of renting or purchasing the item and to furnish the item on a rental or purchase basis, as specified.[19] This requirement would unnecessarily impose financial hardships with little gains. Beneficiaries requiring power mobility currently purchase these items in the vast majority of cases because they have chronic, progressive and lifelong need for the device. Based on its extensive experience in the industry, Hoveround has observed that 99% of the power wheelchairs the company delivers to the Medicare population are prescribed for use well beyond the current 13- (or prior 15-) month statutory rental periods for typical capped rental items.

Under the Medicare statute, suppliers are currently required to offer beneficiaries the

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17 42 C.F.R. § 489.18(a)(3).

18 42 C.F.R. § 424.530.

19 71 Fed. Reg. at 25681.

option to *purchase* the power wheelchair at the time it is initially furnished to them.[20] The statute is silent as to whether a rental option must be offered and whether items must be furnished on that basis, if requested. Early in the 2006 budget reconciliation process, there was a proposal to make power wheelchairs a mandatory rental item. This proposal met with serious objections from the industry and beneficiary advocacy groups alike and was ultimately, and for good reason, excluded from the bill that passed Congress. Indeed, Congress affirmatively reiterated its intent to keep in place the up-front option to purchase. There are sound reasons not to revive the rental requirement here.

Power wheelchairs are designed to preserve an individual's functional ability and, in the Medicare population (the elderly and disabled), are used by those suffering from chronic and degenerating ailments and severe and/or permanent injuries. These individuals for the most part do not have temporary mobility needs. While power wheelchairs are of varying sophistication, they are frequently modified to suit specific body types and functional needs of patients. When provided for those with severe limitations, they are even more likely to be customized and unsuitable for use by another individual.

For power wheelchair manufacturers and suppliers, providing power wheelchairs to Medicare beneficiaries is a considerable, capital-intensive investment, including steps from the point of development of and manufacturing the product to obtaining prescriptions and qualifying the beneficiary under Medicare requirements. Delays in full Medicare payment for each and every unit supplied—regardless of the individual's medical condition and unique circumstances—is an untenable position for all providers of this benefit, regardless of size. This has a particularly devastating impact on small suppliers who are unable to float a large volume of loans to subsidize rentals for a period of time. Such a policy would increase the costs of doing business considerably, which would in turn increase bid amounts—contrary to the goal of achieving savings through competitive bidding.

Furthermore, providing wheelchairs on a rental basis has not been shown to save the Medicare program money. When the equipment is automatically transferred to the beneficiary in the 13th month of the rental period, as is required by statute, Medicare will have paid 105% of the lump-sum payment made if the beneficiary had purchased the product when it was furnished. For these reasons, it is inappropriate and unnecessary for CMS to mandate that contract suppliers offer a rental option to beneficiaries, and Hoverround strongly urges that this proposal not be adopted.

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[20] 42 U.S.C. § 1395m(a)(7)(A)(iii).

VI. ADOPT AN APPROACH FOR SETTING PAYMENT AMOUNTS THAT REASONABLY REFLECTS ACTUAL BIDS

[Determining Single Payment Amounts for Individual Items]

Hoveround is concerned that CMS's proposed methodology for competitive bidding payment amounts will not reasonably reflect actual bid amounts. The formula CMS opted to adopt under proposed 42 C.F.R. § 414.416—*i.e.*, the median of winning suppliers' bids—will by its nature result in a rate that is lower than the bid prices of half of the winning bidders. Many suppliers, including Hoveround, fear that they will not be able to continue to provide products to beneficiaries in the CBAs if the established rates are far below their bid prices. In order to raise the chances that they will be selected to participate in competitive bidding, suppliers are likely to submit bids at or near their margins. Thus, if CMS sets the payment rates at the median of winning bidders' bid prices, up to half of the winning bidders may consider these rates unacceptable and may not be able to continue to provide products to beneficiaries in those areas.

Hoveround believes that alternative approaches would lead to a reasonable payment rate. Specifically, the Company supports the adjustment factor approach that was used in the demonstration projects and is discussed in the preamble to the proposed regulations.[21] Under this approach, CMS would calculate payment rates as follows:

(1) Calculate the average of the winning bids for each HCPCS code;

(2) Calculate the average of the composite bids for a product category;

(3) Establish an adjustment factor (*i.e.*, pivotal composite bid divided by average composite bid) that is intended to bring each winning supplier's overall bids for a product category up to the pivotal bid; and

(4) Multiply the amount from Step 1 by the amount from Step 3.

This approach ensures that the overall payment amount that contract suppliers receive is at least as much as their bid prices. As CMS observes in the preamble to the proposed regulations, suppliers may be less likely to leave the Medicare program if this approach were adopted because there is some assurance that payment rates will be sufficient. Hoveround thus recommends that 42 C.F.R. § 414.416 be amended to incorporate this methodology in lieu of the median approach.

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21 *See* 71 Fed. Reg. at 25679-80.

VII. ENSURE PAYMENT RULES USED FOR HCPCS CODES REVISED MID-CYCLE RESULT IN REASONABLE PAYMENT AMOUNTS

[Gap-filling]

CMS proposes special payment rules in 42 C.F.R. § 414.426 for competitively bid HCPCS codes that are revised in the middle of a competitive bidding cycle. For the most part, Hoveround supports these rules. However, in certain circumstances, the Company believes that CMS should continue to use the codes that were competitively bid and not replace them with new codes until the next cycle.

CMS proposes to calculate rates differently based on the nature of the coding change, so that:

(1) If a single code is split into multiple codes, the supplier would be paid the payment amount for the former code.[22] Therefore, the split into new codes would not impact payment. During the subsequent bidding cycle, suppliers would bid on the new separate and distinct codes.

(2) For codes for several components that are merged into a single new code, the payment policy would differ depending on whether the former codes described (a) components of a single product or (b) multiple products. If the former codes described components of a single product (scenario (a)), the supplier would be paid a rate equal to the total of the payment amounts under the former codes. If the former codes described multiple products (scenario (b)), the new payment amount would be the average (arithmetic mean) of the former payment amounts weighted by the frequency of payments for the former separate codes. For each of the two scenarios, during the subsequent bidding cycle, suppliers will bid on the new single code.[23]

As to the proposal under (2)(b), Hoveround is concerned about the use of a weighted arithmetic mean when a new code replaces multiple codes for similar products. First, it is unclear how the weighting would occur. For instance, would CMS review payments for all suppliers in all jurisdictions or only contract suppliers in CBAs? Furthermore, this formula could result in significantly different pricing in the middle of a bidding cycle. Using the new code would disrupt suppliers' expectations as to the payment levels they would receive for furnishing products to beneficiaries in the CBA. It could also create a disincentive to participate in the program.

One benefit to competitive bidding for suppliers is that, if selected, they are guaranteed a

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22 This applies both to the circumstance in which the former code was for a single product and is split into codes for its components and that in which the former code was for two or more similar products and is split up.

23 *See* 71 Fed. Reg. at 25688-89.

certain price for products furnished to Medicare beneficiaries for a set period of time. Because this proposal injects a sufficient level of uncertainty, suppliers may opt not to participate in or, significantly, upon such a payment change, may choose to exit the program instead of continuing to service the CBA at a lower payment rate.

For this reason, Hoveround asks that, where multiple codes for similar items are merged to a single new code, CMS continue to use the former codes and payment rates for the remainder of the bidding cycle. This could be accomplished by revising 42 C.F.R. § 414.426(d) as follows: "If multiple codes for similar items are merged into a single code, *the codes that were competitively bid and the established payment amounts for those codes, with any adjustments provided under § 414.408(b), will remain in effect for the remainder of the competitive bidding program*."

VIII. CONSIDER SALES VOLUME ASSUMPTION WHEN USING COMPETITIVE BIDDING RATES TO ADJUST PAYMENT AMOUNTS IN NON-COMPETITIVE BIDDING AREAS

[Payment Basis]

CMS proposes to use its statutory authority to adjust payment in other areas based on payment information determined under the competitive bidding program. Such adjustments may not be made prior to 2009, and CMS did not provide a specific proposal as to how this authority would be used. Hoveround requests that stakeholders be given another opportunity to comment on how to implement this provision at a later date once CMS develops a particular proposal.

In the interim, Hoveround strongly cautions CMS to use this authority carefully. Hoveround is particularly concerned that, if competitive bidding payment amounts are applied nationwide in 2009 or later years, this would in effect move the Part B DMEPOS benefit toward an "any willing provider" model—which is not the intent of competitive bidding. Competitive bidding rates will be based on bid amounts that are calculated using an assumed increase in volume. Suppliers assume that there will be few suppliers in each CBA for competitively bid products and, accordingly, that they can offer lower prices because these prices will be offset by the higher volume of products they will furnish. It is inappropriate to apply competitive bidding rates to non-competitive bidding areas because, in non-competitive bidding areas, there would be no concomitant volume-upside to balance out the pricing-downside. At minimum, this means that CMS should not borrow directly from competitive bidding rates in setting fee schedule amounts for items in non-competitive bidding areas.

IX. DISCARD THE PROPOSED REBATE PROGRAM

[Determining Single Payment Amounts For Individual Items]

Under proposed 42 C.F.R. § 414.416(c), CMS proposes to allow contract suppliers that submitted bids for an item below the competitive bidding payment amount to provide rebates to beneficiaries. This rebate would be equal to the delta between the supplier's bid amount and the competitive bidding payment amount for the item. At the PAOC meeting, several committee members, as well as members of the industry, objected to this proposal. Hoveround shares their

concerns that this proposal implicates and may run afoul of the Federal Anti-Kickback Statute (the "AKS") and, for that reason, strongly urges that the proposal not be finalized.

The AKS is a criminal prohibition that provides punishment for any person who "knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person ... to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program."[24] Rebates intended to induce beneficiaries to purchase a particular Medicare-covered item are generally prohibited under the AKS. Hoveround is concerned that adoption of the rebate program would generate significant confusion in the industry as to what is permissible under the AKS and what continues to be prohibited. Hoveround asks that the rebate program not be finalized.

X. SAFEGUARD EXISTING APPEAL RIGHTS

[Administrative or Judicial Review]

The proposed regulation concerning appeal rights under the competitive bidding program (42 C.F.R. § 414.424) tracks closely the statutory provision and prohibits appeals on most decisions made regarding competitive bidding. This includes, for instance, which suppliers are awarded contracts, payment amounts established, and selection of items to be competitively bid.[25] As written, the proposed regulation does not make clear that existing rights of beneficiaries and suppliers to appeal denied claims are preserved.

In the preamble to the proposed regulations, CMS acknowledges that existing rights are undisturbed by competitive bidding. Hoveround requests that this be explicitly stated in the regulation itself, by adding the following subsection (c) to 414.424: "*All existing rights to appeal denied claims are unaffected by this provision.*" In addition, the statement in the regulation that "[a] denied claim is not appealable if CMS determines that a competitively bid item was furnished in a competitive bidding area in a manner not authorized by this subpart" is vague and should be removed and/or clarified. As written, it is not clear what is meant by this language.

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[24] 42 U.S.C. § 1320a-7b(b)(2).

[25] 71 Fed. Reg. at 25682.

XI. REVISE THE PROPOSED GAP-FILLING METHODOLOGY REPLACEMENT TO FOLLOW STATUTORILY-REQUIRED PROCEDURES & ENSURE FAIR PRICING

[Gap-filling]

Hoveround applauds CMS for its recognition of the inherent flaws in the current gap-filling methodology and the agency's decision to replace the current formula with a new methodology that reflects the true prices for new technology. Portions of the proposal in 42 C.F.R. § 414.210(g), however, are so vague as to be unworkable. In addition, the effort to use a functional technology assessment without any procedural safeguards impermissibly circumvents CMS's IR authority. This is particularly troubling given that the IR regulations only recently became final and already are being treated as obsolete. It is essential that any formula adopted here be grounded in both substantive and procedural safeguards and follow a transparent process for establishing reasonable, appropriate fee schedule rates for non-competitively bid products.

At the outset, Hoveround notes that many in the industry have urged CMS to devote considerable attention to this new regulation and specifically have requested that it be considered separate and apart from the proposed regulations for competitive bidding. Hoveround reiterates this request here, and asks that CMS postpone publication of a final rule to provide time for suppliers and other stakeholders to submit additional comments and/or meet with the agency to discuss alternatives. The additional time is needed to give due consideration in separate comments. By including the proposal in the context of the competitive bidding rulemaking—a rule that CMS officials have publicly recognized is only tangentially related to gap-filling—CMS has created needless timing conflicts. Given the resources that need to be expended to comment fully on the competitive bidding rule, suppliers (and CMS, for that matter, since the same individuals are responsible for both competitive bidding and gap-filling) are being pressed to stretch those limited resources. Both rules are simply too important to risk presentation of rushed comments (and/or rushed review of those comments). Hoveround, therefore, requests an additional period of 60 days to comment on the gap-filling methodology.

In the absence of additional time, and to meet the current time line, Hoveround submits the following comments concerning the proposal.

Substantive Criteria

Under the gap-filling proposal, where a new HCPCS code is created and no price information is available from the base period, the fee schedule amount for the code would be calculated by taking into account one or more of the following three data sources: (1) median retail prices (from supplier price lists, manufacturer suggested retail prices, or wholesale prices, plus an appropriate mark-up), (2) existing fee schedule amounts for comparable codes, and/or (3) results of a functional technology assessment ("FTA") of products in the new code. Hoveround supports the move away from the current gap-filling methodology because it relies

on deflation factors that often result in drastic under-compensation for new products.[26] Hoveround believes, however, that the proposed criteria lack specificity sufficient to inform stakeholders as to the formula to be used.

A lack of specificity without proper safeguards offers the public inadequate notice of how the formula would be used. Two examples are illustrative: First, the proposal suggests that pricing for comparable codes could be used as a proxy for the rates applicable for the new code. How would CMS determine which codes are "comparable"? Would significant functional and clinical differences in the products categorized in these codes be considered? How would CMS account for and quantify these differences?

Second, CMS proposes to use median retail prices to set pricing. How will CMS identify retail prices and how will the agency weight the prices? Regardless of the source for the prices, Hoveround suggests that CMS use a *weighted median* so that prices by outlier suppliers that do not provide a significant volume of items to the Medicare program are not given undue importance in setting pricing.

As to the FTA, the notice states that there were three main areas studied in the FTA conducted in CMS's pilot study: (1) Functional Assessment, which evaluated the device's operations, safety and user documentation relative to the Medicare population; (2) Price Comparison Analysis, which involved a cost analysis comparing the product to similar products or alternative treatment modalities; and (3) Medical Benefit Assessment, which focused on the effectiveness of the product using scientific literature and interviews of providers to determine if the product does what it purports to do. Not only is this vague explanation insufficient information for meaningful comments, the FTA analysis oversteps congressional mandates on when the agency can adjust fee schedule amounts and identify alternative "realistic and equitable" amounts. It is improper for CMS to cast aside Congress's grant of IR authority. Further, CMS should not resort to incorporating a coverage analysis to establish pricing. Here, as well, Congress has prescribed how to evaluate coverage. Simply, CMS cannot exercise powers that contradict Congress's specific language in specific statutory grants of authority.[27]

Pricing should be established using objective criteria that can be applied to all products in the same way. A transparent formula, capable of being reproduced for all products must be used. To design FTA criteria that are objective and capable of being reproduced (and we believe that this likely cannot be achieved easily), extensive modifications must be made to incorporate IR

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26 Gap-filling uses current pricing information, which is then deflated back to a base period to be in line with statutory payment methodology for DME and then inflated based on statutorily-prescribed update factors. CMS has traditionally used the percentage increase in the CPI-U to deflate current pricing—which can be an inappropriate deflationary factor if it is not in line with price increases (or lack thereof) over time in the industry.

27 *See, e.g., Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-3 (1984) (holding that "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress"); *see also United States v. Haggar Apparel Co.*, 526 U.S. 380, 393 (1999) (confirming that "rules as to instances not covered by the statute should be parallel, to the extent possible, with the specific cases Congress did address").

and coverage requirements. One approach might be to develop an algorithm with a sequential analysis. The FTA would be the last and final step taken. However, it should *only* be used when the median pricing information or pricing of comparable codes is not available. Most critically, it *should only be used as part of an exercise of CMS's IR authority.*

Procedural Requirements

In addition to the substantive revisions that are needed, CMS's proposal to use an FTA also suffers from a complete lack of procedural safeguards to ensure that appropriate pricing results. Even though this proposal seeks to achieve the results of a coverage and IR analysis, it fails completely to offer any of the procedural safeguards of these latter processes. Particularly where, as here, CMS is moving away from the current gap-filling methodology (which employs some objective criteria) to a vague, subjective set of criteria, procedural safeguards are even more critically needed.

As CMS describes in the preamble to the proposed regulations, the two FTAs that have previously been undertaken in its pilot study (the results of which have not been shared with stakeholders) involved evaluation of the device's safety and effectiveness in improving clinical outcomes. Both of these elements are considered in determining whether an item meets the Medicare statute's "reasonable and necessary" standard and will be covered under the Medicare program.[28] It is significant that over the years the coverage process has become more open. To that end, Congress recently mandated that CMS follow a defined process for making NCDs, including providing an opportunity to appeal the decisions.[29] There is now a fulsome appeals process available for aggrieved parties who believe an NCD provision is unreasonable.[30] Similar processes are available for challenges to local coverage determinations.[31] CMS must not and may not circumvent these procedural requirements by folding a coverage decision into the payment calculation process.

Perhaps most importantly, payment adjustments like those being proposed here are

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28 42 U.S.C. § 1395y(a)(1)(A); *see also* Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapt. 15, § 110.1 (stating that the necessity of equipment is determined based on "when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member" and that reasonableness is determined based on considerations such as whether the expense of the equipment would not be clearly disproportionate to the therapeutic benefits that could ordinarily be derived from it).

29 Congress revised the Medicare statute to require CMS to issue a proposed decision on a request for an NCD within 6 months of the request for coverage (9 months for requests that require outside technology assessments or Medicare Coverage Advisory Committee deliberation). There is to be a 30-day public comment period from the date of release of the proposed decision and CMS is required to publish a final decision (including responses to comments received) within 60 days of the conclusion of this comment period. *See* 42 U.S.C. § 1395y(l).

30 NCDs can be reviewed by the HHS Departmental Appeals Board ("DAB"). To determine whether the NCD was reasonable, the DAB will review the record, may permit discovery and taking of evidence if it is lacking information, and may consult with scientific and clinical experts. *See* 42 USC § 1395ff(f)(1).

31 *See* Medicare Program Integrity Manual (CMS Pub. 100-08), Chapt. 13, § 13.13.

statutorily required to undergo a notice and comment process as well. Under the IR provisions, CMS must analyze a variety of factors and adjust pricing for an item or service upon a determination that the otherwise applicable payment amount is grossly excessive or grossly deficient, which is defined by its own regulations to include a threshold variance of fifteen percent.[32] Once CMS has determined that a payment amount is grossly excessive or deficient, it may establish a payment amount only by considering certain factors, including pricing information and the resources required to produce the products. There is no reason that the FTA should not require similar procedural safeguards. Significantly, CMS may not use its IR authority without first following the required procedural steps:

- For payment adjustments of 15%, CMS must provide notice and opportunity to comment by publishing the proposed and finalized payment adjustment in the Federal Register.

- For payment adjustments of greater than 15% in a single year, more rigorous reviews and procedures are to be undertaken. As to the procedures, CMS must consult with supplier representatives from the industry likely to be affected by the payment change. Notice of the proposed determination must also be published in the Federal Register, with a 60-day public comment period. The Federal Register Notice with the proposed determination must contain an explanation of the factors and data considered in determining that the payment amount is grossly excessive or deficient, list the proposed payment amount, and describe the factors and data used to set this adjusted rate. CMS is to consider any comments submitted prior to publication of a final determination, and discussion responsive to these comments is to be included in the Federal Register Notice announcing the finalized payment determination.[33]

Here, CMS would give itself authority to use the results of an FTA *at any time* to adjust previously-established prices and without identifying any standards. The agency would need only to determine that the pricing methods that were used resulted in payment amounts that do not reflect the cost of furnishing the product. This aspect of the regulation directly conflicts with and circumvents CMS's IR authority, and Hoveround strongly opposes finalization of this proposal.

As stated above, if the functional technology assessment is used—and Hoveround does not believe that it should be used—then CMS should incorporate the FTA expressly into its IR process so that the same procedural requirements are used. Use of this assessment tool as a means of justifying reductions in payment rates otherwise is impermissible. This means that CMS would be permitted to use FTAs only *as part of* the IR process, *i.e.*, to determine whether a payment rate is grossly excessive or deficient and to identify a realistic and equitable amount. This would ensure that fulsome notice and comment were provided prior to any reductions in

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32 IR authority is implicated only where the overall payment adjustment needed to produce a realistic and equitable payment amount is 15% or more. CMS can make an adjustment of less than 15% in a given year under its IR authority, provided that it has been determined that an overall adjustment of 15% or more is warranted. *See* 42 C.F.R. § 405.502(g); 70 Fed. Reg. 73623, 73626 (Dec. 13, 2005).

33 42 USC § 1395u(b)(8)-(9); 42 C.F.R. § 405.502(g)-(h).

payment levels based on a functional technology assessment. Accordingly, the proposed regulation must be revised in its entirety. Although Hoveround opposes the use of the FTA for the reasons stated here, out of an abundance of caution, suggested language is described in **Appendix A** to this comment letter.[34]

Thank you for your considerable efforts to date in implementing the program and for considering Hoveround's comments regarding the proposed regulations. Should you have any questions or comments, we can be reached at (202) 637-2200.

Truly yours,

Stuart S. Kurlander
Esther R. Scherb
Of LATHAM & WATKINS LLP

Cc: Hoveround Corporation
Rebecca L. Spain, Latham & Watkins LLP

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34 Similar changes could be made to the proposed regulation for PEN items and services at 42 C.F.R. § 414.102(d).

Appendix A

Hoveround's Proposed Revisions to 42 C.F.R. § 414.210 (Gap-Filling)

(g) Establishing fee schedule amounts for new items and services.

(1) The DMERC or local carrier uses the process described in paragraph (g)(2) of this section to establish the fee schedule amounts for the items and services included in a new HCPCS code created for a category of items and services payable under this subpart, but only if reasonable charge data are not available to calculate a fee schedule amount.

(i) The fee schedule amounts are updated in accordance with this subpart.

(ii) Items described in Sec. 414.224 are not subject to paragraph (g)(1) of this section.

(2) CMS calculates the Medicare fee schedule amounts for the items and services described in paragraph (g)(1) of this section taking into account one or more of the following:

(i) The *weighted* median retail price for items and services classified under the new HCPCS code (CMS determines the retail price for an individual item and service based on supplier price lists and manufacturer suggested retail prices [delete: , or wholesale prices plus an appropriate mark-up)]; or

(ii) Existing fee schedule amounts for comparable items.

~~(iii) A functional technology assessment of the items or services classified under the new HCPCS code that takes into account one or more of the following factors:~~

~~(A) Functional assessment.~~
~~(B) Price comparison analysis.~~
~~(C) Medical benefit assessment.~~

~~(3): A functional technology assessment described in paragraph (g)(2)(iii) of this section is also used to adjust fee schedule amounts calculated under paragraph (g)(2) of this section if CMS determines that these amounts do not reflect the costs of furnishing the item or service.~~

(3) As used in paragraph (g)(2)(ii), "comparable items" means items that are similar in price, function and clinical application.

(4) If the fee schedule amount for a particular HCPCS code resulting from application of paragraph (g)(2)(i) and (ii) is to be adjusted because it is determined to be grossly excessive or grossly deficient, as described in 42 C.F.R. § 405.502(g), CMS shall use the

procedures required in 42 C.F.R. § 405.502(g).

(5) A functional technology assessment that takes into account one or more of the following factors: Functional assessment; Price comparison analysis; and Medical benefit assessment may be used in conjunction with the determination in paragraph (g)(4).

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June 29, 2006

The Honorable Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1270-P--DMEPOS Competitive Acquisition

Dear Doctor McClellan:

On behalf of the American Optometric Association (AOA), I submit these comments in response to the proposed rule published on May 1, 2006 relating to a new Medicare competitive acquisition program for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and certain miscellaneous issues. The AOA represents more than 34,000 optometrists in the United States. Doctors of optometry are independent primary care health professionals who examine, diagnose, treat, and manage diseases and disorders of the visual system, the eye and associated structures. Optometrists are the most accessible eye care providers in the United States, both for Medicare beneficiaries and the general population.

Submission of Bids Under the Competitive Bidding Program

The proposed rule specifies that "physicians" that are also DMEPOS suppliers must submit bids and be awarded contracts in order to furnish items subject to competitive bidding in an area. The proposed rule also notes that physicians that do not become contract suppliers must use a contract supplier to furnish competitively bid items to their Medicare patients. It also states that physicians will not be required to furnish these items to beneficiaries who are not their patients if they choose not to function as commercial suppliers. In other words, such physicians would not be required to serve an entire competitive bidding area.

In the proposed rule, CMS has chosen, without explanation, to define the term "physician" more narrowly than is typically the case, by limiting it to doctors of medicine

and doctors of osteopathy, thereby excluding other health professionals that meet Medicare's usual definition of the term, such as doctors of optometry. Since the proposed rule does not indicate why this narrow definition is being proposed, commenters are at a distinct disadvantage in trying to offer meaningful input. The proposed definition is also rather mystifying since CMS data show that about 14,000 optometrists currently have DMEPOS supplier numbers.

In any case, the proposed definition of "physician" leaves us wondering whether CMS plans to deny optometrists the opportunity to participate in the DMEPOS competitive bidding program altogether. We certainly find no justification for such a position in the MMA, and we seriously doubt this is what the Congress had in mind. However, even if this is not CMS' intent, the proposed definition would apparently require optometrists (but not certain other categories of "physician" as defined in 1861(r) of the Medicare statute, that is doctors of medicine and osteopathy) to commit to serving an entire competitive bidding area and not just their own patients. And as we discuss in more detail below, this proposed definition would also inappropriately deny to optometrists the option of executing a physician authorization on behalf of their patients. The proposed rule provides no justification for any of this.

This leads us to raise an even more important issue. The DMEPOS products provided to Medicare beneficiaries by the roughly 14,000 optometrists with DMEPOS supplier numbers are lenses (single vision, bifocal or trifocal) and frames provided to individuals following cataract surgery, **and these items are clearly an integral part of what the practice of optometry is all about**. In fact, many of the beneficiaries receiving services post-cataract surgery have likely been patients of a particular optometric practice for many years prior to the surgery. Thus, any Medicare competitive bidding program that effectively prevents some, many or all optometrists from dispensing post-cataract eyeglasses and contacts to such patients would clearly interfere with the practice of optometric medicine and the ability of the affected optometrists to serve their patients. Furthermore, Medicare coverage and reimbursement policies already limit both Medicare's financial exposure and the volume of vision-related DMEPOS products covered by Medicare. See the Social Security Act, Section 1861(s)(8).

There is yet a further wrinkle with respect to vision-related DMEPOS products, the issue of beneficiary financial responsibility. As it stands today, a single HCPCS code, V2020, is used for reporting eyeglass frames though frames are available to beneficiaries in a wide variety of styles and price ranges. Many Medicare beneficiaries actually choose frames that cost far more than what the existing Medicare fee schedule amount covers. In other words, they willingly select frames with features not found in "standard" frames, and they assume the responsibility of paying the difference between the Medicare fee schedule amount and the cost of the frames they have selected. The same thing can be said for lenses, when the patient chooses special materials, special tints, special coatings, or other "non-standard" features. If the HCPCS codes for eyeglass frames and/or lenses were subjected to competitive bidding, it is possible, though far from certain, that Medicare payments for the "standard" products might decline. However, even though competitive bidding would require contract suppliers to

accept assignment, we presume it would still leave in place existing policies relating to advanced beneficiary notices and beneficiary financial liability in cases where they choose to obtain items with "deluxe" features. We further presume that Medicare competitive bidding is not intended to substantially reduce beneficiary access to a broad range of DMEPOS products and brands. If these assumptions are correct, it means that competitive bidding of vision-related DMEPOS products would likely have the perverse effect of increasing beneficiary financial liability (by increasing the difference between the Medicare payment amount and the costs of the items chosen by the beneficiary) or forcing beneficiaries to accept only "standard" frames and/or lenses, either of which would, we assume, cause considerable dissatisfaction among Medicare beneficiaries. Please see Section 3054.4 in the Medicare Carriers' Manual for a description of deluxe frame coverage.

All of the above leads the AOA to the following conclusion: Vision-related DMEPOS commonly dispensed by optometrists should not be subjected to competitive bidding by Medicare. Alternatively, CMS needs to adopt special policies under which all optometrist-suppliers can continue to dispense vision-related DMEPOS products to their patients even if CMS elects to subject some of these products to competitive bidding. Obviously, exclusion of such products from competitive bidding would be a far simpler approach and is the one we recommend.

With respect to special policies that could be adopted for optometrist-suppliers and other physician-suppliers, we suspect there are several possibilities. One option we urge CMS to consider is a policy that would allow such suppliers to submit a bid indicating their willingness to accept the single payment amount for the specified DMEPOS codes being subjected to competitive bidding. We believe that such a policy could still comply with the statutory requirement that a bid be "an offer to furnish an item or service for a particular price and time period," with the single payment amount be deemed to be "a particular price" for certain types of suppliers. For example, the policy could be limited to physician-suppliers who serve only their own patients, not an entire competitive bidding area. If need be, it might be further limited to physician-suppliers for whom revenues from DMEPOS products subject to competitive bidding do not exceed some reasonable dollar threshold. A similar policy might even be extended to very small suppliers and provide a means for addressing the statutory directive in the MMA to "take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the [DMEPOS competitive acquisition] program." In any case, our key message is that DMEPOS products dispensed by optometrist-suppliers and other physician-suppliers are an integral part of their practice, and the Medicare competitive bidding program must not be allowed to interfere with physicians' ability to care for their own patients.

Payment Basis

Section 414.408(c) makes clear that payment for an item furnished under the new Medicare competitive bidding program would be made on an assignment-related basis. As noted in more detail above (in the section on Submission of Bids Under the Competitive Bidding Program), we presume, however, that this leaves in place existing

Medicare policies relating to Advanced Beneficiary Notices and beneficiary financial liability, for example, when the beneficiary requests an item with "deluxe" features. The final rule should make this clear. In the case of vision-related DMEPOS products such as frames and lenses, where beneficiaries today almost routinely request items with "deluxe" features, we believe that competitive bidding would actually be disadvantageous for most Medicare beneficiaries.

Opportunity for Participation by Small Suppliers

As noted earlier, the MMA directs the Secretary to "take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the [DMEPOS competitive acquisition] program." As noted above under Submission of Bids, we believe that relatively small suppliers, especially optometrist-suppliers or other physician-suppliers, who serve only their own patients, need to be given special accommodation under the Medicare competitive bidding program. Above, we describe in more detail one way for doing so.

Physician Authorization/Treating Practitioner

The proposed rule, by limiting the definition of "physician" to doctors of medicine and osteopathy, would apparently deny doctors of optometry the opportunity to execute a physician authorization on behalf of their patients (the mechanism for indicating that a particular brand of DMEPOS is necessary to avoid an adverse medical outcome in a given Medicare beneficiary). As noted above, the proposed rule provides no explanation for the physician definition proposed by CMS and we find nothing in the MMA provisions relating to the competitive bidding program that mandate or justify such a narrow definition for purposes of the competitive bidding program. It seems especially inappropriate given the fact that CMS is also proposing to allow non-physicians, such as physician assistants, nurse practitioners, or clinical nurse specialists, to execute a "physician authorization," presumably including one for vision-related DMEPOS products, while denying the same option to doctors of optometric medicine. In our view, Medicare beneficiaries will be very poorly served by such a policy.

Quality Standards and Accreditation for Suppliers of DMEPOS

All DMEPOS suppliers, whether or not they participate in the new competitive bidding program, will be required to meet quality standards and be accredited by a CMS-chosen independent accreditation organization. And CMS apparently plans to finalize the quality standards through manual instructions, rather than providing a formal opportunity for public comment.

AOA has several concerns regarding the quality standards and the related accreditation process. We worry that CMS is envisioning all of this as a "one size fits all" endeavor, failing to recognize that DMEPOS suppliers today comprise a very diverse set of individuals and organizations, including licensed health professionals (such as optometrists), licensed and accredited providers (such as hospitals), state-regulated pharmacies staffed by licensed pharmacists, and largely unregulated businesses that

solely provide DMEPOS products (and not other professional or facility services). We believe that the quality standards developed by CMS should recognize this diversity and be structured accordingly, and we believe the MMA gives the agency sufficient flexibility to do so.

We are also disappointed that CMS is not planning to provide a formal opportunity for public comment on the quality standards, especially since we understand that very significant changes have been made to the draft standards that were made available for informal comment several months ago. We fear that the revised quality standards will prove unworkable or have other unintended consequences.

Further, we worry that the required accreditation, if not structured properly, could impose an unreasonable barrier to participation in Medicare by certain categories of suppliers. We fear, for example, that optometrist-suppliers and other physician-suppliers, for whom DMEPOS products may be a relatively small share of services provided to Medicare beneficiaries, might find the accreditation process and related costs (including the fee paid to the accrediting organization itself) impractical or financially untenable given the relatively limited revenue derived from such products. In other words, an accrediting process and fee that would make sense for a large DMEPOS supplier providing millions of dollars of products to Medicare beneficiaries throughout a metropolitan area would not make sense for a relatively small supplier, especially an optometrist-supplier or other physician-supplier, who may, for example, only provide a few thousand dollars worth of products to their own Medicare patients. Unfortunately, CMS has not provided much information yet about the accreditation process and associated fees. While CMS might not see much harm in reducing the pool of Medicare DMEPOS suppliers, for optometrists, the ability to dispense certain vision-related DMEPOS products to their patients is an inherent part of their professional practice, and any impediment to this would be a very serious matter.

Low Vision Aid Exclusion

CMS chose to use this proposed rule to assert that the existing eyeglass exclusion under Medicare applies to "eyepieces, hand-held magnifying glasses, contact lenses and other instruments, such as closed-circuit televisions and video magnifiers that use lenses to aid vision." In doing so, we believe that the statutory language at 1862(a)(7), which refers only to "eyeglasses" has been stretched far beyond its breaking point, especially since many or most of the technologies in question were not available at the time Congress approved the original eyeglass exclusion language. Absent more specific Congressional action, we do not believe that CMS can simply expand the exclusion as proposed.

The AOA questions the authority of CMS to arbitrarily define eye glasses to include conventional correction of refractive error and low vision devices in the statement: *"all (low vision) devices irrespective of their size, form, or technological features that use one or more lenses to aid vision or provide magnification of images for impaired vision."*

CMS' choice of the meaning of "eyeglasses" is neither reasonable nor ordinary and not supported by the three principal medical dictionaries:

1. Dorland's Illustrated Medical Dictionary (28th Ed. 1994)
2. Taber's Cyclopedic Medical Dictionary (20th Ed.)
3. Stedman's Medical Dictionary (27th Ed.)

The definition of "eyeglasses" in all three dictionaries limits the term to a lens that *increases the visual acuity of the human eye (Dorland's), corrects a defect in visual acuity (Taber's) or corrects refractive errors (Stedman's).* The definitions do not broadly include all devices "to aid vision or provide magnification of images". There is a clear medical distinction between devices that improve visual acuity of the human eye and those that magnify an object. Visual acuity can only be improved by a lens made specifically for the individual eye, right eye separate from left eye, according to a prescription that is derived by refraction of that eye. The lens may be placed in a frame that sits on the nose, as in spectacles, or the lens may sit directly on the eye, as in contact lenses. Those lenses, either in conventional eyeglasses or contact lenses, focus the light from objects directly on the retina of the individual eye. On the other hand, lenses that magnify the appearance of objects and lenses in a camera, such as used in a CCTV, are not individualized to correct the refractive error of the eye and thus they cannot and do not alter the visual acuity of the eye. As a result, they do not fall within the eyeglasses exclusion.

We appreciate the need for prudence and fiscal responsibility in the administration and expansion in health care policy and do not promote the coverage of routine eye care and provision of eyeglasses or spectacles for Medicare beneficiaries that correct the refractive error only even though conventional vision enhancement with such eyeglasses improves quality of life and promotes higher levels of independence. The AOA strongly feels that physician prescribed spectacles mounted low vision devices/systems are part of the vision rehabilitation process and must be defined in a separate definition.

Physician prescribed low vision systems are integrated into vision rehabilitation plans already covered by CMS enabling many with damaged ocular anatomical structures to compensate for permanent vision impairment. CPT Code 97535 refers to *integration of assistive devices* as part of rehabilitation therapy. Low vision systems may be spectacle mounted, hand held or electronic or in combination, serving as prosthetics for vision function loss caused by damaged ocular structures. Physician prescribed low vision devices or systems are distinct from standard optical prescriptions and eyeglasses that only provide correction of the refractive error. Low vision devices/systems may incorporate the refraction but additionally provide magnification and/or image enhancement allowing the individual to compensate for vision impairment caused by damaged ocular structures thus serving as a prosthetic.

There is precedent for providing prosthetics for replacement of the extracted crystalline lens by compensating spectacles or contact lenses for those with true aphakia for life. As stated previously, CMS allows one pair of spectacles after each cataract surgery

when an intra-ocular lens is implanted for each eye. The difference concerning low vision devices/systems is that the damaged structure causing the vision impairment may be the cornea, retina, optic nerve or other ocular structure.

There are comparisons with prosthetics for functional losses due to disease or damage to other body organs such as hearing aids, orthotics and prosthetic limbs that would support the coverage for low vision systems/prosthetics.

Before an arbitrary decision is made to categorically include physician prescribed, low vision devices/systems with conventional correction for refractive error in a single definition, the American Optometric Association hopes that CMS will make a distinction between conventional spectacles and spectacle mounted low vision devices. The AOA would be willing to work with professionals from related professions to contribute to the research, data and analysis in order to come to an equitable, rational approach to cost effective, comprehensive vision rehabilitation that includes the integration of assistive devices, distinct from standard eyeglasses that correct refractive error only.

We appreciate this opportunity to comment on the proposed rule and we hope this input will assist CMS as it continues the process of implementing the new DMEPOS competitive acquisition program. If you have any questions about these comments, please contact Kelly Hipp, Director of Professional Relations at 703-837-1346, or at KHipp@aoa.org.

Sincerely,

C. Thomas Crooks, III, O.D.
President

POLYMEDICA
CORPORATION

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June 29, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Proposed Rule on Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues

PolyMedica Corporation ("PolyMedica") submits the following comments in response to the proposed rule on *Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues*, 71 Fed. Reg. 25654 (May 1, 2006) (the "Proposed Rule").

PolyMedica is the nation's largest Medicare mail order supplier of diabetes testing supplies. The Proposed Rule directly impacts PolyMedica. Therefore, PolyMedica is a stakeholder in this matter.

PolyMedica's mission is to help Medicare beneficiaries manage their diabetes through compliance, support and education. PolyMedica has implemented a patient service model that goes beyond simply furnishing blood glucose testing supplies. Through educational materials, and frequent telephonic communication with Medicare beneficiaries, PolyMedica assists Medicare beneficiaries in managing their disease to achieve better outcomes and healthier lives.

Initially, our comments are limited to the Proposed Rule. The Proposed Rule does not encompass the DMEPOS Quality Standards. The Quality Standards have been released as guidance, are not final and are not incorporated by reference or otherwise in the Proposed Rule. Therefore, our comments on the Proposed Rule are related only to the Proposed Rule, and not to the draft Quality Standards.

We have divided our comments into a section setting forth what we submit should be the guiding principles of competitive acquisition of DMEPOS (and in particular diabetes testing supplies), including the involvement in the process of mail order suppliers, and a section setting forth our comments on specific provisions of the Proposed Rule.

1. General Comments -- Key Principles.

PolyMedica supports CMS' efforts to implement competitive bidding for DMEPOS and recognizes the significant amount of thought and work that has been invested in developing the

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Proposed Rule. We are encouraged that CMS is taking equally seriously all five of its major objectives for competitive bidding.[1] As it applies to diabetic supplies, we respectfully submit that CMS can successfully meet all of its objectives by adhering to five key principles outlined below (referenced A-E).

A. All Medicare beneficiaries should have access to diabetes testing supplies from suppliers who will assist them in complying with their doctors' prescriptions.

A growing body of objective evidence demonstrates that *competitive bidding for diabetes testing supplies should be implemented in a manner that emphasizes patient education, and strengthens the Medicare beneficiaries' compliance with prescribed testing frequencies.* With diabetes testing supplies, simple and inexpensive education and patient compliance efforts will result in lower overall Medicare program costs. Any implementation that does not require, or through pricing does not permit, educational and patient compliance efforts will only lead to higher overall Medicare program costs.

Diabetes is a serious, incurable, chronic disease marked by high levels of blood glucose resulting from defects in insulin production, insulin action or both. Approximately 10.3 million, or 20.9 percent, of all people aged 60 or older have diabetes.2 If not properly managed, diabetes causes even more serious health problems, and is associated with a number of serious, sometimes life-threatening complications. Adults with diabetes have 2 to 4 times the risk of death from heart disease and 2 to 4 times the risk of stroke than adults without diabetes.3 Diabetic retinopathy causes 12,000 to 24,000 cases of blindness each year, making it the leading cause of blindness in adults 20-74 years old. It is also the leading cause of kidney failure, accounting for 44% of new cases in 2002, and a significant cause of amputations.4

In addition to the human costs of diabetes and its complications, the financial costs are substantial. The total annual economic cost of diabetes was estimated in 2002 to be $132 billion. This includes $92 billion of direct medical expenditures, comprised of $23.2 billion for diabetes care, $24.6 billion for chronic diabetes-related complications, and $44.1 billion for excess prevalence of general medical conditions. Indirect costs of diabetes totaled $40.8 billion.5

Education and compliance support can improve patient outcomes, and reduce the costs to

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1 The five objectives CMS outlined are:

1. To implement competitive bidding programs for certain DMEPOS items.
2. To assure beneficiary access to quality DMEPOS as a result of the program.
3. To reduce the amount Medicare pays for DMEPOS and create a payment structure under competitive bidding that is more reflective of a competitive market.
4. To limit the financial burden on beneficiaries by reducing their out-of-pocket expenses for DMEPOS they obtain through the program.
5. To contract with suppliers who conduct business in a manner that is beneficial for the program and for Medicare beneficiaries

2 American Diabetes Association, *Total Prevalence of Diabetes and Pre-Diabetes,* http://www.diabetes.org/diabetes-statistics/prevalence.jsp, last visited March 3, 2006.

3 American Diabetes Association, *Complications of Diabetes in the United States,* http://www.diabetes.org/diabetes-statistics/complications.jsp, last visited March 3, 2006.

4 *Id.*

5 American Diabetes Association, *Direct and Indirect Costs of Diabetes in the United States,* http://www.diabetes.org/diabetes-statistics/cost-of-diabetes-in-us.jsp, last visited March 3, 2006.

the Medicare program of treating the complications of diabetes, by improving Medicare beneficiaries' compliance with their prescribed blood glucose testing frequencies. The National Institutes of Health states that appropriate glycemic control results in a 40 percent reduction in microvascular (eye, kidney and nerve) disease.6 Further, a recent peer reviewed study with patients from the Joslin Diabetes Center in Boston, published in the Archives of Internal Medicine, shows that straight forward diabetes programs that educate and inform increase compliance with prescribed testing regimens, positively affect patients' self-management and improve blood glucose control. This study is an independent validation that a platform of diabetes management like PolyMedica's can improve outcomes. According to the authors of the study, simple and inexpensive interventions "have the potential to benefit a greater number of patients, at a lower cost, than enrolling small numbers of patients in intensive management programs."7

This is the core to PolyMedica's approach. PolyMedica provides Medicare beneficiaries with educational materials, and telephonic support to Medicare beneficiaries on at least a quarterly basis (and sometimes more frequently depending on a beneficiary's needs), to encourage adherence to their physicians' prescriptions and to improve patient outcomes. Through a series of checks and balances we ensure beneficiaries only receive appropriate quantities of supplies as needed. The result of our efforts prove a much better than average patient compliance rate with prescribed testing frequencies. For example, our own research data indicates that mail order Medicare beneficiaries test nearly twice as frequently compared to beneficiaries obtaining their supplies from other sources (e.g., retail). Yet, even our metrics still fall short – by a third – to the average recommended testing frequency ordered by physicians. By recognizing the value of these services, and requiring the provision of these services by contract suppliers of diabetes testing supplies, CMS will maximize overall program savings and positively impact beneficiaries.

B. <u>CMS should require suppliers of diabetes testing supplies to offer a range of products within each HCPCS code</u>.

PolyMedica stands in full agreement with CMS that beneficiaries should have access to quality DMEPOS. Further, we believe that contracted suppliers of diabetes testing supplies should be required to offer a minimum number of products and product brand options. Although all covered home blood glucose monitors, test strips and related supplies are FDA approved, they are not fungible commodities. It is a commonly assumed that there are "generic" strips that can be applied to a wide variety of glucose monitors. There are no "generic" strips. The testing strip and the meter are unique and inextricably connected to each other. Moreover, diabetes supplies, primarily the glucose monitors, differ in features and quality, and our experience shows that beneficiaries and their physicians have various preferences for brands of monitors, strips and related supplies.

Thus, we believe a requirement that suppliers offer a range of brands is necessary to

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6 National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics Fact Sheet: General Information and National Estimates on Diabetes in the United States, 2005. Bethesda, MD: U.S. Department of Health and Human Services, National Institute of Health, 2005.

7 Moreland, *et al, Use of a Blood Glucose Monitoring Manual to Enhance Monitoring Adherence in Adults with Diabetes,* 166 Archives of Internal Medicine 689, 693 (March 27, 2006)

achieve CMS' stated goal to "contract with suppliers who conduct business in a manner that is beneficial for the program and for Medicare beneficiaries," 71 Fed. Reg. at 25657, as well as to implement § 414.420(b) of the Proposed Rule. Competitive bidding should not be implemented in a way that denies beneficiaries and their doctors a reasonable choice of products, and instead limits them potentially to a narrow span of cheap products within a code. As discussed in more detail below, *we urge that contract suppliers of diabetes testing supplies be required to offer at least three brand options, where at least two are major national brands of blood glucose monitors and strips*. Nevertheless, we do not believe CMS should require that suppliers offer an unreasonably large number of brand options. Rather, we urge CMS to appreciate the importance of maintaining balance between preserving beneficiary preferences and a supplier's ability to provide competitive pricing to the government.

C. Potential contract suppliers should be able to trust the overall integrity of the bidding process.

CMS should implement policies to mitigate against the ill effects of predatory pricing or other manipulative bidding behavior that erodes the integrity of the bidding process. *To this end, we suggest CMS strengthen its quality and accreditation standards, make substantial technical changes to the bidding methodologies, and add a requirement that items not be bid below their marginal cost.* These integrated solutions will best assure the long-term success of the competitive bidding program in and beyond the initial bid cycle.

D. Mail order suppliers and retail suppliers should be treated equally in the competitive bidding process.

The goals of maintaining beneficiary access and maximizing Medicare program savings both can be best achieved by treating mail order and retail suppliers equally in the bid process. Competition from mail order suppliers will maximize savings particularly in areas where retail competition is not robust, either because there are few retail suppliers or because the area is dominated by a large low cost retail supplier. Mail order suppliers also have a greater ability to efficiently serve beneficiaries who live in less densely populated or rural areas. At the same time, retail suppliers are necessary for emergency (i.e., 24 hour) supplies, and because some beneficiaries prefer retail suppliers. *We therefore urge that retail and mail order supplies be bid for an area in a single bid process. We also strongly urge that mail order suppliers not be excluded from the initial supply of items, including specifically diabetes testing supplies, where there is no clinical need for a face to face interaction between the supplier and the beneficiary.* Because the Proposed Rule refers to a mandatory mail order program for replenishment of supplies, we respectfully request CMS to clarify these points.

E. Diabetes testing supplies should be phased-in through a pilot program.

Unlike a number of other major DMEPOS product categories, CMS does not have the benefit of experience from prior competitive bidding demonstrations. Moreover, since diabetes is a much different clinical condition than those competitively bid in the demonstration projects, in terms of its significant prevalence, its chronic nature and its debilitating and costly complications, it is unclear how many lessons can be inferred from the prior demonstrations.

We respectfully suggest that CMS should have a better sense of risks and benefits of competitive bidding for diabetes supplies before it aggressively expands the program. To this end, CMS should obtain data about the impact of reduction of suppliers on access, outcomes, quality of suppliers, and patient safety before it expands to more MSAs. It should also evaluate the impact of competitive bidding on overall program savings (i.e., taking into account increases or decreases in the costs of treating the complications of diabetes), to assess whether competitive acquisition of diabetes testing supplies saves money for the Medicare program.

Accordingly, CMS should use the entire period between October 1, 2007 and October 1, 2009 to pilot and evaluate the impact of competitive bidding for diabetic supplies on the Medicare program before it expands to any further MSAs (especially in view of CMS's expectations for a nationwide program). This would be consistent with CMS's contemplation that it may "phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding." 71 Fed. Reg. at 25670.

In view of the importance of blood glucose monitoring in the management of diabetes and avoidance of the serious complications of the disease, the amount at stake given the ranking of diabetes supplies in DMEPOS, and the significant challenges facing CMS, its contractors, and contracted suppliers with patient education concerning competitive bidding, diabetes testing supplies are especially appropriate for such a phase-in.

We also believe that CMS may want to consider a broader concept for a nationwide or large regional mail order program. To this end, we respectfully suggest that CMS consider implementing a nationwide diabetes testing supply program that would require a higher level of service and disease education and support from the supplier community and would explicitly link these efforts to CMS's other chronic care improvement activities.

Implementing competitive bidding for diabetes supplies in a more careful, but more integrated and comprehensive manner will provide CMS the best opportunity to succeed, and in our estimation, enable it to exceed expectations.

2. Comments on Specific Provisions of the Proposed Rule.

A. Payment Basis -- Adjustment of Payment Amounts in Other Areas. 414.408(e).

We believe it is not appropriate to use payment amounts determined in competitive bidding to make inherent reasonableness adjustments to payment amounts in other areas, particularly in any formulaic manner as suggested in the Proposed Regulation. There are at least two substantial reasons for this. First, in 2009 the competitive acquisition program will apply in *80* of the largest MSAs. Remaining areas will tend to be more rural and less densely populated. For items that can be appropriately furnished by mail, the national and regional mail order programs contemplated by the Proposed Regulation may be implemented by CMS. Other items will be more costly to furnish on a per unit basis because of the lower population densities, involving among other things greater travel times. Therefore there is no reason to suppose that competitive bid payment amounts will be reflective of the costs of providing the items in areas outside of the competitive bid areas. In fact, the Proposed Rule tacitly assumes that there will be

some sort of uniformity or consistency in the payment amounts for items in the competitive bid areas. At best, this assumption is highly suspect. The costs of living in the Northeast and Pacific Coast MSAs are dramatically different from those in Midwest and plains MSAs. In the absence of uniformity or consistency in competitive bid payment amounts, there is even less basis for using such amounts to make inherent reasonableness adjustments to payments in other areas.

Second, it is likely that the successful bidders will achieve savings based on high volumes. In areas that are not competitively bid, there is no reason to expect that volumes will shift among suppliers. Further, suppliers that furnish items outside of 80 of the largest MSAs, other than mail order suppliers, will tend to be small suppliers, as acknowledged by CMS in the Proposed Rule. Small suppliers will have lower volumes than contract suppliers in any event, and will pay more per unit to acquire items from manufacturers and distributors than large suppliers. The amounts of these differences in acquisition costs, and differences in costs of delivery and providing service in less densely populated areas, will not be systemic but will be highly dependent on the areas and volumes involved. Consequently, single payment amounts established for large MSAs on the basis of competitive bidding will have no relation to appropriate payment amounts in areas outside of those MSAs, and it is not reasonable to use these amounts to make inherent "reasonableness" adjustments to payment amounts outside of the competitively bid MSAs.

B. Competitive Bidding Areas.

1. Designation of Areas. § 414.410.

We respectfully suggest that CMS pilot and evaluate the impact of competitive bidding for diabetic supplies between October 1, 2007 and 2009, specifically using lessons learned to prepare for CMS's proposed nationwide mail order program.

Unlike a number of other major DMEPOS product categories, CMS does not have the benefit of experience from prior competitive bidding demonstrations.8 Moreover, since diabetes is a much different clinical condition, both in terms of its significant prevalence and its chronic nature, than those treated by the items competitively bid in the demonstration projects, it is unclear how many lessons can be inferred from the prior demonstrations.9

We suggest that CMS should have a better sense of risks and benefits of competitive bidding for diabetes supplies before it aggressively expands the program. To this end, CMS should obtain data about the impact of reduction of suppliers on access, outcomes, quality of suppliers, and patient safety before it expands to more MSAs. It should also evaluate the impact of competitive bidding on overall program savings (i.e., taking into account increases or decreases in the costs of treating the complications of diabetes), to assess whether competitive

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8 Diabetes testing supplies were not included in the demonstrations in Polk County, Florida and the San Antonio, Texas MSA.

9 For example, on average, most Medicare beneficiaries living with diabetes are not testing their glucose levels as often as their physicians' orders recommend. Thus, given the direct relationship between education, testing frequency and outcomes, implementing a program on a broad scale without understanding the consequences of competitive bidding on a discreet issue like testing frequency could result in serious and costly unintended consequences.

acquisition of diabetes testing supplies saves money for the Medicare program.

Accordingly, CMS should use the entire period between October 1, 2007 and through part of 2010 to pilot and evaluate the impact of competitive bidding for diabetic supplies on the Medicare program before it expands to any further MSAs (especially in view of CMS's expectations for a nationwide program). This would be consistent with CMS's contemplation that it may "phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding." 71 Fed. Reg. at 25670.

In view of the importance of blood glucose monitoring in the management of diabetes and avoidance of the serious complications of the disease, the amount at stake given the ranking of diabetes supplies in DMEPOS, and the significant challenges facing CMS, its contractors, and contracted suppliers with patient education concerning competitive bidding, diabetes testing supplies are especially appropriate for such a phase-in.

Because CMS intends to implement a nationwide mail order program, CMS should not expand competitive bidding for diabetes testing supplies in 2009. An expansion in 2009 would be redundant to the effort to take this program national in 2010 and expose CMS to large implementation costs it would only have to replicate in 2010. The 80-MSA requirement does not have to apply for every product category, and the statutory requirement to expand to 80 should be viewed in the context of items not subject to the national program. Given the large stakes for a national program, there is not a lot of time between fiscal 2008 and fiscal 2010 to apply the lessons learned and make appropriate modification to the process for diabetes testing supplies.

2. Nationwide or Regional Mail Order Competitive Bidding Program. § 414.410(d)(2).

We are cautiously optimistic about the potential of a nationwide or regional mail order competitive bidding program to be implemented for certain diabetes testing supplies and deliver on CMS's five objectives for competitive bidding. PolyMedica is a significant mail order supplier serving close to 900,000 Medicare beneficiaries in all 50 states and Puerto Rico. We appreciate the recognition by CMS and GAO about the benefits of the mail order delivery channel for diabetes supplies to serve beneficiaries on a nationwide scale, regardless of geographic or demographic, or socio-economic conditions.

We have a number of specific suggestions on this initiative that ensure that all five of CMS' objectives for competitive bidding globally will also be satisfied in this program.

While PolyMedica agrees that implementing a nationwide program expansion in 2010 for diabetes testing supplies cannot occur without mail order distribution, we respectfully suggest that CMS supplement its policy rationale by articulating why the core capabilities inherent with large mail order operation are necessary. For example, mail order suppliers like PolyMedica have the ability to reach into less populated areas, where the absence of a robust set of retail options would ordinarily be an issue for the competitive bidding program. Moreover, nationwide and regional mail order suppliers like PolyMedica offer CMS a highly scalable platform to expand and absorb new patient volume in a competitive framework. From a quality

perspective, mail order suppliers like PolyMedica engage in systematic communication with our Medicare beneficiaries, and provide invaluable assistance with supporting them in their efforts to remain compliant with their physician and/or their care teams' plan of care relating to glucose monitoring. We believe the absence of this kind of detail about why mail order was singled out as a source of delivery is causing unrealistic concerns among a number of stakeholders. By supplying a more detailed policy rationale in the final rule, CMS could address a number of these concerns.

CMS also has asked for public comment on the feasibility of requiring all replenishment of diabetes testing supplies to be furnished through mail order suppliers. As noted above, in this letter we do not comment on the DMEPOS Quality Standards. In the case of diabetes testing supplies, however, there is no clinical reason that the initial supplies should not be able to be furnished by a mail order supplier. In fact, our service model, involving patient education and regular patient outreach, is superior to retail distribution because PolyMedica systematically and proactively supports beneficiaries with trained professionals ranging from product specialists to registered nurses who are Certified Diabetes Educators. By contrast, retail, which theoretically affords an opportunity for counseling, in practice, usually involves only a purchase and payment transaction.

We recognize that certain items of DMEPOS such as oxygen may require in person contact, but this should be item specific and not broadly required because it will only diminish the opportunity for savings otherwise available to the program. This is also workable and consistent with a single bid process that does not differentiate between modes of delivery. Therefore, we respectfully request that CMS clarify that nothing in the Proposed Rule would preclude any supplier from furnishing a beneficiary's initial supply of diabetes testing supplies.

In addition, as the nation's largest mail order supplier of diabetes testing supplies we confidently assert that CMS could realize additional value by encouraging or creating incentives for beneficiaries to obtain their replenishment diabetes testing supplies from a supplier like PolyMedica. As stated previously, we possess the ability to customize service and distribution solutions for CMS for the diabetic population, which includes providing these solutions on a national scale.

However, even though a mandatory mail order program for replenishment supplies would obviously drive more volume to mail order providers like us, we nevertheless believe that it is important that Medicare beneficiaries continue to have access to retail options for those who may not be comfortable switching to mail order or for beneficiaries who need an emergency supply (*i.e.*, in under 24 hours). We thus support the American Diabetes Association's public position that any policy should at a minimum assure retail access for emergency situations. In the event that CMS wishes to pursue an overall solution for diabetes testing supplies including a mandatory mail order program, we are confident that we could offer access to retail channels to enable emergency access to their supplies.

In addition to the modifications and clarification sought above, we also believe that CMS may want to consider a broader concept for a nationwide or large regional solution or mail order program that includes a patient compliance component. To this end, we respectfully suggest that CMS consider implementing a nationwide diabetes testing supply program that

would require a higher level of service and disease education and support from the supplier community and would explicitly link these efforts to CMS's other chronic care improvement activities.

Given CMS's emphasis on finding new ways to provide chronic care improvement services to fee for service Medicare beneficiaries (e.g., through the Medicare Health Support Program, the "646" demonstration, Medication Therapy Management, and other initiatives), CMS should consider policies and programs that complement these efforts. According to the Centers for Disease Control, chronic diseases have become the leading cause of death and disability in the United States, and account for 7 out of every 10 deaths, and affect the quality of life of 90 million Americans. In 2002, direct medical costs reached $92 billion and indirect costs (including disability, work loss and premature mortality) totaled $40 billion. Proportionally, Medicare share's of this crisis is even more significant. Medicare beneficiaries who live with chronic illness account for a disproportionate share of Medicare expenditures and those living with diabetes account for about one third of all Medicare spending.

And despite the fact that the incredible human and financial toll of chronic illness in Medicare can be materially ameliorated with relatively straightforward disease and care management programs, the reality is that healthcare providers in the traditional Medicare program struggle every day with diabetic Medicare beneficiaries who simply cannot or refuse to cope with the reality of their condition. This lack of effective self-care management and support system often manifests by Medicare beneficiaries failing to manage their medications properly, adapt their diets appropriately, exercise regularly, and monitor their blood glucose levels persistently in line with their doctor's or care team's plan of care.

To affect the diabetes epidemic in Medicare, it is no longer disputed that the entire healthcare industry—professionals (including specialists and educators), payers (especially Medicare), the Medicare beneficiaries' network (their family and friends), chronic care improvement organizations, and suppliers—must work together to overcome the emotional and psychological issues that prevent appropriate treatment and self-care management.

The more elusive issue is how to cost-effectively implement the best ideas in the context of the delivery system and financial incentives operating in that system. While we remain cautiously optimistic about how a national solution or mail order supply program may provide some incremental savings to CMS, we are more enthusiastic about the potential of a nationwide diabetes supply program that offers enhanced education and support services that contribute to and integrate with other CMS chronic care initiatives. We believe that a program that emphasizes additional education and service levels will more profoundly impact cost and quality.

As we stated in our introductory comments, randomized controlled trials increasingly demonstrate the connection between efforts to improve education about the importance of blood glucose testing with actual improved testing frequency to finally better clinical outcomes.

Given this link, we respectfully suggest CMS should alter the way it thinks about the role and importance of glucose monitoring. Our own research data indicates that mail order

Medicare beneficiaries test nearly twice as frequently compared to beneficiaries obtaining their supplies from other sources (e.g., retail). Yet, even our metrics still fall short – by a third – to the average recommended testing frequency ordered by physicians. Thus, based upon the growing body of objective and independent evidence linking education about the importance of testing to increased testing frequency to better outcomes, we are confident that augmenting our standard efforts to educate and support Medicare beneficiaries, plus coordinating with other CMS chronic care initiatives, will yield significantly better health outcomes.

In our view, CMS has a unique opportunity to transform what may have been initially viewed as a narrow isolated cost savings and program integrity statutory mandate and mold it into a much more robust program that explicitly seeks to integrate with CMS's other chronic care improvement efforts. We hope CMS shares our optimism about the potential strategic import how the mail order diabetic supply community, along with other stakeholders, can play a contributory role in CMS's broader efforts to improve quality while reducing unnecessary costs. We look forward to exploring this idea further with you.

Finally, there have been concerns raised by some observers that CMS may fundamentally change the bidding system in 2010 with the introduction of a national or regional mail order program by creating a separate bidding track for mail order bidders. While PolyMedica does not interpret the rule as creating two separate bidding tracks for the same competitive bid areas, we respectfully request that CMS affirmatively assert that there will only be one bidding track in 2010. CMS and Medicare beneficiaries will benefit the most when all distribution models compete equally with one another.

In the unlikely event that CMS is considering a two tiered bidding process, we would vigorously oppose such a concept. As stated above as part of our key principles, we believe that a mail order and retail distribution channels should be treated equally in the bidding process. Treating mail order and retail differently in the case of diabetes testing supplies will only reduce the ability of the competitive acquisition program to lower costs and maximize beneficiary choice. For example, in rural areas, where competition among local retail suppliers is not robust, having a single competitive bidding process will most effectively achieve CMS' objectives of maximizing savings and beneficiary choice. Therefore, mail order suppliers should bid in the same process as non-mail order suppliers (both for initial and replacement diabetes testing supplies, as discussed below), and the methods of delivery should not be distinguished in the bid process or pricing.

C. Criteria for Item Selection and Product Categories for Bidding Purposes. § 414.412.

Given the way CMS has articulated its criteria for item selection, we understand that diabetes testing supplies are a prime candidate for competitive bidding As a general matter, and as discussed above, in view of the seriousness of the disease and its complications, the substantial costs of treating those complications, the unfortunate trends of noncompliance of beneficiaries with their prescribed testing regimens, and the significant risk of failure to the overall DMEPOS Competitive Bidding Program if diabetes is not implemented well, we respectfully urge that CMS begin its efforts to competitively bid diabetes supplies in a more carefully constructed manner by initiating pilot in a limited number of competitive bidding areas.

With this approach, significant risks are avoided, and lessons can be learned and applied in a larger scale roll out.

More specifically, although we agree with the general proposition that products should be bundled together for beneficiary convenience, the Proposed Rule does not set forth the methodology for grouping items into product categories. It therefore is not possible for us to comment on this methodology. Moreover, because the methodology is not set forth, it is not possible to know what items would be included as diabetes testing supplies or to comment fully on the method of calculating the composite bid, although we do offer some preliminary comments. We respectfully submit that the methodology for grouping items into product categories be specified and that suppliers be afforded an opportunity to comment on the method as well as to comment further on the method for calculating the composite bid and other aspects of the Proposed Rule that may be impacted.

In addition, we believe that the Proposed Rule should state a requirement that to be a contract supplier, a supplier must offer at least three product brand options (meters/strips) to beneficiaries, with an added requirement that at least two of the brand options be made up from this nation's "leading/major" brands. We further suggest that CMS define "leading/major" as a domestic brand having a market share of not less than 10 percent of the overall Medicare fee for service strip volume in the year preceding a bidding cycle.

We fundamentally believe that offering a reasonable selection of high quality products and brands will maintain conditions necessary to maintain and improve quality and will also help assure that CMS contracts with higher quality suppliers who are dedicated to improving quality and help CMS achieve its five primary goals with competitive bidding. Items included within a code, such as blood glucose monitors, have different features such as display size, memory, graphical display, minimum blood sample size, ability to interface with a computer and overall size. Depending upon the beneficiaries' clinical conditions, needs and preferences, different brands and products within a code will be most appropriate for different beneficiaries.

Our specific proposal and precise market share definition is intended to balance the inherent tensions between the program's goals of providing both choice as an important proxy for supplier and product quality and preserving the ability of contracted suppliers to exert some negotiating leverage.

We respectfully submit that CMS runs significant downside risks if it implements policies on either extreme of our suggestions. On one extreme, CMS should not adopt a "any willing brand" policy. Such a requirement would greatly diminish suppliers' bargaining power with manufacturers, which would have a significant adverse impact on the ability of suppliers to achieve savings for the program. On the opposite extreme, CMS should avoid remaining silent on the issue of brand and product choice. In the context of competitive bidding, policy silence would allow potential suppliers to exclusively bid low cost items that will not meet the diverse preferences of the diabetic testing population. It would also significantly distort the bidding process and increase the likelihood of predatory pricing.

Again, we urge CMS to appreciate the importance of maintaining balance between preserving beneficiary preferences and a supplier's ability to provide competitive

pricing to the government. We note that managed care plans often offer a choice of two leading brands of blood glucose monitors and related test strips and supplies, and this strikes a reasonable balance between meeting patient preferences and achieving savings.

This suggested requirement will also effectuate the requirement of SSA § 1847(a)(5)(A) that suppliers be able to furnish a range of brands to fill physician prescriptions and to effectuate the provisions of proposed § 414.20(b) which implement this requirement.

D. Conditions for Awarding Contracts.

1. Quality Standards and Accreditation. § 414.414(c).

It is not clear how the accreditation requirement can be satisfied by a reasonable number of suppliers within the timeframe necessary for the implementation of competitive acquisition. Even if implementation is deferred as much as permitted by the SSA, it may not be practicable to have a sufficient number of suppliers accredited to assure a robust and effective bid process. An accreditation mandate has been proposed while the capacity of accreditation organizations to enable suppliers to comply with this mandate is clearly inadequate. Under the most optimistic view, there is not nearly enough time for suppliers to have a reasonable opportunity to be accredited. As proposed, the capacity gap will impair CMS' ability to achieve a robust and effective bid process. At the same time, we agree that it is critical to the success of the competitive acquisition program that CMS be assured of participation only by high quality, responsible suppliers. We urge a multi-pronged strategy to address these issues. First, as discussed below, key financial standards and bid requirements should be added. Second, a simple and expedited provisional accreditation process should be employed prior to bidding. After bid award, a more comprehensive process should be implemented to assure that contract suppliers meet appropriate accreditation requirements. We believe that CMS can implement a strong accreditation process that minimizes unnecessary regulatory burdens and costs on both CMS and potential suppliers, but also is more robust in its ability to ensure that the bids among competing suppliers are as comparable as possible.

2. Financial Standards. § 414.414(d).

Because the financial standards are not detailed, it is not possible to provide detailed comments. The absence of any transparency with respect to the financial standards is not at all appropriate in view of the centrality of the standards in the bid process. Satisfaction of the standards is a precondition to bidding. If the standards are too restrictive, fewer suppliers will be able to participate in the bid process, diminishing beneficiary choice and potentially adversely affecting the single payment amount. If the standards are not restrictive enough, unsound suppliers may be awarded contracts. These suppliers may not be able to supply beneficiaries at the single payment amount, resulting in impaired access. Further, the method of assessing the financial capability of suppliers planning to meet demand through expansion should be known so that suppliers can assess their and their competitors' ability to meet demand through expansion. CMS' failure to specify financial standards leaves both beneficiaries and suppliers vulnerable, and CMS should specify standards in time for comment prior to the effectiveness of the Proposed Rule. Related issues impacting the bid and bid evaluation process are discussed below.

In addition, we urge that the proposed rule contain standards for rejecting bids that are below marginal cost (i.e., all costs except for allocated corporate overhead). In the absence of such standards, it will be possible for one or more large suppliers to bid below cost in order to become one of the few, perhaps two, contract suppliers in a competitive bid area. In the next bid cycle, after competing suppliers have been driven out of business, ologopolistic behavior will result in higher bid prices than would occur in a competitive environment. A provision that bids below marginal cost will be rejected will protect the program from predatory bidding, and will result in the lower aggregate cost to the program.

Rejection of bids below marginal cost will also prevent the use of forecasted unit cost savings by small suppliers or less sophisticated suppliers which are not based upon any data or information. As noted below, negotiated discounts based on volume that are obtained by large suppliers are highly confidential trade secrets. Small suppliers or less sophisticated suppliers simply do not know the price at which they will be able to obtain items at a forecasted volume. Bid prices by small suppliers based on forecasted unit cost reductions will be made up out of whole cloth. To the extent such a bid results in an award and determination of the pivotal bid, it presents a significant risk that the supplier and other contract suppliers will not be able to meet demand at the single payment amount. The provision of the Proposed Rule for addition of suppliers after bidding does not mitigate this risk, because the added suppliers are required to furnish the items at the single payment amount.

Moreover, it is common that governmental competitive acquisition programs contain rules to exclude bids that are not responsible, and CMS should include rules as described above in the DMEPOS competitive acquisition program.

3. Market Demand and Supplier Capacity. §§ 414.414(d), 414.414(g).

Under the Proposed Rule, only a sufficient number of suppliers need be selected to meet demand. In the proposed rule, CMS states that in some cases this may be two suppliers. In fact, under the Proposed Rule, it is quite likely that two large suppliers would be able to satisfy the demand for any product category in any competitive bid area. This is not the result required or intended by the SSA. The SSA requires that awards be made in each competitive bid area for each product category to "multiple" suppliers. SSA § 1847(b)(4)(B). "Multiple" is not reasonably construed to contemplate two, and we submit that the minimum number of contract suppliers for a product group in a competitive bid area should be greater than two, but should not be so high as to diminish the savings that can be achieved by driving volume to a small number of suppliers.

In addition, we understand and appreciate CMS's need to evaluate whether a group of contracted suppliers will have the capacity in any given CBA to absorb increased patient volume due to one time large shifts in patient volume and future organic growth due to the unfortunate high prevalence rates in diabetes. For these general purposes, CMS should analyze this issue based on both empirical historical data and other standardized and measurable metrics.

We do not, however, support, as described below, the use of figures other than empirical historical data as a basis for determining the pivotal bid. CMS should be able to rely on the number of suppliers purely based on historical data. We do not believe CMS should be

overly concerned about the risks of allowing too many suppliers in a given CBA. As a potential bidder who could ultimately benefit from CMS relying on potential capacity to reduce the number of bids under the pivotal bid, we believe the potential for suppliers to manipulate this concept outweighs the potential competitive advantage. By asking suppliers to provide information about their ability and intentions to absorb additional patient volume, CMS will have sufficient information to add additional suppliers into the pivotal bid array if it appears that the formulaic pivotal bid calculation doesn't produce enough suppliers capable of dealing with anticipated near and longer term demand.

In addition, we believe that assuming the bids are competitive in amount, contract suppliers should be selected to achieve a balance between retail and mail order. Finally, we strongly agree with CMS' position that SSA § 1847 does not permit an "any willing supplier" provision in competitive acquisition of DMEPOS.

4. Weighting Methodology. § 414.414(e).

While we understand CMS' concerns with the use of payment amounts of items in a product category as the weighting basis to determine the composite bid, we also believe that CMS should be equally concerned about the distortions the use of volume creates. For example, a high volume of very low bid payment amount items, on a relative basis, could result in a lower composite bid amount that may not accurately reflect the real market dynamics. Accordingly, we suggest that the lowest distortion would result from a hybrid of the two approaches. Under this methodology, we recommend a 50/50 blend of payment amount and volume. We believe this represents a reasonable balance between two imperfect alternatives that is also easy to articulate.

5. Determination of Pivotal Bid. § 414.414(e).

Although we agree that the approach of determining the pivotal bid appears reasonable, we strongly urge, as stated above, that CMS reconsider the way it intends to apply data about supplier capacity specifically as it applies to the pivotal bid calculation. Rather than rely both on historical data and supplier provided projections about future capacity, we believe CMS should rely instead on historical CMS utilization data alone. As stated above, reliance on supplier self-evaluations or projections of capacity is highly problematic even if CMS expends additional effort to create more standardized and better defined information requirements on the application forms.

For example, small, local suppliers concerned about being put out of business by competitive acquisition could manipulate the system by forecasting significant expansion plans and by submitting extraordinarily low bid amounts they believe are low enough to assure their participation. Such suppliers will have neither the assured capacity they forecast nor the information or management experience to know whether it is financially feasible for them to deliver the items in a product category at the bid price and in the forecasted volumes.

Yet, we recognize the importance of CMS asking suppliers to provide information about their ability and intentions regarding existing and future capacity. Thus, rather than explicitly incorporating future capacity figures into the pivotal bid calculation, CMS could apply it on a CBA by CBA basis on the back end of the pivotal bid determination. This way, CMS

would have sufficient information to add additional suppliers into the pivotal bid array if it appears that the formulaic pivotal bid calculation doesn't produce enough suppliers capable of dealing with anticipated near and longer term demand. We do not believe CMS should be overly concerned about the risks of allowing too many suppliers in a given CBA. As a potential bidder who could ultimately benefit from CMS relying on potential capacity to reduce the number of bids under the pivotal bid, we believe the potential for suppliers to manipulate this concept outweighs the potential competitive advantage.

E. Determining Single Payment Amounts for Individual Items.

1. Single Payment Amount. § 414.416(b).

We submit that the methodology for determining the single payment amount will have an adverse impact on beneficiary access to needed items, and to items that are more costly within a code, and therefore will jeopardize the ability of CMS to achieve its stated objective "to contract with suppliers who conduct business in a manner that is beneficial for the program and for Medicare beneficiaries." 71 Fed. Reg. at 25657.

The single payment amount is set at the median between the pivotal bid and the low bid. There are two probable adverse policy outcomes from using the median price for each item, regardless of whether it involves suppliers who bid above the median or below. For those suppliers that bid above the median, there is a high probability that some or all of these suppliers will NOT be able to furnish the involved items at a payment amount equal to the median. And, for those suppliers that bid below the median (i.e., a group who will receive an amount greater than their bids), dangerous incentives emerge for unfair bid manipulation/gaming. For example, one probable strategy could be for a small and/or unsophisticated supplier to "tuck-in" behind larger and/or more responsible suppliers. In fact, concern for this "tuck-in" hypothetical gaming strategy was raised at the most recent PAOC meeting, where PAOC members cautioned against the ill effects of a methodology that allows suppliers to bid unreasonably low merely to obtain ***potential*** contracted supplier status. Once the median price is revealed, these smaller or unsophisticated suppliers could then determine whether or not to participate in the competitive bidding program. We think this policy undermines the integrity of the bidding process, as all suppliers should be able to assume that every other bidder is bidding prices for each item that they are willing and credibly able to offer.

Additionally, the single payment amount method set forth in the Proposed Rule will create strong incentives for suppliers to attempt to maximize the volume of the least expensive items within a code, and minimize the volume of more expensive items within a code, regards of appropriateness for the beneficiary or the preference of the beneficiary. This could seriously erode access to the more expensive items included in a code, and detrimentally affect beneficiaries.

Another fundamental problem is the bids for each HCPC for all the selected contractors are weighted equally, regardless of whether any contracted supplier's market share is insignificantly small or large. Just as a bidder's market share has meaning in the pivotal bid calculation, so too should that market share have some bearing in the methodology to determine an item's price. We believe, therefore, that market share should have some influence on the final

price.

We believe that CMS can materially improve its calculation for determining the single payment amount for each item by incorporating a variety of adjustments to the pure median pricing scheme. First, we respectfully suggest that CMS eliminate bids that are outside of a reasonable range. We are confident that CMS possesses enough market data or has the expertise and resources to acquire such knowledge to understand what kinds of savings are reasonable in each category. This idea also was raised at previous PAOC meetings, and was specifically highlighted again at the most recent public PAOC meeting discussing the Proposed Rule.

Second, we suggest that CMS combine the median price methodology along with the average price of the selected bids weighted by each potential contracted supplier's existing market share. This blend of methodologies will better reflect what the market is realistically suggesting is the best price without allowing undue influence by dominant players or manipulative behavior by smaller or less sophisticated actors.

Finally, we also support a return to the adjustment factor that was used in the initial set of competitive bidding demonstrations. Notwithstanding CMS's concerns about the net effect of the adjustment factor, we believe that the integrity of the bidding process is ultimately maintained if there is a meaningful nexus between each supplier's composite bid and the requirement to establish HCPC level pricing.

These specific suggestions on improving the methodology to determine a single payment amount along with creating a financial standard that does not allow supplier to bid items below marginal cost will help maintain the integrity of the bidding process, and ensure that contracted suppliers will provide Medicare long-term sustainable savings.

2. Rebate. §414.416(c).

There is no place in Medicare for inducements that distort utilization patterns and encourage overutilization. The rebate proposal raises significant inducement and anti-kickback issues. We do not believe the provisions of the Federal health care program anti-kickback statute or the Medicare anti-inducement statute can be repealed by a CMS regulation. The HHS Office of Inspector General has on numerous occasions expressed the view that the provision of things of value to beneficiaries violates these laws.

Assuming, however, that the OIG would approve the rebate proposal as an exception under these laws, we submit that the same policies underlying these laws militate against the rebate provision. The policies underlying the laws include that the rebate will have an adverse impact on the quality of care. The OIG has specifically cited a concern that such inducements lead to a "race to the bottom" which creates strong "incentives to cheat on the quality" of the involved items or services. HHS OIG Advisory Opinion 02-14 (September 30, 2002). These incentives will be particularly pronounced in a competitive bidding environment with reduced payment amounts. The rebate provision also violates the single payment amount provision of the Act, by permitting different payment amounts for different contract suppliers. Finally, we submit that suppliers will have more than adequate incentive to bid aggressively in

the competitive acquisition program without the rebate provision, and that it therefore should be eliminated.

F. Terms of Contracts

1. Non-Discrimination. Preamble.

We strongly object to the provision in the preamble to the Proposed Rule that contract terms will include a requirement that contract suppliers make available to all beneficiaries inside and outside of competitive bid areas the same products that they make available to other customers. 71 Fed. Reg. at 25681. We believe this is unrealistic, will impair beneficiary access, and limit the savings that otherwise will be achieved through competitive bidding.

The entire premise of the competitive acquisition program is that it will result in lower payment amounts for codes than the fee schedule amounts. To achieve the lower payment amounts, suppliers must retain the ability to limit the brands that they make available within a particular code. By requiring parity in formularies between competitively bid areas and non-competitively bid areas would force a supplier to either reduce its formulary for all areas they serve, or inhibit their ability to achieve saving for the government they otherwise could.

Moreover, the range made available to persons who are not Medicare fee for service beneficiaries is irrelevant because the payments amounts for those persons may be different from the competitive bid amount, and the supplier may be restricted to a specific brand or brands based on contracts between the payors and manufacturers.

We understand that the purpose of this requirement is to protect beneficiary choice of products, and to assure that beneficiaries are not limited to the least expensive item within each competitively bid code. While we fundamentally agree with this objective, we believe a more effective way to accomplish it is to require bidding suppliers to offer at least three product options, with two comprised of the major brands, as discussed above. This approach of creating a formulary balances the interests between preserving product and brand diversity and enabling the supplier to generate and then pass through savings to the payer. It is critical to the success of competitive bidding that suppliers have the practical ability to negotiate with manufacturers, and that manufacturers have a reason to negotiate with suppliers. We therefore urge that our specific proposal relating to choice of products be adopted instead of this section's preamble's non-discrimination proposal.

2. Change of Ownership. § 422(d).

While we recognize the legitimate need of CMS to carefully scrutinize the acquisitive behavior of non-contract suppliers to ensure that they are not circumventing the bidding process, we respectfully submit that the Proposed Rule regarding change of ownership is overbroad and fails to take into account legitimate and practical considerations applicable to public companies.

Following on the reasons articulated by CMS for this section of the Proposed Rule, § 422(d)(1) should be modified to make it clear that it does not apply where a contract

supplier purchases or acquires another supplier (or is the surviving party in a merger). Also, if a party that purchases or acquires a contract supplier does not intend to be a contract supplier, there is no reason for the § 422(d)(1) requirement to apply. We respectfully submit CMS should clarify these points.

In addition, although notice is appropriate, we submit that if the acquiring supplier already is a contract supplier in good standing with CMS, there is no compelling reason to require an additional review as to its qualifications. Moreover, while we understand the need for CMS to conduct oversight and diligence if the acquiring supplier is not a contract supplier, we submit that the requirements for approval of the acquisition and of the acquirer as a contract supplier, should be clearly specified. Yet within this context, we urge that the Proposed Rule clarify that the requirements for an acquirer are no more burdensome than the requirements to be a competitive bidder and contract supplier initially (e.g., the acquirer should be accredited and meet the financial standards for contract bidders.).

As indicated, we do not believe it appropriate to impose requirements on acquirers that are not imposed on initial contract suppliers. In addition to impeding transactions that are in the interest of the program and beneficiaries, such requirements could result in an unequal burden on contract suppliers, which is not necessary in view of the fact that the CMS has determined not to initially impose the requirements on bidders. Nevertheless, if any additional requirements are to be imposed, they should be made explicitly, so that parties understand and can comply with them in advance of incurring substantial transaction costs. This will improve overall competitiveness and efficiency in the delivery of bid items to beneficiaries.

In addition, in smaller transactions it is customary for signing and closing to be simultaneous, to minimize cost. Although we believe it important to maintain the prior notice option, we also suggest that notice promptly after the transaction would be appropriate to the protection of the program and Medicare beneficiaries. After such notice, CMS could determine that the acquirer is not eligible to be a contract supplier. In this case the Proposed Rule provides a mechanism for CMS to select another contract supplier without re-bidding the product category. The acquiring supplier in this circumstance would evaluate its acceptability as a contract supplier and accept the risk that CMS would not find it acceptable as a contract supplier. This would enable small transactions to proceed efficiently and without undue delay where the acquiring supplier is confident that it will be acceptable as a contract supplier, and provide for prior review in those cases (generally larger transactions) where it is important to have certainty regarding the acceptability of the acquirer in advance of the closing of the transaction.

Maintaining the integrity of the bidding process is one of our central themes in our response to the Proposed Rule, and we support CMS's efforts to ensure that the bid process not be circumvented. However, the rules created to defend against these risk should not constructed with the presumption that all acquisitive behavior is not in the best interest of the program or beneficiaries. We believe that many acquisitions of contract suppliers will be in the interest of the program and Medicare beneficiaries. We therefore urge the Proposed Rule adopt requirements for approval to be more specific, and the processes associated with approval (e.g., timeframes, documentation) developed in a manner to not unreasonably delay or constrain transactions.

Finally, we urge that to the extent notice is required, the Proposed Rule should make it clear that the notice will be confidential and exempt from disclosure under exemption 4 of the Freedom of Information Act ("FOIA"), and the regulations of the Department of Health and Human Services promulgated thereunder, as trade secrets and commercial or financial information obtained from a person and privileged or confidential. *See,* 5 U.S.C. § 552(a)(4); 45 C.F.R. § 5.65. This is necessary so that public companies can appropriately maintain sensitive non-public information, and at the same time assure that disclosure is made appropriately when that disclosure is timely under securities regulations, in the interests of and to protect shareholders.

* * *

Thank you for your time in considering these comments and suggestions. PolyMedica appreciates and supports CMS' efforts to expand access to the regulatory process to suppliers for the improvement of delivery of quality healthcare to the beneficiaries of the Medicare Program. We welcome the opportunity to work with CMS in resolving the issues contained in this document. Please feel free to contact me directly at the following phone number (781) 486-8111 with any questions that you may have.

Sincerely,

David Kreiss
Chief of Government Affairs

The POWER MOBILITY Coalition
WORKING TOGETHER for FREEDOM and INDEPENDENCE

June 30, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW.
Washington, DC 20201

VIA COURIER

RE: **Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues [CMS-1270-P]**

Dear Dr. McClellan:

On behalf of the Power Mobility Coalition (PMC), a nationwide association of manufacturers and suppliers of motorized wheelchairs and power operated vehicles (POVs), we are submitting the following comments concerning the Notice of Proposed Rule Making entitled, *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues* (herein referred to as the "NPRM") that was published in the Federal Register on March 1, 2006. 71 Fed. Reg. 25654-25703. In essence, the NPRM seeks to establish and phase–in new quality standards and a competitive bidding reimbursement environment for Medicare DMEPOS suppliers.

While the PMC understands that the Centers for Medicare and Medicaid Services (CMS) was mandated by legislation to establish a competitive bidding program for DMEPOS[1], the system as set out in the NPRM is complex, overly restrictive and needlessly anti-competitive. Robert Baum and David Van Sleet, members of the Program Advisory and Oversight Committee (PAOC) who manage aspects of the Department of Veteran's Affairs (VA) competitive bidding program, remarked at the PAOC meeting on May 23, 2006, that they were concerned with the unyielding nature of the NPRM. Baum and Van Sleet noted that the VA competitive bidding

[1] *See* the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (P.L. 109-173) § 302(b)(1).

program affords greater flexibility by allowing suppliers to go outside the contract to meet the needs of the beneficiary. It is the PMC's hope that CMS' final rule will reflect this more flexible approach, thereby ensuring quality DMEPOS is provided to eligible beneficiaries.

With this in mind, the PMC has identified the following specific concerns:

P. Quality Standards and Accreditation for Suppliers of DMEPOS

All Suppliers Must be Accredited Prior to Competitive Bidding Implementation

The PMC is very supportive of CMS' draft quality standards and the new accreditation requirement established in the MMA. Such new standards are imperative to preserve program integrity and ensure that there is a meaningful barrier of entry into the Medicare program for lawful suppliers. Yet, under the NPRM, suppliers will be allowed to submit bid applications and be awarded contracts even if they are not accredited.

Program integrity is paramount to ensure Medicare beneficiaries receive the highest quality of products and services from lawful suppliers. Stringent quality standards coupled with mandated accreditation of suppliers will rid the Medicare program of unscrupulous actors and reinforce the integrity of those suppliers who play by the rules.

Implementing competitive bidding and allowing non-accredited suppliers to participate in the bidding process is contrary to CMS' priority to safeguard Medicare resources and beneficiaries. Allowing non-accredited suppliers to bid and be awarded contracts will cause major disruption if the contracted supplier cannot obtain accreditation and the contract must then be terminated and subject to a rebid. In addition, non-accredited suppliers would have lower overhead and, as a result, would be able to submit lower bids which could artificially lower the single payment amount for accredited contracted suppliers.

Quality Standards should be Subject to Meaningful Notice and Comment

According to the NPRM, the new quality standards for DMEPOS suppliers will be issued through Medicare program instruction and will not be subject to the safeguards inherent in the Administrative Procedures Act.

CMS has afforded the opportunity for stakeholders to comment on the draft quality standards that were released that year, and the PMC is appreciative of the changes to the draft standards that were articulated at the PAOC meeting held in May. Stakeholders, however, will have no further opportunity to comment on these standards even if the final standards diverge greatly from the draft standards.

At a minimum, DMEPOS stakeholders should have an opportunity to provide meaningful comment on the final quality standards and accreditation process prior to its implementation.

DMEPOS Stakeholders Should Have Other Meaningful Opportunities to Comment Prior to Competitive Bidding Implementation

In many ways, the NPRM poses more questions to DMEPOS suppliers that it answers. For example, the NPRM fails to name the final quality standards; fails to mention the MSAs and product areas that will be subject to competitive bidding; and fails to name the nationally–recognized accreditation bodies. Mandatory accreditation and competitive bidding mark major sea changes in the way DMEPOS suppliers conduct business. DMEPOS stakeholders must have the opportunity to comment on these major changes, or at a minimum, the PAOC should meet upon release of the final rule and be afforded the opportunity to comment and suggest changes to the final competitive bidding rule prior to implementation.

J. Administrative or Judicial Review

Non-Winning Suppliers Must Have Expedited Appeal Rights

The NPRM states that "Section 1847(b)(10) of the Act provides that there will be no administrative or judicial review … for the ... [a]warding of contracts under a competitive bidding program …." 71 Fed Reg 25682. Suppliers who have a reasonable grievance should be able to challenge a determination of the Competitive Bidding Implementation Contractor (CBIC) before an independent entity or Administrative Law Judge to ensure fairness and due process.

Suppliers will be staking resources and, in certain instances, survival of their business on contracts awarded by the CBIC. Despite the most vigilant of oversight, it is not impossible to conceive situations where the bidding process could be circumvented or in someway compromised. As a result, suppliers must be afforded the right to contest questionable

determinations. To ensure no disruption in DMEPOS to beneficiaries, however, any independent appeals process must be expedited.

H. Determining Single Payment Amounts for Individual Items

Section 414.416(c)-Rebate Program

The Rebate Program Is Impractical

The program established by the NPRM will "allow contract suppliers that submitted bids for an item below the single payment amount to provide the beneficiary with a rebate." 71 Fed Reg 25680. Contracted suppliers could provide the difference between the single payment amount and their winning bid price as a "rebate" to beneficiaries; however, this arrangement is on tenuous legal footing, establishes a poor precedent, and provides no real benefit to either suppliers or beneficiary.

Current law prohibits suppliers from offering inducements and other incentives for the purpose of enticing beneficiaries to receive services from a specific Medicare supplier. The "rebate" program, by codifying the allowance of inducements in the form of a rebate, is contrary to these important safeguards. The NPRM prohibits suppliers from advertising the inducement, instead allowing CMS to promote the suppliers' rebate programs on the Medicare website. This just makes CMS complicit with and a conduit for possible violations of the Federal Anti-Kickback statute. For these reasons and others, the PMC recommends that CMS eliminate the rebate program as part of the NPRM.

C. Payment Basis

Section 414.408(e)-Authority to Adjust Payments in Other Areas

CMS Lacks the Authority to Fix Fee Schedule Amounts with Competitive Bidding Rates

The NPRM indicates that after 2009, CMS plans to utilize data collected from competitive bidding pricing to adjust the fee schedule that is the basis of payment for DMEPOS in non-competitive bidding areas. 71 Fed Reg 25664. It is unclear on what basis that CMS derives the authority to set DMEPOS pricing using competitive bidding data. Moreover,

Congress decidedly limited competitive bidding to the largest Metropolitan Statistical Areas (MSAs) in the MMA.

Providing and servicing DMEPOS items in rural and underserved areas (those MSAs most likely not to be directly affected by competitive bidding) are often times more expensive than providing DMEPOS in larger MSAs. These areas experience increased transportation costs, more difficulty in employing and retaining qualified personnel and increased cost in recruiting and maintaining beneficiary referrals.

CMS already has inherent reasonableness authority to adjust DMEPOS pricing if they can demonstrate that Medicare is paying too much (or too little) for a particular item or product. Competitive bidding should not be used to circumvent specified inherent reasonableness authority so that CMS can unilaterally depress DMEPOS pricing without valid statistical evidence or input from impacted stakeholders.

Section 414.408(f)-Limitation on Beneficiary Liability

Competitive Bidding Must have No Impact on Cash Sales of PMDs

Many DMEPOS suppliers, especially suppliers of power mobility devices (PMDs), sell directly to beneficiaries through cash sales at retail outlets. Most of these beneficiaries do not meet the Medicare definition of medical necessity, yet still benefit from access to PMDs.

Even in such cash sales, suppliers are mandated to submit a claim to the Medicare program yet the NPRM places a limitation on beneficiary liability for DMEPOS furnished by non-contracted suppliers. This provision must be amended to ensure that retail sales of DMEPOS can continue to Medicare beneficiaries who wish to purchase a PMD even if they do not meet the Medicare national coverage determination.

I. Terms of Contract

Section 414.422(c)-Repairs and Replacement of Patient Owned Items

Contracted Suppliers Should Compensated Via Fee Schedule to Repair or Replace Beneficiary-Owned DMEPOS

The NPRM requires a contracted supplier to repair and/or replace items of beneficiary owned DMEPOS in a competitive bidding area. Suppliers will have no idea how many repairs or replacement DMEPOS they will need to supply. As a result, it will be impossible for suppliers to factor these costs into their bids. To ensure fairness, therefore, the PMC recommends that CBICs reimbursement for repairs and replacement of beneficiary-owned DMEPOS items (not originally supplied by the contracted supplier) be subject to the fee schedule amount (adjusted for inflation).

Section 414.422(d)-Change in Ownership

Competitive Bidding Should Have No Impact on a Supplier's Ability to Change Ownership

While CMS has a fiduciary duty to ensure that every supplier is accredited and meets quality standards, CMS cannot deny contracted supplier status, or unreasonably withhold its approval of new ownership, on the basis that the new ownership may not meet the capacity stated in the contract. Contracted suppliers in competitive bidding areas will most likely experience an increase in the value of their businesses and, therefore, should be able to take advantage of the market place without interference from government agencies, if they wish to lawfully transfer ownership.

Section 414.422(f)-Suspension or Termination of a Contract

Contracted Suppliers Should Be Allowed an "Opportunity to Cure" if They Are Found in Breach

The NPRM allows CMS to terminate a contract if the DMEPOS supplier is in breach. Suppliers, however, should be given an opportunity to cure the breach or appeal the determination before the contract is terminated. Often times, suppliers are unaware they are in

breach of contract and can easily resolve the issue without necessitating termination which has the potential to disrupt access to DMEPOS by needy beneficiaries.

F. Submission of Bids

Section 414.408-Bidding Requirements

All Bid Costs, Including Cost of Accreditation, Must be Reflected in the Bid Price

The NPRM states that the bid price should only reflect the cost of providing and servicing the DMEPOS item. Yet, suppliers who wish to participate in the Medicare program must now adhere to new quality standards become accredited and incur costs in preparing and submitting bids. Costs of this overhead will be substantial and, among small suppliers, will represent a major capital expense just to participate in the Medicare program. Bids for DMEPOS, therefore, should include the cost of overhead and accreditation, as well as service and product costs.

Section 414.412-Product Categories for Bidding

Product Categories Must Be Defined Narrowly

The NPRM requires all suppliers to bid on every item within a particular product category. For PMD suppliers, it is imperative that product categories are defined narrowly. Many suppliers of power wheelchairs and POVs do not deal with, or service complex high-end rehabilitation wheelchairs. High-end rehabilitation chairs are often custom fitted and require more skilled care than provided by PMD suppliers. If CMS includes a broad category of wheelchairs in the bid application, many suppliers would be precluded from bidding since they do not offer both the high-end rehabilitation chairs and the more standard PMDs.

R. Establishing Payment Amounts for New DMEPOS

Section 414.210(g)-Establishing Payment Amounts for New DMEPOS Items (Gap-Filling)

Gap Filling for New HCPCs Codes Fails to Incorporate Manufacturing Data

The NPRM suggests an alternative gap-filling methodology for the introduction of new product codes, like the new HCPC codes recently introduced for PMDs. This gap-filling methodology will be modified by:

- making effort to utilize existing fee schedule amounts, if applicable, in establishing payment amounts for new HCPCS codes, including pricing from comparable items;
- discontinuing the practice of deflating supplier prices back to the time of the fee schedule base period;
- using functional technology assessment, in part or in whole, as another pricing method.

While the PMC appreciates CMS' recognition of the past problems plaguing other gap-filing methodologies, the methodologies presented in the NPRM are not objective and fail to directly make a price/value assessment of the product. Specifically, none of the methodologies discussed in the final rule incorporates manufacturer data, instead relying on "technical assessments" by experts in the therapeutic/technological aspects of the product, and not the pricing. It is imperative, therefore, to ensure that manufacturer and other stakeholder data is incorporated into any gap-filing methodology to ensure appropriate pricing for new HCPC codes.

G. Conditions for Awarding Contracts

Section 414.414(b)-Supplier Eligibility

Information Requested of Suppliers Is Overly Broad

The PMC asks that CMS define sanctions further to allow suppliers to understand which occurrences to report on bid applications. The language of the NPRM states that a supplier must disclose information pertaining to debarments, sanctions or other legal actions affecting the supplier. However, the draft "Form A: Application" goes further and asks suppliers to disclose

information about prior or pending investigations. *See* "Form A: Application, p. 5. This has expanded the scope of certification beyond precedent. Federal Acquisition Regulation Certification, 48 C.F.R. § 52.209-5, requires disclosure of civil judgments, criminal convictions, and indictments but does not go so far as to require disclosure of the existence of a mere investigation. The greatly expanded scope of inquiry included in the proposed form is arbitrary and vague and greatly exceeds the also vague language included in proposed 42 C.F.R. §414.414(b). We have great concern that a supplier's eligibility to submit bids may be affected without adequate process.

The PMC agrees with the NPRM that suppliers who are disbarred from any federal health care program should not be eligible to bid. Federal investigations, however, are merely fact-finding tools. Suppliers have the right, like every other American, to be presumed innocent and should not be negatively impacted in the bidding process based on such criteria.

Section 414.414(d)-Financial Standards

Financial Information Needs to be Clearly Stated and Evaluated Prior to Bid Submission

Part of the new quality standards include financial criteria to ensure that suppliers have the necessary capital to participate in the Medicare program. This determination of financial viability, therefore, should be established prior to submission of bids. In addition, the PMC feels that audited financial statements are not necessary as part of the bidding process and will add considerable cost to the supplier's bid application.

Section 414.414(e)-Composite Bids

More Details Needed to Explain the Composite Bid Calculation

In determining bid applications, the NPRM suggests that the CBICs use a "composite bid" to aggregate the supplier's bid over an entire product category. The NPRM, however, fails to indicate how the bids for each products will be weighted. Suppliers need to know what weighted factors will go into the composite bids so suppliers will be better able to determine how best to bid each HCPCS code within a particular product category.

Section 414.414(e)-Market Demand and Supplier Capacity

Safeguards Must Be Put in Place to Ensure Suppliers Can Meet Capacity

It is imperative that contracted suppliers are able to serve the entire capacity of a competitive bidding area. The number of beneficiaries who may need DMEPOS is not static. As Hurricane Katrina demonstrated, a major national disaster could have a huge impact on a competitive bidding area if a large number of persons relocate into that area (as many residents of New Orleans moved to Houston and other regions after the hurricane). To ensure that capacity is met, the PMC recommends that the CBICs use a factor of 130% to identify need. This would ensure that more suppliers will remain in the competitive bidding area and that a contract would not have to be rebid if a supplier is terminated or even if a cataclysmic event occurs that results in a shift in population.

Section 414.414(f)-Assurance of Savings

Suppliers Should be Allowed to Bid Above Fee Schedule

By mandating that no supplier bid be above the current fee schedule, the NPRM is overly restrictive, anti-competitive and smacks of price fixing by CMS. Costs of DMEPOS fluctuate and are dependent on a number of different factors, some of whose costs may increase to an extent that out paces the fee schedule amount. Most recently, the price of gasoline has close to doubled in the past year, severely impacting the delivery costs to DME suppliers and subsequently increasing their overhead. Annual inflation updates often fail to completely capture every price increase, especially if the cost of the item (i.e. gasoline) increases faster than the overall economy.

Safeguards Must Be Put In Place to Deter Suppliers from Undermining the Bidding Process

Unscrupulous actors could undermine the bidding process by bidding at an unrealistic low rate to ensure inclusion in the market. Unfortunately, this strategy could artificially lower the single bid price, making it difficult for all winning suppliers to serve beneficiaries at such reduced rates. CBIC personnel must be on the lookout for bids that are well-below the historical fee schedule amount and be leery of suppliers trying to undercut the market rate just to gain

market share.

CMS Should Allow Any Willing Supplier to Participate in the Medicare Program

If a Medicare participating supplier is willing to meet the terms of the contract for a particular DMEPOS product or service, including reimbursement amount, that supplier should be able to serve beneficiaries in the competitive bidding area. Such a provision would make the competitive bidding program more flexible while preserving the cost-savings priorities of the Medicare program. Moreover, such an arrangement will ensure the viability of a greater number of smaller suppliers who are at a distinct disadvantage under competitive bidding. Allowing any willing supplier to participate in Medicare will also allow beneficiaries to resume continuing relationships with their existing supplier and will ensure beneficiary access since capacity will not be compromised.

K. Opportunities for Participation by Small Suppliers

Access to SBA loans for Capital Improvements and Cost of Accreditation for Small Suppliers

To be considered as part of the competitive bidding pool, DMEPOS suppliers will now be required to be accredited and adhere to new quality standards. Yet, such requirements constitute an unfunded mandate to suppliers to pay for administrative functions and services that supplement the duties performed by CMS contractors like the National Supplier Clearinghouse (NSC). While some larger suppliers can afford to pay for such services, many smaller suppliers are "mom and pop" operations that lack the resources to pay the large fees charged by accreditation bodies or to make the capital improvements necessary to get accredited.

Failure to help small suppliers with the costs associated with accreditation and quality standards will adversely limit participation in any national acquisition bidding program to large suppliers who may already posses a competitive advantage in their ability to offer lower bids as a result of their volume purchasing. Moreover, many small suppliers serve rural and underserved urban communities where larger suppliers may not operate. If CMS fails to provide some special consideration to these smaller players, like providing access to low-interest Small Business Administration (SBA) loans, Medicare beneficiaries in these more difficult to reach areas, are at risk as access is being compromised.

A Minimum Number of Small Suppliers Should Be Included in Every Awarded Contract

CMS is required, under statute, to "take the appropriate steps to ensure that small suppliers have an opportunity to be considered for participation" in competitive bidding. One way to ensure this participation is to set aside at least one contract for each bidding item for a small supplier (as defined by the SBA as having less that $6 million in receipts). This would afford small suppliers some hope that they can "compete with the big boys" and that "mom and pop" suppliers will remain viable even in a competitive bidding areas.

L. Opportunity for Networks

CMS Should Not Place Limitations on Small Supplier Networks

CMS indicated that they will allow small suppliers to form networks in an effort to ensure greater participation by small suppliers. Yet, by imposing an arbitrary 20% limitation on the market share of the network, CMS is curtailing the ability of small suppliers to form networks and participate in competitive bidding. The NPRM should eliminate this 20% restriction and, instead, provide more incentives that encourage small supplier networks to flourish.

Respectfully Submitted,

Eric W. Sokol
PMC Director

Stephen M. Azia
PMC Counsel

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Empi®
Your Partner in Rehabilitation Outcomes

June 26, 2006

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1270-P

Re: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Dear Administrator McClellan:

Empi, Inc. ("Empi") is pleased to have the opportunity to comment on the proposed rule, CMS-12710-P, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") and Other Issues. Empi is the leading Medicare provider of transcutaneous electrical nerve stimulation ("TENS") device which are used to relieve pain and promote recovery. Empi respectfully requests that the Centers for Medicare and Medicaid Services ("CMS") exercise its statutory discretion to not select TENS devices as one of the initial product categories that will be subject to the 2007 phase-in of the Medicare DMEPOS competitive bidding program. As we explain below, including TENS devices in the 2007 phase-in would force CMS to try to configure a competitive bidding program best suited for commodity type products into one dealing with differentiable products, which could compel many beneficiaries to use inferior TENS products without achieving measurable savings for the Medicare program. Since we understand the policy directive you have been charged with, which is to attempt to lower health care costs while preserving quality, we look forward to working with CMS on the continued implementation of the competitive bidding program and the specifics of the TENS market.

Background: TENS and Empi

TENS is an FDA Class II medical device that employs low-level electrical stimulation to relieve pain and promote recovery. TENS is most commonly used to treat back pain, but is also effective for the treatment of arthritis, strains and sprains, and neuralgia, among other conditions. TENS is frequently prescribed as an adjunct to physical therapy for conditions related to chronic pain and post-surgical or post-trauma acute pain. TENS works in two ways: first, by using

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electrical stimulation to disrupt the body's transmission of pain messages; and second, when the stimulation is sufficiently intense to cause mild muscle twitching, by inducing the body to produce its own natural pain reliever, a neurohormone called endorphin.

TENS provides patients and clinicians with a safe and cost-effective alternative to drugs for the relief of pain. And, given the removal of Vioxx™ and Bextra™ from the market during the latter part of '04 and early '05, physicians are faced with an increasingly limited armentarium of pain interventions. The result is a national health care crisis resulting from physical dependence and addiction to opiates and narcotics. In the U.S., more than 200 million prescriptions are written for opiates such as Oxycontin™ each year (Dendrite International 2004). The direct and indirect cost associated with these medications can be reduced by increased reliance on non-systemic interventions such as TENS.

Empi is a market-leading manufacturer of electrotherapy devices based in St. Paul, Minnesota, with facilities in South Dakota, Kentucky and Florida, and is the leading Medicare provider of TENS devices. Empi's digital Epix VT uses a microprocessor to store twelve distinct pre-programmed electrotherapy regimens, thus affording clinicians the flexibility to tailor treatment to the needs of individual patients and to make the devices easy to use by patients. The Epix VT is the only available TENS device to incorporate this feature. The Epix VT is also the only TENS device on the market to feature biosourced, biaphasic waveform, which ensures the constancy of the electrical stimulus, and provides an additional measure of patient comfort and safety. These unique features make the Epix VT the most popular TENS device on the market.

Finally, Empi is the only TENS manufacturer to provide periodic post-sale monitoring of its devices, an essential product support service. Empi provides TENS devices to over 187,300 patients per year with an effective, low cost pain therapy treatment, which is in many cases a preferred alternative to prescription drugs which have systemic side effects and potentially higher costs. In addition, to support these devices and this service level, Empi has developed nationwide service capabilities and a robust and on-going research and development program to continue to improve the products.

The Proposed Rule: Selection of DMEPOS Product Categories

As the Proposed Rule observes, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") "mandates a larger role for competitive bidding within the Medicare program," including the establishment by the Secretary of Health and Human Services ("HHS") of "competitive bidding programs for the furnishing of certain DME and associated supplies."[1] Section 1847(a)(1)(B)(ii) of the Social Security Act (the "Act") gives CMS the authority to phase in the competitive bidding program with its direction to focus, "first among the highest cost and highest volume items or those items that the Secretary determines have the largest savings potential."[2]

Among the factors that CMS proposes to weigh in "making determinations about an item's potential savings as a result of the application of competitive bidding," are different items'

[1] 71 Fed. Reg. 25657 (May 1, 2006).
[2] 42 U.S.C. 1395w-3(a)(1)(B)(ii).

annual Medicare DMEPOS allowed charges.[3] CMS estimates that "approximately 10 product categories will be selected for competitive bidding for 2006 and as many as 7 or 8 of the selected product categories will be among the 10 largest in terms of allowed charges. The remaining 2 or 3 product categories will come from the top 20 eligible DMEPOS policy groups and their 2003 allowed charges."[4]

TENS Devices Should not be Subject to Competitive Bidding in 2007

CMS should exercise its discretion under Section 1847(a)(1)(B)(ii) of the Act to exclude TENS devices from the 2007 phase-in of the competitive bidding program for several reasons. First, TENS devices in fact constitute a miniscule percentage of Medicare charges. Second, because until CMS has a better understanding of how to do competitive bidding in a non-commodity environment, the competitive bidding program defies the wide variation in quality—and, accordingly, price—within the TENS device market. By grouping all TENS devices within a single product category for the purpose of competitive bidding this will induce many patients to purchase inferior devices. Third, some TENS device manufacturers, including Empi, include within the cost of their devices a post-sale periodic monitoring services to ensure that the device is functioning properly. Low-cost providers generally do not. This would further complicate the nature of competitive bidding since not every medical device company would be offering similar products when they were to make their bid.

1. TENS Devices are a Low-Volume Product Category Relative to Other DME

The total allowed Medicare charges for TENS devices is very small relative to other DME products, with annual expenditures of approximately $10 to $15 million. Indeed, as Table 4 in the Proposed Rule indicates, TENS devices constituted less than one-tenth of one percent of allowed Medicare charges for DMPOS. Nor are TENS devices among the twenty-four highest volume DME items listed in Table 3 of the Proposed Rule.[5] Moreover, the overwhelming majority of DMEPOS reimbursed by Medicare are compressed into a very few high-volume product categories. According to the Proposed Rule, the top five categories alone account for a full 77% of allowed Medicare charges, with proportionate volume declining dramatically thereafter. Several policy groups, such as oxygen, wheelchairs, and diabetic supplies have charges in excess of $1 billion. Indeed, TENS devices, at number 20 on the list, account for only .4% of the charge volume of the fifth-ranked product category, Hospital Beds/Accessories, and about 12% of the charge volume of the tenth-ranked product category, Lower Limb Orthoses. As such numbers suggest, TENS devices are not among Medicare's "highest cost and highest volume" DMEPOS items, and do not offer the program substantial "savings potential," as required by the Act.

2. Including TENS Devices Within the First Phase of the Medicare Competitive Bidding Program Will Compel Many Patients to Purchase Inferior Devices

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[3] 71 Fed. Reg. at 25671.
[4] *Id.* at 25691.
[5] *Id.* at 25670.

Available TENS device vary widely in quality and technological sophistication; accordingly, the market is properly stratified by price. We are concerned that the competitive bidding program is not yet structured to take into account these variances and we believe that it will require a significant amount of planning and development to design the program to be effective in achieving the dual goals of saving money while providing consumers with appropriate high-quality healthcare. As we described above, Empi's digital Epix VT uses a microprocessor to store twelve different pre-programmed electrotherapy regimens, thus affording clinicians the flexibility to tailor treatment to the needs of individual patients. This kind of customization is unavailable on the typically imported non-digital devices with which Epix VT competes. The same features that make the Epix VT the most popular TENS device, however, even with the advances in technology, also make it more costly to manufacture, and hence, by necessity, more expensive. Empi simply cannot and should not compete on price with the low-cost, technologically inferior, imported devices. To require Empi to do so by including TENS devices in the 2007 phase-in of competitive bidding before the sophistication of competitive bidding processes can be developed after seeing how the market reacts to competitive bidding in the easier commodity product categories would be to treat as fungible products that, in reality, are highly differentiated in terms of clinical efficacy. Inferior devices will prevail in a poorly designed competitive acquisition process, and as a result patients will receive sub-optimal therapy.

3. Many TENS Device Manufactures do not Provide Periodic Service and Monitoring of Their Devices

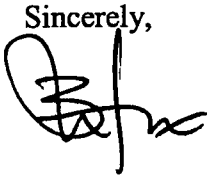
Finally, Empi provides post-sale periodic service monitoring of its Epix VT devices in order to ensure that they continue to function properly. By contrast, many of the low-cost TENS device manufacturers do not offer this important service. As in the case of pre-programmable therapy regiments, this feature contributes to the relatively higher cost of the Epix VT. Again, by treating as fungible TENS devices, such as the Epix VT, that include this important monitoring service and less expensive devices that do not, a competitive bidding process that is not properly designed to take into account this service component would ensure that many Medicare patients are deprived of a superior product.

For the reasons outlined above, primariliy that including TENS devices in the 2007 phase-in portion of the competitive bidding program would not result in measurable savings to the Medicare program, TENS devices should not be part of the phase-in program. Including TENS could also put in place a competitive bidding system that could have as an unintended consequence of an appropriate policy initiative, the result that many beneficiaries would be compelled to use inferior TENS product. CMS should therefore exercise its statutory discretion to not select TENS devices as one of the ten product categories that will be subject to the 2007 phase-in of the Medicare DMEPOS competitive bidding program.

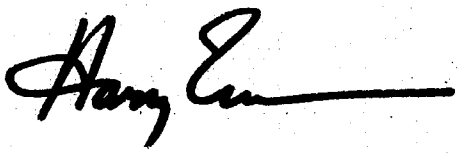
We look forward to working with CMS over the next two years on refinements to the Competitive Bidding Program to ensure that beneficiaries will have access to high quality TENS devices and that a competitive bidding scenario can be developed that works in a non-commodity marketplace. We would be happy to meet with your staff to discuss TENS products and their Medicare market in more detail and to continue to provide assistance in developing ways to

lower Americans' healthcare cost while providing the high-quality, technologically advanced medical devices Americans deserve and desire.

Sincerely,



Barry Hix, MBA, MPH
Vice President – Marketing and National Accounts



Harry L. Zimmerman
Executive Vice President – General Counsel

cc: Laurence Wilson, Director, Chronic Care Policy Group

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THE MEDGROUP

June 30, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
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Washington, D.C. 20201

Hand Delivered and Via Electronic Mail: http://www.cms.hhs.gov/eRulemaking

Re: (File Code CMS-1270-P) Notice of Proposed Rule Making entitled "Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues"

Dear Dr. McClellan:

I am writing on behalf of The MED Group (MED), a nationwide network of independently owned home medical equipment and rehab technology companies. We have approximately 250 member companies with over 800 operating locations across the country. Our member companies provide products and services to hundreds of thousands of Medicare beneficiaries within their local communities. Please visit www.medgroup.com for more information on our organization and membership.

We also are members of and serve on the Board of Directors of the American Association for Homecare (AAH) and the National Coalition for Assistive and Rehab Technology (NCART).

To begin, we want echo the concerns expressed by the American Association for Homecare that the information in the NPRM is inadequate to serve as a basis for public comments on several important issues. A rule making procedure must provide notice of a proposed agency action with reasonable specificity to solicit informed public comments. The NPRM falls short of this standard with respect to how §5101 of the Deficit Reduction Act of 2005 (DRA) and the final quality standards that will apply under competitive bidding. As you know, §5101 forces Medicare beneficiaries to own their capped rental or oxygen equipment at the end of a statutory period of continuous use. Without establishing the scope of this new requirement and how it will dovetail with competitive bidding, the NPRM is incomplete and vague, limiting our ability to comment.

We are aware that CMS will publish regulations to implement the DRA in the near future. However we need an opportunity to assess and comment on how the new rules will apply under the framework for competitive bidding. We suggest that CMS issue an interim final rule to allow additional comments on this issue prior to publishing a final rule implementing competitive bidding. In addition, because the NPRM fails to identify the Metropolitan Statistical Areas (MSAs) and the DMEPOS items that will be subject to competitive bidding, we request that CMS also schedule a meeting of the Provider Advisory and Oversight Committee (PAOC) before it begins to implement the program.

Although we understand CMS's concerns about meeting the deadlines in the MMA, it is imperative that CMS allow stakeholders an opportunity to comment on the quality standards before they become final. Allowing time for additional comments is unlikely to significantly delay the program. It is also appropriate inasmuch as CMS by-passed the procedural protections of the APA and the oversight of the Office of Management and Budget that would otherwise be part of a rulemaking procedure applicable to the standards. In any event, as we stated above, competitive bidding is a radical departure from the traditional DMEPOS benefit, and CMS has no experience with this program on a wide scale. Consequently, CMS should tolerate delays and not rush the quality standards or any other aspect of competitive bidding.

MED appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' Notice of Proposed Rule Making entitled "Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues". As requested, we have indicated the "issue identifier" at the beginning of each comment. The following are our comments and recommendations:

1.) "General"- **Getting It Right Is More Important Than Rushing Implementation.** CMS should push back the implementation date of October 1, 2007 to a more reasonable timeframe. In addition, CMS should stagger the bidding in MSAs over a twelve month period to allow for an orderly roll out of the program. This will also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread. The aggressive implementation plans particularly hurt small providers. Small providers will not have time to create networks, which eliminates them as a practical option for small businesses that want to participate.

2.) "General"- **CMS Must Publish An Updated Implementation Timeline.** CMS must publish an implementation timeline that at a minimum identifies the following steps and expected completion dates: a.) Publication of Supplier Standards; b.) Approval of accrediting organizations; c.) Issuance of final regulation; d.) Publication of final 10 MSAs and product categories; e.) Commencement of bid solicitations; f.) Conclusion of bid solicitations; g.) Announcement of winning bidders; h.) Education of beneficiaries and medical community; and i.) Implementation within each MSA. It is expected that the publication of such a timeline will highlight the significant problems that lie ahead based on an overly aggressive implementation plan.

3.) "General"- **The Program Advisory And Oversight Committee Must Be Included In The Review Of Public Comments And The Development Of The Final Rule.** CMS must include the Program Advisory and Oversight Committee in the review of the public comments received during the 5/1/06 through 6/30/06 comment period and the subsequent development of the Final Rule. To not do so excludes the important counsel and advice of key stakeholders in a critical process and goes against the very intent of Congress in establishing the PAOC in the first place.

4.) "General"- **Beneficiaries With Medicare As Secondary Insurance Should Be Excluded From Competitive Bidding.** CMS should exclude those Medicare beneficiaries that have Medicare as a secondary payor from inclusion in the competitive bidding program. These beneficiaries' claims should be processed and paid under the standard fee schedule.

5.) "Payment Basis"- **Medicare Advantage Beneficiaries Should Be Included Under The Grandfathering Provision.** The NPRM does not address the impact of competitive bidding on Medicare Advantage patients who leave their plan to reenter traditional Medicare. These patients may have a provider who is part of the MA plan network, but that may not be a contract supplier. What rules will apply to this patient population under competitive bidding? Will these patients have the opportunity to continue to use their existing supplier when they reenter the traditional Medicare program? We recommend that patients moving from an MA plan to traditional Medicare be given the option of remaining with their existing provider under the grandfathering provisions proposed in the NPRM.

6.) "Payment Basis"- **Allow Traveling Beneficiaries From Competitive Bidding Areas to Be Serviced At Standard Medicare Allowables.** (proposed §414.408(f)) The NPRM states that if a beneficiary is visiting a non-competitive bidding area and requires service, the supplier would be paid at the single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. This proposed plan will make it difficult for beneficiaries to obtain products and services in some areas. Although it is current Medicare policy, the maximum payment difference from one State to another is currently only 15%, while the difference between a single payment price under competitive bidding and the fee schedule amount in a non-bid area could be substantially more than that. If a beneficiary receives service in non-bid area, CMS should pay the traditional Medicare allowable amount based on the beneficiary's permanent residence for up to five months.

7.) "Payment Basis"- **Provide Details On How Pricing Will Be Used After January 1, 2009.** CMS has the authority to use payment information for covered items furnished on or after January 1, 2009 that are included in a competitive bidding program. However, no information is provided on how CMS intends to do this. It is critical for CMS to make every effort to understand any regional cost differences (i.e. labor costs, delivery costs etc.) to ensure that the savings would be comparable if a competitive bidding program was established in that MSA. Moreover, CMS must complete this analysis to ensure that any

reduction in payment would not negatively impact appropriate access to medically necessary equipment. CMS needs to issue a separate NPRM addressing this issue to allow for substantive comments on specific proposals.

8.) "Competitive Bidding Areas"- **Do Not Extend Competitive Bidding Beyond Defined MSA Boundaries.** (proposed §414.410) The proposed rule refers to the possibility of extending the implementation of competitive bidding to areas adjacent to selected MSAs. This is not provided for in the legislation and should not be done.

9.) "Criteria for Item Selection"- **Product Selection Must Be Made With Beneficiary Welfare In Mind.** CMS must be sensitive to and implement provisions to prevent the many problems competitive bidding may create for beneficiaries. These include an individual beneficiary having to deal with multiple suppliers. The inappropriateness of including items that are custom and service oriented in nature must also be recognized. CMS cannot rely solely on costs and volume for product selection. Issues such as supplier access and medical necessity of beneficiaries who use the items must be addressed. Competitive bidding should not be a substitute for appropriate medical policy.

10.) "Criteria for Item Selection"- **The Methodology For Calculating The Potential For Savings Must Be Specified.** CMS should explain and clarify what specific measures will be used to decide an item's potential savings as a result of competitive bidding. Specifically, CMS should address the following: (A.) *Annual Medicare DMEPOS allowed charges*: Is there a threshold expenditure level that will trigger inclusion in a product category? (B.) *Annual growth in expenditures*: Is there a threshold growth percentage and does it vary by the dollar size of the category? (C.) *Savings in DMEPOS demonstrations*: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects? (D.) *Reports & studies*: Which ones and types will be considered? Who will review the studies and determine their validity and applicability for modeling Medicare program savings? (E.) *Allowed Charges*: Does this mean paid claims?

11.) "Criteria for Item Selection"- **Complex Rehab And Assistive Technology Items Must Be Excluded From Competitive Bidding.** We are concerned that the only reason identified for products to be excluded from the competitive bidding program is purely based on calculated potential savings. MED believes that Congress certainly intended that consideration be given to the clinical outcomes for Medicare beneficiaries. MED recommends that CMS accept the recommendations of PAOC members and presenters during the February 2006 PAOC meeting that complex rehab and assistive technology devices be exempted from competitive bidding. We do not believe that products that are evaluated, fitted, configured, adjusted or programmed to meet the specific and unique needs of an individual with a primary diagnosis resulting from injury or trauma or which is neuromuscular in nature are appropriate for a competitive bidding program.

MED also recommends that CMS exclude wheelchair cushions, adaptive seating and positioning products and speech generating devices from the competitive bidding program. Clients in need of complex rehab or assistive technology typically require a complete system to meet their functional and medical needs. A complete system means various pieces of equipment, each meeting a specific medical or functional need, have been determined to be compatible technologies.

12.) "Criteria for Item Selection"- **Exclude Manual Wheelchairs, Power Wheelchairs, And Related Accessories From First Round of CB.** The methodology that CMS proposes for item selection relies on historical data and does not take into account recent and expected changes in a benefit that will affect utilization. For power wheelchairs, recent changes in the HCPCS codes, a new LCD, and new fee schedules will significantly change utilization for these items. The same can be said for plans for expanded manual wheelchair codes. Specifically, CMS would lack the cost and volume data required under the formula in the NPRM to select an item. CMS would be unable to determine which codes within this product category are the highest cost and highest volume for Medicare using current data.

MED recommends that CMS exclude all manual and power wheelchair and accessory codes from the 2007 round of competitive bidding. This would allow time for CMS to implement new HCPCS codes for power and manual wheelchairs, gain accurate utilization data and assess how the coding changes impact cost before attempting to determine which if any of these products would produce adequate savings while ensuring Medicare beneficiaries achieve their desired clinical outcome. MED recognizes that power wheelchairs are high in utilization and cost. However, we also believe that significant savings will result from the vast changes in coverage and conditions for payment that have occurred in this product category over the last year and the additional coding, coverage and payment changes that are imminent. There must be ample time to analyze the true impact of the changes before determining if any of these products are appropriate for competitive bidding.

13.) "Submission of Bids under the Competitive Bidding Program"- **Only Companies Currently Servicing Medicare Beneficiaries In An MSA Should Be Allowed To Submit A Bid For That MSA.** Any company that submits a bid should have a track record of serving the targeted geography to validate its capabilities and service record. Only those entities should be eligible for consideration in the bidding process.

14.) "Submission of Bids under the Competitive Bidding Program"- **The Current HCPCS Codes Are Inadequate To Effectively Implement Competitive Bidding.** (proposed §414.412) CMS proposes not to require suppliers to provide every brand of products included in a HCPCS code. However, regardless of what brands the contract supplier furnishes, the single payment amount for the HCPCS code would apply. The current code sets are inadequate and therefore requiring suppliers to only supply an item that meets the descriptor of the code will not adequately meet the needs of Medicare beneficiaries.

The current coding system, especially for complex rehab and assistive technology, groups items into very general codes. In many cases the items are designed for a similar use, but because of anatomical anomalies, asymmetries, tone, functional limitations etc., beneficiaries must have access to a specific device within a code. Unfortunately due to differences in design, product cost and other factors, the costs associated with the devices are fundamentally different.

A basic example of problems within the current HCPCS code set is the current code for headrests- E0955. This code currently is used for all levels of headrests. However, an extremely broad range of technology falls within this code. The most basic item, a flat single pad with no adjustability and fixed, non-adjustable hardware, would be the item most suppliers would base their bid on. However, this same code represents products with multiple pads that are independently adjustable and contoured to allow intimate interface with the beneficiary's head, and includes hardware that is adjustable in multiple directions that will also swing out of the way for transfers. The price differential between a basic headrest that merely supports the head when the beneficiary is tilted or reclined is significantly less than the headrest that controls the head, keeps it in proper alignment to prevent tonal reflexes and allows the beneficiary to drive a power wheelchair using an alternative input device controlled with precise head movements.

While focused and aggressive efforts are occurring that will hopefully develop an appropriate code set for rehab and assistive technology devices, the current HCPCS code set is grossly inadequate to support competitive bidding.

15.) "Submission of Bids under the Competitive Bidding Program"- **Product Categories Must Be Narrowly Defined.** (proposed §414.412) Suppliers may choose to bid on one, some, or all of the product categories, but if a provider bids on a category, that provider must bid on each item included in the category. CMS must define product categories narrowly, to make sure that they are consistent and representative of the products that a supplier might actually furnish.

For example, including a broad category for wheelchairs or power wheelchairs could be very problematic. Suppliers who do not specialize in rehab may not carry power wheelchairs under certain codes. Similarly, suppliers who do specialize in providing equipment to patients with complex needs may not carry all of the power wheelchairs designated by that product category. Current HCPCS codes are too broad, encompassing items that represent vastly different technologies. CMS should develop narrow product categories so that providers may submit proposals for more standard bases with general purpose seating and positioning products compared to high end complex rehab technology services. It is dangerous to the end user for non-qualified providers to be submitting bids for services that they do not provide.

16.) "Conditions for Awarding Contracts"- **Only Companies That Are Accredited Should Be Eligible To Bid.** Only accredited providers should be eligible to submit bids. CMS should not proceed with competitive bidding until it is sure that this is possible. CMS needs to identify the criteria it will use to identify the accrediting bodies now. CMS should grandfather all providers accredited by organizations that meet the criteria CMS identifies. CMS should also allow additional time for providers to analyze the quality standards in conjunction with the NPRM rule. The quality standards will affect the cost of servicing beneficiaries and are an integral part of the bid process.

17.) "Conditions for Awarding Contracts"- **An Appropriate Screening Process Must Be Developed To Determine Which Submitted Bids Will Qualify For Consideration.** (proposed §414.414) CMS should clearly identify a screening process that will be used to determine whether a submitted bid will be given any consideration. This process should include, at a minimum, three steps that a bid must go through before it is entered into the bidding pool. First, is the company accredited? If not, the bid is rejected. Second, does the company meet the financial standards? If not, the bid is rejected. Third, is the claimed "capacity" realistic? If not, the capacity is lowered to an appropriate number. Only after the satisfactory completion of these three steps should a company's bid be processed for further review and consideration as to pricing.

18.) "Conditions for Awarding Contracts"- **A Bidding Company Should Be Required To Submit Specific Financial Information To Verify Financial Capability.** This information should consist of: (A.) Two year comparative financial statements prepared in accordance with Generally Accepted Accounting Principles or another recognized basis of financial reporting. The financial statements must be accompanied by a "review" report from an independent Certified Public Accountant (CPA). The CPA should be a member in good standing of the American Institute of Certified Public Accountants. Audited financial statements should not be required as they place an undue expense on the bidding company. (B.) Certificate of Insurance verifying a minimum of $1,000,000 in general liability coverage and listing other appropriate insurance policies in force. (C.) Letters from two primary product suppliers confirming a satisfactory business relationship. Specific steps also need to be established to allow a consistent evaluation of all companies. These steps should be published in the final rule.

19.) "Conditions for Awarding Contracts"- **A Factor Of 130% Should Be Used In Calculating Supplier Capacity Needed In An MSA.** (proposed §414.414(e)) In determining the number of suppliers needed, CMS should apply a factor of 130% to the identified Market Demand. This would promote more competition in the market, ensure more suppliers remain in the market to serve non-Medicare payors, and ensure better competition for any future bidding rounds. In addition, this minimizes the need to recruit more suppliers (that bid above the pivotal bid) if one of the contracted suppliers is terminated or elects to drop out of the competitive bidding program.

20.) "Conditions for Awarding Contracts"- **Competitive Bidding Must Be Competitive And Sustainable.** CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS has not identified any process through which it will seek to determine that the bids are either.

21.) "Conditions for Awarding Contracts"- **Provisions Must Be Developed To Guard Against Unrealistic Bid Amounts.** (proposed §414.414) Suppliers could bid an extremely low price and indicate extremely low capacity to ensure inclusion. If too many use this strategy it could profoundly impact the single bid price.

22.) "Conditions for Awarding Contracts"- **Safeguards Must Be Put In Place To Ensure Realistic "Capacity" Amounts Are Assigned To Bidding Companies.** (proposed §414.414(e)) Significant problems will result if companies are allowed to claim unrealistic capacity. A company should not be permitted to claim a capacity greater than 25% over the number of products provided to Medicare beneficiaries the previous year. Overly aggressive claims of additional capacity will be very difficult to validate and reasonable parameters must be set.

23.) "Conditions for Awarding Contracts"- **A Company Should Be Able To Bid For Only A Portion Of An MSA.** The draft rule requires that a bidding company service the entire MSA. This presents significant hardship to small businesses and may result in poor service in certain areas. A better solution is to allow a bidding company to indicate by zip code what areas of the MSA they will cover.

24.) "Conditions for Awarding Contracts"- **Do Not Restrict Submitted Bid Amounts.** (proposed §414.414(f)) CMS proposes not to accept any bid for an item that is higher than the current fee schedule. This would require that the bid amount be equal to or less than the current fee schedule. It is acknowledged that CMS cannot contract for an amount higher than the fee schedule. However, requiring that the bid be equal to or less than the fee schedule as a requirement artificially restricts bidding. CMS should allow suppliers to bid based on the true costs associated with each bid item. CMS can then use this information to determine whether the savings is adequate to justify awarding contracts for these items. Concerns stated in the NPRM about a shift in utilization to higher priced items could be eliminated through appropriate coverage policies. This strategy better ensures that Medicare beneficiaries have access to the most appropriate device to meet their medical needs.

25.) "Conditions for Awarding Contracts"- **Establish The Single Payment Amount At The Pivotal Bid Level.** CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the "winning suppliers." This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and

services in the competitive bidding area due to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects. More importantly, we believe Congress did not have this methodology in mind when it authorized competitive bidding under the MMA. CMS should set the payment amount at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This method was used in the two demonstration projects. No contract supplier should be forced to accept a payment amount that is lower than its bid.

26.) "Conditions for Awarding Contracts"- **Allow For Appropriate Transfer Of Awarded Contract As Part Of Business Sale.** Do not make it harder for providers to sell their businesses. The proposal to restrict the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. While it is appropriate for CMS to consider the buyer's quality and financial stability, CMS should not make approval of the acquisition contingent on the need to preserve capacity within the MSA. If the sale of a contracted supplier does not weaken the company's ability to deliver service per their competitive bidding agreement and post-sale that company continues to meet the contract requirements, the contracted supplier and its new ownership should retain the contract.

27.) "Conditions for Awarding Contracts"- **Judicial and Administrative Remedies Must Be Provided.** CMS should include a procedure for debriefing suppliers who did not win a bid and provide an opportunity for a review to determine at a minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

28.) "Determining Single Payment Amounts for Individual Items"- **Rebate Provisions Must Be Eliminated.** (proposed §414.416(c)) The NPRM describes a rebate program that allows contracted suppliers to rebate the difference between their bid and the established payment amount to the beneficiary. There is no legal basis under the law for permitting rebates. Providing rebates is contrary to other laws applicable to the Medicare program, namely the Anti-Kickback Statute and the Beneficiary Inducement Statute. Providing rebates also is contrary to the statutory requirement that beneficiaries incur a 20% co-pay. The OIG has stated in several Fraud Alerts and Advisory Opinions that any waiver of co-pays likely violates both the Anti-Kickback Statute and the Beneficiary Inducement Statute.

29.) "Determining Single Payment Amounts for Individual Items"- **Provide More Details On The "Composite Bid" Calculation.** The NPRM describes a methodology of creating a "composite" score to compare suppliers' bids in a category using weighting factors to reflect the relative market importance of each item. CMS should provide suppliers with the weighting factors it will use to evaluate the bids in each MSA so that suppliers are able to determine how best to bid each HCPCS item within a category.

30.) "Terms of Contract"- **Modify Requirement That Winning Supplier Must Repair Patient-Owned Equipment.** (proposed §414.422(c)) It is appropriate for winning suppliers to be required to service any equipment they provide. However, this requirement should not be placed on equipment that is supplied by others. The current reimbursement rates for service and repair are inadequate and it is impossible for a bidding supplier to factor these unknown costs into their bids.

31.) "Terms of Contract"- **Eliminate Limitation That Only Winning Suppliers May Repair Patient-Owned Equipment.** (proposed §414.422(c)) Any Medicare supplier should retain the opportunity to service and repair durable medical equipment should they so choose.

32.) "Terms of Contract"- **Restrictions On What Products Can Be Supplied To Individuals Outside The Medicare Program Must Be Eliminated.** (proposed §414.422) The terms and conditions section states "non-discrimination- meaning that beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier provides to other customers". This is unrealistic. In order for suppliers to bid lower prices they must either provide lower cost products or reduced services. Competitive bidding should be more like a contract with managed care where formularies are used. Medicare will be fully aware of what Medicare beneficiaries will receive, but it should not limit what customers outside of the competitive biding program receive.

33.) "Terms of Contract"- **Do Not Require Wining Suppliers To Take On Beneficiaries That Are Currently Using Capped Rental Equipment From Another Supplier.** (proposed §414.422(c)) Under a capped rental scenario, accepting a new beneficiary transfer after several months of rental with another supplier is unrealistic. It is impossible for a bidding supplier to factor in the cost of taking on beneficiaries that began service with another Medicare Supplier. If this requirement is to remain, then a new rental period should start when the beneficiary begins to receive an item from a wining supplier.

34.) "Opportunity for Participation by Small Suppliers"- **Require That A Minimum Number Of Small Suppliers Be Included As Wining Contract Suppliers.** At a minimum, small business suppliers in an amount equal to the number of other winning bidders should be allowed to participate in the contract assuming they submitted a bid at or below the current allowable amount. In addition, any small business that submits a bid within 110% of the pivotal bid should be allowed to participate if they are willing to accept the payment amount and meet all other requirements.

35.) "Opportunity for Networks"- **Clarify Network Regulations To Maximize Small Business Participation.** (proposed §414.418) The regulations covering networks should be clarified to provide for the following: (A.) CMS should permit existing legal entities to coordinate the formation of networks and to establish whatever participation criteria they choose so long as they meet the related bidding standards and criteria. These entities should be

responsible for forming the network, submitting bids, quality control, and ongoing communication and management. (B.) Individual network members should be able to do their own billing and collecting operating under the awarded Network Contract. This would protect small suppliers from having to incur additional expenses from having to pay a network to do the activities they are capable of performing. (C.) If a network member falls out of compliance with accreditation or quality standards, the network should be able to terminate that member's contract and, if necessary, recruit one or more new members to provide coverage in the terminated member's service area. This would also apply if a network member elects to drop out of the network. Provisions must be made should these events occur within the contract period.

36.) "Opportunity for Networks"- **The Market Share Limitations Of Networks Should Be Increased To 50%.** (proposed §414.418) Market share limitations for networks should be increased to 50%. Anything less than that places network members at a disadvantage as compared to other large single legal entities that may bid. This would penalize small suppliers. Capping it at 50% still provides adequate competition in the area and also meets the legislative requirement that there be at least two winning bidders.

37.) "Gap-filling"- **HCPCS Changes Within CB Product Categories During The CB Contract Must Be Priced At Realistic Levels.** CMS proposes that when revisions to HCPCS codes for items under a competitive bidding program occurs in the middle of a bidding cycle and a single HCPCS code for two or more similar items is divided into two or more separate codes, the payment amount applied to these codes will continue to be the same payment amount applied to the single code until the next competitive bidding cycle. This is not an equitable or logical solution. A new code would be created due to a difference in the product or technology. It is unreasonable to expect suppliers to be able to provide two different products at the same cost. A more appropriate procedure must be developed that would allow pricing based on the costs of each separate item.

38.) "Gap-filling"- **Different Alternatives To Gap-Filling Must Be Developed.** (proposed §414.210(g)) It is good to see the acknowledgement of the problems and inappropriateness of the gap-filling pricing methodology. However, the provision for replacing the gap-filling methodology for setting fees for new DMEPOS items is inappropriate for inclusion in the Competitive Acquisition NPRM. The three methodologies proposed to replace gap-filling are not objective and not directly related to price/value assessment. In addition, none of the methodologies appear to involve the manufacturer and his/her health economic or other support data. Rather, the proposed rule calls for functional and medical benefit assessments to be conducted by CMS contractors who may or may not have expertise in the technology/therapeutic area. The proposal to use these methods to adjust prices that were established using gap-filling at any time after January 1, 2007 makes it all the more important to include the manufacturer and other knowledgeable entities in the process.

39.) "Regulatory Impact Analysis"- **The Data And Assumptions Used Dramatically Understate The Negative Impact On Medicare Suppliers.** This section paints a much more optimistic view of the eventual number of suppliers in the group of winning bidders. It is completely unrealistic to use the results of two very limited demonstration projects impacting only a small number of suppliers for projecting the impact of a national program involving over 100,000 suppliers. Given the significant problems with the provisions of the NPRM, it is extremely unlikely that the projection of approximately 50% of bidding suppliers being awarded a contract would occur. This underlies the necessity of significant changes to the NPRM. The true potential results will be contingent on CMS's incorporation of the above recommendations and those received from others during the public comment period.

Thank you for your detailed review of these comments and those submitted by other industry associations, providers and other stakeholders. The implementation of Competitive Bidding is fraught with potential land mines and we have very strong concerns on its current status and timeline. It is critical additional time be allowed to address the many regulatory, operational, and educational issues that have been presented during the comment period.

We look forward to the inclusion of the recommendations in the final published standards and the related implementation of mandatory accreditation. We also stand ready to work collaboratively with CMS on this matter and other Medicare DMEPOS issues. Please feel free to contact me directly if we can be of further assistance.

Sincerely,

Don Clayback

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June 30, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

Re: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; CMS 1270-P

Dear Dr. McClellan:

Pride Mobility Products Corp. is the world's leader in the design, development and manufacture of mobility products - power wheelchairs, lift chairs, scooters, and vehicle lifts - for people with disabilities and mobility impairments. With corporate offices in Exeter, Pennsylvania and subsidiaries in the United Kingdom, the Netherlands, Italy, Canada and Australia, Pride is devoted to establishing the global representation that will ensure our ability to best serve our customers. Our company is committed to working with the Medicare program to ensure appropriate coverage, payment and access to power mobility devices (PMDs).

GENERAL COMMENTS:

Power Wheelchairs

Pride Mobility recognizes that CMS and its contractors have given extensive consideration to the many proposals within the Notice of Proposed Rule Making (NPRM). However, Pride Mobility is very concerned with the potential inclusion of power wheelchairs in the initial and subsequent implementation scheduled to occur in 2007 and 2009 respectively. There are numerous reasons why including such products in competitive bidding is not appropriate especially at this point in time.

First, in talking with legislators and staff involved in the Medicare Modernization Act (MMA) conference negotiations, it is clear that congressional intent was to implement competitive acquisition for "off the shelf" durable medical equipment (DME) items, and not items that are individually tailored to address a patient's medical need. Due to the uniqueness of the individual beneficiary, a high degree of specialized service by a mobility specialist is required to most appropriately determine the best product to address the beneficiary's medical condition. Power wheelchairs that are designed for regular use are measured, fitted, adapted and programmed in consideration of the patient's body size, disability, period of need, or intended use in accordance with the prescription and instructions from the patient's physician. In addition, power wheelchairs require significant service and instruction in order for the beneficiary to safely operate such sophisticated medical equipment. Exempting power wheelchairs will preserve Medicare beneficiary access to quality products and services individually configured to address their medical needs as prescribed by their physician.

Secondly, due to the coding initiative currently underway at the Centers for Medicare and Medicaid Services (CMS) it will be extremely difficult to demonstrate significant savings since no data will be available to meet that threshold requirement for "significant savings" as outlined in the MMA. Pride Mobility strongly recommends that the Secretary take the time necessary to evaluate claims data under

the new power mobility device (PMD) coding system prior to considering their inclusion in competitive bidding. The mandatory accreditation requirement alone will ensure quality care and cost savings to the Medicare program.

Need For Interim Final Rule With Comment Period

The information in the NPRM is inadequate to serve as a basis for public comments, because a critical piece – the final quality standards – has not been released. Prior to implementing competitive bidding, Pride Mobility recommends that CMS issue an interim final rule to provide for additional stakeholder comments. This is a reasonable request since the NPRM does not provide specific information about the metropolitan statistical areas (MSAs) or DME items to be included, and the final quality standards have not been published yet. CMS should also schedule a meeting of the Program Advisory Oversight Committee (PAOC) once an interim final rule is published. This will allow an opportunity for industry input once additional program details are released before publishing a final rule and initiating program implementation.

Need For Comment Period on the Final Quality Standards

Pride recommends that CMS allow stakeholders an opportunity to comment on the quality standards before they are finalized. It was reported during the May 22 CMS Program Advisory and Oversight Committee (PAOC) meeting that the agency received comments from 5,600 organizations and individuals on the draft supplier standards, and that the final standards will likely differ significantly from the draft. At the very least, CMS should schedule another PAOC meeting once the final quality standards are published.

Pride Mobility strongly supports a requirement that all DMEPOS suppliers billing the Medicare program meet the quality standards and be accredited. Providing for an additional comment period is unlikely to significantly impact the overall implementation timeline. Regardless, CMS should be open to any necessary delays in order to ensure appropriate implementation of the competitive acquisition program and not rush to implement the quality standards or any other aspect of competitive bidding. Pride strongly supports the mandatory accreditation requirement and believes that this should be the first requirement CMS looks for in evaluating the bid pool to select winning bidders.

Overall Implementation Timeline

CMS needs to establish an implementation timeline that identifies the remaining process leading-up to competitive bidding. Given the number of steps that must be commenced and completed prior to implementation, we urge CMS to adopt a realistic timeline and not rush through the process. The remaining steps include:

- Publication of the supplier standards
- Selection of the accrediting bodies
- Publication of interim final and final regulations
- Publication of the initial 10 MSAs and product categories
- Publication of the Request For Bid (RFB)
- Evaluation of bids and selection of contract suppliers
- Education of beneficiaries and referral sources
- Implementation within each MSA

COMMENTS ON SPECIFIC PROVISIONS IN THE PROPOSED RULE:

Authority to Adjust Payments in Other Areas ((§414.408 (c))

Pride Mobility understands that the Secretary has the authority to use payment information for covered items furnished on or after January 1, 2009 that are included in a competitive bidding program, to adjust payment amounts for the same DME items in areas not included in the competitive bidding program. CMS is proposing to use this authority but provides no detailed methodology for doing so. Pride Mobility requests CMS issue a separate NPRM addressing this issue and allow for public comments on the proposal.

Competitive Bid Areas (§ 414.410)

Stagger Implementation

The NPRM is silent on whether CMS will commence competitive bidding in 10 MSAs at the same time, or stagger the initial implementation of competitive bidding in 2007. We recommend that CMS phase-in the first 10 MSAs. This will allow CMS to identify and correct problems as competitive bidding begins before any problems become widespread.

Establishing the Competitive Bidding Area

CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established in an MSA. CMS must identify the MSAs in which it will commence competitive bidding in 2007 in an interim final rule. CMS should also schedule a meeting of the PAOC after it identifies the MSAs.

Criteria for Selection of Items

Section 1847(a)(1)(B)(ii) of the Act gives CMS the authority to phase in competitive bidding "first among the highest cost and highest volume items of those items that the Secretary determines have the largest savings potential. In addition, section 1847(a)(3)(B) of the Act grants the authority to exempt items for which the application of competitive bidding is not likely to result in significant savings. Based on these provisions, CMS proposes to exempt items outright or on an area by area basis using area specific utilization data. Pride Mobility understands that the goal of competitive bidding is to reduce costs. However, we do not believe that competitive bidding of power wheelchairs would result in significant savings as stated earlier due to the extensive services -- measuring, fitting, adapting or programming -- in consideration of the patient's body size, disability, period of need, or intended use in order to provide the most appropriate power wheelchair in line with the physicians prescription. In many cases, simulation with trial equipment is necessary to ensure that the device/system will meet the demands of the beneficiary now and if necessary adapt to the changing needs of the beneficiary as their disease progresses.

Coding Issues and Item Selection

The methodology that CMS proposes for item selection relies on historical data and does not take into account recent changes in a benefit that will affect utilization. For power wheelchairs, recent changes in the HCPCS codes, a new LCD, and a new fee schedule will significantly change utilization for these items. Specifically, CMS will lack the cost and volume data required under the formula in the NPRM to select an item. CMS would be unable to determine which codes within this product category are the highest cost and highest volume for Medicare using current data. We recommend that CMS not include power wheelchairs in the initial rounds of competitive bidding because no claims data from the new code system will be available to show that additional significant savings could be achieved by including them in the program. Moreover, assuming that the coding, pricing and coverage changes result in appropriate utilization for these products, in future years there likely will not be a rationale for including power wheelchairs in competitive bidding under the formula CMS has proposed.

In addition to believing that no significant cost savings will be available for these items, Pride Mobility believes that to attempt to competitively bid these devices would result in a negative impact on the clinical outcome for the beneficiary. CMS included K0004 high strength lightweight manual wheelchairs in the competitive bidding demonstration in San Antonio, TX. CMS had proposed including K0005 ultra-lightweight manual wheelchairs also, but after receiving comments from the industry, CMS decided to exclude this category of products. Therefore, the K0004 products are the closest CMS has come to demonstrating the impact of competitively bidding items that are uniquely prescribed for an individual. While K0004 coded products are not all equally configurable, we did learn some important information about the clinical impact for beneficiaries based on the San Antonio demonstration project.

In the November 2003 *Final Evaluation Report, Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS*, page 181, section 4.5 Wheelchairs and Accessories evaluates the impact of competitively bidding this class of wheelchairs. The report states that "referral agents raised a number of issues about wheelchairs". Further, the reports states, "Referral agents also found that the prescriptions needed to be very detailed to ensure that beneficiaries got the required product" and "prior to the demonstration, referral agents used suppliers who would provide wheelchairs with removable arms and adjustable leg rests as standard equipment. After the demonstration, they found that some suppliers stopped providing this equipment in every case, opting to do so only if these features were specifically ordered". The report also indicated a change in the service/delivery model for these wheelchairs. Some referrals noted that, prior to the demonstration, suppliers usually either had a physical therapist on staff or the wheelchair would be delivered by someone who was familiar with the product and how to measure its fit. When the wheelchair was delivered, the supplier delivering the chair would have the beneficiary sit in the chair and check the fit. However, during the demonstration, referrals reported examples of wheelchairs being delivered and left folded with no attempt to check fit and delivery staff being unknowledgeable about the products being provided or how to adjust or check for proper fit. As one considers the products moving up the category of wheelchairs, products are more sophisticated and provide for more individual configuration and customization to best address the functional needs of the patient. Regular use power wheelchair products require a labor intensive evaluation on the part of the supplier and in collaboration with a physician/clinician to ensure that product solutions meet the medical needs of the beneficiary. PMD providers employ trained and knowledgeable staff to perform the technology evaluations, fittings, adjustments as well as technicians to repair and service these products. Pride Mobility provided comments regarding the draft supplier standards that encourage CMS to create specific standards for Rehab and Assistive Technology providers. We believe this will ensure that all Medicare beneficiaries will be better served.

Pride Mobility recommends that CMS exclude power wheelchair and all accessory codes from the 2007 and 2009 rounds of competitive bidding. This would allow time for CMS to implement new HCPCS codes for power wheelchairs, gain accurate utilization data and assess how the coding changes impact cost before attempting to determine which if any of these products would produce adequate savings while ensuring Medicare beneficiaries achieve their desired clinical outcome. Pride Mobility recognizes that power wheelchairs are high in utilization and cost. However, we also believe that significant savings will result from the vast changes in coverage and conditions for payment that has occurred in this product category over the last year and the additional coding, coverage and payment changes that will be in place by the end of the year. There must be ample time to analyze the true impact of the changes before determining if any of these products are appropriate for competitive bidding. In addition, it is important to note that mandatory accreditation alone will provide additional savings to the Medicare program.

Submission of Bids Under the Competitive Bidding Program (proposed §414.412)

Product categories for bidding purposes

We have great concern that products will be bid based on product categories. The wheelchair category for example includes many different levels of technology and sophistication -- from a basic manual wheelchair (K0001) to a scooter/POV to an advanced rehab power wheelchair. Including all these products in the same category for the purposes of bidding is highly problematic due to the individual medical policy groupings that do not always follow the product groupings.

Requirements to Bid on all Products in a Category

According to the NPRM, suppliers may choose to bid on one, some, or all of the product categories, but if a provider bids on a category, that provider must bid on each item included in the category. CMS should define product categories narrowly, to make sure that they are consistent and representative of the products that a supplier might actually furnish. Including a broad category for wheelchairs could be very problematic. As stated earlier, power wheelchair codes are in the process of being revised. A high probability exists for compromised patient care due to the breadth of the category combined with the complexity of needs for the high-end rehab patient. Most power wheelchairs are individually configured to best address the patient's medical needs. Due to the high probability of inappropriate equipment being provided initially to a patient, as well as the subsequent provision of the appropriate equipment, it is highly probable that a categorical bidding process will be more costly in the long run to the Medicare program.

Manual wheelchairs HCPCS codes will be subjected to a similar recoding process beginning in 2007. Due to its greater breadth as a category, manual wheelchairs will probably cost more to bid categorically for similar reasons. Rehab technology patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the proposal in the NPRM, a provider who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. Those providers who are awarded a winning bid in a category for "Wheelchairs" could end up not being a winning bidder for the associated seating. In effect, many patients may need to deal with two or more providers for a single rehab wheelchair. This situation could lead to access issues in areas of the country where a winning provider is not equipped to provide the complexity of multiple seating and positioning services required in that area.

Conditions for Awarding Contracts

Quality Standards and Accreditation (proposed §414.414(c))

The NPRM states that CMS will allow a "grace period" during which unaccredited providers can participate in the bidding process. Unaccredited providers who are winning bidders may complete accreditation during the unspecified grace period. Winning bidders who do not become accredited during the grace period will loose the contract supplier status. Because the overwhelming majority of DME suppliers are small businesses, it is likely that many suppliers will not be accredited at the time they are awarded contracts. As a result, bids from providers who are ultimately disqualified will be considered in the determination of the pivotal bid and single payment amount. By definition, *only* accredited suppliers should be eligible to bid. CMS should not proceed with competitive bidding until it is sure that all suppliers who may want to submit bids have had an opportunity to get accredited.

Further, the evaluation of the supplier's financial stability must take place before the bid prices are arrayed and the pivotal bid is selected. Bids from disqualified providers should not be considered in

selecting the winning bid point or setting the payment amount. CMS should consider the following evidence of supplier's financial stability:

- Dunn & Bradstreet Report
- Insurance Certificates
- Trade References
- Income / Balance Sheets
- Letters of Credit
- Reviewed financials

Finally, CMS needs to identify the criteria it will use to select accrediting bodies *now*. CMS should be encouraging accreditation rather than discouraging it and should grandfather all providers accredited by organizations that meet the criteria CMS identifies. We recommend that CMS "fast track" accreditation in the manner that was suggested during the PAOC meeting so that CMS can publish a notice soliciting public comments on the organizations that are seeking designation as an accrediting body. CMS' goal should be to promote an aggressive accreditation campaign to assure that providers in any MSA with a competitive bidding program are accredited *before* the bid solicitations are published.

Evaluation of Bids (proposed §414.414(e))

Market Demand and Supplier Capacity

The NPRM states that CMS will evaluate market capacity and supplier capacity to determine the number of suppliers necessary to service beneficiaries in an MSA. We agree that CMS must carefully evaluate capacity issues to ensure adequate access to DMEPOS items in a competitive bidding area. Under the methodology proposed in the NPRM, CMS would array the composite bids from lowest to highest and count up from the bottom until it identifies the point where the bidders' cumulative capacity is sufficient to service the MSA. This will be the winning, or "pivotal" bid. This methodology does not include any mechanism to "rationalize" the bids to ensure that there are no unreasonably low bids. Although competitive bidding is premised on the theory that suppliers will submit their "best bid," in fact there will be suppliers with small individual capacity who may submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity. We recommend that the bid solicitation and evaluation process include safeguards against this type of bidding strategy. We suggest one option below under the discussion on the single payment amount. At the very least, CMS should eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. If these safeguards are not part of the process, CMS can have no assurance that the competitive bidding payment amounts are sustainable over time. The NPRM also states that if at least two suppliers are at or below the pivotal bid amount, CMS would designate the two suppliers as winning bidders. We urge caution in adopting this minimalist approach. CMS should select more suppliers than necessary to meet minimum capacity requirements in the competitive bidding area. Any number of circumstances, such as a natural disaster, could create unanticipated access problems for beneficiaries in the MSA. It is unlikely that CMS could address these types of access problems quickly enough to avoid serious disruption to patient care. Pride Mobility recommends that CMS consider using 130% of anticipated Medicare volume as the threshold for the number of suppliers needed in an area. We believe this would promote more competition in the market, ensure more suppliers remain in the market to serve non-Medicare payors and ensure better competition for any future bidding rounds. In addition, this minimizes the need to recruit more suppliers (that bid above the pivotal bid) if one of the contracted suppliers is terminated or elects to drop out of the competitive bidding program.

Composite Bids

Determine the Pivotal Bid

Section 1847(b)(2)(A)(iii) of the Act prohibits awarding contracts to any entity for furnishing items unless the total amounts to be paid to contractors in a competitive bidding area are expected to be less than the total amounts that would otherwise be paid. CMS proposes not to accept any bid for an item that is higher than the current fee schedule. Pride Mobility believes that CMS should allow suppliers to bid based on the true costs associated with each bid item. CMS can use this information to determine whether the savings is adequate to justify awarding contracts for these items.

Selection of New Suppliers After Bidding (proposed §414.414(h))

CMS proposes to only select as many suppliers as necessary to meet projected demand. However, CMS further suggests that if a supplier falls out of compliance with any of the requirements identified in the regulation and in the bidding contract, it may be necessary to suspend or terminate their contract. This could result in unmet demand. In these situations, CMS proposes to contact remaining contract suppliers to see if they could absorb the demand. If an unmet demand remains, CMS proposes then to refer to the list of suppliers that submitted a bid for that product category in that round of competitive bidding areas, use the list of composite bids that they arrayed in lowest to highest, and proceed to the next supplier on the list. Pride Mobility is concerned that such a process would result in a single payment amount being developed using bids from suppliers that do not meet Medicare's standards. We support the industry's recommendation that CMS use 130% of capacity for the pivotal bid. This better ensures the single bid price will be indicative of bids submitted by qualified suppliers in the event that a contract supplier is subsequently suspended or terminated from a competitive bidding program.

Determining Single Payment Amounts for Individual Items (proposed §414.416)

CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the "winning suppliers". This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects. More importantly, we believe Congress did not have this methodology in mind when it authorized competitive bidding under the MMA.

CMS should set the payment amount at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This method was used in the two demonstration projects. An alternative, which would also provide an assurance that the submitted bids are "rational" and not unreasonably low, is to pay contract suppliers an amount equal to their individual bids. Although we understand that the MMA requires CMS to pay a "single payment amount" and that CMS intends to comply with this requirement, the statutory payment basis is the fee schedule amount or the actual charge, whichever is less. Consistent with this requirement, CMS could calculate a single payment amount equal to the pivotal bid and require winning bidders to submit claims in the amount of their bid – the actual charge – not the single payment amount. This approach also achieves price "transparency" for CMS and beneficiaries.

Rebate Program (proposed §414.416(c))

The NPRM describes a rebate program that allows contract suppliers to give the beneficiary a rebate in an amount equal to the difference between their bid and the single payment amount. CMS proposes to make the rebate program voluntary and would not allow suppliers to advertise the rebate to beneficiaries. Instead, CMS would distribute program materials in the competitive bidding area that would identify contract suppliers that offer rebates. We have concerns about the program integrity ramifications

surrounding this proposal and do not understand how CMS can reconcile a rebate program of this type with the statutory prohibition on beneficiary inducements under §1128A(a)(5) of the Act.

Specifically, §1128A(a)(5) prohibits the offering or transfer of remuneration when an individual or entity knows or should know that it is likely to influence the beneficiary's selection of a provider or supplier. Remuneration includes anything of value and would apply to the rebate proposed by CMS. While the statute contains exceptions to the definition of the term "remuneration," the rebate program proposed in the NPRM does not fit any of the statutory exceptions. For example, "remuneration" does not include unadvertised waivers of coinsurance or deductible amounts for individuals who have been determined to be in financial need. The rebate offered by contract suppliers under the CMS program would not fit into this exception. We are also unaware of any guidance from the Office of Inspector General (OIG) of the Department of Health and Human Services that would authorize the program CMS proposes. In light of the statutory prohibitions of §1128A(a)(5), CMS lacks the authority to implement a rebate program. We strongly recommend that CMS withdraw this proposal.

Terms of Contracts (§414.422)

Repair or Replacement of Equipment

CMS will require contract suppliers to accept all beneficiaries within the competitive bidding area. CMS will also require contract suppliers to repair or replace beneficiary owned equipment under the competitive bidding program. As we mentioned above, we recommend that CMS allow a new period of continuous use to begin when a beneficiary switches to a contract supplier. This preserves the beneficiary's choice and protects the contract supplier who may have to furnish equipment to the beneficiary without adequate compensation for the item or the service it requires. The repair of patient owned equipment should be treated as a separately bid item on the RFB. In other words, CMS should solicit bids for the repair of patient owned equipment. We assume that replacement equipment will be provided and paid for in an amount equal to the single payment amount for the items or the contract supplier's bid, depending on the payment methodology CMS adopts in the final rule.

Change in Ownership (proposed §414.422(d)

Pride Mobility agrees that it is reasonable for CMS to review a change of ownership to determine whether the buyer meets the quality standards before granting the new company contract supplier status. However, CMS cannot unreasonably withhold its approval of a change of ownership and should not deny winning supplier status to a new owner on the basis that its capacity is not necessary within the competitive bidding area. CMS should approve a change of ownership if the new entity will meet applicable quality standards and comply with the other requirements of competitive bidding.

Administrative or Judicial Review (proposed §414.424)

CMS should include a procedure for debriefing suppliers who did not win a bid and provide for a formal review process to determine at a minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

Opportunity for Participation by Small Suppliers

CMS has taken a very narrow view of its obligation to ensure that small suppliers are adequately represented among contract suppliers. CMS' proposal for allowing networks does not consider the practical hurdles involved in creating new legal entity. Under the timelines that CMS has announced, it will be difficult to establish networks that can meet the eligibility requirements for submitting bids. Consequently, this may not be a viable option for most suppliers. CMS has also stated that the market share for supplier networks cannot exceed 20%. CMS should expand this to allow greater participation by small suppliers.

Opportunity for Networks (proposed 414.418)
Pride Mobility recommends that CMS provide significant clarification as to what the requirements are for a group of suppliers to form a network for the purposes of bidding under the competitive acquisition program. It is important that CMS not place unreasonable restrictions on the establishment of networks. The 20% market share limitation outlined in the NPRM should be removed. This is unnecessarily restrictive and does not apply to individual entities that bid on their own.

Beneficiary/Stakeholder Education
Extensive education must be provided by CMS to the supplier's referral sources, such as physicians and clinicians practices, home health agencies, health insurance companies, HMOs (Health Managed Organizations), hospitals, physical and occupational therapists, and others. These entities and the individuals they employee are an integral part of helping coordinate care of beneficiaries. CMS has a responsibility to provide education to them on the competitive bidding program and mandates under the program, including the formal complaint system and how to lodge a complaint and what resources CMS is providing to remedy issues and problems.

Quality Standards and Accreditation for Suppliers of DMEPOS
Accreditation (§424.58)
Pride Mobility strongly believes that only companies that are accredited should be awarded a bid contract. CMS should not proceed with competitive bidding until suppliers have ample time to become accredited once CMS issues the approved list of accrediting entities. CMS should be encouraging accreditation rather than discouraging it, and should grandfather all providers accredited by organizations that meet the criteria CMS identifies. We recommend that CMS "fast track" accreditation in the manner that was suggested during the PAOC meeting so that CMS can publish a notice soliciting public comments on the organizations that are seeking designation as an accrediting body. CMS' goal should be to promote an aggressive accreditation campaign to assure that providers in any MSA with a competitive bidding program are accredited before the bid solicitations are published. CMS should also schedule a PAOC meeting after it publishes the final quality standards to receive industry input on impact of the standards when applied to the framework for competitive acquisition outlined in the NPRM.

Establishing Payment Amounts for New DMEPOS Items (Gap-filling) (proposed §414.210(g))
Pride Mobility appreciates CMS' recognition of the inadequacies inherent in the gap-filling methodology. CMS proposes to implement a new gap-filling methodology that would rely on a technology assessment process to establish fee schedule amounts for new HCPCS codes and for new DMEPOS products. CMS has used gap-filling since 1989 to estimate what the average reasonable charges would be for a new item if the item had been paid for under Medicare during the fee schedule base period. Under the current gap-filling methodology, CMS "deflates" the current manufacturer suggested retail price (MSRP) for an item using the CPI-U to estimate its 1986 MSRP. CMS then trends that price forward using the legislatively mandated covered item update for the item through the current year. Since the gap-filling methodology assumes that the MSRP increases are consistent with increases in the CPI-U, and in reality the covered item update was 0% or "frozen" numerous times by Congress, gap-filling can result in Medicare payment amounts that are too high or unrealistically low. The gap filling formula has and will continue to become more and more problematic due to fee schedule freezes legislated by Congress.

According to the NPRM, CMS has engaged contractors to evaluate technologies for the purpose of making payment and HCPCS coding decisions for new items. CMS states that its purpose in engaging the contractors was to identify technologies that provide demonstrated clinical benefits and recognize those benefits over existing technologies. Although the NPRM does not identify what products CMS assessed, they were assessed in three main areas:

- Functional Assessment – to evaluate the device's operations, safety, and user documentation relative to the Medicare population. Health care providers were asked to determine how and under what circumstances they would prescribe the product for a Medicare beneficiary.
- Price Comparison Analysis – to evaluate the costs of the product compared to similar products on the market or alternative treatment modalities.
- Medical Benefit Assessment – to evaluate the effectiveness of the product. Scientific literature reviews and interviews with health care providers were conducted to determine if the product significantly improved clinical outcomes compared to other products and treatment modalities.

CMS is proposing to use these three types of assessments to help set fee schedule amounts when new HCPCS codes are created for a category of items. CMS would also use the technology assessment to determine whether new HCPCS codes need to be established for new products and to determine the payment amount for new items. CMS intends to use the technology assessment process any time after January 1, 2007 to adjust payment amounts that were previously established using the gap-filling methodology if it determines that those pricing methods resulted in payment amounts that do not reflect the cost of furnishing the item.

We are encouraged to know that CMS recognizes that the current gap-filling methodology can have arbitrary results. We also agree that CMS should depart from the practice of "deflating" current MSRP to arrive at a gap-filled amount and that CMS should use the median current retail price for new items to establish the payment amount. We remain concerned, however, because the proposal for a technology assessment process is vague and lacks any opportunity for stakeholder participation. More importantly, CMS' only authority to adjust payment amounts for an item or a category of items is the IR authority under §1842(b)(8) and (9), and CMS is not authorized to depart from this authority.

Under the IR methodology established by Congress, CMS must make a determination that using the "standard rules for calculating payment" results in a payment amount that is not inherently reasonable. Congress explicitly directed the Secretary to identify the factors that it would use to determine when a payment amount is not "inherently reasonable" because it is either grossly excessive or grossly deficient. CMS must use "valid and reliable data" in making this determination and in establishing a new payment amount. Importantly, IR includes specific procedural safeguards that apply to determinations to adjust a payment amount by more than 15%. For payment adjustments greater than 15%, CMS must consider (among other factors) the "potential impact of such a determination on quality, access, and beneficiary liability, including the likely effect on assignment rates and participation rates."

Under the proposal in the NPRM, CMS could avoid complying with the IR methodology simply by migrating existing products into new HCPCS codes. Congress specifically required notice and comment and the use of valid and reliable data under the methodology to protect beneficiaries and providers from poorly conceived payment reductions that affect access. CMS cannot use a technology assessment to make a payment adjustment based on a determination that a payment amount does not "reflect the cost of furnishing the item" because those factors cannot serve as the basis for a special payment adjustment under §1842b (8) and (9).

We do not disagree that CMS should establish fee schedule amounts for new products using the median retail price for the item. However, to the extent that CMS intends to use a technology assessment to establish a payment amount or a new HCPCS code for new products, we cannot provide meaningful comments without additional information. At a minimum CMS must identify the factors it would consider in deciding to initiate a technology assessment and establish mechanisms to solicit participation from interested stakeholders. More importantly, this proposals has ramifications beyond the DMEPOS competitive bidding program and CMS may receive limited stakeholder input by including it in this

NPRM. Pride Mobility strongly recommends that CMS initiate a separate rulemaking process to address this issue and allow for broader stakeholder participation.

Regulatory Impact Analysis

The Proposed Rule CMS predicts that, nationally, 37% of the total number of DME suppliers will be eliminated in each bidding round. A 37% decrease in the number of suppliers means an even higher increase in patient load for the remaining suppliers. For example, say the current ratio of patients to DME suppliers is 10,000 patients per one hundred DME suppliers, that is 100 patients per supplier. What happens if the number of suppliers decreases by 37%? The new ratio is 10,000 patients per 63 suppliers or 159 patients per DME supplier. Clearly the patient load per supplier has jumped from 100 to 159, a 59% increase! This remains true regardless of the number of patients or DME suppliers that are used in the calculation. In the actual CBAs the effect will be even greater, as 50% of bidding suppliers will be excluded from the program in their immediate geographic areas. The problem with these figures is that, going back to page 87 of the Proposed Rule, we are told that CMS had asked the Program Advisory and Oversight Committee (PAOC) for advice on supplier market capacity. The PAOC informed CMS at the Feb. 28, 2005 meeting that most suppliers would be able to increase their capacity by up to 20%, with a higher percentage for less labor intensive items like diabetic products. This was the only hard figure on potential capacity increase mentioned in the Proposed Rule.

Increasing capacity for a DME supplier is not really that easy. Because of accreditation, they must thoroughly train and test all new employees for competency (usually a year process). This is not just a simple matter of new inventory. Licensed professionals must be hired, additional facilities and vehicles purchased, new credit extended, billing issues resolved, etc. Clearly, if there are increases in patient load above 20% in life support services, there are real dangers both to the patient and accreditation standards. The targeted 37% cut in available suppliers will forcibly raise the patient load for each contracted supplier by 59%. This is an extremely difficult workload increase for any health care company in a short timeframe. Imagine a hospital suddenly raising its patient census by 59% before there has even been an opportunity to expand its qualified staff and facilities? This proposed cut in participating suppliers is arbitrary and presents an unacceptable peril to the home health care system. Furthermore, it endangers accreditation standards, state licensing standards and the risk of malpractice lawsuits. Based on the initial advice of the PAOC, the patient load increase per supplier for all life support services should be no higher than 20%.

It is our view that the term "Competitive Bidding" is a misnomer for a flawed system, which might more accurately be described as "Selective Contracting." It is also our belief that the two pilot projects have demonstrated significant negative consequences for beneficiaries by effectively eliminating the normal, healthy competition that currently exists between the DMEPOS provider community to provide beneficiaries with fast, efficient, and effective products and services. While this National Competitive Bidding (NCB) option may, in some instances, result in product price reduction, it will at the same time severely reduce overall patient access, choice and service. This will ultimately result increased care costs to other areas of the hospital system and health care continuum; e.g., increased length of stay in inpatient/acute settings and/or increased patient re-admission frequency or disease severity, etc. from moving to a "low price" model being encouraged by NCB.

Fundamental Issues

The proposed rule appears to primarily utilize cost and volume for product selection. Unfortunately, the potential negative impacts in terms of overall patient access and inclusion and continuity with established care plans and protocols does not appear to be addressed. Consideration to overall medical appropriateness needs to be considered, as well as overall patient access to care and services.

Potential cost considerations that will affect many other areas of the overall health care continuum do not appear to be adequately considered or addressed. There appears to have been no examination of negative cost implications for physicians, clinicians, home health care providers, hospice, inpatient and outpatient hospitals, integrated healthcare delivery systems and owned providers, as well as multiple and various other healthcare providers. It is very important that protections and minimization of overall cost impacts throughout the health care continuum be clearly identified, discussed, and fairly addressed in the final rules. Pushing "costs" out of products alone will most certainly result in detrimental cost-shifting and even cost increases in other areas of the continuum.

Pride Mobility appreciates the opportunity to submit comments on NPRM. Please feel free to contact me if you have any questions or need further clarification on our comments or recommendations. I can be reached at 1-800-800-8586 or sjohnson@pridemobility.com.

Sincerely,

Seth N. Johnson
Vice President, Government Affairs

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June 29, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

File Code CMS-1270-P: Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan:

The National Alliance for Infusion Therapy, representing manufacturers of enteral nutrition formulas, supplies, and equipment, offers these comments in response to the proposed rule issued by the Centers for Medicare and Medicaid Services (CMS) on May 1, 2006 implementing the Medicare Part B competitive acquisition program (hereinafter the "competitive acquisition program" or the "competitive bidding program").

We appreciate the complexity of the many tasks facing CMS in developing the competitive bidding program for Part B items and services. This is a massive undertaking that must be completed within a very short timeframe. We commend CMS for its efforts to launch this program in a timely fashion. Our comments are offered in the spirit of cooperation and support for CMS' overarching goals to protect Medicare beneficiaries' access to Part B items and services.

Perhaps because of the complexity of the proposed competitive bidding program, we believe CMS should publish the final rule as an interim final rule with comment period. The proposed rule is unlike most proposed rules in that this rule lays out a number of unanswered questions without CMS having committed to a concrete proposal on particular topics. The preamble's section on the criteria for product selection, for which CMS requests comment on very general criteria for subsequent product selection, and the preamble discussion regarding the application of competitively bid rates in other areas of the country, are two examples of this practice. In addition, the Part B quality standards have not been issued in final form yet.

Without question, both stakeholders and CMS would benefit from comments that reflect the application of the final quality standards to this program.

At this juncture, it is difficult to project what the final rule will look like on a number of important issues where CMS did not propose a specific course of action. For that reason, we suggest that CMS issue the final rule as an interim final rule with comment period, so that the public will see, for the first time, CMS' decisions on an array of issues and thus will have an opportunity to comment on concrete proposals.

This would be more than good and fair policy. It also would be consistent with applicable law. Section 1871(a)(4) of the Social Security Act (hereinafter "Act") provides that a final rule will be treated as a proposed rule if it includes provisions that are not "logical outgrowth(s) of a previously published notice of proposed rulemaking." Congress clearly was concerned about the type of situation where a proposed rule does not flesh out CMS' intent with enough specificity so that the final rule's provisions surprise the public that commented on the proposed rule. On several points, this proposed rule approaches this line.

Part B Quality Standards

We would like to address briefly an important issue with respect to the development of Part B quality standards. Section 1847(a) of the Act requires CMS to develop quality standards that would apply to the provision of most Part B items and services. These quality standards are important to the functioning of the competitive bidding program that is the subject of the proposed rule. Importantly, however, the quality standards are not limited to those items subject to competitive bidding. The standards will apply equally to those Part B items and services that are not subject to competitive bidding and which will continue to be reimbursed pursuant to the otherwise applicable payment methodologies.

There should be no argument with the principle that Medicare payments, whether determined by fee schedule or via competitive bidding, should be sufficient for efficient suppliers to comply with the quality standards. The standards will have little meaning or effect if Medicare payment levels are woefully inadequate in relation to the costs associated with the tasks required of suppliers. This is, we believe, an important point that CMS should affirm in the final rule.

There have been numerous instances in the past where CMS and/or the Office of Inspector General (OIG) concluded that payments levels for an item or service were excessive because payments either were in excess of the suppliers' acquisition costs or were greater than the costs reflected in a literal reading of the coverage criteria. For example, Medicare coverage for enteral nutrition is limited to the nutrients, supplies and equipment, without explicit recognition of the services and other obvious overhead costs incurred in the provision of enteral nutritional therapy. The OIG has issued several reports indicating that payment for enteral nutrition was either greater than the suppliers' acquisition costs for the items and equipment, or

were greater than what is necessary to simply deliver the nutrients, supplies and equipment. Either way, the reports were seriously flawed and misleading.

With the development of meaningful quality standards, we believe CMS and the OIG now are required to factor the costs of compliance with these standards into their assessments of adequacy of reimbursement. It would be a most illogical development if these assessments continue to be conducted as if the quality standards have no applicability, meaning or cost. We request that CMS acknowledge that the costs of compliance with applicable quality standards should be taken into account in future consideration of reimbursement issues.

Our comments below are focused on the following topic areas identified for comment in the proposed rule: (1) criteria for item selection; 2) payment basis; 3) competitive bidding areas, and 4) gap-filling. In addition, we offer comments on the application of basic federal procurement principles to the proposed competitive bidding program.

Executive Summary of NAIT Comments

- NAIT believes that enteral nutrition is not a good candidate for inclusion in the first phase of the competitive bidding program. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services within the scope of the competitive bidding program. It creates serious policy and operational issues for nursing homes as well as for CMS itself. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

- If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for DME patients.

- If CMS ultimately subjects enteral nutrition to competitive bidding, it should modify the proposed payment structure for enteral pumps and, consistent with current law, ensure that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

- The competitive bidding areas should be limited to the geographic scope of the selected metropolitan statistical areas ("MSAs"), and should not encompass contiguous areas.

- The proposed gap-filling provisions are too vague and undefined, and appear to be in conflict with the limitations on CMS' authority to modify existing payment

rates. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders as to how existing payment levels can and should be adjusted when existing codes are modified.

Criteria for Item Selection

We understand that competitive bidding is intended to be a far-reaching initiative that will achieve two important objectives: (1) improve the level of care for Medicare beneficiaries requiring Part B items and services, and (2) reduce Medicare expenditures, including the amount of beneficiary co-payments.

Both, obviously, are admirable goals. At this point, however, we do not believe enteral nutrition's inclusion in the *first* phase of the competitive bidding program in 2007 would make significant progress towards those goals, and instead would present costly and complicated administrative challenges for CMS and its contractors. As explained below, enteral nutrition presents some of the most challenging obstacles for inclusion in the competitive bidding program, and we believe it would be an odd selection for the competitive bidding program to begin with in light of CMS' objective of getting off to a successful start of this enormously complex program.

Enteral nutrition involves the provision of nutrients by tube into the patient's stomach or intestine. It is appropriate for patients whose lower gastrointestinal tract functions normally but who are unable to swallow, who have a gastric obstruction or who cannot otherwise ingest adequate amounts of food and fluids by mouth. Medicare Part B covers enteral nutrition formulas, supplies and equipment under the prosthetic device benefit when enteral nutrition is necessary for the patient to maintain weight and strength commensurate with his or her general condition.[1]

It is clear that CMS has the discretion under the Act to (a) exclude products and product categories from the 2007 phase of the competitive bidding program, which CMS acknowledges in the preamble to the proposed rule, and equally importantly, (b) exclude products and product categories in particular settings, such as nursing homes, from the 2007 phase of the competitive bidding program.

Section 1847(a) of the Act expressly distinguishes between where Congress intended the Secretary to exercise significant discretion and those where it did not. The statute provides that the Secretary "**shall** establish and implement programs under which competitive acquisition areas are established" and that the programs "**shall**" be phased in so that competition occurs in a certain number of the largest MSAs by certain times. However, the statute also provides that the program "**may**" be phased in first among the highest cost and highest volume items and services or those with the greatest savings potential, and that the Secretary "**may**" exempt certain rural and low population density areas and items and services for which competitive acquisition is not

[1] Medicare Coverage Manual, Section 65-10.2.

likely to achieve significant savings. The statutory language specifically directs the Secretary to establish competitive acquisition areas on a certain schedule, but permits flexibility in design and implementation to encourage efficient operation. By stipulating that the competitive acquisition areas "**may** differ for different items and services," Congress gave the Secretary wide discretion to choose those products and services that are most amenable to competitive bidding (and to exclude products and product categories that are not) and to first implement the program in the MSAs of his choosing.

These grants of discretion gave the Secretary sufficient flexibility to implement the program in the most effective way possible. It also is clear, then, that if there is evidence that it would be in the interests of a successful competitive bidding program to exclude nursing homes from the first implementation phase, the Secretary has the discretion to do so.

Factors Determining Product Selection

CMS lists several factors for determining the products to be selected in competitive bidding in the 2007 phase:

- Level of Medicare expenditures
- Rate of growth in expenditures
- Number of suppliers
- Demonstration project experience
- Reports and studies

We will address each of these factors' application to enteral nutrition.

I. Level of Medicare Expenditures

Enteral nutrition is listed in the proposed rule as fourth in total Medicare expenditures for Part B items for 2003. That number, however, is seriously misleading, since enteral nutrition is not a monolithic therapy provided in one setting. Rather, enteral nutrition, for policy purposes, should be divided into three parts:

(1) Enteral nutrition provided to residents in long term care facilities ;
(2) Enteral nutrition provided in the home to patients who also qualify for the home health benefit; and
(3) Enteral nutrition provided in the home to patients who do not qualify for the home health benefit.

Historically, a clear majority of Medicare Part B enteral patients are residents of long term care facilities. The percentage of enteral patients who are in long term care facilities increased from 2003 to 2004 to approximately 56%, based on the data described below. This fact is extremely relevant to CMS' ultimate decision of whether to include enteral nutrition in the

2007 phase of competitive bidding. We understand, based on our involvement with CMS in the development of the new Part B quality standards, that the enteral-specific standards apparently will not apply to these enteral patients, and thus will not apply to the majority of Part B enteral patients. Thus, enteral patients in long term care facilities are and will continue to be treated pursuant to the nursing home conditions of participation, not the Part B standards.

Similarly, we understand that those enteral patients qualifying for the home health benefit are and will continue to be treated pursuant to the home health conditions of participation, not the enteral-specific Part B standards. Thus, the only segment of the enteral patient population who will be subject to the Part B enteral-specific quality standards are home enteral care patients who do not quality for the home health benefit, a distinct minority of the Medicare enteral patient population. That small segment of the population does not involve Medicare expenditures anywhere near the top ten items of expenditures.

II. Rate of Growth

Our analysis of enteral claims data from the years 2002-2004 indicates that Medicare payments for enteral nutrition are far from skyrocketing.[2] The rate of growth of Medicare

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[2] Using data obtained from the Centers for Medicare and Medicaid Services, we calculated the aggregate allowed charges under Medicare Part B for all enteral formulas, equipment and supplies during calendar years 2002, 2003 and 2004. In addition, we determined the percentage of enteral formula claims for Medicare beneficiaries residing in nursing homes versus Medicare beneficiaries residing in their own homes.

We obtained from CMS the Physician Supplier Procedure Summary Master File (PSPSMF) for 2002, 2003 and 2004. We spoke with the appropriate CMS contractor (ResDAC provides support for users of the PSPSMF) to clarify our understanding of the various data fields within the PSPSMF. The PSPSMF for each calendar year includes procedure-specific billing data for all physician and supplier services provided to Medicare beneficiaries during the calendar year. To be included in the PSPSMF, a claim must be processed by the Medicare Part B carriers on or before June 30th of the subsequent year.

By reviewing the DMERC medical policies for enteral nutrition and other notices published by the four durable medical equipment regional carriers (DMERCs), we compiled a comprehensive list of all of the alpha-numeric HCPCS codes for enteral formulas, equipment and supplies in effect at any time during the years examined. This resulted in a list of 30 alphanumeric codes.

To determine the total allowed charges for all of these codes, we identified the total allowed charges for each code for claims processed by one of the four DMERCs, and we aggregated these amounts. The "allowed charges" reflects the total dollar amount for claims that the Medicare carriers agreed to pay. Medicare does pay the full "allowed charges." Typically, the beneficiary (or their Medigap policy) is responsible for 20 percent.

To determine the percentages of enteral expenditures arising from Medicare beneficiaries residing in traditional homes versus nursing homes, we examined the "place of service" field for all enteral formula claims in the PSPSMF processed by one of the four DMERCs. For this analysis, we defined nursing home claims to include claims identified in this field as arising from a skilled nursing facilities, nursing homes or intermediate care facilities for the mentally retarded. We defined claims attributable to the tradition home setting to include all claims designated as "home" in the place of service field. In combination, the nursing home and traditional home claims defined in this manner accounted for over 99 percent of all enteral formula claims.

allowed charges increased by 1.7% from 2002 to 2003, and actually decreased by approximately 5% from 2003 to 2004. Thus, Medicare allowed charges for enteral nutrition in 2004 were $20,624,897 less than they were in 2002. Clearly, this is not an area that requires immediate action and attention from CMS to restrain inexplicable increases in the rates of Medicare expenditures. If this factor truly is an important criterion in CMS' product selection, then enteral nutrition is a poor choice for inclusion in the 2007 phase of competitive bidding on that basis.

III. Number of Suppliers

We do not have information about the number of enteral nutrition suppliers.

IV. Demonstration Project Experience

Enteral nutrition was not tested successfully during the two demonstration projects and was categorized as not as well suited for competitive acquisition by CMS. Enteral nutrition originally was included in CMS' Polk County, Florida demonstration project that tested competitive bidding for certain Part B items. Importantly, enteral nutrition was removed from that demonstration after the first phase of the project. We believe it was removed primarily because most enteral patients reside in long term care facilities, where the application of the competitive bidding regimen would be difficult and confusing. Thus, use of competitive acquisition to set prices and pay for enteral nutrition in Medicare has not been tested sufficiently or successfully.

In addition, based on its own analysis of the data from the DMEPOS competitive bidding demonstration projects, CMS concluded in its final report to Congress that enteral nutrition was not as well suited for competitive acquisition.[3] Recently, CMS staff echoed this perspective, indicating that certain products may not be suitable for competitive acquisition because Medicare will not realize sufficient savings to justify the administrative expense of the competitive acquisition program.

Importantly, enteral nutrition was the only therapy in the demonstration projects where the majority of patients are in a setting other than the home. Competitive bidding clearly was designed by Congress with the home care patient in mind, a concept that the long term care component of enteral nutrition would greatly complicate. We address this issue in greater detail in the section below about long term care facilities.

V. Studies and Reports

CMS alluded to reports and studies as providing evidence and guidance as to product categories that are over-reimbursed under current fee schedules and where competitive bidding

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[3] Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies.

could bring needed changes to payment levels. As a principle, this is a sensible criterion. Our issue with this approach, however, rests with the caliber of the studies CMS is likely to rely upon in its analysis.

The OIG has issued many reports over the years about a wide array of product categories. A number of these studies were not written, or designed, to reflect all of the issues faced by policymakers on a particular subject. Instead, they were focused largely on a narrow issue or a small subset of issues, and as a result the reports often reflect a skewed perspective of (1) the particular problem and (2) the suggested solution to that problem.

This clearly has been the case with respect to OIG reports about enteral nutrition. A number of OIG reports about enteral nutrition contain estimates about supplier acquisition costs for enteral formulas, supplies and equipment, and compares those acquisition costs with Medicare payment rates. The OIG often describes the gap between the acquisition costs and payment rates as "waste" or "abuse", despite the fact that the OIG has never focused on -

- The services and functions required of enteral nutrition suppliers to provide good quality care,
- The costs associated with these services and functions, or
- If payment rates are limited to the acquisition costs of items and equipment, then no supplier will be able to remain in business to provide enteral nutrition to Medicare beneficiaries.

Since policymakers are aware that enteral nutrition involves more than the delivery of formulas, supplies and equipment to beneficiaries, as most recently evidenced by the issuance of quality standards in this area, OIG reports such as the ones described above have limited value to CMS as a foundation for decision-making. Despite the clear limitations of the OIG reports on enteral nutrition as well as their seriously misleading conclusions, CMS indicated in the proposed rule that it wants to include these type of reports in its analysis of what product categories are best suited for inclusion in the competitive bidding program. We understand that CMS cannot simply ignore OIG reports, but we do urge CMS to place such reports in the proper context and determine whether their findings are supported by other sources of information. In the case of enteral nutrition, we believe you will find that the reports are largely inaccurate portrayals of what is involved in the provision of enteral nutrition and the costs associated with such therapy.

If CMS wishes to use outside sources to gather information about enteral nutrition functions and costs, we urge CMS to consult with the American Society for Parenteral and Enteral Nutrition (ASPEN), the clinical society for physicians, nurses, dietitians and pharmacists involved in the provision of enteral nutrition. ASPEN has developed quality guidelines as to the functions and services required for enteral nutrition. Likewise, we suggest CMS consult with the Joint Commission on the Accreditation of Healthcare Organizations and other accrediting organizations as to their perspective on what is involved in the provision of enteral nutrition.

In addition, the OIG studies could not have reflected the costs associated with accreditation, either in terms of the administrative costs of seeking and maintaining accreditation or the costs of complying with the new Part B quality standards that are the bases of accreditation. In light of this clear discrepancy, we urge CMS not to rely heavily on OIG reports in determining product selection for the competitive bidding program.

The reasons for excluding enteral nutrition from the first phase of the competitive bidding program are not limited to the criteria set out above. There are important other bases for omitting enteral from the 2007 portion of competitive bidding, including the following:

Enteral Patients in Long Term Care Facilities

As indicated above, most enteral nutrition is provided in nursing facilities, which presents issues that go far beyond the scope of the competitive acquisition program. It is apparent that CMS and its contractors will be burdened with numerous complex issues to implement the competitive acquisition program even in the most basic manner possible. Attempting to use competitive acquisition for products used in long term care facilities raise a whole host of issues involving access and choice that are not easily resolvable, especially in the immediate timeframe.

Nursing facilities have a special relationship with their residents. In most instances, the facility is the resident's home. The nursing facilities are responsible for coordinating the work of an array of clinicians, providers and suppliers to meet patient health care needs, and they are held accountable for the quality of these services. Nursing homes must meet detailed conditions of participation to participate in the Medicare and Medicaid programs as well as a wide array of additional quality standards. Because of their multiple responsibilities in this regard, nursing facilities traditionally have established long-standing relationships with selected suppliers based on experience, trust and respect for their level of professionalism.

For these reasons, most nursing facilities will be extremely concerned if they are forced to admit unfamiliar suppliers into their facilities to provide services, supplies, and equipment to their residents. Nursing facilities must be able to select the suppliers that the facilities believe can best enable them to meet resident needs and comply with applicable standards. The competitive bidding program would interfere with their ability to make these decisions, and potentially interrupt ongoing relationships that have worked to the benefit of their residents.

CMS' demonstration projects did not test a model of competitive bidding that involved long-term care facilities. This is extremely important, because the proposed rule reflects an overly simplistic view of how long term care facilities operate and how they could fit into the competitive bidding program. We are concerned that the proposed rule appears to reflect a view that a nursing home is simply a supplier that does not have to travel to treat its patients. The only

recognition that a nursing home is different in any respect is the provision that a nursing home can limit its participation in the competitive bidding program to treating its own residents. What is surprising is the clear implication that a nursing home actually has to be a winning bidder just to treat its own residents. Residents in nursing homes usually are more impaired than home care patients and require a different regimen of care. Primarily for that reason, it would not be a fair or accurate process to combine nursing home bids with home care bids for a particular products category.

The proposed rule also does not account for Part B suppliers whose entire business is treating beneficiaries who are residents of nursing homes. Nursing home suppliers have very different businesses than home care suppliers. They are not interchangeable, and should not be combined into a single grouping to demonstrate that an area has a certain number of suppliers.

We do not understand how there can be fair and responsible competitive bidding when there are at play different quality standards, different settings of care, and different patient needs. As explained below in the section on competitive pricing principles, competitive bidding requires bidders to have to meet the same requirements in the same context. The nursing home component flies in the face of this principle. With all respect, we do not believe CMS has considered the differences and particular problems the nursing home setting brings to the competitive bidding program. We urge CMS to refrain from selecting products for inclusion in competitive bidding if, as with enteral nutrition, most of the Medicare market for those products is in the long term care setting.

Application of Quality Standards

The competitive bidding program is predicated in large part on the application of the Part B quality standards and the requirement that every participating supplier be accredited in accordance with the accreditation provisions of the proposed rule. This is an important component of the overall scheme of the competitive bidding program, wherein bidders will have similar costs and will benefit from a generally level playing field. That makes perfect sense – again, except with regard to enteral nutrition.

For the enteral patient population, there will not be one set of quality standards – there will be **three** sets of standards: the conditions of participation for long term care facilities; the conditions of participation for home health agencies; and the quality standards under development in connection with the competitive bidding program. This creates a unique problem for enteral nutrition.

As described above, most of the enteral patients are in long term care facilities. Most of these patients receive enteral nutrition from suppliers that focus only on the long term care market. Likewise, enteral nutrition is provided to homecare patients by suppliers that focus solely on the homecare market. In other words, the quality standards and the enteral suppliers in the homecare setting will be significantly different from the quality standards and enteral

suppliers in the long term care setting. The application of the home health conditions of participation to those homecare enteral patients who qualify for the home health benefit only further complicates an already complicated situation.

Thus, it would be highly illogical to subject all of enteral nutrition to the competitive bidding program at this point, because of the involvement of the three different sets of quality standards. The costs of compliance with the standards differ, due in large part to the fact that the settings of care differ. Further, we do not believe it is a feasible option to simply limit the competitive bidding program to homecare enteral patients, since those patients make up less than half of the enteral patient population and thus CMS would not achieve the savings envisioned by the MMA. Regardless, the administrative costs of sorting out the various enteral patient populations and standards within the context of the competitive bidding program would be disproportionate to any value derived from applying competitive bidding to this area.

Tracking Beneficiary Satisfaction

In a September, 2004 report entitled "Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies," the Government Accountability Office (GAO) emphasized the importance of ensuring continued quality, especially given that the implementation of bidding will create an added incentive for suppliers to cut costs. In GAO's view, the central focus of these efforts should be "continued monitoring of beneficiary satisfaction," perhaps through a toll-free complaint hotline and through beneficiary surveys.

This may be impractical and unrealistic for beneficiaries receiving enteral nutrition. Medicare only covers enteral nutrition for patients who are completely dependent on it for nutrition due to permanent nonfunction or disease of structures that normally permit food to reach the small bowel. Beneficiaries receiving enteral formula through Medicare are by and large victims of serious strokes suffering from severe dysphasia or individuals with head or neck cancers. The seriousness of such conditions not only prevents traditional nutrition through swallowing, but also may preclude effective communication or a self-assessment of the quality of their treatment. It would be unrealistic to expect these beneficiaries to monitor and provide feedback on the quality of the enteral formula they receive, through a hotline, through surveys, or otherwise. Nor, in any event, is it likely that the beneficiary or even a guardian would be capable of making a technical assessment of the quality of the enteral formula treatment. Given the importance of assuring continued quality during a transition to a significantly revised pricing system, it would be prudent for CMS initially to focus on those items and supplies for which quality can be readily assessed and assured through monitoring efforts.

We have two additional concerns if CMS ultimately decides to subject enteral nutrition to the competitive acquisition program.

Payment Basis: Enteral Nutrition Pumps

Under current payment policy, monthly rental payments for enteral pumps were calculated originally on the basis of the purchase price for the particular type of pump. Once the purchase price was determined, the monthly rental payments were set at 10% of that purchase price up to a maximum of 15 months. This has been different from items in the DME capped rental category, wherein monthly rental reimbursement for capped rental items has been 10% of the purchase price for the first 3 months and then it is reduced to 7.5% of the purchase price for each of the remaining months of coverage.

However, the proposed rule would reduce monthly rental payments for enteral pumps under the competitive bidding program for the months 4-15 to 7.5% of the purchase price. In other words, under the competitive bidding program, rental payments for enteral pumps would be determined as if enteral pumps were capped rental items.

Enteral pumps are not capped rental items. Rather, they are covered under the prosthetic device benefit and reimbursed under a fee schedule specifically tailored for enteral nutrition. Further, Congress explicitly rejected an attempt by CMS in 1989 to put enteral pumps in the DME capped rental category.[4] CMS' proposal for the competitive bidding program would effectively negate an explicit act of Congress. If enteral pumps are to be included in the competitive bidding program, they should be reimbursed on the same basis as they are now – 10% of the purchase price for up to 15 months.

There does not appear to be any policy basis for CMS' proposal regarding enteral pumps, other than simply to further reduce payments for these items. That objective alone, we submit, is not enough to counter Congress' intent in keeping enteral pumps separate from the DME regulatory scheme.

Payment Basis: Grandfathering

The proposed rule does not extend grandfathering provisions to enteral nutrition. Instead, it limits all grandfathering protections to DME and oxygen items. We understand that the statute requires grandfathering only for those items, but we believe the statute does not prohibit CMS from extending grandfathering protections to other products that are subject to the competitive acquisition program in the interests of program efficiency.

The policy bases for grandfathering DME and oxygen items apply with equal force to enteral nutrition. Beneficiaries already on service often develop trusting relationships with their enteral suppliers, and many would prefer to continue that relationship for the entire course of their therapy. In addition, the responsibility for servicing and maintaining enteral pumps would be an important issue for the new contract enteral supplier. The contract supplier will be liable for the servicing and maintenance of enteral pumps which it did not provide to the beneficiaries.

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[4] Section 6112 (b), Omnibus Budget Reconciliation Act of 1989 (Pub. L 101-239)

Enteral pumps are not capped rental items, but the duration of the rental payments for such pumps is limited to 15 months. At the very least, it would be sensible to permit the "old" enteral supplier to continue with an enteral patient until the 15 month rental period elapses.

Necessary Steps Prior to Subjecting Enteral Nutrition to Competitive Acquisition Program

As indicated above, we are strongly urging CMS to delay application of competitive bidding to enteral nutrition until a later phase of the program. The issues that we have raised regarding nursing homes, quality standards and operational issues peculiar to enteral nutrition make it clear to us that these issues cannot be resolved in the short timeframe leading up to the 2007 phase of the competitive bidding program. We recommend instead that CMS and representatives of the various enteral nutrition stakeholders work together to resolve the many issues that pertain to enteral nutrition.

In particular, we suggest the following actions:

- Clarify the different requirements and obligations specific to enteral suppliers regarding nursing homes and their residents
- Integrate the Part B product-specific standards applicable to enteral nutrition with the nursing home quality standards
- Clarify the different requirements and obligations specific to enteral suppliers regarding home health agencies and their patients
- Integrate the Part B enteral standards with the home health quality standards

Competitive Bidding Areas

The proposed rule provides CMS with the authority to designate competitive bidding areas in the initial phase of the competitive acquisition program as extending beyond the boundaries of the selected metropolitan statistical areas (MSAs). We do not believe this proposal is consistent with the statute.

Section 1847(a)(1)(B) of the Act specifically provides that CMS is to phase in the competitive bidding program so that competition occurs in 10 of the largest MSAs in 2007 and 80 of the largest MSAs in 2009. The statute authorizes expansion of the competitive acquisition program to areas beyond MSAs only after 2009. Section 1847(a)(1)(B)(i)(III).

If Congress intended competitive bidding areas to include areas *outside* of the MSAs in 2007 and 2009, it would have authorized CMS to include those areas as it did for expansions occurring after 2009. It did not do so. The fact that Congress was so specific in its language on this point makes it clear that CMS is not authorized to venture beyond the borders of MSAs in the 2007 phase of the program.

In addition to health policy issues raised above, we have several concerns regarding the application of basic federal procurement principles to the proposed competitive acquisition program, which we summarize below.

Competitive Pricing Issues

The Medicare Modernization Act ("MMA") reflects a clear Congressional intent that, to the maximum extent practicable, CMS is to utilize the concept of competitive pricing in its implementation of the competitive bidding program. The expression of this Congressional intent first appears in Section 302 (b) of the MMA which begins by changing the heading of Section 1847 (a) to read: "COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES....(a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS." The provision then directs the Secretary to "establish and implement programs under which competitive acquisition areas are established...for the furnishing...of *competitively priced* items and services..." (italics added) and provides that "[p]ayment under this part for *competitively priced items* and services...*shall be based on bids submitted and accepted* under this section for such items and services." (italics added.) Sections 1847(a)(1)(A), (b)(5)

The term "competition" is defined as " a market condition in which a large number of independent buyers and sellers compete for *identical commodities*..." Webster's Third International Dictionary (1976) A price is "the amount of money given or set as the amount to be given as a consideration for the sale of a *specified thing*." Black's Law Dictionary, Sixth Edition (1991) at 1188. (italics added.) "Pricing means the process of establishing a reasonable amount or amounts to be paid for supplies or services." Federal Acquisition Regulation (FAR) 2.101. In light of these definitions, it appears that when Congress directed CMS to establish a program that entails "furnishing...of *competitively priced* items and services" it understood that the constituent elements of the program would include: a number of independent sellers who can furnish specified items or services that are identical as to function and who can offer to sell the items or services at a specified amount or price.

CMS has correctly chosen to characterize the Congressionally mandated use of competitive pricing as a program of "competitive bidding" for DMEPOS. The Government Accountability Office has long considered issues relating to competitive bids and, in doing so, has aptly described the characteristics of an invitation for bids, stating that it:

> "...must contain specifications that are sufficiently descriptive in language to permit full and open competition, and to permit evaluation of bids upon a common basis. ...the invitation must provide objectively determinable standards against which the bids can be evaluated on an equal basis to determine the acceptability of the low bid" McBride and Tuohy, Government Contracts, Section

10.10 citing *Science Management Corp,,* B-181281, 74-1 CPD 6 (1974) (emphasis added.)

Thus, competitive pricing and its fraternal twin competitive bidding both require that those competing to sell an item or service to the government must be given the opportunity to make their bids, submit their offers or propose their prices on the same item or service and under conditions that allow evaluation of their bids, offers or prices on an equal basis whether the outcome is to a be a single award or, as is the case here, awards to multiple bidders.

With that as background, we believe the application of these competitive pricing principles raises important concerns regarding the proposed competitive bidding program.

First, in addition to the policy and fairness issues we described earlier in these comments, we believe the application of competitive bidding to enteral nutrition would be counter to basic competitive pricing principles. The application of different quality standards, and the existence of different markets within the enteral nutrition area, means that the competition for contracts could not be on an equal basis. Enteral nutrition suppliers that focus solely on the nursing home market will have a different business and cost structure from enteral nutrition suppliers that focus solely on the homecare market. A competitive bidding program that combines the two types of enteral suppliers into one bidding group clearly is inconsistent with competition on an equal basis.

Secondly, Section 414.414(h)(1) of the proposed rule provides that "Subsequent to the awarding of contracts under this subpart, CMS may award additional contracts if it determines that additional contract suppliers are needed to meet beneficiary demand for items under a competitive bidding program." To select additional contractors, CMS plans to use bids previously submitted by bidders in the specific product category for which additional contract suppliers are needed to make award. Id. CMS plans to offer award first to the disappointed bidder whose composite bid is the first composite bid above the pivotal bid for that product category. Id.

This is an inappropriate method for the acquisition of additional contractors following award. First, by awarding contracts after award without competition, CMS would violate the clear language of the statute, which requires that CMS conduct a competition for the award of any contracts for the items specified by the statute. The statute states: "[t]he Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services." Sec. 1847(b)(1). A post-award contract award to the next-in-line disappointed bidder who participated in the initial competition is not a competitive acquisition. It is not a continuation of the original competition. It is a sole-source acquisition. (See 41 U.S.C.A. § 253(a),(c) (West 1987 and Supp. 2006); see 48 C.F.R. 2.101 for the definition of sole source acquisition.) Sole-source awards to contractors for items and services within competitive acquisition areas are not authorized by the statute.

Gap-Filling Proposal

CMS proposes to modify its current gap-filling procedures and instead use far more subjective criteria in developing payment levels for new products and for new HCPCs. We agree that the current gap-filling practices should be revised – they are not well understood and probably result in payment levels that are significantly lower than the payment levels found in the private sector.

That said, we must strongly oppose the particular modification proposed by CMS. CMS simply listed a number of general factors for determining gap filling amounts, without any indication how they would be used. CMS is proposing to give itself what appears to be virtually unfettered authority to choose and apply payment criteria for any new product. Perhaps of greater concern is CMS' intention to apply this broad authority to new codes. It would appear that CMS could trigger this authority by simply modifying a HCPC for a product category, thus reorganizing and creating a new code. By doing so, CMS could set aside the existing fee schedule and substitute its own judgment as to what is a reasonable payment level based on the general factors listed in the proposed rule.

Congress has provided CMS with the specific authority to modify payment amounts if CMS determines after a prescribed analysis that the payment levels are grossly excessive or grossly deficient. Section 1842(b)(8) of the Act. This so-called "inherent reasonableness" authority is set out at 42 CFR 405.502 and includes a number of procedural and substantive safeguards to ensure that CMS and its contractors do not act arbitrarily. None of those safeguards is present in the CMS proposal on gap-filling. The scope and limitations of CMS' inherent reasonableness authority will be meaningless if CMS can use its gap-filling authority to change payment levels for existing products merely by first changing the HCPC codes for those products.

Inherent reasonableness may only be used if payment levels are determined to be grossly excessive (or grossly deficient), which CMS has defined by regulation as being at least 15% more or less than a reasonable level of payment. CMS must use valid and reliable data in its analysis and its calculation of new payment levels. Part B suppliers must have the opportunity to comment on the finding that payments are grossly excessive and on the new payment level determined by CMS or its carriers. In addition, if CMS seeks to make an adjustment that will have a significant effect on a substantial number of small suppliers, it must publish an analysis in the Federal Register pursuant to the Regulatory Flexibility Act.

Further, CMS has defined to some extent how it will interpret various factors in its application of inherent reasonableness. CMS and its carriers also must consider the effects on the Medicare program, including

1. The effects on the Medicare program, including costs, savings, assignment rates, beneficiary liability, and quality of care.

2. What entities would be affected, such as classes of providers or suppliers and beneficiaries.

3. How significantly would these entities be affected.

4. How would the adjustment affect beneficiary access to items or services.

In addition, the carriers must evaluate the comments received on the proposed notice. And, to ensure the use of valid and reliable data, CMS or the carrier must meet the following criteria to the extent applicable:

(i) Develop written guidelines for data collection and analysis.

(ii) Ensure consistency in any survey to collect and analyze pricing data.

(iii) Develop a consistent set of survey questions to use when requesting retail prices.

(iv) Ensure that sampled prices fully represent the range of prices nationally.

(v) Consider the geographic distribution of Medicare beneficiaries.

(vi) Consider relative prices in the various localities to ensure that an appropriate mix of areas with high, medium, and low consumer prices was included.

(vii) Consider criteria to define populous State, less populous State, urban area, and rural area.

(viii) Consider a consistent approach in selecting retail outlets within selected cities.

(ix) Consider whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population.

(x) Consider the products generally used by beneficiaries and collect prices of these products.

(xi) When using wholesale costs, consider the cost of the services necessary to furnish a product to beneficiaries.

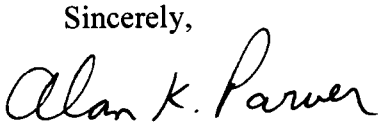
Additional factors apply if CMS seeks to modify payment levels by more than 15% in a given year. Yet, none of these processes and criteria, which result directly from several statutes and recommendations of the Government Accountability Office, will have any applicability if CMS chooses to use its gap-filling authority instead of its inherent reasonableness authority to adjust payment rates. We do not believe CMS has the legal authority to modify payment levels for existing, covered products by manipulating the particular HCPCs for those products. Where Congress sought to provide CMS with the authority to modify payment levels, it did so in an explicit and structured manner. The proposed rule on this issue appears to be little more than a reach for additional authority to undertake actions that could be precluded under the inherent reasonableness authority or would be more time-consuming under that authority. Congress, by its actions on inherent reasonableness, effectively limited CMS to the scope of that authority.

Thus, the proposed rule would act to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS could create a new HCPCS category, use the vague "functional technology assessment" to compare older, similar products already on the market to newer products and bundle all of these into the new HCPCS. CMS could then use the revised "gap filling" process to reprice the existing products and new products establishing what amounts to a revised payment. Since there is already a statutory avenue for addressing excessive or deficient payment under the "inherent reasonableness" methodology, the new regulations would at best be duplicative of these provisions. At worst, they would act as a contravention of existing law.

There may well be a need for the development of new codes in the future, and we are not suggesting that the current coding structure is somehow untouchable. We strongly believe, however, that if and when coding modifications must occur there must be a far more formal, transparent and inclusive process for determining reimbursement for the items in the new codes than is proposed in this regulation.

Thank you for the opportunity to provide comments on the proposed rule. NAIT looks forward to working with CMS as this program unfolds in the coming months and years. If you have any questions or desire additional information, please contact me at 202-624-7225.

Sincerely,



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Bayer HealthCare

June 29, 2006

By Hand Delivery

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Re: CMS-1270-P: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Medicare Prescription Drug Benefit

Dear Administrator McClellan:

Bayer HealthCare ("Bayer") submits these comments to the Proposed Rule titled "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (CMS-1270-P). We appreciate the Centers for Medicare and Medicaid Services' ("CMS") careful consideration of these comments and other suggestions from the supplier, physician, and patient communities. We commend CMS for its thoughtful implementation of the competitive bidding program and look forward to working together to develop an effective program that reduces costs for the Medicare program without compromising access to the quality diabetes care management products currently available to beneficiaries.

We are impressed by CMS' energetic efforts to plan the implementation of the competitive bidding program as Congress intended. We appreciate CMS requesting comments on these proposals and we would like to take the opportunity to offer specific suggestions with respect to the provision of durable medical equipment ("DME") products and supplies to beneficiaries with diabetes and more general comments to facilitate the overall implementation of the competitive bidding program. Due to the unique issues that are associated with the clinical

management of diabetes, we believe that it is critical that CMS incorporate the following thoughts and suggestions into the final rule.

Summary of Bayer Recommendations:

- CMS should exclude blood glucose monitors and other diabetes-related supplies in the initial phase of the competitive bidding program to ensure a smooth transition of these products into the new supply system since uninterrupted access to supplies is critical for management of diabetes and the prevention of complications associated with the disease.
- CMS should recognize the longstanding policy of the United States government to give small businesses an opportunity to compete for government contracts by declining to waive provisions of the Federal Acquisition Regulation that protect the interests of small businesses. In addition CMS must establish a means of providing assistance and information to beneficiaries and evaluating their satisfaction during and after the implementation process in order to maintain access to and quality of DME items supplied through competitive bidding.
- CMS should further ensure the participation of smaller suppliers by strengthening its networking provisions to give small businesses a meaningful opportunity to participate in the bidding process, which will benefit the process as a whole by expanding the pool of available bidders.
- CMS should continue to respect the clinical expertise of physicians and the individual needs of beneficiaries by ensuring that successful bid suppliers provide the brand and model of equipment and supplies that have been prescribed by the treating physician just as CMS required of its Medicare Part D plan providers.
- CMS should abandon the provision of rebates to beneficiaries by suppliers who bid below the single payment price due to the unfair advantage that these suppliers will have over other suppliers who are unable to provide such rebates and the serious fraud and abuse risks that would result from the implementation of this provision.
- CMS should not import bid prices into non-bid areas because of the lack of an economically sound method for transferring prices to a fundamentally different economic system.
- CMS should reconsider its requirement that non-competitive bidding suppliers receive the payment amount set by the beneficiaries' home competitive bidding area ("CBA") when the suppliers are providing supplies to beneficiaries who are traveling to other CBAs or to non-bid areas, in order to minimize the risk of refusal of local suppliers to provide products at rates that are lower than what they would normally receive for an item.

- CMS should more explicitly articulate the fundamental technical aspects of the bidding process and discuss how it will evaluate the sustainability of bids. CMS should seriously consider basing the pivotal bid of each competitive bid area on 125 percent of projected demand to avoid shortfall in supplies.
- CMS should reconsider use of a pivotal bid to establish the payment amount for an item because this methodology carries an inherent risk of failing to secure contracts with an adequate number of suppliers.
- CMS should reconsider its desire to force all beneficiaries to participate in a nationwide mail order system given the important role of local retail pharmacists in disease management and both the preference of, and convenience for, many beneficiaries who would chose to continue obtaining their diabetes-related supplies, which are widely available at the local retail level, from their neighborhood pharmacy. We recommend that CMS adopt the same geographic access provisions as CMS applied under the Medicare Part D program.
- CMS should use the CPI-health index to make inflation increase calculations more accurate, and CMS should explain how this provision operates for items that are currently under a price freeze in the fee schedule.
- CMS should modify the change in ownership provision by removing the sixty-day prior notification requirement and allowing successor entities to continue supplying beneficiaries in a CBA as the winning contract supplier as long as they meet the general requirements for contract suppliers.
- CMS should quickly establish thorough quality standards to assist suppliers in submitting the most accurate bid possible and CMS should set a separate comment period on its quality standards to more fully examine the impact and interplay of the quality standards with the competitive bidding program.
- CMS should exclude new DMEPOS items from the competitive bidding process to allow for the integration and acceptance of the new technology into the medical community before adding it to the list of bid items and applying the proposed gap-filling methodology. CMS should hold a second comment period to address the complexities related to the gap-filling process.
- CMS must establish an emergency provision that will allow beneficiaries to obtain needed DMEPOS from their old suppliers during the transition to the new supply system to avoid short term access issues.

I. Serious Health Consequences of Diabetes and Need to Provide Quality Diabetes-Related Supplies and Services

Bayer is a major manufacturer of blood glucose monitoring equipment and supplies that has been providing high quality diabetes-related products to generations of beneficiaries. Bayer's commitment to supplying patients with diabetes with the necessary blood glucose monitoring equipment and supplies has played a role in fighting the growing epidemic of diabetes. This is because, unlike most durable medical equipment, blood glucose monitors are diagnostic as well as therapeutic. Blood glucose monitors enable beneficiaries with diabetes to accurately self-diagnose their blood glucose levels, which in turn allows them to achieve desired therapeutic results by altering their diet or medication dosages. Medicare beneficiaries depend on wide access to high quality diabetes-related supplies and services to ensure their long-term welfare.

Diabetes, both Type 1 and Type 2, is characterized by elevated levels of sugar in the blood. Type 1 diabetes, a malfunction of the immune system, affects approximately a million people in the United States.[1] In Type 1, the immune system destroys the cells in the pancreas that make insulin.[2] In Type 2, the body's cells are not sufficiently receptive to insulin, or the pancreas makes too little of it, or both.[3] Approximately 95 percent of all cases are Type 2 diabetes.[4] This is of concern because Type 2 diabetes afflicts roughly 20 million Americans and is the nation's fastest growing health problem.[5]

Educators and public health experts are alarmed by the explosive growth of diabetes as it continues to be the only major disease with a death rate that is still rising.[6] The deadly disease now contributes to the deaths of 225,000 Americans each year.[7] The American Public Health Association has stated that diabetes "is clearly one of the most important threats facing us."[8] The American Diabetes Association has noted that the disease could actually lower the average life expectancy of Americans for the first time in more than a century.[9]

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[1] *See* Richard Perez-Pena, *Beyond 'I'm a Diabetic,' Little Common Ground*, N.Y. TIMES, May 17, 2006.
[2] *See* N.R. Kleinfield, *Diabetes and Its Awful Toll Quietly Emerge as a Crisis*, N.Y. TIMES, Jan. 9, 2006.
[3] *See id.*
[4] *See id.*
[5] *See* Perez-Pena, *Beyond 'I'm a Diabetic,' Little Common Ground.*
[6] *See* Ian Urbina, *Rising Diabetes Threat Meets a Falling Budget*, N.Y. TIMES, May 16, 2006.
[7] *See id.*
[8] *See* Urbina, *Rising Diabetes.*
[9] *See* N.R. Kleinfield, *Diabetes and Its Awful Toll Quietly Emerge as a Crisis*, N.Y. TIMES, Jan. 9, 2006.

Diabetes is the leading cause of kidney failure, blindness and non-traumatic amputation.[10] Just in the city of New York alone, there are roughly 2,000 largely avoidable diabetes-related amputations every year.[11] Patients with diabetes are two to four times more likely than others to develop heart disease or have a stroke, and three times more likely to die of complications from flu or pneumonia, according to the Centers for Disease Control ("CDC").[12] According to the CDC, during a twenty-four hour period, 4,100 people are diagnosed with diabetes; 230 amputations occur in people with diabetes; 120 people enter end-stage kidney disease programs; and 55 people go blind.[13]

Diabetes is destructive not only to an individual's body but also poses serious economic and social consequences. The American Diabetes Association estimates that the disease costs the U.S. economy about $132 billion per year for treatment and lost productivity at work.[14] Health officials fear that within a generation or so, a huge wave of new cases could overwhelm the public health system and engulf growing numbers of the population where cities will be crippled by the disease's damage.[15]

Although diabetes is a chronic disease, careful and consistent blood glucose monitoring can reduce negative health outcomes. Increased blood glucose levels affect every major organ in the body, and failure to adequately control blood glucose levels can lead to kidney failure, blindness, heart attacks, strokes, loss of feeling in the hands and feet, and decreased blood flow in the legs.[16] Loss of sensation and decreased blood flow in the legs can lead to ulcers, gangrene, and ultimately amputation of the lower extremities. These serious complications of diabetes can be minimized or at least delayed when the disease is controlled. In fact, diabetes is recognized as one chronic disease for which quality improvement efforts can make great strides.[17]

The most vital part of controlling diabetes is accurate and consistent daily self-monitoring of blood glucose levels. Blood glucose monitors allow beneficiaries with diabetes to check their blood glucose level to ensure that it is neither too high or too low. This daily diagnostic testing is the only way that

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[10] *See id.*
[11] *See* Ian Urbina, *In the Treatment of Diabetes, Success Often Does Not Pay*, N.Y. TIMES, Jan. 11, 2006.
[12] *See* Kleinfield, *Diabetes and Its Awful Toll Quietly Emerge as a Crisis.*
[13] *See id.*
[14] *See* Urbina, *supra* note 11.
[15] *See* Kleinfield, *supra* note 12.
[16] *See* CDC, *Prevent and Control Diabetes*, at 4, *available at* http://www.cdc.gov/diabetes/pubs/prevent.htm (last visited Jun. 15, 2006).
[17] *See* HHS, Agency for Healthcare Research and Quality (AHRQ), *Diabetes Care Quality Improvement: A Resource Guide for State Action*, No. 04-0072, at 18 (Sept. 2004), *available at* http://www.ahrq.gov/qual/diabqguide.pdf (last visited Jun. 14, 2006).

beneficiaries have to maintain their blood glucose level as close as possible to the normal range, which is the key to controlling their disease and minimizing the risk of complications. The first step for every beneficiary with diabetes in managing their disease and avoiding these potential complications is to obtain the correct glucose monitor. Selecting the right monitor is a critical and personal decision that a patient and doctor must make together based on the patient's individual needs. Not all monitors are the same. For example, some have features that allow older patients with arthritis to maneuver and handle the monitor more easily. Some monitors have larger screens that can be read by patients with visual impairments.

Tailoring the blood glucose monitor to the needs of patients so that patients can consistently and accurately monitor their diabetes is essential. Once a beneficiary is using a device that is suited to his or her needs, it is important that the beneficiary continues to have access to the strips and other supplies that are unique to the monitoring system that he or she is using. If the blood glucose monitoring system does not match the beneficiary's needs, the beneficiary may not be motivated to continue self-testing. We urge CMS to remember, when determining how best to implement the competitive bidding process for durable medical equipment, the unique issues associated with beneficiaries with diabetes and the high risk of harm that may result if these beneficiaries do not have access to appropriate, high-quality diabetes monitoring supplies to help keep in check what is one of the most significant public health concerns.

II. Competitive Bidding Areas (Proposed § 414.410)

Given the lack of statutory mandate to include diabetes care items in the 2007 competitive bidding program and the lack of inclusion of diabetes care items through the demonstration projects, exclusion of the diabetes-related supplies in the 2007 phase of the competitive bidding program is warranted. We encourage CMS to implement competitive bidding for diabetes-related supplies in a controlled manner within a limited area.

If CMS decides to include diabetes-related supplies in the competitive bidding program, we request that CMS exercise its discretion to exclude diabetes-related supplies from the competitive bidding program in this initial phase of the implementation. The Medicare Modernization Act ("MMA") clearly does not require CMS to include diabetes care supplies within the ten Metropolitan Statistical Areas ("MSAs") selected for competitive bidding in 2007. Since CMS has not yet identified the specific products that will be included in the 2007 phase, it can easily and should reserve the diabetes-related items for a later phase, consistent with the discretionary authority granted by the MMA.

Since the San Antonio and Polk County demonstration projects did not include diabetes care items, CMS simply has insufficient history to proceed with

these products in the ten largest MSAs in 2007. Without the experience afforded by a demonstration project, the potential for beneficiary harm exists due to potential barriers to access and increased risk of beneficiary non-compliance. The competitive bidding report issued by the Government Accountability Office ("GAO") noted CMS' decision not to include glucose monitors and supplies in the San Antonio and Polk County locations "because beneficiaries must frequently use brand-name supplies with their monitors."[18] CMS was rightly concerned that there are complicated operational issues for implementing competitive bidding for diabetes-related supplies due to certain beneficiaries' need for specific brands of glucose test strips.[19] Unfortunately, CMS still does not have any information on how access to diabetes-related supplies will be affected by the competitive bidding program. Furthermore, CMS has limited knowledge of how the quality standards will affect the availability of a wide pool of suppliers who are able to provide diabetes-related supplies or their willingness to participate in the program itself. The additional information available after a demonstration project for diabetes-related supplies or a limited implementation phase can be invaluable in anticipating unforeseen problems with beneficiary access and assisting CMS in maximizing its cost savings.

Despite CMS' extraordinary effort and careful consideration in establishing the Medicare Part D program, there were unexpected operational issues that arose during the course of implementation. That experience should impart CMS with a sense of caution about proceeding with sweeping programmatic changes without significant data on the impact of those changes.

If and when CMS decides to include diabetes-related supplies in the competitive bidding program, Bayer recommends that CMS implement competitive bidding for blood glucose monitoring items in a controlled manner initially within a limited area to test access, quality and cost savings. A thoughtfully designed, limited implementation plan is entirely consistent with the MMA. Careful control and analysis of the data derived from such an approach will support CMS in implementing a successful competitive bidding program for diabetes care management supplies. More importantly, controlled implementation will also provide greater protection to beneficiaries who depend on access to quality diabetes care management products. The long-term health and wellness of beneficiaries with diabetes cannot be placed in jeopardy by an inadequate program design or flawed implementation.

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[18] *See* GAO, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies*, Sep. 2004, at 10.
[19] *See id.*

III. Implementation Contractor (Proposed § 414.406) - Federal Acquisition Regulation Waiver and Beneficiary Satisfaction

CMS intends to use one or more Competitive Bidding Implementation Contractors ("CBICs") to help with design, oversight, access and quality management, bid evaluation, and beneficiary outreach and education for the competitive bidding program. We have two concerns regarding the Proposed Rule's description of CMS' use of CBICs. We believe that waiver of all requirements of the Federal Acquisition Regulation ("FAR")[20] will decrease the opportunity for small businesses to compete with larger firms to become a contract supplier. We believe that CMS must provide, through the CBICs, easily accessible help for beneficiaries who may experience difficulties integrating into the new system. In addition, CMS must provide a means for beneficiaries to rate their experience with suppliers in order to maintain high quality service.

A. Federal Acquisition Regulation Waiver

Bayer opposes the waiver of the FAR to the extent that small business interests are not adequately protected by such waiver. Such a waiver would both undermine the Small Business Act and the effectiveness of competitive bidding by decreasing the pool of suppliers and, ultimately, reducing the potential for cost savings.

It is the policy of the United States to give small businesses the opportunity to participate in federal procurements, both as prime contractors and as subcontractors, pursuant to the Small Business Act, Pub. L. 85-536, enacted in 1958, as well as the FAR. In addition, it is the policy of the federal government to encourage the participation of socially and economically disadvantaged businesses in federal procurements.

The Small Business Act best explains the basis for a longstanding policy favoring significant participation of small businesses in federal procurements. In relevant part, it states:

> The essence of the American economic system of private enterprise is free competition. Only through full and free competition can free markets, free entry into business, and opportunities for the expression and growth of personal initiative and individual judgment be assured. The preservation and expansion of such competition is basic not only to the economic well-being but to the security of this nation. Such security and well-being cannot be realized unless the actual and potential capacity of small business is encouraged and developed. It is

[20] *See* 48 C.F.R. ch. 1.

> the declared policy of the Congress that the Government should aid, counsel, assist, and protect, insofar as is possible, the interests of small-business concerns in order to preserve free competitive enterprise, to insure that a fair proportion of the total purchases and contracts or subcontracts for property and services for the Government (including but not limited to contracts or subcontracts for maintenance, repair, and construction) be placed with small-business enterprises, to insure that a fair proportion of the total sales of Government property be made to such enterprises, and to maintain and strengthen the overall economy of the Nation.[21]

This national policy, which reflects the intent and will of the Congress, is implemented through various provisions in the FAR regulations. For example, FAR § 19.201(a) states: "It is the policy of the Government to provide maximum practicable opportunities in its acquisitions to small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns. Such concerns [small, disadvantaged, or women-owned businesses] shall also have the maximum practicable opportunity to participate as subcontractors in the contracts awarded by any executive agency, consistent with efficient contract performance."[22]

Consistent with this policy, government contracting officers are required to include clauses entitled "Utilization of Small Business Concerns"[23] and "Small Business Subcontracting Plan"[24] in various solicitations and contracts. Undoubtedly, the policy to favor small business concerns and the interests of socially and economically disadvantaged businesses must be considered "to the fullest extent consistent with contract performance."[25] Under the subcontracting clause, a bidder must propose a subcontracting plan that includes, among other things, goals for subcontracting dollars to be spent related to small and small disadvantaged businesses and a description of the bidder's efforts to ensure that such businesses will have an equitable opportunity to compete for subcontracts.

In sum, the policy of the federal government, as reflected in both the Small Business Act and the FAR, is to provide small and small disadvantaged businesses with a fair opportunity to participate in federal procurements of all types. Such participation is essential to the continued growth of the national economy and, as stated in the Small Business Act, to the security of the United States. Any

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[21] *See* 15 U.S.C. § 631(a).
[22] *See also* FAR § 19.202-1 ("Small business concerns shall be afforded an equitable opportunity to compete for all contracts that they can perform to the extent consistent with the Government's interest.").
[23] *See* FAR § 52.219-8.
[24] *See* FAR § 52.219-9.
[25] *See* FAR § 52.219 8(b).

proposal that would eliminate or minimize such opportunities, such as a proposal that would waive, on a blanket basis, the FAR provisions discussed above and other FAR provisions requiring the participation of such small businesses, would be contrary to, and undermine, this longstanding and important national policy. It also would reduce competition, limit the number of bidders, and thereby operate to undermine the effectiveness of competitive bidding.

B. Monitoring Beneficiary Satisfaction With CBICs

Bayer encourages CMS to specify clearly in the final rule or require CBICs to identify the necessary telephone and internet resources that beneficiaries may use to raise questions and concerns related to the competitive bidding program. It is extremely important that beneficiaries have readily available access to information during their transition from their former suppliers to their new contract suppliers. Beneficiaries must be able to report the myriad of difficulties that they may face as the DMEPOS competitive bidding program is implemented for the first time, including problems with locating a new supplier or service quality concerns. We believe that the risk of negative press reports, even despite CMS' excellent efforts to launch this program, concerning the competitive bidding program will be significantly reduced if such contact information is readily available and apparent to the beneficiary population.

In addition, we strongly recommend that CMS establish a survey mechanism so that beneficiaries will be able to rate their satisfaction with the suppliers that they have chosen, as recommended by the September 2004 GAO report. While the Proposed Rule states that CMS may make available information on products for which suppliers will give rebates, it fails to provide a method to obtain feedback from beneficiaries regarding their satisfaction level with their contract supplier and disseminating this valuable information to other beneficiaries. Providing this information regarding the quality of service will assist beneficiaries in making an informed choice when deciding who they would like to fill their DMEPOS needs. The GAO report on competitive bidding recommended CMS' adoption of a survey program and stated that "routine monitoring of beneficiaries' concerns, complaints, and satisfaction can be used as a tool to help ensure that beneficiaries continue to have access to quality items."[26] We agree that such an evaluation system is essential to maintaining high quality of care long-term. Without such feedback, CBICs will be ill-equipped to judge, and thus monitor, either the quality of products that suppliers are providing or the accessibility of needed supplies to beneficiaries.

[26] *See* GAO, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies*, Sep. 2004, at 17.

IV. Opportunity for Networks (Proposed § 414.418)

The Proposed Rule allows suppliers to form networks in order to submit a single bid for certain product categories. We commend CMS for proposing various opportunities to encourage the participation of smaller suppliers in the competitive bidding program. We are encouraged by CMS' willingness to consider suggestions regarding various aspects of forming potential networks, including the types of legal entities that should be allowed to submit single bids for a product category under the competitive bidding process. We appreciate CMS' concerns regarding anti-competitive issues and value its efforts to ensure that networks will be formed in an appropriate, efficient fashion that serves the needs of beneficiaries. However, significant changes to the proposed networking rules are necessary to make them viable and effective.

A. Support for Conditions That Networks Must Satisfy

1. *Independent Eligibility to Bid*

We generally support CMS' articulated conditions for potential networks that are considering the submission of a single bid. In particular, we support the requirements that each member independently must be able to comply with all necessary accreditation and quality standards. We believe this rule is important to retain in the final rule.

2. *Financial Standards*

We believe that, consistent with the antitrust guidance regarding financially integrated joint ventures, CMS should permit networks, whether through appropriate insurance or otherwise, to meet the applicable financial standards on a network basis. This will permit smaller suppliers a meaningful opportunity to participate. By increasing the number of potential bidders, this modification will further ensure cost savings.

3. *Need for Further Safeguards to Ensure Quality Service and Items*

We believe CMS should implement further safeguards to prevent networks from being formed that do not provide beneficiaries with quality service and items. We urge CMS to closely analyze bids submitted by networks to verify that the information collected and provided accurately reflects the services available across the bidder's geographic area of operation.

B. Reservation of Network Provisions for Smaller Suppliers and Problems with the Twenty Percent Limitation

As written, the network provisions are not adequately reserved as a mechanism for smaller supplier bidding. Small suppliers should be the focus of the network provisions because such a focus would increase the pool of bidders, help to reduce program costs, and reflect the intent of Congress. We seek CMS' clarification on whether the network provisions apply to big suppliers or chains, given the ambiguity on the face of the Proposed Rule.

The Proposed Rule and the twenty percent limitation ignore the dynamic nature of these markets and appear to be designed to punish the suppliers who are most successful at meeting the needs of consumers. For example, if Network A is created in the first year of competitive bidding from suppliers who collectively have nineteen percent of the market, and Network A outperforms all of its competitors such that thirty percent of consumers choose to buy from it, it would appear that the "reward" for excellent service would be to require the break up of Network A in the second year of the competitive bidding program so that Network A's Medicare market share does not exceed the twenty percent ceiling.

The notion of an across-the-board twenty percent ceiling for networks is itself inconsistent with antitrust doctrine. Although antitrust review is highly dependent upon the facts found in specific markets, federal antitrust agencies have often acknowledged that, in various situations, market shares much higher than twenty percent pose no serious risk of anticompetitive conduct or consequences. CMS should set forth a sliding scale that exceeds twenty percent dependent upon various factors (such as the size of the independent entities in the market with which the network must compete) or permit networks to participate above twenty percent on an assumption of the antitrust risk basis.

C. Allowing Network Members to Bid Individually

Possible network members should not be forbidden from also bidding individually. This limitation on allowing network members to bid individually, in effect, discourages smaller suppliers from using the network option. This proposal, furthermore, poses a risk of threatening the ability of competitive bidding from being implemented in any area that does have network bids, as failure of the network bid could lead to the exclusion of so many suppliers as to deny CMS the necessary number of suppliers to serve the area adequately.

D. Providing Appropriate Time to Allow Small Suppliers to Create Networks and More Antitrust Guidance

Exploring the idea of establishing networks and coordinating such efforts will be an extremely time-consuming process. It is vital that CMS provide

adequate time for implementation of the networking provision. Small suppliers must not only locate appropriate networking partners but they must also select an entity that will coordinate the price information in a manner consistent with antitrust laws.

The current antitrust rules appear to require small suppliers to employ a "messenger model" in which a third-party will serve as the data collector that would not release the prices offered by other members of the network. We seek further clarification from CMS regarding the need to use a messenger model. We request that CMS work with antitrust authorities to provide additional guidance that would allow unimpeded financial and clinical integration of networks.

V. Physician Authorization/Treating Practitioner (Proposed § 414.420)

The Proposed Rule authorizes the Secretary to establish a process for certain items under which a physician may prescribe a particular brand or mode of delivery of an item within a particular HCPCS code if that physician or treating practitioner determines that use of that particular item would avoid an adverse medical outcome for the patient. When a specific item or mode of delivery is requested, contract suppliers would be required to furnish that item or mode of delivery, assist the beneficiary in locating another contract supplier within the competitive bidding area ("CBA") that can provide the particular item, or consult with the physician or treating practitioner to find a suitable alternative product or mode of delivery. The Proposed Rule requires the physician or treating practitioner who is willing to revise the order to memorialize it in a revised written prescription.

Bayer is supportive of a mechanism to allow physicians or treating practitioners to tailor medical treatment to specific patient needs by recommending specific products or modes of delivery. Indeed, we believe that this element of the proposal is absolutely essential to the appropriate implementation of competitive bidding and, particularly, the implementation of the program in a fashion that ensures a minimally acceptable level of quality. This mechanism is required to ensure that quality DMEPOS products become available to beneficiaries with variable medical needs.

The differences in glucose monitors, for example, can be critically important for many Medicare beneficiaries. Health care professionals consider many factors when selecting a diabetes care management system for a beneficiary with diabetes. These factors include the amount of blood required to perform a test if the beneficiary has difficulty obtaining a blood sample, the test strip size if the beneficiary has dexterity problems, the blood hematocrit range of the test if the beneficiary has a medical condition causing a low blood hematocrit, the size of the system display if the beneficiary has visual acuity problems, and data management features if the beneficiary has difficulty manually recording results. Unless the health care professional is able to choose the product that the health care professional

believes best serves the needs of the beneficiary with diabetes, the ability of the beneficiary to comply with the diabetes care treatment plan set forth by the health care professional is at risk. Given the limitation on multiple purchases of monitors in a given period under current DMEPOS policy, this would effectively result in many beneficiaries not having their needs met.

Thus, this type of consequence, the hindrance or failure of the patient's ability to comply with a diabetes care regimen, clearly constitutes an adverse medical outcome for patients with diabetes. We are concerned that contract suppliers will not appreciate or ignore the significant health impact that a particular type of blood glucose monitor will make on a certain beneficiary, particularly those with manual dexterity or visual impairments. CMS has the obligation to explain to the contract suppliers what constitutes an "adverse medical outcome" as part of its overarching mandate to protect beneficiary welfare and their access to essential medical products. This is consistent with CMS' actions in the Medicare Part D context where CMS was careful to explain to Part D contractors what CMS' expectations were in relation to appropriate beneficiary care such that Part D contractors could implement only limited cost control measures so as not to jeopardize the quality of services and access to necessary products. We request that CMS explicitly state in the final rule that the differences in diabetes care products may help avoid adverse medical outcomes for certain beneficiaries with diabetes under appropriate physician supervision and judgment.

In order for the protection afforded to beneficiaries by this provision to work appropriately and as intended, CMS must ensure that physicians or treating practitioners will be able to request an item through a simple process that is not burdensome to the physicians or treating practitioners. If the process used to implement this safeguard is burdensome, the process will discourage use of the safeguard and, thereby, result in the very problems that the safeguard was intended to prevent in the first instance.

VI. Rebate Program (Proposed § 414.416(c))

CMS proposes that contract suppliers that submitted bids for an individual item below the single payment amount should be permitted to provide beneficiaries with a rebate. The rebate may be equal to the difference between their actual bid amount and the single payment amount. The proposal does not contain provisions that condition the receipt of rebates on the financial need of beneficiaries, so there are no restrictions on which beneficiaries might receive the rebates. In addition, the proposal does not limit the amount of the rebate, other than stipulating that it not exceed the difference between a supplier's bid price and the single payment amount for that item. Thus, there is no correlation between the amount of the rebate and the beneficiary's co-payment or deductible. No proposition is in place to ensure that the rebate does not exceed the beneficiary's expenses.

While we appreciate CMS' laudable goal of trying to minimize beneficiary expenses, we think that the proposal should not be adopted. We have serious concerns about the implementation of Section 414.416(c). We believe that this proposal should be abandoned because it presents unacceptable fraud and abuse risks and will undermine the ability of successful bidders to compete on an equal basis.

The provision lacks any mechanism for ensuring that these rebates do not constitute an inducement for beneficiaries to use services unnecessarily or to favor certain providers over others in violation of both the Anti-Kickback Statute and the Anti-Beneficiary Inducement/Civil Monetary Penalty Provision. The proposed provision is simply and flatly inconsistent with the policies articulated by Congress, CMS, and OIG as expressed repeatedly in statutes, regulations, advisory opinions, and fraud alerts.

We believe that providing beneficiaries with monetary rebates will lead to increased utilization and spending, depriving the Medicare program of the very savings competitive bidding is designed to achieve. The use of rebates is fundamentally inconsistent with the cost-saving rationale that led Congress to pass the competitive bidding provision.

A. Good Faith Financial Need for a Waiver of a Co-Payment to Avoid Civil or Criminal Penalty

The provision of rebates or other remuneration to beneficiaries by healthcare suppliers or providers may violate civil and criminal statutes if it has the effect of influencing a beneficiary's choice of supplier or provider. Under the Anti-Kickback Statute, remuneration of any kind is prohibited if it is intended to reward or induce any order of any item payable under a federally funded health care program, including the Medicare program.[27] Allowing contract suppliers that bid below the single item payment amount to give cash rebates to beneficiaries will inevitably violate this basic criminal law. Although the OIG has permitted the waiver of patient obligations in situations where there is good faith financial need on the part of the beneficiary, the rebate provision is not in any way focused on such circumstances.

Similarly, the Anti-Beneficiary Inducement Prohibition imposes civil penalties on anyone who "offers to or transfers remuneration to any individual eligible for benefits... that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service."[28] Clearly the proposed rebates would affect the choice of supplier. Although the Civil Monetary Penalty provision, like the Anti-Kickback

[27] *See* 42 U.S.C. § 1320a-7b.
[28] *See* 42 U.S.C. § 1320a-7a(a)(5).

Statute, does not apply to good faith financial need waivers, that exception simply cannot justify the CMS proposal.

B. CMS' Position on Beneficiary Remuneration

In a wide variety of contexts, CMS has consistently stated that the offer of remuneration to beneficiaries is inappropriate. CMS' proposed policy permitting rebates to beneficiaries in the absence of any bona fide financial need is particularly surprising, given the dearth of utilization controls at the disposal of the government in the DME context. CMS' competitive bidding proposal is flatly inconsistent with CMS' own recent rejection of need-based patient assistance offered by individual manufacturers in the Part D context, notwithstanding the presence of broad, alternative utilization controls in Part D.

Furthermore, the Proposed Rule allows rebates to be realized by beneficiaries as direct monetary payments. In other contexts, the provision of money or cash equivalents has been rigorously avoided and considered particularly problematic. For example, Medicare Part C's Medicare Advantage rebates do not constitute any direct transfers of funds to beneficiaries and are only applied to supplemental health programs.[29]

A hospital outpatient rebate, allowed under 42 U.S.C. § 1396r–8, is distinguishable from the current proposed competitive bidding rebate because its purpose is to lower co-payments closer to the standard percentage for co-payments for the same services when provided at other sites of service. CMS' current competitive bidding proposal, however, would eliminate all co-payments in some cases and would take the co-payment below the amount that would otherwise typically apply in every case. By eliminating or substantially lowering the financial contribution of beneficiaries, CMS will unintentionally but inevitably increase utilization and overall costs.

C. OIG's Position on Rebates Outside of a Good Faith Financial Need Context

The OIG has consistently advised that waivers of co-payments and deductibles in circumstances analogous to the proposal implicate the fraud and

[29]Section 1854(b)(1)(C)(ii) of the Social Security Act specifies that "A rebate required under this subparagraph shall be provided through the application of the amount of the rebate toward one or more of the following: (I) PROVISION OF SUPPLEMENTAL HEALTH CARE BENEFITS AND PAYMENT FOR PREMIUM FOR SUPPLEMENTAL BENEFITS. . . (II) PAYMENT FOR PREMIUM FOR PRESCRIPTION DRUG COVERAGE. . . (III) PAYMENT TOWARD PART B PREMIUM." The Corresponding regulation, 42 C.F.R. § 422.266, mirrors the language of the statute. It states that "[t]he rebate required under this paragraph must be provided by crediting the rebate amount to one or more of the following: (1) Supplemental health care benefits. . .(2) Payment of premium for prescription drug coverage. . .(3) Payment toward Part B premium." 42 C.F.R. § 422.266(b).

abuse laws.[30] One fraud alert, targeted toward beneficiaries, warned Part B participants to "be wary of 'no out-of-pocket expense' offers," and specifically stated it was aimed at providers who "routinely waive Medicare deductible and co-payment charges."[31] OIG has also issued several advisory opinions regarding waiver of co-payments that consistently state that such waivers implicate the fraud and abuse laws.[32] Yet, this practice the OIG has identified to be problematic is exactly what the Proposed Rule would allow some suppliers to do if they happened to bid below the single payment amount.

In summary, the proposed rebate provision is inconsistent with current policy as it is expressed in the applicable statutes, regulations, and enforcement guidance. It should be rejected because it will lead to increased utilization that will decrease the savings competitive bidding may otherwise generate for the Medicare program.

VII. Authority to Adjust Payments in Other Areas (Proposed § 414.408(e))

CMS proposes to use the payment information determined under the competitive bidding program to adjust the payment amounts for the same DMEPOS in areas not included in the competitive bidding program for covered items furnished in 2009.[33] The proposed rule also states the possible general criteria CMS will use when deciding whether to exercise its authority under Section 1834(a)(1)(F)(ii) of the Social Security Act, which allows CMS to determine if such a course of action would be prudent. The criteria CMS will utilize to determine if it will use competitive DMEPOS prices to adjust prices outside of the bid areas are: (1) the savings needed for particular covered items and (2) the basis for adjustment including both the starting point for any such adjusted price and the method for adjustment. The Proposed Rule does not contain the specific methodology that would be used to adjust payments in other areas.

A. Summary of Bayer's Suggestions

We do not believe that CMS should attempt to use prices from within competitive bidding areas in areas that have not been bid competitively. While use of competitive bid prices outside of bid areas appears to be a plausible way of

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[30] The OIG issued a special fraud alert that unequivocally stated that providers who routinely waive Medicare co-payments may be held liable under the Anti-Kickback Statute. *See* 59 Fed. Reg. 242 (1994). This statement was reaffirmed in a later OIG Advisory Opinion, No. 97-4 (Sept. 1997).

[31] *See* HHS OIG Special Fraud Alert: Routine Waiver of Copayments and Deductibles Under Medicare Part B (May 1991).

[32] *See, e.g.,* OIG, Advisory Opinion No. 97-4 (Sept. 1997) (stating that the failure of a company to attempt to collect co-payments from beneficiaries, where an employer insurer refused to pay them, would be a violation of the Anti-Kickback Statute and Beneficiary Inducement Statute).

[33] *See* 71 Fed. Reg. 25654, 25664 (May 1, 2006).

securing additional savings in theory, in fact it would be very difficult to actually translate bid prices into economically sound prices for use outside of the competitive bid areas. This is because there is no principled way to account for the economic and other differences between competitively bid and non-competitively bid areas.

Even geographically contiguous competitive bid areas that are demographically similar will serve as a poor bases for determining reimbursement for non-competitively bid areas, as the absence of competitive bidding is itself too great and too fundamental a difference. Failure to account for all of these economic factors by attempting to impose bid prices in areas that have not undergone competitive bidding will undoubtedly lead to the unintended result of inadequate access and poor quality of care. CMS also should consider how the lack of CBIC oversight and other educational or administrative resources, which are an inherent part of the activities in competitive bidding areas, will affect the ability of the suppliers to provide quality access for the deflated reimbursement rates. It is a dangerous policy to implement competitive bid prices without a competitive bid process that will bring the necessary safeguards to bear.

B. Competitive Bid Areas Will Have Fundamentally Different Economic Environments Than Areas That Have Not Been Through the Bidding Process

The payment amounts derived from the competitive bidding program are a result of calculations that suppliers will make in anticipation of a greater market share as a consequence of the reduction in the total number of competitors. During the bidding process proposed by CMS, a set number of suppliers is awarded the right to furnish the item to beneficiaries. Suppliers assume that they will experience an increased volume in sales by winning a competitively bid contract. Taking that assumption into account, suppliers will set prices with the understanding that the increased volume can help cover overhead and other fixed costs.

Conversely, the suppliers in areas that have not been through the competitive bidding process cannot be assured that the imposition of a lower price will result in an increased share of Medicare business. There is no way for CMS to eliminate competitors in these areas to compensate suppliers for the lower prices, without going through the bidding process. In fact, there is no way for CMS to know, without undergoing the competitive bidding process, if the suppliers in any given area can meet a higher demand even if some of their competitors chose to leave the market due to the lower prices. Nor is there any way for CMS to predict which suppliers will be able to meet demand at lower prices and still maintain a profitable business. These facts are critical to ensuring that quality products are accessible to all beneficiaries.

Another complicating factor is the high potential for the competitive bidding process to favor large national suppliers as winners in any given bid area

because they are most likely to have the resources to service the increased volume, even at the lower single payment amount. Unless CMS targets only non-bid areas that are also serviced by large national suppliers, it would run the risk of adjusting prices in local areas serviced by small, regional outlets based on bid prices submitted by a different supplier mix. This would be grossly unfair.

All of these differences must be accounted for when setting the price in non-competitive bid areas, even where prices in bid areas locally, regionally, or nationally are or appear to be similar. Due to the fundamentally different assumptions that were the basis of the payment amounts from the competitive bidding program, as discussed above, it is inappropriate to apply them to contexts where the underlying factors are absent. CMS should not rely upon a process and a group of safeguards in some areas where competitive bidding prices apply and then fail to adopt that same process and those same safeguards in other areas where CMS proposes to use those same prices.

Non-bidding areas are fundamentally different than those subject to competitive bidding. Suppliers in areas that have not been through the bidding process should not have the lower bid prices imposed upon them without the attendant increase in volume accomplished through the elimination of competitors, a process that ensures that requisite quality safeguards are in place, and a means to ensure that adequate numbers of suppliers will continue to serve the market, notwithstanding the lower prices.

C. The Mechanisms Suggested in the Proposed Rule Appear to Be Inadequate

The Proposed Rule suggests a percentage adjustment of actual bid prices to account for the differing economic circumstances. The Proposed Rule fails to set out the extent of the proposed adjustment or the nature of the criteria that would be applied in making the adjustment. The lack of basic clarity in the proposal prevents the submission of truly meaningful and substantive comments regarding this issue. However, we believe that a percentage adjustment in any form underestimates the complexity of imposing artificially determined prices onto a free market system.

There is no standard methodology for imposing such artificial prices on a previously supply and demand driven system. Though the prices in a non-bid area are stipulated by the fee schedule, the suppliers in any given area competing for DMEPOS business are those that are able to provide product at the bid price. CMS has no relevant precedence to draw from in applying this kind of adjustment. Certainly a flat percentage adjustment to a bid price will not adequately account for differences in the ability of suppliers in non-bid areas to provide products at prices that suppliers in competitive bid areas have selected.

In summary, the best way to realize needed savings for a given item in areas that have not been through the competitive bidding process is to implement the same competitive bidding process. Failure to do so will undoubtedly lead to quality of care and access issues that stem from artificially imposing prices from a foreign economic system onto a local system that operates in a fundamentally different way. There is no feasible way to account for the differences in economics that will lead to a stable and efficient market for the item whose price is transferred. CMS should not take a risk with such an important benefit by blindly proceeding to apply bid prices in non-bid areas despite the obvious economic and market barriers to carrying out this policy. Such a course of action would be contrary to CMS' mission to "protect and improve beneficiary health" and to "foster high quality care."[34] The only equitable way of applying these payment amounts to non-competitive bidding areas, for both suppliers and beneficiaries, would be for CMS to conduct competitive bidding in that area. Failure to proceed in this fashion runs an unacceptably high risk of leading to quality of care and access issues.

VIII. Requirement to Obtain Competitively Bid Items from a Contract Supplier (Proposed § 414.408(f))

CMS proposes that a beneficiary who is traveling from a CBA to another CBA will be required to obtain supplies from a contract supplier. If the beneficiary travels from a CBA to a region that is not covered by the competitive bidding program, the beneficiary will be required to obtain supplies from a supplier that has a valid Medicare supplier number. The payment to the supplier in either case would be based on the single payment amount for the item in the CBA where the beneficiary maintains a permanent residence.

Bayer is concerned that suppliers across the nation will be affected adversely by this provision. The payment that a supplier may receive for a beneficiary that maintains a permanent residence in a CBA will be most likely lower than what they normally receive in reimbursement. In other words, Medicare suppliers that are providing services outside of the CBA will be forced to accept pricing that is lower than normal for servicing that beneficiary. Such non-competitive bidding suppliers will not have the increased volume to offset the lower pricing, as contract suppliers will within a CBA.

In an effort to minimize unfairness to the non-competitive bidding suppliers, CMS should compensate the supplier that is supplying a beneficiary who has traveled from a CBA to the supplier's region that is not covered by the competitive bidding program the fee schedule amount or, if applicable, the Federal Employee Health Benefit Program schedule amount. If CMS decides to proceed with applying the single payment amount, CMS should make every effort to educate

[34] *See* http://www.cms.hhs.gov/MissionVisionGoals/ (last visited Jun. 13, 2006).

non-competitive bidding suppliers regarding what to expect for payments in such situations. The education on non-competitive bidding suppliers will facilitate the ability of beneficiaries to access the equipment that they need and minimize the risk that non-competitive bidding suppliers will decline to provide services at those same rates in non-competitively bid areas.

IX. Evaluation of Bids (Proposed § 414.414(e)) – Need for Appropriate Technical Bidding Requirements

We recommend that CMS carefully review the capacity of suppliers and establish measures to examine the sustainability of bids.

A. Market Demand and Supplier Capacity (Proposed § 414.414(e))

The Proposed Rule is based upon the speculative proposition that it can accurately predict demand and supply conditions for numerous products in highly fluid and complex markets. Significantly, CMS and other federal agencies have not been able to make these predictions accurately in the past. For example, in the implementation of the Part D program, beneficiaries skewed the estimated demand and supply conditions by overstocking drugs out of concern that there would be unavailability of necessary drugs during the transition period. CMS has not provided any meaningful opportunity in this Proposed Rule to comment on this important question because CMS has not explained how it proposes to address these critically important issues of demand and supply.

A critical aspect of striking the appropriate balance between demand and supply is the capacity of individual contract suppliers to meet the variable needs of an increasing Medicare population. CMS should carefully determine the minimum capacity threshold that contract suppliers must be prepared to meet and consider incorporating an extra margin of 25 percent. This rate is reasonable because this cushion will avoid disruption of services if unanticipated circumstances, such as natural disasters, arise within a specific CBA. Without this additional cushion, it is possible that suppliers may be awarded bids without the ability to appropriately meet beneficiary demand over the course of the contract. Other, more qualified suppliers may be excluded from the program as a result.

Similarly, CMS should consider offering contracts to suppliers beyond the capacity threshold, whatever number that is, and identify supplies so that 125 percent capacity is served.

Once CMS has calculated a reasonable capacity threshold, we urge CMS to scrutinize individual bids to ensure that suppliers can meet the appropriate capacity standards. It should also examine the geographic distribution of contract suppliers within a CBA and secure an adequate number of suppliers to realistically service the entire bidding area. Beneficiaries' needs will not be adequately met if the

number of suppliers necessary to achieve capacity is evaluated by CMS in a manner that unduly restricts available distribution channels. In other words, CMS should consider not only if the supplier can serve the area but also how easily it will be for the beneficiary to actually reach the supplier.

To implement this review in a fair manner, we also request that CMS clarify the expectations related to evaluating "capacity." It is unclear to us whether CMS will be analyzing a supplier's capacity for each item in a product category or the highest volume item in a product category. Will CMS select a supplier who can meet the highest volume capacity in one item, but has significantly reduced capacity for another item in the same category? Given the uncertainty surrounding this important issue, we respectfully ask CMS to provide more information in its final rule.

B. Composite Bids (Proposed § 414.414(e))

The composite bid process creates incentives for a supplier to manipulate the system by submitting low bids on certain items and high bids on others to reach a favorable composite score. We urge CMS to carefully structure the composite bid process to minimize such opportunities for suppliers to present information that will yield a composite score not truly reflective of the costs or the type of services and items that will be provided. Otherwise, CMS may inadvertently exclude qualified suppliers.

We seek further clarification on these issues of demand, supply and sustainability in the final rule promulgated by CMS.

X. Determination of Competitive Bidding Payment Amounts (Proposed § 414.416(b)) – Single Payment Amount

The Proposed Rule contemplates a pivotal bid that would reflect the point at which an adequate number of potential contractors necessary to serve an area had been identified. Under the Proposed Rule, that number of bidders is then offered a contract that each bidder may either accept or reject. This presents the chance, even a likelihood, that the adequate number of suppliers determined by CMS will not, in fact, be available in a given competitive bidding area.

We are concerned that the median determination methodology proposed by CMS contains certain deficiencies that will result in disadvantaging suppliers who have submitted valid and appropriately supported bids. These suppliers will not receive adequate reimbursement to cover their operations in the competitive bidding program. The proposed methodology results in roughly half of the winning suppliers receiving less than they bid for a particular item. This, unfortunately, may translate into a payment level that is below what an excellent supplier offering the greatest capacity may be able to accept.

This methodology is inconsistent with the methodology utilized in the demonstration projects and we are unclear why CMS is rejecting that tested approach. In the demonstration project, each winning supplier received at least as much as the supplier bid. This approach is the least likely to unfairly disadvantage suppliers who submit fair and honest bids, and the most likely to encourage successful bidders to participate in the program. Consistent with the methodology applied in the demonstration projects, we recommend that CMS require that the winning supplier must receive, at a minimum, the payment level that the supplier has bid.

We are also concerned that the Proposed Rule does not provide a mechanism for CMS to examine the sustainability of bids. By this we mean an assessment of whether the bid amount reflects a legitimate estimate of the reimbursement necessary for a supplier to cover its cost during the entire contract period while meeting the relevant quality, delivery, service, scope and similar requirements of the program. A thoughtful review may reveal that the majority of supplier capacity is above the pivotal bid and that the single payment amount is not sustainable or reasonable. In order to address this issue, we recommend that CMS either: (1) perform an analysis that tests the sustainability of the bids before the unsustainable bids pollute the bid pool or (2) re-calculate the single payment amount based on bidders that qualify for and can perform fully under CBA contracts, even if a disqualified bidder was used to determine a pivotal bid.

XI. Nationwide or Regional Mail Order Competitive Bidding Program (Proposed § 414.410(d)(2))

CMS is currently considering the establishment of a nationwide or regional competitive bidding program for certain items such as diabetes-related testing supplies after January 1, 2010. CMS envisions the submission of competitive bids by mail order suppliers in 2010. The proposed implementation of a nationwide or regional mail order competitive bidding program for diabetes-related testing supplies raises patient benefit concerns and small supplier concerns, particularly in light of the lack of the required experience and expertise necessary to implement this proposal with any reasonable confidence. We are concerned that mandatory mail order service for diabetes testing supplies would severely limit patient choice and deny many beneficiaries functional access to these supplies. We also urge CMS to examine closely how a mail order competitive bidding program will affect small businesses.

A. Limited CMS Experience with Diabetes-Related Care Items in Competitive Bidding Program

Given that a number of the components of competitive bidding have not been included in the San Antonio and Polk County demonstration projects, including diabetes care management items, CMS simply has insufficient experience

to proceed with such an ambitious proposal. Significantly, even with respect to those items included in the prior demonstration projects, there is not any mail order channel experience for diabetes-related care items in the competitive bidding program. In light of the significant doubts that exist about CMS' ability to implement competitive bidding successfully, even in its essential, mandated elements, CMS should not unnecessarily complicate the implementation challenge it faces by adding a mail order component to that effort in a premature fashion without the benefit of needed experience and testing of that concept.

B. Impact on Beneficiaries

Broad, mandatory mail order programs for supplying diabetes testing supplies would not be convenient for *all* Medicare beneficiaries, and CMS should make every effort to retain patient choice in treatment options and furnishing of critically necessary supplies in the face of a diabetes epidemic. Contrary to the underlying assumption that mail-order delivery is a "convenience for beneficiaries" in the GAO report,[35] mail-order delivery is just one of multiple channels of distribution that beneficiaries choose to obtain their blood glucose monitoring supplies. The majority of patients obtain many of their diabetes care management supplies at retail pharmacies. We urge CMS to preserve the choices that beneficiaries currently have in the method through which they receive their vital medical supplies for the monitoring and treatment of their diabetes.

Mandatory replacement of all supplies such as test strips and lancets for Medicare beneficiaries through mail order suppliers effectively limits access to these critical items to the poorest and most vulnerable segment of the beneficiary population. As noted above in section I, patients with diabetes already encounter significant hurdles in obtaining adequate test strips and diabetes monitoring supplies and suffer avoidable health consequences.[36] Some Medicare beneficiaries do not have a regular place of residence with secured methods of receiving mail supplies. Other beneficiaries cannot successfully maneuver various phone numbers to seek assistance from mail order suppliers. Medicare beneficiaries greatly benefit from the personal counseling and disease therapy management provided by their retail pharmacists.

Bayer has significant concerns that the premature development of a mail order option will raise issues about the adequacy of patient education and counseling services, such that patient compliance and persistency may be undermined. We request CMS to conduct further studies to ascertain that implementation of such a program will not result in unintended consequences. If

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[35] *See* GAO, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies*, Sep. 2004, at 14.

[36] Ian Urbina, *In the Treatment of Diabetes, Success Often Does Not Pay*, N.Y. TIMES, January 11, 2006.

CMS decides to proceed with the implementation of a mail order competitive bidding program for diabetes-related items, Bayer urges CMS to preserve options for beneficiaries for whom mail order would be difficult and to implement it on a voluntary basis only.

C. Impact on Small Suppliers

Furthermore, a nationwide mail order competitive bidding program will severely limit the participation of small suppliers who specialize in particular regions and lack the capacity to service patients across the nation. This will decrease the parties available to bid, which, in turn, will undermine the ability of competitive biding to secure cost savings.

There is also a concern that fruitful relationships between individual beneficiaries and their suppliers, such as local pharmacies, will be unjustifiably disrupted. Beneficiaries often rely on expertise provided by pharmacists who observe and point out any potential drug interactions and provide invaluable information beyond the dispensing of supplies or medication.

In sum, Bayer challenges the notion that mail order delivery is convenient for all beneficiaries and urges CMS to review carefully the impact that implementation of a nationwide mail order competitive bidding program will have on beneficiaries and small suppliers. Implementation of a broad, mandatory mail order competitive bidding program may jeopardize beneficiaries' access to diabetes-related testing supplies and, ultimately, raise the cost of the federal health care program as beneficiaries with diabetes suffer the ravaging effects of the disease without proper monitoring and access to testing supplies.

XII. Payment Adjustment to Account for Inflation (Proposed § 414.408(b))

CMS proposes to apply an annual inflation update to the single payment amounts established for a competitive bidding program. Beginning with the second year of a competitive bidding contract, CMS will update the single payment amounts by the percentage increase in the CPI-U for the 12-month period ending with June of the preceding calendar year. This is consistent with the method that the DME fee schedule is updated. CMS believes that this proposal will obviate the need for a supplier to consider inflation in the cost of business when submitting its bids for furnishing competitively bid items under a multi-year contract.

While we appreciate CMS' efforts to address the inflation issue, we are concerned that application of an annual inflation rate to the single payment amounts will not adequately take into consideration other factors that may merit an increase in the single payment amounts. The use of the CPI index and not the more relevant CPI-health index will understate the relevant inflation. CMS has used specific

inflation rates in other contexts, as in the inflation factor with end-stage renal disease drugs as implemented in 2004, and should follow that precedent here.

We are also concerned how this inflation factor will apply to items that are currently under a freeze for fiscal years 2007 and 2008.[37] It is our understanding that diabetic testing supply costs are ineligible for inflation factor application since they are class II devices subject to the freeze imposed by statute.[38] We urge CMS to clarify whether the inflation factor would apply notwithstanding the prior restriction. We point out that the inflation freeze in the fee schedule context is distinct from the application of the inflation factor in the competitive bidding program. CMS needs to consider this in its entirety.

XIII. Change in Ownership (Proposed § 414.422(d))

Consolidation in the industry is inevitable as the competitive bidding program is implemented. Thus, the competitive bidding program needs to address this reality and allow for greater adaptability and flexibility in allowing suppliers to change ownership status. The current proposed Section 414.422(d) requires modification so as to avoid onerous restraints on changes of ownership involving contract suppliers.

The Proposed Rule, as it stands, fails to take into consideration the short time period in which acquisitions or mergers often occur in the marketplace. While we appreciate CMS' concern for an appropriate analysis of the change in ownership, we ask that CMS modify the current sixty-day prior notice requirement. Suppliers should have the flexibility to provide notice as the transaction closes or

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[37] *See* 42 U.S.C. § 1395m(a)(14)(H) for 2007— (i) subject to clause (ii), in the case of class III medical devices described in section 360c (a)(1)(C) of title 21, the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and (ii) in the case of covered items not described in clause (i), 0 percentage points; and
42 U.S.C. § 1395m(a)(14)(I) for 2008— (i) subject to clause (ii), in the case of class III medical devices described in section 360c (a)(1)(C) of title 21, the percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and (ii) in the case of covered items not described in clause (i), 0 percentage points; and
42 U.S.C. § 1395m(a)(14)(J) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year.

[38] *See* 21 C.F.R. § 862.1345 "Glucose test system. (a) *Identification.* A glucose test system is a device intended to measure glucose quantitatively in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma. (b) *Classification.* Class II."

when the parties sign a letter of intent if the transaction is due to close in less than a sixty (60) day period.

A successor entity should be allowed to continue supplying beneficiaries in a CBA as the winning contract supplier as long as it meets the general requirements for contract suppliers. While we appreciate CMS' concerns and desire to retain discretion to terminate a successor entity's contract with CMS for failure to comply with the general requirements, we do not think such broad discretion is warranted or consistent with ensuring appropriate access. The removal of any supplier determined to have been necessary to ensure adequate access at the time that contracts are entered into runs the inevitable risk that there will be insufficient suppliers to meet the necessary demand. This risk is unacceptable and unfair where a successor entity is willing to comply with the requirements of the applicable competitive bidding contract.

XIV. Quality Standards and Accreditation (Proposed § 414.414(c))

CMS notes in the Proposed Rule the statutory mandates limiting the award of a contract to entities that fully comply with the quality standards specified by the Secretary. CMS plans to further clarify quality standards at a later time. Bayer fully supports CMS' efforts to award contracts only to suppliers that fully comply with all accreditation requirements and quality standards but encourages CMS to implement the competitive bidding program only after the application of the relevant standards. Quality standards are an important part of CMS' effort to reduce fraud and abuse within the DMEPOS industry and ensure that beneficiaries are receiving high quality items and services.

Bayer, however, does urge CMS to provide further clarification regarding the quality standards that will be relevant to competitive bidders. Stakeholders have had to respond to the Proposed Rule regarding competitive bidding without having had the benefit of knowing the final quality standards. In order for suppliers to submit accurate bids under competitive bidding, suppliers need to be able to identify all fixed and variables costs in order to accurately determine a bid price for competitive bidding. It is unreasonable to expect a supplier to be able to quantify the additional costs incurred by compliance with the new quality standards without having adequate knowledge and experience with the financial reporting, quality standards, and accreditation requirements. CMS should not implement competitive bidding until the quality standards have been fully established and applied.

To allow greater and more substantive dialogue within the industry and medical community, CMS should set a second comment period to allow suppliers to evaluate how the newly issued quality standards will work in conjunction with the competitive bidding program.

XV. Establishing Payment Amounts for New DMEPOS Items (Gap-Filling) (Proposed § 414.210(g))

Bayer is concerned about the broad implications of the changes to the gap-filling process under the Proposed Rule and urges CMS to have a separate comment period to address the complex issues surrounding the gap-filling methodology. Bayer also requests that new technology be excluded from the competitive bidding cycle in which the product is introduced.

CMS has no formal process for establishing reimbursement amounts for new DMEPOS items. Currently, when a new DMEPOS item is introduced, CMS uses an informal and somewhat crude "gap-filling" process to determine the fee schedule rate. Since the product typically has no available historical pricing data, this crude process estimates what the average reasonable charges would have been for the item if Medicare had provided reimbursement during the fee schedule base period. The gap-filled base fees are updated by the covered item updates and are subject to regional fees, and ceiling and floor limitations. In certain circumstances, CMS may calculate the current payment amount by deflating the price of the product and then essentially re-inflating it.

CMS is proposing to establish a formal gap-filling process in the Proposed Rule. This proposal is a significant change to the existing, informal practice. Among other things, CMS plans to discontinue the practice of deflating supplier prices and manufacturer suggested retail prices to the fee schedule base period. CMS also plans to use a functional technology assessment process.

While we support CMS's desire to formalize this process, we strongly encourage CMS to undertake a separate notice and comment period to allow suppliers and other stakeholders to fully address the complicated issues related to this proposal. The changes CMS is proposing and the impact they have on the Medicare DMEPOS fee schedule and the competitive bidding program are significant. The Proposed Rule is not the appropriate place for this discussion.

In addition to our general concern about the timing of this topic, we also believe it is inappropriate for CMS to include new technology and new items, even if subject to a reasonable gap-filling process, in the competitive bidding program. Suppliers did not consider the availability or costs of these items when calculating their bids. It is unfair and unreasonable to assume that these new items will have no material impact on direct and indirect supplier costs. Instead, we recommend that CMS exclude the new technology from the competitive bidding cycle in which the product is introduced or for a defined period of two years after the product is brought to market.

This approach is consistent to what CMS has done in other contexts. When new technology is introduced into the market, there is an inevitable passage

of time before the medical and patient communities accept and integrate the new technology, and the operational costs and benefits are fully realized. To reflect the ordinary course of market acceptance, CMS should not arrive at a gap-filled price immediately after an item is introduced into the market, nor should the item be inserted into the list of products subject to competitive bidding. This slight deferral of inclusion of the new technology is analogous to the management of new technology in the hospital inpatient and outpatient payment systems. In this context, CMS has created temporary APC pass through payments based on acquisition costs to reflect the higher cost of the new technology. These rates are used until such time as that technology can be assessed and the payment rate created under the standard methodology.

For ease of administration, we urge CMS to exclude this new technology from the competitive bidding cycle in which the item is introduced or two years, whichever is longer. We suggest CMS similarly delay calculating the new payment rate for the item under the Medicare fee schedule.

XVI. Payment Basis (Proposed § 414.408)

The Proposed Rule does not appear to contemplate an emergency exception in which beneficiaries may obtain supplies from their original suppliers for a short duration of time under limited circumstances. Bayer is concerned that a grandfathered supplier or a non-contract supplier will refuse to assist the beneficiary who lives within a CBA. The proposed grandfathering provision does not apply to patients with new medical needs and the proposed payment basis provisions do not address situations in which a beneficiary is in dire need of an item or service and is not able to be immediately assisted by the new contract supplier. Thus, we recommend that CMS establish an emergency exception that allows beneficiaries to receive supplies from their current supplier even after the commencement of the competitive bidding program for a short period to ensure that beneficiaries do not have a disruption in their services or supplies.

XVII. Conclusion

We thank CMS for its tremendous efforts in implementing the competitive bidding program in a fair and effective manner. We appreciate this opportunity to share our thoughts and concerns with you. We are happy to discuss any of these issues and welcome any questions that you may have.

Sincerely,

Sandra S. Oliver
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cc: Herb Kuhn
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Re: **Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues [CMS-1270-P]**

Dear Dr. McClellan:

The Electrical Bone Growth Stimulator (EBGS) Coalition appreciates this opportunity to provide specific comments on a provision included in subpart M of the background section of the Notice of Proposed Rulemaking entitled "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues, [CMS-1270-P]" published in the *Federal Register* on May 1, 2006.

The EBGS Coalition is comprised of the three leading manufacturers of external bone growth stimulator devices (noninvasive osteogenic stimulators), which are classified as class III devices under section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act. Our coalition members are Orthofix Incorporated, EBI, and DJO Incorporated (formerly dj Orthopedics, Inc.). Coalition members currently represent 100 percent of the American market for osteogenic stimulators. These devices are used to treat nonunion fractures of the appendicular skeletal system, congenital pseudarthrosis, failed fusions of the appendicular system and to serve as an adjunct to spinal fusions. These devices are all classified by the Food and Drug Administration (FDA) as class III devices and must receive premarket approval by FDA to ensure that they are safe and effective before they can be marketed.

Orthofix Incorporated, a global diversified orthopedic products company, offers a broad line of minimally invasive surgical, as well as non-surgical, products for the spine, reconstruction, and trauma market sectors that address the lifelong bone-and-joint health needs of patients of all ages—helping them achieve a more active and mobile lifestyle. Orthofix Incorporated's products are widely distributed around the world to orthopedic surgeons and patients.

EBI is a pioneering global leader in electro and biomechanical medicine and one of six strategic business units of Biomet, the fifth largest producer of orthopaedic products worldwide. EBI designs, develops, manufactures and markets products used primarily by orthopaedic medical specialists in both surgical and non-surgical therapy. EBI features innovative electrical stimulation and external fixation devices, in addition to a comprehensive line of spinal and orthopaedic support products.

DJO is a global medical device company specializing in rehabilitation and regeneration products for the non-operative orthopedic and spine markets. Marketed under the DonJoy, ProCare, and Aircast brands, the Company's broad range of over 600 rehabilitation products, including rigid knee braces, soft goods, and pain management, are used in the prevention of injury, in the treatment of chronic conditions and for recovery after surgery or injury. The Company's regeneration products consist of bone growth stimulation devices that are used to treat nonunion fractures and as an adjunct therapy after spinal fusion surgery. Together, these products provide solutions throughout the patient's continuum of care.

THE PROPOSED RULE PROVIDES NO SPECIFIC PROPOSAL FROM THE AGENCY ON CLASS III DEVICES

In background Section I, Subpart M of the May 1st proposed rule, CMS solicits comment on how to determine the appropriate payment update percentage for class III devices in 2007 and 2008.[1] CMS in its proposed rule offers no specific payment update proposal on which to comment. The Coalition asserts that a full CPI-U payment update is warranted in 2007 and 2008, as discussed below. The Coalition also looks forward to working with the agency to provide additional comments on an appropriate update percentage for class III devices.

CONGRESS PROVIDED SEPARATE AND UNIQUE PAYMENT UPDATES FOR CLASS III DEVICES

Section 302 of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) provides for a distinct payment update for class III devices in 2004 through 2006 that differs from the payment update for class II devices and specifically excludes class III devices from competitive bidding. For class III devices, the MMA states that the payment update for 2004 through 2006 should be the percentage increase in the CPI-U for the year involved. The MMA further mandates that the Secretary has the authority to determine the appropriate payment update for 2007. In 2008, the payment update is set in statute at the percentage increase in the CPI-U.

The following provides additional information regarding our comments and recommendations.

1. CMS SHOULD FOLLOW CONGRESSIONAL DRECTION AND PROVIDE A SEPARATE PAYMENT UPDATE FOR CLASS III DEVICES FOR 2007

The Coalition urges the Secretary to establish a class III device payment update for 2007 based upon factors unique to class III devices. In order to assist the Secretary in setting payment updates for class III devices, Congress directed the GAO to conduct a study containing recommendations on the appropriate update percentage for class III medical devices furnished to Medicare beneficiaries in 2007 and 2008. In 2008, the MMA

[1] 71 Fed. Reg. 25,654, 25660 (May 1, 2006).

establishes a payment amount equal to the 2007 payment, increased by the percentage rise in the CPI-U. For subsequent years (*i.e.*, 2009 and later), the MMA provides for a payment update of the CPI-U for class III devices.

In contrast to the payment updates provided to class III devices, the MMA subjected class I and class II durable medical equipment to a payment freeze for five years (*i.e.*, zero percentage update), from 2004 through 2008. In addition, the MMA established a competitive acquisition program for certain class I and class II devices that fall within certain specified categories, beginning in 2007. Congress chose to differentiate between most class II and class III devices in providing class III devices a payment update and exempting them from competitive bidding in part because it believed that there are important differences in clinical complexity and ongoing costs associated with class III devices that would warrant these differential treatments.

2. GAO REPORT ON CLASS III DEVICES DOES NOT PROVIDE NECESSARY GUIDANCE TO THE AGENCY FOR AN APPROPRIATE PAYMENT UPDATE

In Subpart M of the background section, the proposed rule states that CMS will consider the recommendations in the GAO report in determining the appropriate update percentage for class III devices in 2007 and 2008. However, the GAO report did not provide an update percentage for class III devices as specifically mandated by Congress in the MMA. It is unfortunate that the GAO missed an important opportunity to provide CMS with guidance on an appropriate payment update percentage for class III medical devices. Furthermore, the GAO report failed to consider the clinical complexity of class III devices and the factors unique to class III devices that contribute to changes in ongoing and future costs and which are not captured in the initial retail price of such devices. Such ongoing costs include continuing regulatory obligations, labor, continuous product improvement, and service components necessary to ensure positive health outcomes for the Medicare beneficiaries who use these devices. These ongoing costs and clinical complexities warrant an appropriate payment update separate from competitive bidding.

3. COALITION COMMENTS REGARDING SPECIFIC PAYMENT UPDATE PERCENTAGE FOR CLASS III DEVICES IN 2007 AND 2008

An appropriate update factor for class III devices should reflect the unique and ongoing costs associated with providing these complex medical devices to a vulnerable patient population. Noninvasive osteogenic stimulators account for over 95 percent of the class III devices covered by Medicare Part B under the durable medical equipment benefit.

Often these devices are prescribed for patients who suffer from bone fractures or fusions that have otherwise failed to heal properly. In many instances, osteogenic stimulators provide a non-invasive treatment option that can avoid an initial (or additional) surgical intervention, which is especially important for Medicare's elderly and disabled patient populations. Fair and adequate reimbursement must exist to ensure that Medicare

beneficiaries continue to have meaningful access to these important class III devices.

Determining an Appropriate Update for Class III Devices

Bone growth stimulators are class III devices that require a great deal of patient-specific technical service. Each device must be designed and configured for the fracture being treated. This includes the need to calibrate these devices for each individual patient. These services are performed by technicians who are specially-trained by the manufacturer for each particular device.

The bulk of the costs for a class III device is not due to the manufacturing of the device itself. Instead, most of the costs associated with providing bone growth stimulators arise from the ongoing and labor-intensive services required to provide for the safe and effective use of these complex medical devices on a patient-by-patient basis. Approximately half of the total costs are attributable to these ongoing, specialized labor costs and other non-manufacturing personnel costs. In addition to these costs, the support and overhead costs related to appropriate distribution of these devices reflect a considerable percentage of the total costs.

Medicare payment updates have not adequately recognized the expected and reasonable increases in costs associated with supplying osteogenic stimulators to Medicare beneficiaries. For example, during the last decade (from 1996 to 2005), Medicare payment rates have not kept pace with the increases in costs of manufacturing and supplying these class III devices:

- Medicare payment rates for class III devices have increased by about 17 percent during the last decade.

- The specialized labor costs associated with supplying these devices (as measured by employee compensation for all workers) have increased by about 40 percent during the last decade.

- The distribution support and overhead costs (as measured by the CPI-U) have increased by about 28 percent during the last decade.

This comparison strongly suggests that a positive update is needed for class III devices in 2007. An update equal to the CPI-U will only partially close the gap between the increases in manufacturers' costs and Medicare payments. An update that is less than the CPI-U would be even more inadequate.

CMS Should Not Link Class III and Class II Updates

In its study, the GAO focused on how initial prices are established for class III devices under Medicare Part B as compared to a small, non-representative subset of class II devices. The GAO concluded that the initial Medicare payment rates for all classes of medical devices were set consistently by CMS based on retail prices or an equivalent measure.

The GAO missed a critical point that distinguishes class III devices from most other items of durable medical equipment. The underlying cost structure of supplying medically complex class III devices differs from the underlying cost structure for class II devices. As a result, aligning the Medicare updates for these two classes of devices is inappropriate.

The GAO did not include evidence to determine the appropriate Medicare payment update factor for class III devices in its study. In addition, the GAO study did not address the ongoing specialized labor and distribution support costs required to ensure the safe and effective use of these complex devices. As a result, CMS should not rely upon the GAO's conclusions for establishing future Medicare updates for class III devices.

In addition, the GAO did not examine other important and ongoing costs associated with the provision of these devices. For example, the GAO did not evaluate the ongoing research and development costs related to clinical improvements and new indications.

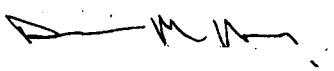
CONCLUSION

For the reasons stated above, we urge CMS to establish a positive update for class III devices in 2007 that takes into account the full costs of manufacturing and supplying these complex devices to Medicare beneficiaries. The GAO study is flawed, especially with respect to the GAO's failure to take into account the full and legitimate costs associated with supplying this labor-intensive therapy.

In light of these findings, an appropriate update for class III devices for 2007 should not be less than the CPI-U. Congress has highlighted the importance of ensuring that Medicare beneficiaries have ongoing access to class III devices under Medicare Part B. However, we are especially concerned by the lack of any proposal set forth by CMS in this notice, which frustrates our ability to provide meaningful comment.

We would welcome the opportunity to meet and communicate further with CMS on this important issue. Please do not hesitate to contact me at 202-898-6360.

Sincerely,



Denise M. Henry

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By Hand-Delivery

June 30, 2006

Mark B. McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

CMS File Code: CMS-1270-P

RE: Comments Regarding Issues Raised in the Proposed Rule Regarding the Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") and Other Issues

Dear Dr. McClellan:

Orthofix Inc. ("Orthofix") submits the following comments in response to the Centers for Medicare and Medicaid Services' ("CMS") proposed rule related to the competitive acquisition of certain durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS"). See 71 Fed. Reg. 25,653 (May 1, 2006). The company's comments discuss the failure of the General Accountability Office ("GAO") Report to meet its statutory objective of providing supportable recommendations to the Secretary of the Department of Health and Human Services (the "HHS Secretary") and articulate why Class III devices deserve a full inflation update for 2007 and 2008.

Orthofix is a medical device company that specializes in surgical and non-surgical orthopedic products for the spine, reconstruction, and trauma market sectors. The company's products are designed to address the lifelong bone-and-joint health needs of patients of all ages, helping them to achieve a more active and mobile lifestyle. Orthofix designs, develops, manufactures, markets and distributes medical equipment used principally by musculoskeletal medical specialists for orthopedic applications.

I. Introduction

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") provided the HHS Secretary with the authority to determine the appropriate fee schedule update percentages for Class III Durable Medical Equipment ("DME") for CYs 2007 and 2008. Pub. L. No. 108-173, § 302(c)(1), 117 Stat. 2231 (codified at 42 U.S.C. § 1395m(a)(14)). The MMA also directed the GAO to submit a

report to Congress and to the Secretary with recommendations on the appropriate update percentages for Class III DME. Id. § 302(c)(1)(B). In March 2006, the GAO published the results of its study. GAO Report No. GAO-06-62 (March 2006). However, the GAO Report is methodologically flawed and fails to meet the Congressional objectives set forth in the MMA. As such, CMS should not rely on the GAO's findings when it sets the Class III payment rates.

At the outset of these comments, we emphasize that Class III devices (and particularly bone growth stimulators, which represent the vast majority of Medicare covered Class III devices) are fundamentally different from Class II devices. These products are technically complex and require ongoing cost outlays and services that are unnecessary for other devices. To ensure bone growth stimulators' effectiveness, technicians are specially trained to calibrate the device for an individual patient's needs.

A full inflation update for bone growth stimulators is warranted because of the costs arising from: 1) the regulatory burdens required to maintain a product's safety and effectiveness (a pre-requisite for Medicare beneficiaries); 2) the labor associated with appropriately servicing and training an individual to utilize a Class III device; and 3) the research and development and related fees required to innovate improvements in a device's effectiveness, including clinical trials. These substantial costs justify continuation of the modest inflation update policies that were established in the MMA.

II. CLASS III DEVICES SHOULD RECEIVE A FULL CPI UPDATE

As discussed above, most of the costs associated with the sale of bone growth stimulators arise from the ongoing and labor-intensive services required to provide for the safe and effective use of these complex medical devices on a patient-by-patient basis. Approximately half of the total costs are attributable to these ongoing, specialized labor costs and other non-manufacturing personnel costs. Additional costs are then incurred for support services and overhead costs related to appropriate distribution of these devices.

Unfortunately, Medicare payment updates have not recognized the expected and reasonable increases in costs associated with supplying bone growth stimulators to Medicare beneficiaries. During the last decade alone (from 1996 to 2005), Medicare payment rates have not kept pace with the increases in costs of manufacturing, servicing and supplying these Class III devices. While Medicare payment rates for Class III devices have increased by about seventeen percent during this time, the specialized labor costs associated with supplying these devices (as measured by employee compensation for all workers) have increased by about forty percent. Furthermore, the distribution support and overhead costs (as measured by the CPI-U) have increased by about twenty-eight percent during the last decade. This data strongly suggests that a positive update is needed for Class III devices in 2007.

III. Congress Differentiated in the MMA Between Class III Medical Devices and Devices that Require Less Regulation to Ensure Safety and Efficacy (Class I and II Devices)

In enacting the MMA, Congress noted the distinction that the Food and Drug Administration ("FDA") draws between categories of medical devices. H.R. Rep. No. 108-391, at 572 (2003). FDA classifies medical devices into three different classes (Class I, Class II, or Class III) depending upon the amount of regulation necessary to provide a reasonable assurance of safety and efficacy. 21 U.S.C. § 360c(a). Class III devices represent life sustaining or life supporting devices, or devices which otherwise present a potentially unreasonable risk of illness or injury, or are of substantial importance in preventing impairment of human health. Id. § 360c(a)(1)(C).

Congress recognized important differences between Class III and other devices in several specific ways in the MMA. First, Congress excluded these Class III devices from the competitive acquisition program for certain DMEPOS. 42 U.S.C. § 1395w-3(a)(2)(A). This exclusion was placed into the Conference Report (the earlier House version of the competitive bidding provisions had no such exclusion) because the Conferees fundamentally believed that the technical complexity and services required to assure the safety of these devices for Medicare beneficiaries warranted separate treatment. Significantly, no other specific exclusions for devices from the competitive acquisition program were included in the MMA despite aggressive efforts from industry.

Second, for purposes of determining payment updates, Congress distinguished between Class III and other devices. The MMA provides no payment update for other devices between 2004-2008. 42 U.S.C. § 1395m(a)(14). By contrast, Class III devices received an update for 2004-2006 and 2008 that corresponded to the consumer price index for all consumers ("CPI-U"). Id. For 2007, the payment update for Class III devices will be determined by the HHS Secretary, taking into account the GAO Report. Id.

The distinctions that the MMA draws between Class III and other devices reflect Congress' recognition that Class III devices are critical to patients' well-being and often necessitate larger investments from manufacturers. In addition, Class III devices frequently require considerable investments in time and resources for servicing to ensure peak performance in these life-supporting devices. The GAO Report, though, ignores many of these important differences and fails to achieve Congress' objectives.

IV. The GAO Report Uses an Inappropriate Analytical Construct that Compares Class III to Class II Devices

The GAO's broad statutory directive under the MMA was to make "recommendations on the appropriate update percentage" for Class III devices to be used for devices furnished in 2007 and 2008. Pub. L. No. 108-173, § 302(c)(1)(B), 117 Stat. at 2231. Rather than examining all costs borne by Class III devices to determine the appropriate payment update, the GAO Report compared whether the CMS schedule

rate-setting methodology accounted for the premarketing costs of both Class II and Class III devices, respectively.

This comparative approach inappropriately assumes that the payment update should be uniform for both Class II and Class III devices in the absence of significant differences in how the premarketing costs are incorporated into the CMS rate-setting methodology. Although not expressly stated, the GAO Report essentially adopts the position that Congress' payment freeze for Class I and Class II devices is also appropriate for Class III devices if all premarketing costs are accounted for in the rate-setting methodology.

This position is contrary to the intent of the MMA. The motivating rationale for the DMEPOS competitive acquisition program and the payment freeze for non-Class III devices was to align the prices that Medicare paid for DME with the prices observed in the marketplace and paid by other federal programs. In June 2002, the HHS Inspector General testified before a subcommittee of the Senate Appropriations Committee that "[o]ur price comparison demonstrates that Medicare overpays for some medical equipment and supplies."[1] A release by Chairman Bill Thomas of the Committee on Ways and Means referenced this Congressional testimony in highlighting provisions in the MMA Conference Report that established a transition to DMEPOS competitive bidding and enacted a multiple year payment freeze for many DME products.[2] Significantly, although the MMA Conference Report also references the June 2002 testimony of the HHS Inspector General, the Conference Report specifically excludes Class III devices from the competitive bidding provisions and provides separate payment updates for Class III devices. H.R. Rep. No. 108-391, at 575, 577-78 (2003).

Any analytical approach that assumes that the payment update should be based on a comparison between Class II and Class III devices is inappropriate. Congress clearly intended to treat these devices as separate categories for payment purposes. Thus, recommendations related to the payment update for Class III devices should focus on the cost structure of Class III devices – and not on a comparison with the costs associated with Class II devices. By not examining the complete cost structure of Class III devices and any increases, both real and inflationary, that would necessitate a payment update, the GAO Report failed to meet the statutory objective Congress set for it in the MMA.

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[1] Testimony of Janet Rehnquist, Inspector General, Department of Health and Human Services, before the Senate Committee on Appropriations, Subcommittee on Labor, HHS, and Education (June 12, 2002), available at, http://www.oig.hhs.gov/testimony/docs/2002/020611fin.pdf (last visited June 22, 2006).

[2] Committee on Ways and Means, "Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Medicare DME Freeze and Competitive Bidding Saves Beneficiaries and Taxpayers Money" (Nov. 19, 2003), available at, http://waysandmeans.house.gov/media/pdf/healthdocs/dmesummary.pdf (last visited June 22, 2006).

V. The GAO Report Fails to Consider Increasing Costs Borne by Class III Devices After the Initial Approval and Launch of the Product

Even if it were appropriate for the GAO Report to compare Class II and Class III devices in setting forth payment update recommendations, the Report is flawed in another significant way because it focuses on premarketing costs only. This narrow focus is improper given the GAO's broad statutory directive to provide recommendations to the Secretary about the appropriate payment update for 2007. Accordingly, recommendations related to the payment update must account for unanticipated cost increases that occur after a medical device has entered the market.

CMS' schedule rate-setting methodology is based on a manufacturer's retail price or historic reasonable Medicare charges from a base year, generally updated by an annual percentage. 42 U.S.C. § 1395m(a)(2), (14). When the only available price information is from a period other than the base period, a Medicare contractor must apply certain deflation factors to approximate the base year price for gap-filling purposes. Medicare Claims Processing Manual, Pub. 100-04, Ch. 23, § 60.3. The incorporation of premarketing costs into the base year price is critical to ensure that the CMS schedule rate-setting methodology adequately reimburses the costs associated with supplying a medical device.

Even so, an accurate base year price or approximation is only one piece of the reimbursement puzzle. Congress has also generally provided annual updates to the DMEPOS payment amounts. 42 U.S.C. § 1395m(a)(2), (14). These annual updates typically reflect the increases in the CPI–U. Id. At the very least, these increases reflect the inevitable increasing costs associated with inflationary pressures. Despite the fact that the CPI-U had increased over the previous year, the GAO Report does not address the need to provide a payment update to account for these post-marketing cost increases.[3]

In addition to cost increases stemming from inflation, Class III devices face other post-marketing costs that are not accounted for in the GAO Report. These costs include substantial regulatory expenditures not typically born by other devices. Class III devices are subject to premarket approval, 21 U.S.C. § 360e(a), and, under the Medical Device User Fee and Modernization Act of 2002 ("MDUFMA"), each premarket application ("PMA") or supplement generally must be accompanied by a user fee. Pub. L. No. 107-250, 116 Stat. 1588 (codified at 21 U.S.C. § 379i). Although the GAO Report observes that user fees paid in the premarketing period are likely incorporated into the base price of a device, the Report does not account for the difference in user fees paid in the post-marketing period for PMA supplements. The costs associated with

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[3] Congress set forth a specific methodology for other DMEPOS payment updates tied to the CPI-U. See 42 U.S.C. § 1395m(a)(14)(B), (D), (F). This methodology ties the payment update to the percentage increase in the CPI-U (U.S. city average) in the 12-month period ending with June of the previous year. Id. Based on data reported by the Bureau of Labor Statistics, the CPI-U index (U.S. city average) increased from 194.5 in June 2005 to 198.7 in February 2006 (1982-84 =100). Bureau of Labor Statistics, Consumer Price Index – All Urban Consumers, Series Id. CUUR0000SA0 (Not Seasonally Adjusted), available at, http://data.bls.gov/cgi-bin/surveymost

these supplements are significantly higher than those associated with Class II devices. For example, the user fee for a panel-track supplement for a Class III device is $259,600 and the user fees for a 180-day supplement and real-time supplement (Class III devices) are $55,814 and $18,691, respectively. 70 Fed. Reg. 46,872, 46,873 (Aug. 11, 2005).

The fees cited above are not incurred infrequently. The need for PMA supplements arises regularly, and the GAO Report does not capture these potentially significant regulatory fees.[4] For example, Orthofix's bone growth stimulator has been the subject of twenty-seven supplements since the PMA was approved on February 21, 1986. In the future, Orthofix will be required to pay user fees each time it files a supplement. These supplements are pursued to facilitate a product's safety and effectiveness and to improve patient compliance with a product.

The central premise of the GAO's recommendation to link the payment update of Class II devices to Class III devices is that the cost components for each of these classes will be built into the initial retail price of a product. That assumption is simply inaccurate, especially in the post-MDUFMA fee-paying environment. Today, if a company submits a supplement to the FDA, it will pay substantial user fees. These fees did not exist – and more importantly – could not have been anticipated at the time when Orthofix or other manufacturers of Class III products established their initial retail prices.

Additionally, these regulatory fees represent only one category of post-marketing costs that the GAO Report did not consider and that would support a positive payment update for Class III devices. As the GAO Report notes with respect to premarketing costs, PMA supplements may also require the submission of technical data which may require a significant volume of testing, clinical data, and extended review times that increase product costs. Because these costs are incurred after product launch, it would be difficult to predict these costs or to factor them into any base year price.[5] However, these costs are not trivial or unimportant.

Recently, an FDA Advisory Committee recommended that FDA not down-classify certain non-invasive bone growth stimulators after receiving extensive testimony regarding the technical expertise necessary to develop and design these Class III devices.[6] This recommendation confirms the distinct regulatory status of these Class III devices and the need for CMS and the GAO to carefully consider the post-marketing costs associated with them. As was stated by researchers and physicians alike during the recent FDA panel meeting, very small changes in the magnitude or other output

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[4] See FDA Website, CDRH PMA Database, available at, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/PMA.cfm?ID=10195 (last visited June 22, 2006).

[5] The GAO Report asserts that costs incurred in the development of a new device "are premarketing costs related to that device and not costs related to marketing the existing device." GAO Report, at 13. However, the Report never explains why it failed to consider research and development costs associated with improving a device or developing new uses for the same device – costs that cannot necessarily be predicted or, if foreseen, adequately measured.

[6] Summary, Orthopaedic and Rehabilitation Devices Panel (Updated June 5, 2006), available at, http://www.fda.gov/cdrh/meetings/060206-summary.html (last visited June 22, 2006).

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Massachusetts Podiatric Medical Society

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June 26, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. McClellan:

In the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), the Centers for Medicare & Medicaid Services (CMS) used the definition of physician that excludes podiatric physicians. I urge CMS to change the definition from 1861(r)(1) to 1861(r)(3) to include podiatric physicians and insure that patient care is not harmed.

If I see a patient who I diagnose with a fracture of the mid-foot, I may decide that it is medically necessary and appropriate to use a walking boot to treat my patient. I want to make sure the patient is not putting weight on the injured extremity and I need to make sure the walking boot fits properly for that patient. If I am not a supplier in the new program, I will not be able to do that and my patients will suffer.

Many of our members prescribe and supply select DMEPOS items as part of patient care. We do not supply items to individuals who are not our patients and believe that requiring us to do so would harm Medicare beneficiaries who are our patients. Our members have valid supplier numbers and adhere to the existing 21 supplier standards. We are subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

CMS will allow MD and DO suppliers to competitively bid to supply DMEPOS only to their patients and will permit them to execute a physician authorization. As physicians in the Medicare program, we should have those same rights. We use DMEPOS items as an integral part of patient care and urge CMS to use the 1861(r)(3) definition of physician in finalizing its regulations.

Sincerely,

James P. Ioli, DPM, FACFAS
President

LAUREL
HEALTH CARE COMPANY

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June 21, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: 42 CFR Parts 411, 414, and 424 Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule

Dear Sirs:

I have reviewed the above proposed rule and have the following concerns:

- It appears the rule would be applied to all beneficiaries with Part B coverage, including those residing in a nursing facility.
- Most nursing facilities currently coordinate the acquisition and billing of DMEPOS necessary for the care of there patients. Nursing facilities serve as the DMEPOS supplier or arrange for services with a DMEPOS supplier.
- CMS has a track record of wanting nursing homes to be responsible for acquiring and billing all supplies and services necessary for its nursing home residents. The original Balanced Budget Act mandated Part B consolidated billing for nursing homes.
- CMS and the States hold each nursing home responsible for assuring that the right supplies are delivered to the right residents at the right time. Penalties are stiff when nursing facility residents do not receive prescribed supplies and services.
- Under the proposed rule, it would appear that nursing homes will be at the mercy of CMS contracted "low bidders" to provide the right supply to the right resident at the right time. I fear that these "low bidders" are going to be focused on the home care market and not the needs of nursing facilities or their residents.
- When the CMS "low bidders" fail to meet the need of nursing home residents, will CMS and States say "That's OK nursing homes, we won't hold you accountable for the substandard care afforded your residents"? Currently, nursing homes are held accountable for the actions of all outside suppliers and service providers.
- I strongly urge you to exempt nursing home residents from the DMEPOS low bid supplier process. At a minimum, allow nursing homes to match the average DMEPOS price as DMEPOS suppliers for their nursing facility residents.

Sincerely

Roger Obenauf
Director of Specialty Services

8181 WORTHINGTON ROAD • WESTERVILLE, OHIO 43082

www.laurelhealth.com

614.794.8800 FAX: 614.794.8805

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PHARM·A·SAVE
GRANITE FALLS

115 N. Granite Avenue • P.O. Box 990
Granite Falls, WA 98252
(360) 691-7778 • FAX (360) 691-4458
Email: pharm-a-save@msn.com

June 12, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO BOX 8013
Baltimore, MD 21244-8013
Re CMS-1270-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments for consideration as a Small Pharmacy for consideration as CMS develops the final regulation.

I strongly object to CMS'alternative proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers; this restricts the beneficiaries' choice. The proposal would severely restrict beneficiaries' access to needed items and supplies (especially in rural areas) and may compromise patent health outcomes.

The competitive bidding program should NOT include common DMEPOS supplies such as diabetic testing supplies. If CMS intends to centralize and consolidate the provision of DMEPOS items and supplies, the agency should limit the competitive bidding program to those unique products that could be provided by a central supplier.

I urge CMS to take steps to ensure that small suppliers which include the majority of pharmacy based suppliers who can participate in the competitive bidding program. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to be compete in large metropolitan areas .After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier.

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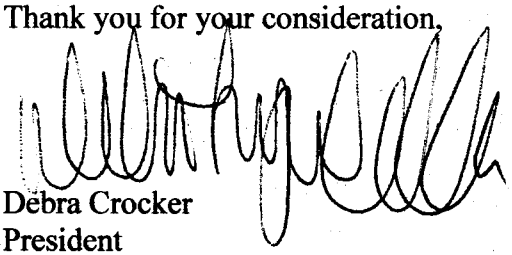
CMS must take these steps to preserve the beneficiaries' convenient access to DMEPOS supplies and maintain established provider to patient relationships. I currently provide testing supplies and other items in my practice and without these revisions to the final regulation; I will be unable to continue providing these valuable services to my rural community.

Thank you for your consideration.



Debra Crocker
President
Pharm-A-Save Inc.
Provider Number 0246250002
NABP number 49-15712

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HEALTH PRO LLC

COMPREHENSIVE LONG-TERM CARE AND PART B SOLUTIONS FOR OVER A DECADE

By express mail

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam:

We understand that you are considering proposing inserting a competitive process in the delivery of enteral nutrition products in the long term care industry. We have to voice our concern in opposition to this action as it relates particularly to our residents on enteral therapy as this will place our residents and their caregivers into a precarious environment that could place them at more risk than they are already.

1. **Nursing facility patients are more vulnerable and require a higher acuity level of care**. Patients that reside in nursing facilities are more clinically complex with multiple complexities than patients cared for at home. They have established care plans which could be interrupted as a result of competitive bidding. Patient access to quality products and services, like disease-specific enteral nutrition therapy, could be compromised resulting in serious complications and overall increased costs of care.

2. **Competitive bidding has not been successfully tested in skilled nursing facilities**. Enteral products were dropped after the first round of the Polk County demonstration in order to concentrate on non-institutional settings. In a final report it was concluded that enteral nutrition "is not as well-suited for competitive bidding" as other products tested.

3. **Competitive bidding puts patient safety at risk**. Suppliers of enteral nutrition products and services to nursing home patients are highly specialized. The potential for a facility to lose their choice of a preferred supplier or to have the ability to provide the products on their own puts patient's health and safety at risk.

3959 ELECTRIC ROAD, SUITE 400 • ROANOKE, VIRGINIA 24018
TELEPHONE: 540-777-1011 • FACSIMILE: 540-777-1004
TOLL FREE: 866-281-1044
www.HealthCareLimited.com

We ask that you please reconsider this action in favor of long term care residents who are most vulnerable, and who must be assured of the timely and accurate delivery of products necessary for life, the ones that demand the most care on the most timely basis and their care givers.

Very truly yours,

Donna P. Grayson

167

Crowne

June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Evergreen Nursing Home. We are located in Evergreen, Alabama. We are a 61 bed skilled nursing facility employing approximately 85 people. We offer Physical, Occupational, and Speech therapy.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Evergreen Nursing Home we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

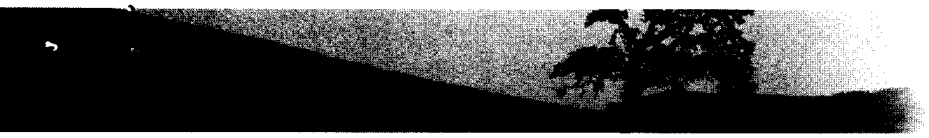
I appreciate your attention to this matter.

Sincerely,

Ann Smith

Ann Smith, R.N., Administrator

Evergreen Nursing Home, LLC • 100 Sanders Drive • Evergeen, Alabama 36401 • (251) 578-3783



amelia nursing & rehabilitation center

Managed by Amelia Life Care, LLC

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam:

We understand that you are considering proposing inserting a competitive process in the delivery of enteral nutrition products in the long term care industry. We have to voice our concern in opposition to this action as it relates particularly to our residents on enteral therapy as this will place our residents and their caregivers into a precarious environment that could place them at more risk than they are already.

1. **Nursing facility patients are more vulnerable and require a higher acuity level of care**. Patients that reside in nursing facilities are more clinically complex with multiple complexities than patients cared for at home. They have established care plans which could be interrupted as a result of competitive bidding. Patient access to quality products and services, like disease-specific enteral nutrition therapy, could be compromised resulting in serious complications and overall increased costs of care.

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3. **Competitive bidding puts patient safety at risk**. Suppliers of enteral nutrition products and services to nursing home patients are highly specialized. The potential for a facility to lose their choice of a preferred supplier or to have the ability to provide the products on their own puts patient's health and safety at risk.

8830 Virginia Street Amelia, Virginia 23002
(804) 561-5611 (804) 561-5533 Fax www.ameliacare.com

We ask that you please reconsider this action in favor of long term care residents who are most vulnerable, and who must be assured of the timely and accurate delivery of products necessary for life, the ones that demand the most care on the most timely basis and their care givers.

Very truly yours,

Virginia M. Snead

Virginia Snead, Administrator

OXYGENSUPPORTSYSTEMS

(800) 554-1115

P.O. Box 845, Cherry Hill, NJ 08003-0845 www.oxygensupport.com FAX (856) 931-1123

June 28, 2006

Centers for Medicare and Medicaid Services
Attn: CMS-1270-P
Mail Stop C4-26-05 7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Sir or Madam,

Please consider the following comments on the Competitive Acquisition for DME to be my concerns about the future quality of the American healthcare system.

As owner of a respiratory company for 27 years I am distressed by the impact of a "winner take all" process on the quality of care now provided to our patients. The proposed change will, over time, erode the high service component of all Home Medical Equipment providers.

Competitive bidding will consolidate the DME industry on the basis of equipment acquisition costs, not on any component of service to the patient. Those companies which remain in business will naturally be the largest companies, who undeniably enjoy economies of scale in the acquisition of equipment. As we must now accept in other industries, customer service for DME will undoubtedly be outsourced or configured to an on-line capability by mega-providers to further reduce costs. Imagine your most senior family member obtaining service for continued use of their medical equipment in this "do it yourself" way. Beneficiaries and their physicians will also face severely limited choice to go to another provider in order to receive improved care and service. Our senior citizens deserve our compassion. We must not make it any more difficult for them to obtain needed service that realistically includes frequent ongoing instruction, on their home medical equipment and it's safe and proper use.

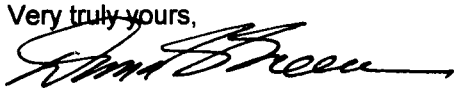
Further proposed rule changes, like the 36-month cap on oxygen equipment, will exacerbate the decline of an industry that is presently very competitive in the quality of care provided. The oxygen cap will reward providers who concentrate on aggressive marketing to obtain new referrals, but who then provide minimal levels of care for each patient because the incentive to provide ever-improving care is gone. Dissatisfied patients who seek better care will find fewer and fewer providers interested in them as the 36th month approaches.

From all reports, the exact savings of competitive acquisition are uncertain. And, in my mind, other cost saving methods have not been adequately explored. Take, for example, Congress' mild interest in enforcing Medicare's existing provision to obtain providers' lowest price for Medicare beneficiaries. News reports stated that the government declared the program unfeasible after receiving "more than 150 letters" from hospitals, drugstores and other providers. Do you think those 150 objections may have come from providers giving large discounts to HMO patients?

153 Harding Avenue, Bellmawr, NJ 08031 (856) 931-1121
22 S. Third Street, Hammonton, NJ 08037 (609) 561-2225
8 Franklin Street, Riverside, NJ 08075 (856) 461-4222
3370 S. Delsea Drive, Vineland, NJ 08360 (856) 765-1000
7317 Oxford Avenue, Phila, PA 19111 (215) 831-8121

All the debates about Medicare cost saving, including competitive acquisition, are being orchestrated by, and will favor, the largest medical providers who have the most to lose if quality of care remains the standard for competition in healthcare. The adoption of these changes will usher in an era of mediocre and impersonal care that American's will rue forever when it finally confronts them in their healthcare.

Very truly yours,



Dana S. Green, President

1170

Crowne

June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator Crowne Health Care of Eufaula located in Eufaula Alabama And we are a Licensed 180 Bed Skilled Nursing Facility with an Special Alzheimers Unit. We employee 230 people.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Crowne Health Care of Eufaula we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,

Bryan Saylor

Crowne Health Care of Eufaula, LLC • 430 Rivers Avenue • Eufaula, Alabama 36027 • (334) 687-6627

CROWNE MANAGEMENT LLC 401 (K)

171

June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Crowne Health Care of Greenville located at 408 Country Club Drive, Greenville, AL 36037. This facility has 118 beds and 150 employees. Crowne Health Care of Greenville offers skilled nursing care along with therapy rehabilitation which includes occupational, speech and physical therapy

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Crowne Health Care of Greenville we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,

Bryan Jones, Administrator

501 WHETSTONE STREET ** MONROEVILLE, AL ** 36460
OFFICE (251) 743-3609 ****** FAX (251) 575-5618

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RESNA

National Office: Suite 1540, 1700 N. Moore Street, Arlington, VA 22209-1903
703/524-6686, Fax: 703/524-6630, TTY: 703/524-6639
Website: www.resna.org

Canadian mailing address: P.O. Box 969, Etobicoke Station U
Etobicoke, Ontario M8Z 5P9, Canada

June 27, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1270-P; Section 2e: "criteria for item selection"

To Whom it May Concern:

The RESNA Standards Committee on Wheelchair and Related Seating submits the following comments regarding the criteria for item selection (section 2e) in CMS-1270-P. In 2003, the majority of wheelchair cushions were classified under the E0192 code. Since the 2003 high volume item analysis, the change in wheelchair cushion coding has resulted in several new codes for these items. The emphasis on performance-based testing for wheelchair cushions has allowed better differentiation of product performance. Cushions in the "skin protection," "positioning," "skin protection and positioning," "adjustable skin protection," and "adjustable skin protection and positioning" categories require a high level of service delivery for proper application.

The broad E0192 code has been segmented into multiple codes. These codes are differentiated by the specific testing criteria based on functional performance. During development of the performance based testing, we have needed to address the myriad of manners in which cushions perform. For example, positioning cushions must address postural alignment, accommodation or correction. Therefore, our testing must allow for cushions to perform in any or all of these manners. Extending our test development into the prescriptive environment, practitioners must also do the same. Practitioners must determine through evaluation the individual's needs and appropriately determine the wheelchair cushion that meets these needs.

A competitive bid product category that reduces the commercial options available restricts the practitioners' range of appropriate options, which results in restricting beneficiary access to appropriate intervention. Cushions in the "general use" classification are the only products suitable for competitive acquisition.

Sincerely,

Patricia E Karg

Patricia Karg, Chair
RESNA Standards Committee on Wheelchair and Related Seating

JOSEPH T. HOGAN, D.P.M.
PODIATRIST

41 Oak Street
Binghamton, N.Y. 13905

(607) 723-7454
Fax (607) 723-1567

502 Fifth Avenue
Owego, N.Y. 13827

(607) 687-5252

DIPLOMATE:
American Board of Podiatric Surgery
American Academy of Pain Management
Amer. Board of Podiatric Orthopedics & Primary Podiatric Medicine
Amer. Board of Quality Assurance & Utilization Review Physicians

FELLOW:
American College of Foot Surgeons
Amer. College of Foot & Ankle Orthopedics & Medicine
Founding Fellow: Amer. Professional Wound Care Assn.
American College of Podiatric Medical Review

Adjunct Clinical Assistant Professor - N.Y. College of Podiatric Medicine
Adjunct Clinical Assistant Professor - Temple University College of Podiatric Medicine
Adjunct Clinical Associate Professor - DesMoines University College of Podiatric Medicine & Surgery

173

June 22, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Electronic Comments

Dear Dr. McClellan:

I am writing to urge the Centers for Medicare & Medicaid Services (CMS) to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) from 1861(r)(1) to 1861(r).

As a podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. These individuals are my patients and they rely on me to use my best medical judgment and clinical skills in treating them. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to my patients only and the right to execute a physician authorization.

In my practice, I use a variety of DMEPOS items. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries.

I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r) before finalizing the regulations for the competitive acquisition program. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

Sincerely,

Joseph T. Hogan, DPM

Joseph T. Hogan, DPM

West Gate Village, LLC

Mark Manning, Administrator

Telephone (251) 867-6077
100 Pineview & Third - P. O. Box 49
Brewton, Alabama 36427

174

ahca

June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at West Gate Village LLC. We are a 129 bed skilled nursing facility in Brewton, Alabama. We utilize therapy services and employee an average of 185 employees.

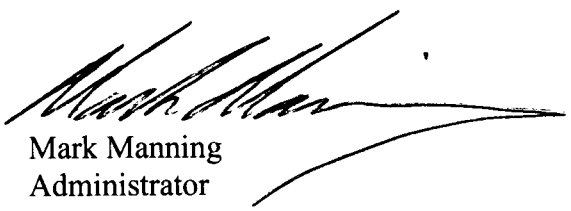
The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At West Gate Village, LLC we have numerous residents whose care could be interrupted as a result of the implementation-jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.



Mark Manning
Administrator

Original

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Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1270-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

RE: Comments for Medicare Program Competitive Acquisition
File Code: CMS-1270-P

As a small 20 year businessman, employing 14 people in Augusta, Georgia, I am submitting these comments knowing that my one voice will likely not be adhered to. As an American, the land of opportunity, I know that this is one thing I can do to "hopefully" make a difference.

Having been in this business of home medical equipment for 20 somewhat years, it makes me angry, depressed, and frustrated to see a "not socialized medicine" industry be destroyed by this ridiculous effort to "bid" out health care services and develop a two tier health care system. Two tier for "those that have" and those that "have not."

As everything in government the MMA of 2003, established this program with instructions to see it implemented. And that may be my first objection. Little or none of the details of the program are in place, for this program to take place. So it seems we should look at what was the "objective". If it really is to cut spending, then why not cut spending instead of reorganizing the program. Since 1980, almost 20 years we have developed and streamlined the current program. Each and every year we find ways to cut spending through fee reductions, freezing of CPI, apply inherent reasonableness, etc. etc. So my first point made is: Just cut fees, until providers no longer provide the service. End of conversation. American business philosophy of supply and demand takes over and all money spent on planning, implementation, and administration of all these new programs is saved. Eliminate all these bureaucratic jobs, more money saved.

After reading, hearing, and seeing the NPRM's, first they do not make clear all the things we need to know to react and implement. Secondly, they add more burdensome layers of rules, policies, and regulation that few persons can explain. Having said that I will still attempt to respond to some of the things I feel strongly about.

1. The cost of participate far outweighs the profitability left to the Medicare program. It will drive out or eliminate many or most smaller providers. Any trick to allow "networking" of small providers is not feasible or reasonable.

2. Selection of the ten MSA's has already been biased if the three largest Metropolitans are excluded. Admittingly they will be included later but there

is something wrong with the plan if "anyone" can get themselves excluded. "If it's not good for the "goose" theory!"

3. The law required an oversight committee (PAOC) CMS has explicitly rejected or ignored many of the committee's recommendation. What then was the purpose of this PAOC committee? Doesn't seem the American way that some must follow the rules but not CMS.

4. MSA's not identified. How can a business plan a bid if we don't have the rules? Another obvious attempt or inability for CMS to do there job in a timely fashion. Stop the program until all the rules are written, and thought through.

5. Equipment not identified. If we really thought the program will save money than identify what items the savings are going to be taken from. It is a joke that we should be planning a bid and we don't yet know on what equipment. But don't forget the law says it must meet certain savings but no one can identify from where?

6. Rebates: In the 1980s and 1990s, discussion of rebates was considered illegal or deceptive at best. Providers were threatened with exemption from the program. Now that it is CMS's idea, it is "legal" or a good idea. Fraud and abuse is being suggested and non controllable.

7. If you participate and win the bid, you can't sell your business. These are business rules applied in dictatorships. The American economy is based on free enterprise and supply and demand. Where does our government get off on dictating the free enterprise system? If bidders lose their "business", which in the program will happen, the program will not suffer but the patients and beneficiaries will. This locked in concept will make it again limit fewer companies willing to take the risk and therefore eliminate even more small businesses.

8. Accreditation: In theory, it sounds good, but in reality it is part of the problem. It adds layers and layers of additional costs to any operation and yet the program wants their cake and eat it too. You don't have agencies available to accredit everyone for seven to eight years. So delay the accreditation requirement until you have the agencies available. Or better yet let the patients /beneficiaries dictate the quality or value they get by giving them their choice to deal with their local companies and let competition control the value.

Conclusion:

In general, the entire plan or competitive bidding is bad policy. The reasons are obvious but yet we continue to spend years working on this program and still do not have the rules drawn up. Small business and local providers are being eliminated. Patients, the

Medicare beneficiaries that worked and contributed to the program "were promised reasonable health care." It is their tax dollars that we are "wasting!" Be man enough to admit this bureaucratic mistake and ditch the program. If you can't control your budget and spending, admit it and let's fix it. Quit creating these administrative monster programs that you can't even finalize into a plan. Cut the fees, let the American business philosophy of supply and demand do its job that it has been doing for hundreds of years. Get CMS, the politicians, and any other bureaucrats out of this program and cut the fees. I believe two things will happen. Those that cannot compete on level playing grounds will exit the program. Second, if beneficiaries will continue to have a choice, that choice, that this program is taking away, will deteriorate the quality of their health care. There will be no competition, the quality goes away, the technological advances go away, but the "two tier" health system develops. The health care system for those that "have" and those that "have not."

David J. Petsch
Owner
Petsch Respiratory Services
104 S. Belair Road
Martinez, Ga 30907
Medicare Provider # 1293470001

176

Ankle + Foot Center

Seth J. Okun, D.P.M.
Steven M. Blustein, D.P.M.
Martin Port, D.P.M.
George F. Williams, D.P.M.

Michael A. Fleeter, D.P.M.
Robert E. Creighton, D.P.M.
Juan J. Rivera, D.P.M.
Kenneth Friedman, D.P.M.

Iliya Beylin, D.P.M.
Scott M. LaBohn, D.P.M.
Andrew Saffer, D.P.M.
Amanda M. Bartell, D.P.M.

Tampa
2835 W DeLeon St., Ste. 101
Tampa, FL 33609
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Tampa
13907 N. Dale Mabry
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Tampa, FL 33618
(813) 963-1833

Temple Terrace
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Tampa, FL 33617
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Riverview
7243 Hwy. 301 S.
Riverview, FL 33569
(813) 671-3100

Plant City
1408 W. Reynolds St., Ste. A
Plant City, FL 33566
(813) 754-9876

Brandon
320 Oakfield Dr. #D
Brandon, FL 33511
(813) 571-0123

Apollo Beach
201 Flamingo Drive
Apollo Beach, FL 33572
(813) 641-9305

St. Petersburg
5750 5th Ave. North
St. Petersburg, FL 33710
(727) 384-5540

Clearwater
1700 McMullen Booth Rd.
Ste. A2-2
Clearwater, FL 33759
(727) 725-2719

Zephyrhills
38105 13th Ave.
Zephyrhills, FL 33542
(813) 715-4747

New Port Richey
6331 SR 54
New Port Richey, FL 34653
(727) 845-0880

June 28, 2006

Mark B. McClellan, M.D., PhD.,
Adminstrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS - 1270-P
Mail Stop : C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

Dear Dr. McClellan:

My name is Steven M. Blustein and I am a practicing Podiatrist for over 20 years in the state of Florida. I am Board Certified in Foot and Ankle Surgery and have been providing Podiatric, medical and surgical services to patients in the Tampa Bay area for the last two decades.

As a Podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as a daily part of patient care. These individuals are my patients and they rely on my expertise to provide the best medical judgment and skills when treating them. I maintain a valid DMEPOS number, I am subject to the same Stark requirements as MD's and DO's, and adhere to the current supplier standards. As a Podiatric physician, I should be given the same consideration that is given to MD and DO suppliers, including the ability to supply select DMEPOS items to my patients as well as, of course, the right to execute a physician authorization.

I am writing to urge the Centers for Medicare and Medicaid Services (CMS) to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment prosthetics, orthotics, and supplies (DMEPOS) from 1861(r)(1) to 1861(r)(3).

I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r)(3) before finalizing the regulations for the Competitive Acquisition Program. I wish to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan Statistical Area (MSA), my patients will be negatively impacted.

In my practice I daily see severe fractures, ankle injuries, and complicated ulcers and foot pathologies requiring DMEPOS items to properly treat. I strongly request that you consider this letter and I thank you in advance for your consideration.

I remain respectfully yours,

Steven M. Blustein, D.P.M., D.A.B.P.S., F.A.C.F.S..

SMB/sjr

Enc.

177

BRASSTOWN PROFESSIONAL PHARMACY, INC.
13-A2 MURPHY HWY
BLAIRSVILLE, GA 30512
(706) 745-2303*FAX (706)745-2332

June 25, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1270-9
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-1270-P

To Whom It May Concern:

I appreciate the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments for consideration as CMS develops the final regulation.

I object to CMS' proposal that would require beneficiaries to obtain replacement supplies of certain items, such as, blood glucose testing supplies. I feel that as a pharmacist, I should be able to offer these supplies to diabetic patients and explain the importance of testing blood sugars, just as it is important for me to explain the importance of their diabetic medications. The beneficiaries should have easy access to the these much needed supplies, and if they are unable to obtain them at the local pharmacy, this might compromise the health outcome of many diabetic patients.

I would like to see CMS take steps to ensure that small suppliers, such as my independent pharmacy/DME business, can participate in the bidding program. Small suppliers should be alowed to designate a smaller market in which to provide DMEPOS . It would be impossible for small suppliers to compete in large metropolitan areas, therefore, small suppliers should be allowed to designate a smaller market to provide DMEPOS.After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment for each item should be allowed to do so.

As much as I am concerned about my business, I must say, that my customers, your beneficiaries, should more importantly have easy access to DME supplies, and to be able to maintain an established provider/patient relationship. Currently, I provide the following types of DME in my practice: wheelchairs, w/c cushions, diabetic shoes, diabetic testing supplies, walkers, crutches, leg braces (knee, ankle), back braces and supports, ostomy products, mastectomy products, and hospital beds. Without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients.

In conclusion, I urge CMS to revise the regulation to include small suppliers and give them the opportunity to participate in the bidding program, so that we can not only stay in business, but that we might be a help to your beneficiaries, who are in our small town.Thank you for considering my view.

Sincerely,

Amy S Galloway, RPh

Amy S. Galloway, R.Ph.
13-A2 Murphy Hwy
Blairsville, GA 30512
(706) 745-2303
(706) 745-2333 (fax)

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100

FedEx Express USA Airbill

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1 From This portion can be removed for Recipient's records.

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Company CARE MED RESPIRATORY SERVICES

Address 1911 N US HIGHWAY 301 STE 340 Dept./Floor/Suite/Room

City TAMPA State FL ZIP 33619-2661

2 Your Internal Billing Reference

3 To

Recipient's Name CENTERS FOR MEDICARE SVCS. Phone 410 786-7195

Company DEPT. OF HEALTH & HUMAN SERVICES

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8400 3001 6730

0248148629

4a Express Package Service *Packages up to 150 lbs.* Delivery commitment may be later in some areas.

- [X] FedEx Priority Overnight — Next business morning
- [ ] FedEx Standard Overnight — Next business afternoon
- [ ] FedEx First Overnight — Earliest next business morning delivery to select locations
- [ ] FedEx 2Day — Second business day
- [ ] FedEx Express Saver — Third business day

FedEx Envelope rate not available. Minimum charge: One-pound rate

4b Express Freight Service *Packages over 150 lbs.* Delivery commitment may be later in some areas.

- [ ] FedEx 1Day Freight* — Next business day
- [ ] FedEx 2Day Freight — Second business day
- [ ] FedEx 3Day Freight — Third business day

*Call for Confirmation:

5 Packaging * Declared value limit $500

- [X] FedEx Envelope*
- [ ] FedEx Pak* — Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak
- [ ] Other

6 Special Handling Include FedEx address in Section 3.

- [ ] SATURDAY Delivery — Available only for FedEx Priority Overnight and FedEx 2Day to select ZIP codes
- [ ] HOLD Weekday at FedEx Location — Not available for FedEx First Overnight
- [ ] HOLD Saturday at FedEx Location — Available only for FedEx Priority Overnight and FedEx 2Day to select locations

Does this shipment contain dangerous goods? One box must be checked.

- [X] No
- [ ] Yes — As per attached Shipper's Declaration
- [ ] Yes — Shipper's Declaration not required
- [ ] Dry Ice — Dry Ice, 9, UN 1845 ____ x ____ kg

Dangerous Goods (including Dry Ice) cannot be shipped in FedEx packaging.

- [ ] Cargo Aircraft Only

7 Payment *Bill to:* Enter FedEx Acct. No. or Credit Card No. below. Obtain Recip. Acct. No. [ ]

- [X] Sender — Acct. No. in Section 1 will be billed.
- [ ] Recipient
- [ ] Third Party
- [ ] Credit Card
- [ ] Cash/Check

Total Packages	Total Weight	Total Charges
1	1.4	Credit Card Auth.

†Our liability is limited to $100 unless you declare a higher value. See the *FedEx Service Guide* for details.

8 Release Signature *Sign to authorize delivery without obtaining signature.*

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

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447

NO POUCH NEEDED.
See back for peel and stick application instructions.

1 of 1

Proposed Rule - Competitive Bidding NPRM Comments

Scheduled MSA's Competitive Bidding Rollout for 2007

As a small business involved in the Polk County Florida Competitive Bid Demonstration Site, the process was long and cumbersome. If anything was learned from this process, it should be that attempting to roll out all of the top 10 MSA's during 2007, will represent a huge task requiring resources not there and risking the ability for CMS to identify problems that occur during a bidding process. **The NPRM does not have the best interest for small Providers, since their schedule for the rollout will give National Companies the advantage for bidding and prevent small companies from organizing into networks to best qualify for the bidding process**. CMS is also estimating that 50% of the Providers may go out of business. Of course, this number does not include the National Companies. This disadvantage is compounded by the fact that CMS has not published the products that will be included in the bid. Not every Provider will have all of the products and services ready to roll out with such a short time frame.

Only Accredited Providers Are Eligible To Submit Bids.

We support this criteria, since we have been Accredited since 1993 and foresee many fraudulent companies falling out of the system. However, there needs to be additional time for credible providers to seek accreditation. About 30% of the companies in the country are Accredited. The capacity for Accreditation from the several entities offering Accreditation in the nation will not be able to Accredit all those seeking Accreditation, since it takes well over six months for a Provider to prepare for Accreditation. The timing selected by CMS should not proceed until ample small businesses have been Accredited. CMS should also publish and identify those entities selected for Accreditation well ahead of the RFB. In any case, **CMS should grandfather those of us who are already Accredited**, regardless of what Accrediting Body you are accredited with and allow time for us to analyze the NPRM against the quality standards we now meet. In addition, not all of those Providers Accredited need time to analyze their costs and criteria, since it is a very costly endeavor to be Accredited. **We estimate that our costs to maintain Accreditation Status costs us in excess of $ 50,000.00 a year, between human resources, training, maintaining standards, etc.** This is a great financial burden for a small business. We have endured cuts in allowable, changes in the capped rental, oxygen cap and competitive bidding coming will affect the cost of servicing beneficiaries and should be considered an integral part of the bidding process. To provide time for winning bidders to acquire accreditation will not provide for the fallout of fraudulent companies out of the system and may result in the fallout of winning bidders, thus creating chaos in coverage and patient service.

Competitive Bidding Process

CMS needs to set up some criteria for Lowball bids, since the bidders are assuming they will receive an amount higher than they bid, based on the pivotal bid principle. CMS will need to clarify this process better. Bids should not be disqualified nor should the lowest bid be the scenario for the winning bid. CMS should consider that some of the Southern States increase in business during the winter months, due to patient influx for just a few months. To select products for the competitive bid based on submitted claims is erroneous, since many of the equipment categories listed in the top 20 group, increase by 30% during the winter months which are December thru March. Utilization changes with patients in and out of HMO's also add to this census.. The process CMS proposes to use, in order to meet projected demand per MSA and measure supplier capacity are not in favor of the small business concern. It favors the National Companies who are high volume regional suppliers. The NPRM fails to mention the % of small businesses or small business networks that will be considered for winning bidders and it fails to mention what safety measures are included to guarantee a

balanced award of the bids. **There is 83% medium to small business Providers as compared to National Companies. The winning bidders should fairly represent those quantities or percentages when awarding the bid in order for it to be fair and equitable.**

Concentrators are at the top of the 20-product category mentioned in the NPRM. What role does the portable system with unlimited refills play in this bid process? Patients are supplied with multiple cylinders to help reduce delivery expenses. Will these cylinders be included in the cap? CMS needs to weigh the negative impact the NPRM will have with the portable system and more so with small DME businesses and on the competitiveness of the second and third rounds of competitive bidding. Small businesses awarded the bid will have to invest in inventory for the first round. What cushions will exist during the second and third rounds for those small businesses that made their investment during the initial round, if they do not participate in the subsequent rounds.

Only companies presently servicing patients in the MSA area selected for CB should be entitled to bid. No company outside these areas, not servicing the specific MSA should be entitled to come in and Bid. Providers established in the specific MSA area for no less than 1-2 years, should be the only ones eligible to bid.

Finally, over the years, a number of companies, both small business and national companies have been investigated, have been found to have either committed fraud, or has had questionable behavior in their billing practices, violation of kickback laws, inducement for referrals, solicitation of patients and have settled with the CMS program for millions of dollars. Yet, these companies continue to participate with Medicare and any company small or large with this history should be denied participation in the bid process. Some of these same companies are members of PAOC board, providing CMS with input for the NPRM.

Competitive & Potential Savings

1) How will CMS determine how many MSA's need to be selected per product category?
2) What supplier capabilities or capacity thresholds will be used to determine the number of Providers or is there a dollar amount that will determine this?
3) What is the financial threshold that CMS will be looking at for establishing Financial Stability. CMS needs to consider that Financial returns have been decaying due to the unending number of allowable reductions, capped equipment, capped maintenance reduction, etc. It is not uncommon for a company to be in the 5-10 % profit margin and still possess Financial Stability. Credit Lines should be taken into account when determining Financial Stabilities and years in business.
4) What are the criteria for determining savings in any of the Equipment Groups. No true analysis was published in the Polk County Demonstration Site. The collapse of businesses, bankruptcies leaving vendors with AR, unemployment benefits, State Aid, Government sponsored training to align the hundreds of employees in new industries, Welfare Aid for employees impacted in areas already saturated with filled jobs and a low unemployment rate. What was the administrative cost of CMS before/during/after? What were the "true" savings?
5) CMS is performing and receiving studies and reports, but there is no indication how much these will weigh in determining it is validity and it is usefulness when performing program savings.

Gap Filling Methodology

We feel CMS should do away with this methodology for setting fees for new DMEPOS, since it will affect or do away with new technology. This provision is totally inappropriate and ineffective. These issues should be addressed via a different process as individual items, based on their individual merits of new technology as it becomes available.

It's my Life's Savings

Do not restrict me from selling my business if I am a winning bid provider. I have worked long and hard, been up many evenings at 2 and 3 AM in the last 32 years to service patients, and used my life's earnings to support my business. Do not place restrictions on what is personal property. True, many companies were bought out after the Polk County Demonstration Site, which resulted in one National Company owing almost 80 % of the oxygen business in that county. Place a cap on how much another company can purchase instead, to maintain the competitive balance. Do not restrict me from selling my business if I am NOT a CB, since I may need to salvage some of my investment, if getting out of the business is inevitable without CMS. Do not punish me for wanting to retire and/or not be able to do anything with my business

Rebates: Is This The Same As A Kickback?

Since I have been in business, kickbacks have been and are against the law. The NPRM describes the rebate program that "allows contracted suppliers to rebate the difference between their bid and the established payment amount to the beneficiary". This is contrary to what CMS has forbidden for years and is contrary to other laws applicable to the Medicare Program. It has forever been an item listed in the Fraud and Abuse Law that any waiver of the patients' co-pay without a hardship is in violation of both the Anti-Kickback and Beneficiary Inducement Statues. This has long been an OIG topic in many Fraud and Abuse advisories or memorandums. There is little or none legal basis under the laws for this program. In my view, a rebate is just another word for kickback. You also request that this information cannot be conveyed to the beneficiary or marketed to the beneficiary, but you make no mention that physicians or referral sources should be excluded as well. If it cannot be marketed to the recipient, it should not be marketed to the referral source as well. Rebates should be completely excluded from the NPRM, since it could open a Pandora box for those providers looking to work the system, cut corners and willing to enter into gray areas.

Networks & Sub-Contractors

The use of subcontractors should not be limited to a Network only that represents a number of small Providers. The NPRM needs to clarify the following:

1) Is the Network Administrator needs to be Accredited?
2) Can the Network Administrator Submit claims and receives payments on behalf of the Providers belonging to the Network?
3) Can a Provider participate in a network for one product category and bid for another product independently?
4) Can a Provider that fails to win a bid, later participate in a Network?
5) What criteria does a Network Administrator need to meet in this Bid Process?
6) 20% maximum of the Medicare Market within a competitive area. Will a National Company that holds more than a 20% market share already is excluded from the bid process. It is not uncommon for any of the National Companies to hold greater than 20% of the Medicare market share in a particular product.
7) Any company winning the Bid should be allowed to subcontract as necessary

Patient Care, New Technology And Quality Of Service

Patient Care, Quality of Life, Quality Service and New Technology is what Medicare patients really want. They also want their Choice of Care and their freedom to choose what is best for their health care. The patient does not care for rebates, nor do they care to have health care choices made for them. Patients are always looking for new technology that will improve their quality of life, slow down there progressive diseases, make them feel better and thus obtain longer life. To simply choose the lowest bidder or a bidder who has only serviced a handful of patients or is a "Jack of All Trades" will not accomplish any of the above

A company that specializes or has a lot of experience in oxygen/respiratory over a company who is big in wheelchairs and has a handful of oxygen patients are not the same and should not be considered equal.

Each company, based on their specialty must be the obvious choice for the patient. How is CMS going to tell the difference when the bids are awarded.? We would never dream of bidding on Electric Mobility Products or TENS devices, since that is not our area of expertise. Under the NPRM, I can bid In addition, sub-contract these items, although I am not an expert in this area. " A Carpenter is a Carpenter and a Plumber is a Plumber.

This process will have an impact in the Quality Care of Patients. It is typical for Governmental Bids to award their bids to the lowest bidder. A good example is the VA, who requires Accreditation, among 20 other stringent requirements. These bids result in companies low balling their bids and the government turning an eye to the other 20 requirements due to the savings. CMS should perform a Patient Satisfaction Survey across the nation in the top ten MSA's to determine what VA & Medicare patients feel of their home care services. We know, for we had a VA contract for 9 years and the horror stories we heard from those patients we were assuming for their care at the time of conversion brought to light the poor service, poor care and prehistoric equipment being used, half of which was not performing to manufacturing specifications. CMS must implement checks and balances to prevent this.

Change of Ownership

"The successor entity agrees to assume all obligations and liabilities borne by the prior contract supplier under the contract". This statement implies that any and all equipment nearing a cap, will be the responsibility of the new Provider. If the equipment cost is $ 500.00 and there are two months left for the equipment to cap, the allowable is $ 50.00, the new Provider will only receive three months of rental and forfeit $ 350.00 on the cost of the equipment?, or carry the warranty on what could be old equipment that has already capped. In another example among many, what happens to overpayments made to the previous supplier. Does the new supplier have to accept liability for these overpayments?, specially if the previous Provider went out of business or sold to another Provider.

Furnishing of Items

"A supplier agrees to furnish items to any Medicare Beneficiary who maintains a permanent residence in, or who visits, the CB are and who requests those items from the supplier" This statement does not mention anything about a MB that has already capped on their equipment through a supplier in their area of residence. A typical example would be a patient that travels for the winter to the south for 2-4 months, their equipment has already capped, their equipment was left at home and we provide this equipment to the patient with the knowledge that we will not be reimbursed or is the patient forced to transport their own concentrator, bed, wheelchair, etc.? Alternatively, will the MB pay 100% of the fees from the Provider in the South? Please, note that many southern states increase their patient census by as much as 30% during the months of November thru March.

New Equipment, Used Equipment, Warranties

This area is very vague. A MB receives a "NEW" piece of equipment that is normally warranted by the manufacturer for 12 months on their original date of service. The CB extends the manufacturer warranties to the patient. When the equipment caps, this warranty is at its end. Does the CB have to provide extended warranties no longer provided by the manufacturer? It is now a used piece of equipment, but it was new when issued to this patient.

A patient qualifies for a Manual Bed, but the CB provides a Semi-Electric bed at no extra cost to the MB or CMS. The CB receives allowable for the Standard bed only. Once the equipment caps, the CB retrieves their Semi Electric bed and provides a standard bed, since that is all CMS paid for?. Up until December 31, 2005, the Semi Electric bed was left due to the Maintenance Program of 2 months billing per year to keep the electric bed working. Under the new guidelines, a manual bed is practically maintenance free as compared to a semi electric bed paid as a manual bed. Will this exchange be allowed, or will the patient just have to do with a manual bed from original service date?

Purchased & Rented Equipment

The criteria for this area are very complicated. After reading it several times, I am still somewhat confused. CMS needs to consider that many DME software programs will need to be revamped in order to accommodate these schedules and electronic transmission, adding additional expenses to small business concerns.

Financial Standards

No Certified Audited Financials should be included. This is an added Financial burden on the small business. Large Public Companies are required to perform these as part of their participation as a Public Company. Small businesses would increase their expenses by $ 3-5,000.00 for this process.

Sufficient Number of Suppliers

In an MSA area where there are over 2,000 oxygen patients and only two companies are selected, only National Companies with their financial resources will prevail. CMS needs to revisit this process to allow small businesses to participate and have an equal level of opportunity for bid participation. What are the criteria ? 500 patients per bidder? 250 per bidder? CMS needs to expand the awards of their bids in those categories that will allow for more winning bidders. At least 2, should be at least 10, so that all can bid and compete on the same level.

The fair way to award the bids could be addressed three ways:

1) Companies interested in participating with the Medicare Program must submit a Bid. Failure to submit a Bid will place you out of the program. Rather than to award winning bids, determine the allowable or pricing by product of the selected bid from the bid results. Allow any and all companies that originally submitted a bid to decide whether they want to participate or not at the selected fees from the bids. If a company selects to participate in a product category, they must provide all of the products that are lumped into that bid. This way, the MSA remains competitive and negative impact on small businesses is diminished. These companies would still have to be or become accredited and meet all of the selected standards.

2) The selection and quantity of bidders selected to participate should be based on Provider experience and length of time in providing that product or service. A Provider providing oxygen for ten years and experience in handling hundreds of patients on oxygen should prevail over a Provider with one year experience and just a small handful of Oxygen patients. For example: If an MSA has 50-60-70- 80 %, etc. of oxygen patients or any other product category listed on the bid being serviced by small businesses, the awarding of the bids should provide for 50-60-70-80% of the companies selected to be small business, as compared to National Companies. This would allow for a fair distribution of the Bids between small and national companies. Please, note that many of the National Companies already own a percentage of the market that exceeds your criteria. **CMS should research what market share each bidder already has by product category and disqualify any from the bid in that particular MSA, if that bidder already exceeds or could exceed the market share allowed by the Competitive Bid.**

3) Most Government bids,(i.e. Veterans Administration, Medical Supplies bids, nursing, etc.) have clauses that guarantee percentages of the bid award to small business concerns, veteran owned, disabled owned, minority owned, women owned, as long as their bids fall within the parameter the bidding agency is looking for as part of the bid. This would provide a degree of guaranteed participation for small businesses, which drive the economy, are more prong to provide higher caliber of services and products in order to fulfill the bid requirements. Not that larger companies would not, but there is a tendency to focus more on higher profit margins with large companies as compared to small businesses , since large companies owe their shareholders dividends.

Re-competing Competitive Bidding Contracts.

Unless the bid process is made more small business favorable, we foresee that small businesses will not be around for the second phase. The 37% CMS of businesses is estimating that will not receive contracted status, will damage the competitive edge during the next two rounds. Further, if there is no limit placed on the large National Companies to purchase small winning bidders or keep these companies within a percentage of the share of market, CMS will have the same issue as it now exists in Polk County. This county has one company that holds more than 70% of the Medicare oxygen market, never participated in the bidding process, will offer minimal sources to bid, unless they are national entities, rather than small businesses.

Breach of Contract

CMS must re-structure their method for on-site inspections, since in the past many Provider Numbers have been revoked due to factual errors. The contracted on-site inspectors are in many cases neither inefficient, nor observant enough and their reports are submitted with erroneous adverse findings. This could result in financial hardship to the CB.

MSA Areas Listed in the NPRM

Several of the MSA areas listed in the NPRM include multiple counties. These have been combined in order to make it a top 25 MSA location and in some cases between the top 10 MSA's. A good example is Tampa, St. Petersburg and Clearwater. There is no indication about the adjacent cities that surround these. Is a Clearwater City address the only area that will be in the bid or will the adjacent cities such as Oldsmar, Madeira Beach, Indian Rocks Beach, etc., be included in the Clearwater MSA. The same stands for Tampa and St. Petersburg with dozens of adjacent communities as well that are not listed in the MSA. Further, each of these counties has Providers that do not cross the county lines. The demonstration site included all of Polk County, but for purposes of this Bid, they are lumping counties, without much consideration to those communities, cities and towns that have different names within the MSA.

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FEDERAL AFFAIRS DEPARTMENT

June 28, 2006

via Express Mail
Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8013

RE: Low Vision Eyeglass Exclusion (414.15)

Dear Dr. McClellan:

On behalf of the American Academy of Ophthalmology (Academy) I am writing to comment on the proposed for Low Vision Device Exclusion under the Medicare Program. The Academy is the world's largest organization of eye physicians and surgeons, with more than 27,500 members. Over 16,000 of our members are in active practice in the United States. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule.

CMS has proposed the adoption of a definition of "Eyeglasses" under The Social Security Act that is not reasonable and conflicts with Congressional intent.The definition of "eyeglasses" proposed by CMS fails to make the distinction that Congress made between lenses that correct refractive errors in eyes with normal visual function and lenses and devices that enlarge images to make them visible to eyes with subnormal visual function.

The Academy appreciates the need for fiscal responsibility in the administration of Medicare policy and is not requesting coverage of routine eyeglasses or spectacles for Medicare beneficiaries (related to refractive error only). We would like to work with CMS and others to define/develop appropriate coverage/policy for low vision devices/systems that should be part of the vision rehabilitation process. CMS must make a distinction between conventional spectacles and low vision devices.

Eyeglasses Exclusion from the Act

In the Social Security Act 1395y; 1862(a)(7) Congress states:
"Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services -
"where such expenses are for routine physical check-ups, eyeglasses (other than eyewear described in section 1861(s)(8) of this title) or eye examinations for the purpose of prescribing, fitting or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes."

Conversely, the eyewear described in section 1395x; 1861(s)(8) are:
"prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens."

Accordingly, one pair of conventional eyeglasses or contact lenses may be furnished subsequent to each cataract surgery with insertion of an intraocular lens. When used for this purpose, eyeglasses are deemed by Congress to be prosthetic devices replacing all or part of the eye.

CMS's Proposed Meaning of "Eyeglasses"

CMS maintains that the usage of the term "eyeglasses" in the Act is ambiguous and proposes to adopt the following meaning of "eyeglasses":
"all devices irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision."

CMS should adopt a meaning of "eyeglasses" that is reasonable and ordinary, as recently held by the United States Supreme Court:
"Where a statute's plain terms admit of two or more reasonable ordinary usages, the Commission's choice of one of them is entitled to deference. See, e.g., Verizon Communications Inc. V. FCC., 535 U.S. 467, 498, 122 S.CT. 1646, 152 L. Ed.2d 701." National Cable v. Brand X Internet, 125 S.Ct. 2688, 2691 (2005).

CMS' choice of the meaning of "eyeglasses" is neither reasonable nor ordinary and not supported by three medical dictionaries:

1. Dorland's Illustrated Medical Dictionary (28th Ed. 1994)
2. Taber's Cyclopedic Medical Dictionary (20th Ed. date)
3. Stedman's Medical Dictionary (27th Ed, date)

The definition of "eyeglasses" in all three dictionaries limits the term to a lens that *increases the visual acuity of the human eye (Dorland's), corrects a defect in visual acuity (Taber's) or corrects refractive errors (Stedman's).* The definitions do not broadly include all devices "to aid vision or provide magnification of images". There is a clear medical distinction between devices that improve visual acuity of the human eye by adjusting the abnormal focus and those that magnify an object for use by the patient with visual disability. Visual acuity can only be improved by a lens made specifically for the individual eye according to a prescription that is derived by refraction of that eye. The lens may be placed in a frame as in spectacles, or the lens may sit directly on the eye as a contact lenses. Those lenses, either in conventional eyeglasses or contact lenses, focus the light from objects directly on the retina of the individual eye. On the other hand, lenses that magnify the appearance of objects and lenses in a camera, such as used in a CCTV, are not individualized to correct the refractive error of the eye and thus they cannot and do not alter the visual acuity of the eye. As a result, they should not fall within the eyeglasses exclusion.

CMS bases its choice of the meaning of "eyeglasses" upon the definition of the term contained in Dorland's, *"a lens for aiding sight"*, but mistakenly interprets Dorland's meaning. The scope of the term is controlled by Dorland's definition of the word "lens": *" a piece of glass or other transparent substance so shaped as to converge or scatter the rays of light, especially the glass used in appropriate frames or other instruments to increase the visual acuity of the human eye."* In turn, Dorland's defines "visual acuity" as: *The ability to discriminate visually between forms, measured by Snellen's test type or, sometimes, by Landolt's rings.*

The definition of eyeglass contained in Taber's Medical Dictionary tracks Dorland's: *"A glass lens used to correct a defect in visual acuity.* Stedman's Dictionary is narrower in scope and equates eyeglasses to spectacles that sit on the nose. The commonality of definitions among the three dictionaries lies in the

improvement of visual acuity, by correcting refractive errors of the eye. CMS should choose among these three definitions in adopting a reasonable and ordinary meaning to interpret the intent of Congress in excluding eyeglasses from Medicare payments, but it does not propose to do so. Instead it devises a new meaning of the term that causes all visual aids to be excluded from Medicare coverage.

CMS can take no comfort in the holding by the United States Court of Appeals for the 1st Circuit in Warder v Shalala, 149 F.3d 73 (1998) *"that the Secretary has the discretion to interpret the statute and to assign a product to a particular Medicare category even when this will result in non-coverage determinations by Medicare"*. CMS maintains that this statement supports its proposed exclusion of *"all devices irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision."* We disagree noting that the holding in Warder v. Shalala is controlled by the United States Supreme Court's ruling in National Cable v. Brand X Internet requiring that CMS interpret the Social Security Act using the reasonable and ordinary meaning of terms contained in the Act.

Exception to the Eyeglasses Exclusion

Because the Act contains the term "conventional eyeglasses", CMS argues that eyeglasses must have been intended by Congress to broadly mean *"all devices irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision"*. The term, eyeglasses as understood in its reasonable and ordinary sense, includes two subcategories: conventional eyeglasses and contact lenses. Conventional eyeglasses are spectacles - a frame that sits on the nose and contains lenses that correct the refractive error of each eye. Contact lenses are lenses that sit directly on each eye and correct the refractive error of that eye. The function of spectacle lenses and contact lenses is identical. The prescription for both is derived from the same refraction, corrects the same refractive error, and thereby increases visual acuity. Congress deemed conventional eyeglasses and contact lenses provided after cataract surgery as prosthetic eyeglasses, since they provided a replacement for a missing or defective part of the eye. This is consistent with CMS's exclusion from reimbursement of refractive surgery, which also corrects the eye's refractive error.

Congress made an exception to the eyeglasses exclusion for conventional contact lenses after cataract surgery. In section 1862 (a) (7) of the Act CMS argues *that "by applying the eyeglass exclusion to contact lenses, the statute reinforces the interpretation that the use of lenses to aid impaired vision is the scope of what is excluded by the eyeglass exclusion and not just lenses supported by frames that pass around the nose and ears."*
The contact lens used in this situation is to correct refractive error and not all types of visual impairment. There is no evidence of Congressional intent to limit the exclusion to spectacles only; rather, the Congressional intent was to limit the exclusion to lenses that correct refractive error.

The reasonable ordinary usage of the term eyeglass, as described above, is a glass that corrects the refractive error of the eye and improves visual acuity.

Contextual Interpretation of the Eyeglasses Exclusion

CMS' proposed definition of eyeglasses disregards the context of section 1862(a)(7) of the Act. This was aptly stated by the court in Currier v. Thompson, 369 F.Supp.2d 65, 72 (D. Me. 2005):

"The text of the original statute, when combined with the legislative history, casts new light on section 1862(a)(7), at least as first enacted. Subparagraph 7 was clearly directed to annual and routine medical matters, such as physicals, periodic hearing aid checkups, and immunizations. The portion of the subsection addressing eyeglasses is consistent with this underlying intent. Further, the absence of the

later parenthetical language on eyewear highlights the fact that there is no comma between "eyeglasses" and "eye examinations for the purpose of prescribing, fitting, or changing eyeglasses." This juxtaposition encourages the conclusion that, as first enacted, Congress used the term eyeglasses in tandem with its exclusion of payment for 'prescribing, fitting, or changing.' In other words, Medicare would pay neither for glasses nor the examination that prescribed, fitted or changed them. Also, the absence of the term 'eyewear' makes it less likely that Congress, as urged by the Secretary, distinguished between eyeglasses in the more general sense and eyewear. Finally, the statutory language jibes with quoted legislative history, which addressed the eyeglasses exclusion in the same context as a routine physical and distinguished more elaborate treatment, such as those involving cataracts.

Assuming the statutory language as originally enacted would include eyeglasses that are worn, but not lenses that are not, the next question is whether the subsequent amendments of section 1395y(a)(7) alter the original meaning. This subsection was first amended in 1968 when the phrase, 'procedures performed (during the course of an eye examination) to determine the refractive state of the eyes,' was added. Pub. L. No. 90-248, Section 128. In 1990, the parenthetical phrase 'other than eyewear described in section 1395x(s)(8)' was added. Pub. L. No. 101-508, section 4153(b)(2)(B). This Court could locate no legislative history to explain either amendment. However, the text of each amendment suggests neither was intended to achieve a wholesale revision of the subsection; each amendment only tweaked the exclusion to respond to developments."

The Process of Vision: Visual Function versus Functional Vision

The process of vision has several stages: focusing of the image onto the retina, followed by image capture by the retina, and subsequent transmission to the brain, where it gives rise to visual perception.

When the first stage is defective, the retinal image is blurred, preventing the detection of fine detail and resulting in reduced visual acuity. When the cause is a refractive error (myopia, hyperopia, astigmatism, presbyopia) the blurred image can be sharpened with conventional correction (eyeglasses, contact lenses). Such lenses sharpen the image, but do not change its size (visual angle).

When the second stage is defective, the retina cannot capture and transfer a clear or complete image, no matter how well focused it is. The only solution to this functional deficit is to increase the actual or apparent size of the object, which consequently changes the size of the retinal image. Magnification can be achieved by a variety of means, including by:

1. Bringing the object of regard closer.
2. Providing larger objects, such as large print books or notes written with a broad tipped pen.
3. Providing a magnified image of the object, such as on the screen of a video-magnifier (CCTV). Note that the camera built into the video magnifier includes a lens; this lens, however, produces a minified image on the image sensor. The magnification of the screen image is produced entirely by electronic means.
4. Making objects appear larger through the use of lenses or sometimes mirrors. These lenses do not affect the sharpness of the retinal image, but only its size. Since these lenses affect a quality of the object, they need to be in a position that is fixed relative to the object (at their focal distance). In hand magnifiers the lens-to-object distance must be maintained by the user; in stand-magnifiers it is maintained by the stand. As long as the appropriate lens-to-object distance is maintained, the eye-to-lens distance can be variable; the lens-object combination can be held away from the eye or close to it.

Devices Outside the Eyeglass Exclusion

An eye whose subnormal visual acuity is not caused by a refractive error and therefore cannot be restored to normal visual acuity by correcting the refractive error with eyeglasses – spectacle or contact lenses – is in a pathological state with a permanent visual impairment caused by disease, injury, or congenital defect. CMS recognizes visual impairment as a pathological state qualifying for rehabilitation training by occupational therapists when the visual impairment results in a functional deficit. CMS recognizes visual impairment to include best corrected visual acuity ≤20/70, or central scotoma, or visual field deficit. Rehabilitation therapy to enable the patient to perform necessary activities of daily living in spite of visual impairment often includes, but is not limited to, the application of magnification devices to the performance of these activities. These devices do not correct the visual acuity through the correction of refractive errors; they are prosthetics that replace part of the function of a non-functioning organ.

When used by individuals with a permanent moderate, severe or profound visual impairment, hand, stand, and head-mounted magnifiers and portable CCTVs may be considered prosthetic devices, just as eyeglasses are prosthetic devices when used by individuals who have had their lens removed by cataract surgery. Alternatively they may be considered orthotic devices in that they replace or improve the function of a malfunctioning body part or organ.

Medicare Part B will reimburse patients for expenses incurred for items or services *provided they are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member*." 42 U.S.C. Sections 1395k(a), 1395y(a)(1)(A); 42 C.F.R Sections 411.15(k). Reimbursable items include *durable medical equipment which is used in the patient's home.* 42 U.S.C. Section 1395x(n), 1395x(s)(6); 42 C.F.R. Section 410.38. As per C.F.R. Section 414.202, an item qualifies as durable medical equipment (DME) if it:

1. *Can withstand repeated use*
2. *Is primarily and customarily used to serve a medical purpose*
3. *Generally is not useful to an individual in the absence of an illness or injury; and*
4. *Is appropriate for use in the home.*

Stationary CCTVs meet all four of these criteria for durable medical equipment. They certainly withstand repeated use, are not only primarily and customarily used to serve a medical purpose, but are essential to serve a medical purpose for individuals with a severe or profound impairment of visual acuity (≤ 20/200) or with a small island of remaining central vision. They are useful only to individuals with visual impairments, they are not useful for any purpose in individuals with normal visual acuity, and they are appropriate for use in the home. Like hand, stand, and head-mounted magnifiers, they do not correct visual acuity; indeed, the eye does not even look through the camera lens used in the CCTV.

Conclusion

CMS does not have the authority to exclude Medicare payments for *"all devices irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision."* Congress intended the eyeglasses exclusion to apply exclusively to lenses that correct refractive errors that thereby increase the visual acuity of the human eye. Only conventional eyeglass lenses and contact lenses appear to fit this description.

The Academy appreciates the opportunity to comment on the proposed rule. CMS should make a distinction between conventional eyeglasses and devices/assistive technology that are part of a comprehensive vision rehabilitation effort and the Academy is willing to contribute to the development of such policy. In the meantime, if there are additional questions and/or comments regarding the cost of ophthalmology code inputs we encourage CMS to contact us. Again, the Academy would like to thank you for providing us with the opportunity to comment and looks forward to CMS's response to our comments.

Sincerely,

Michael X. Repka, MD
Secretary for Federal Affairs

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VNA Home Health of Maryland

7008 Security Boulevard, Suite 200
Baltimore, Maryland 21244-2504
410-594-2600 1-888-523-5000
www.vnamd.com

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1270-P - Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

June 28, 2006

RE: 1270P – Regulatory Impact Analysis-Effect on Beneficiaries – Sect E. pg.41

To Whom It May Concern:

The VNA Home Health of Maryland is a Home Health Agency that has been servicing the Greater Baltimore Metropolitan area and surrounding counties since 1895. Our agency is multi-disciplined, providing a full complement of skilled home care services.

The professional staff of our agency has followed with great interest the pending CMS Competitive Bidding initiative, and as health care professionals have very real concerns about the efficacy, implementation and ultimate results of the proposal in its current state. Our staff is particularly struck by the apparent lack of consideration of the considerable intensive areas of specialization required to adequately address patient needs.

In creating an atmosphere that rewards the "super store" approach, patients with complex and specialized needs for DME, cannot be serviced adequately, leading to the following adverse results. 1) Lack of adequate accessibility to quality services, especially in the larger Urban Metropolitan areas that have historically been best served by the small local entrepreneur who understands their clientele; are especially understanding of their needs, and can provide services in a timely and convenient manner. 2) The goal of any health care delivery system should be to provide the best possible opportunity for the patient to achieve a quality of life which will allow that patient to assume independent living and to become productive members of society to the greatest extent possible. A system that fails to adequately address the specialized needs of the medically complex patient, is a system that is more concerned with short term savings, at the expense of those patients who are the most vulnerable. 3) The incredible cost of avoidable acute care, necessitated to correct conditions that where allowed to degenerate due to poorly fitted, and inappropriately directed durable medical equipment, which is an absolute consequence of a system that is solely based on the lowest cost, without adequate regard for the complex and specialty needs of the patient.

VNA Home Health of Maryland

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Enclosed please find two letters from our staff, one from and Occupational Therapist, and one from a Registered Nurse, both of whom having had decades of experience in their respective fields, addressing these concerns. We respectively request that these comments be include in the official record, and that CMS take a serious look at the potentially disastrous effects of this initiative, and create a task force with Industry participation, to develop a program which adequately addresses CMS'S concerns of escalating costs, without potentially jeopardizing the welfare of the very beneficiaries they have been mandated to service.

Yours very truly,

Barry M. Ray, CEO
VNA Home Health of Maryland

WinCare

P.O. Box 7276 – Rocky Mount, NC 27804 – (252) 443-2872

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MEMORANDUM

TO: Centers for Medicare and Medicaid Services

FROM: Sarah Drewry, Director of Field Service
Compliance Director

DATE: June 20th, 2006

RE: Concerns with Competitive Bidding

The main goal of a Durable Medical Equipment company is to provide products and to receive reimbursement. The competitive bidding rule will take away the "any willing provider" environment that was established and will focus on the competitive market, where bidding will be required in order to receive reimbursement. When dealing with nursing facilities, patients and families, is this really where our focus needs to be?

There are several points of this rule that concern us as a Durable Medical Equipment company.

- The competitive bidding rule has not been successfully tested in the skilled nursing facility setting. This rule will affect skilled nursing chains throughout the United States. It would seem that there would be a focus on testing in this situation when it will affect so many people.
- Putting the safety of your patients at risk. A provider of enteral nutrition to skilled nursing facilities is a specialized market. When having to sacrifice your "choice" provider, you are putting your patients at risk.
- How can a program be implemented without accreditation guidelines being established? At this time there has been no information released about how companies that are being affected by this rule will become accredited with the program.

The Competitive Bidding rule that is currently in legislation will make this process much more of a competitive market. When dealing with someone's well being, is that really the most important thing that suppliers need to be concerned with?

Thank you for considering our thoughts.

SBD:slp

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WELDON PHARMACY, INC.
1280 HUEYTOWN ROAD
HUEYTOWN, AL 35023
205-4912805

June 15, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Sevices
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Re:CMS-1270-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments for consideration as CMS develops the final regulation.

I strongly object to CMS' alternative proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers-this restricts beneficiaries' choice. This proposal would severely restrict beneficiaries' access to needed items and supplies and may compromise patient health outcomes.

The competitive bidding program should not include common DMEPOS supplies such as diabetic testing supplies and ostomy and urological supplies. If CMS intends to centralize and consolidate the provision of DMEPOS items and supplies, the Agency should limit the competitive bidding to those unique products that could be provided by a central supplier.

I urge CMS to take steps to ensure that small suppliers-which include the majority of pharmacy-based suppliers–can participate in the competitive bidding program. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to compete in large metropolitan areas.

After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier.

CMS must take these steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established provider/patient relationships.

I currently provide the following types of DMEPOS in my practice diabetic testing supplies, ostomy and urological supplies, nebulizers and inhalation supplies, ambulatory equipment{canes, walkers, crutches}, bedside commodes,and diabetic shoes, and without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients.

In conclusion, I urge CMS to revise the regulation to :

1. Competitive Bidding Areas
2. Criteria for Item Selection
3. Opportunity for Participation by Small Suppliers

Thank you for considering my view.

Sincerely,

Steve Weldon, Rph.
Weldon Pharmacy, Inc.

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Virginia Home Medical

Comments on CMS Competitive Bid Proposal For Home Medical Equipment and Supplies

June 28, 2006
Submitted by Thomas E. Inman II, President
Respiratory Home Care of Virginia Inc., t/a Virginia Home Medical
11842 Canon Boulevard
Newport News, Virginia 23606

Centers for Medicare & Medicaid Services
42 CFR Parts 411, 414, and 424
[CMS-1270-P] RIN 0938-AN14
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Virginia Home Medical has been a Medicare provider for over twenty eight years. Our company's focus is providing respiratory services to patients in there homes or places of residence. In addition, we do supply Home Medical Equipment (HME).

History

Competitive acquisition for HME was engrossed in legislation in the 1980's. Based on the debate offered at the time it was assumed by the industry the driving force behind competitive acquisition by HCFA was because a comparison was made between the different amounts paid by the Veteran's Administration (VA) vs. Medicare for basic DME (hospital beds & mattresses, wheelchairs, walkers, etc.) and home oxygen services.

An analysis of the major differences between these two procurement models is necessary. First, as far as the industry is aware HCFA never conducted an "apples to apples" total cost savings comparison of the VA procurement model and the proposed competitive bid model now under consideration by CMS. The VA system operates more like an "a la carte" menu, whereas, the CMS model has always been an "all you can eat buffet" model. As a previous VA contracted we have first hand experience of the subtle differences and will attempt to outline the major ones below:

► as noted above, the major difference between the two models is the "a la carte" vs. an "all you can eat buffet" comparison. It is best described as a "service" buyer (the VA) compared to a "commodity" buyer (CMS). Based on our specific experience with the VA here is an outline of the major differences between the two procurement models:

• historically the CMS reimbursement methodology for stationary oxygen systems has always been reimbursed utilizing a single modality neutral rate. The VA's "a la carte" model paid a separate rate for tanks, concentrator or liquid systems. Also the VA allowed for the billing of any supply item used in excess of the contract allowance (i.e. cannulas, tubing, face masks, humidifiers, connectors, sterile water, etc.). Additionally, when portable systems were furnished the VA paid for the rental of the portable system and for the contents **of each portable tank consumed** during the rental period. In our experience we routinely received up to $600 per month for portable "contents" on a single patient. Also, when after hours or extra service calls were necessary the VA had a line item in the contract which allowed us to bill them for the service component provided. And finally, we provided monthly respiratory therapist/technician visits which were billed and reimbursed as a separate line item each month.

▶ conducting business with VA required minimal administrative cost. All that was necessary for the delivery, setup and billing for a VA patient was a physician's prescription and a signed delivery/visit ticket from the veteran. Billing was accomplished by submitting a single invoice monthly for all the veterans on the contract. The VA paid 100% of the charges and no expense was incurred trying to collect co-payments from the veteran.

▶ the VA system allows for only one provider to provide services to a limited number of beneficiaries. It is a "winner takes all" model. It should also be noted VA veterans requiring these services are the minority market share in every MSA as compared to the Medicare population. This creates a market segment which providers never consider essential to their survival. Unlike our VA experience the model CMS is proposing affects the majority of our patient base and thus it cannot be viewed, budgeted or bid as a marginal business segment.

Marketplace

It should not go unnoticed the dramatic differences in the HME Medicare marketplace since the idea of competitive acquisition was developed by HCFA. First and foremost as it relates to home oxygen services providers are being paid in the neighborhood of 42% less (not adjusted for inflation) today than back in the 1980's when competitive acquisition was first proposed. Given the compounding affect of increases in labor rates, health and casualty insurance, payroll taxes, accreditation cost, utilities, occupancy cost and fuel for delivery vehicles the average provider's return on investment has dramatically fallen over the past twenty years. Couple this with the ever growing trend of increasing capital requirements to acquire emerging technologies the industry's profit potential has been severely limited if one is to remain competitive in the marketplace.

Simply stated, the marketplace of today does not even resemble the marketplace of the 1980's. For the above stated reasons, and others unmentioned, the evolved procurement system CMS currently utilizes coupled with a very competitive service model employed by the industry provides the government with efficiencies not realized in other government procurement models. The current system is working to the government's advantage.

An example of this is the rapid growth of an expensive oxygen modality being provided to CMS beneficiaries under HCPC codes are transfilling oxygen concentrators. The acquisition cost of these new oxygen concentrators is up to seven times more than a traditional oxygen concentrator. Currently the industry is providing these devices and billing under the current E1390 concentrator code. CMS may not even be aware of the increased cost and benefit to the system associated with this new technology. Additionally there is no way for the provider to recoup their higher cost of providing new technology. There are many more examples where CMS is unable to keep up with emerging technologies with appropriate HCPC billing codes. The dilemma for providers is the question of legal exposure of providing equipment to beneficiaries and not having an appropriate HCPC code to bill under. How will this issue be handled under the competitive acquisition program?

MSA Issues

It is obvious to the marketplace that competitive acquisition will create a two tiered delivery system for CMS beneficiaries. The obvious cause of this dichotomy is the creation of a two tiered pricing system. Providers in MSA's coming under the competitive acquisition program will by definition receive less reimbursement than those providers outside said MSA. Any marketplace analysis will clearly reveal a provider receiving more reimbursement for the same HCPC will be able to provide a higher level of service and/or better (i.e. more expensive) equipment. Does this not go against the fairness doctrine mandate by Congress to CMS to apply the same standards and quality to all Medicare beneficiaries?

The abstract application of allowing CMS to define the MSA marketplace as it sees fit, as long as the boundaries include contiguous zip codes, is ludicrous. CMS has no relative experience nor published reports that this author is aware of in analyzing the specific factors which define the current geographic marketplace within and surrounding all MSAs for HME products and services. The arbitrary nature of CMS's approach is inappropriate and potentially harmful to Medicare beneficiaries residing on the fringe of every MSA in this country. The potential fallout from CMS's approach here is after competitive acquisition is up and running two Medicare beneficiaries living a block apart will be provided service under two separate market models and reimbursement scenarios. The impact is obvious to all but the uninformed. This author does not believe a two tiered delivery system was every the Congressional intend.

It should not go unnoticed there is a major difference between the legislation creating competitive acquisition for HME and the existing competitive acquisition model currently being employed by CMS in the managed care arena. The facts beg the question (beyond Congressional intent) of why does the current CMS competitive acquisition program for managed care (HMO) services allow the marketplace to utilize the "any willing provider" concept. It seems to have been completely ignored for HME services. If ever there was a major concern in the small business sector of dealing with the federal government this single issue clearly demonstrated there is no concern whatsoever of

"leveling the playing field" to assist the small business segment of the provider community. One must ask why should multi billion dollar corporations be allowed the eminent protection of "any willing provider" in their market segment and an industry consisting of virtually all small businesses be excluded from this practice? One can only hope CMS will realize once competitive acquisition experiences several bid cycles and sees the greatly reduced number of providers it will realize the road for a monopoly or duopoly will have been paved. What then will be the impact on lower prices and higher service? Additionally, it should be understood large national HME companies are not interested in serving small rural marketplaces where patient population is much less dense. What will happen to the fewer small providers in these rural markets outside MSA's if CMS invokes the lower MSA pricing model to them? Does CMS believe the large national companies will flock to the rural marketplace in the event their model creates a vacuum? In the years ahead this single issue holds great risk to Medicare beneficiaries living in very rural areas.

Proposed Bid Regulations

Currently CMS has only provided incomplete information regarding the rules and regulations for competitive acquisition. A whole universe of questions exist due to CMS lacking clarity in there release of proposed regulations in this NPRM. Some vital questions are unable to be asked because the basic outline of a business model cannot be constructed due to CMS completely missing the point of offering up a complete set of regulations before issuing the NPRM. Simply stated CMS released just enough information to confuse the issue and the industry. Instead of doing their homework and thinking the entire competitive acquisition reimbursement model through, CMS offered up an abstract model which has only increased the confusion within the industry. That being said it begs the question of how after two completed competitive bid demonstration projects could CMS not know what their competitive acquisition model should look exactly like?

Numerous issues have been created by CMS's lack of disclosing complete information. The more obvious ones will be outlined below:

► Supplier standards have not been defined by CMS. Based upon the more than 5,500 comments sent to CMS on the draft supplier standards CMS has an obligation to publish the final draft standards for public comment before moving forward with any competitive acquisition program. CMS has created an informational "black hole" by not being responsible to the industry, Medicare beneficiaries and Congress in openly and accurately communicating the exact standards applying to the competitive acquisition program. Anything short of a full disclosure and appropriate period for public comment before the standards are adopted smacks in the face of every PAOC member and what is ultimately the right thing to do.

Additionally, CMS has not accepted any information other than anecdotal comments at the PAOC meetings as to the capacity of the industry's current accrediting bodies to be able to accomplish CMS's requirement of accreditation during the unknown length of the CMS defined "grace" period before a winning bidder will be allowed to participate. Has

the potential impact on access in the MSA's under competitive bid even been considered should the winners not be able to achieve accreditation within this "grace" period? This is another example of a complete absence of planning on CMS's part.

▶ how can CMS expect to receive truly competitive bids when bidders are not allowed to submit bids at a higher rate than CMS currently pays? It was clearly demonstrated in the Polk County, Florida and San Antonio, Texas projects that CMS was paying below the market rate for certain items. Thus when the winning bid was calculated the reimbursement rate went up. If that was the market rate for a product in that specific market how can CMS create a system where beneficiaries will be denied access to products at truly competitive and fair rates?

▶ the issue of the methodology of the bid rate being set by the "pivotal" bid creates more problems than it solves. The "pivotal bid" will not be the rate products are reimbursed at. The reimbursement rate will be set by taking the median of the lowest submitted bid and the "pivotal bid" amount. This concept requires the intelligent bidder to carefully think about the rate he will bid. By definition he must consider there is a significant chance that after the bids are evaluated he may be required to lower his bid even further to be allowed to participate should his bid be above the median rate established by CMS. Additionally, the median rate may not even be equal to an actually submitted bid amount. **In what other approved federal government acquisition program is the fictitious "bid" rate allowed to set a price?**

The logic of this bidding structure begs for an explanation. The affect it will have on bidders is for them to hedge their bids realizing they may have to participate at a lower rate than they bid. The very concept of a truly competitive bid is for the bidder to offer his absolute lowest price. The pivotal/median bid methodology smacks in the face of the intent of a truly competitive bid model. It simply will not work as a bid methodology and produce the desired results.

▶ the proposed requirement for winning bidders to be forced to supply upgraded equipment at the bid price is ludicrous. How stupid does CMS think the professional HME provider is? On one hand CMS states they want the lowest price possible and then turns around and includes a stipulation which makes it **impossible** for anyone to calculate the impact to their bid. If the physician can order an upgraded product and CMS takes the position the upgraded item is included in the bid it will have a devastating impact on the marketplace. An analogous example would be for the DOD to publish a RFB for the rental of vehicles for TDY personnel at bases throughout the continental United States. The example here would be that the rental car agencies would have to submit a per diem rate as their bid, but every base commander could require them to supply anything from a Ford Taurus to an Infinity Q45 sedan. With the inventory to be supplied out of the bidder's control, how can anyone submit an intelligent bid? What CMS needs to do is supply the manufacturer, make and model which will be required to meet the bid for each and every HCPC code contained in the RFB. Anything short of detailing exactly what is included will drastically affect the outcome of the CMS bid process. As noted above, the industry is currently absorbing the higher cost of new technology for which appropriate HCPC billing codes do not exist. Competitive acquisition will destroy the provider/patient relationship by requiring the use of ABN's for newer technologies not

covered by the bid. The point here is, "saying it isn't so" doesn't make it true. CMS has a long way to go before it has any clear understanding of how **competitive** the current marketplace really is.

▶ a parallel to the above topic is the apparent disregard by CMS of how the third party payer system operates in this country. Specifically, providers of products and services in the private health care delivery system are acknowledged as intelligent businessmen by the insurance companies with which they have contracts. To a payer, including HMO's and managed care payers, every insurance company has created a preauthorization/benefit eligibility system where providers are encouraged, and even required in some cases, to determine the insured's eligibility and entitled benefit package **before** the provider provides services. Where does CMS come up with the position that the marketplace will operate in a vacuum created by them concerning Medicare beneficiaries who enjoy limited benefits for the products being bid? CMS's position that the successful bidders must assume **unlimited** liability for providing products to beneficiaries with limited benefits is ludicrous and an insult to anyone with an IQ over 75. Again this is another example of a regulation which makes it impossible for the informed, intelligent bidder to be able to calculate their cost for a product. For the above stated reason CMS has a moral obligation to create a system inclusive of **all** its programs to allow providers **instant** access to the Common Working File to determine both eligibility and benefit dollars remaining by HCPC billing code **before** services are required to be provided. The entire health insurance universe operates using this system. It is simply nonsense for CMS to believe all providers would be financially strong enough to withstand the ever increasing drain on resources created by its requirement to take "all comers" regardless of whether payment would ever occur. The provider is placed in the untenable position of possibly loosing money on every transaction. CMS must rethink its approach regarding bidding requirements for all capped rental items.

▶ the most troubling proposal being offered by CMS is the revocation of a supplier's access to due process. It begs the question, how can a government agency revoke one of the rights any citizen or entity is guaranteed under the constitution? I am not aware of any other government agency which has successfully suspended a contractor's appeal rights. CMS does not have the right to simply **regulate** away the appeal process contained in the Medicare program. It is simply wrong.

▶ CMS's proposal allowing a provider, who's bid falls below the establish reimbursement rate, to rebate some or all of the difference between their bid and the reimbursement rate to the beneficiary boggles the mind of every ethical provider in the country. It smacks in the face of Stark and can only have a detrimental effect on the entire competitive acquisition program. Did CMS ever consult or receive an opinion from the Office of Program Integrity in the Attorney General's office? If so what input did they offer concerning "rebates"? If not consulted, why not?

For over a quarter of a century my experience, as well as the industry's, has been never ending examples from HCFC (CMS), Congress (Stark legislation) and the OIG of demonstrating a "zero" tolerance for "remuneration" in **any** form to occur between a provider and a beneficiary either before or after services are provided.

The proposal offered by CMS will actually create scenarios where a Medicare beneficiary covered by a secondary insurance policy can engage in a CMS rebate program and

actually make money off his rental equipment. This is because his secondary insurance company pays his co-insurance and deductibles. Thus any rebate offered would be money in the beneficiary's pocket. How in good conscience could CMS think a rebate program would ever serve the best interest of the program?
The prohibition on a provider advertising such a program is simply naïve and further demonstrates CMS's complete lack of knowledge on how a competitive marketplace works. The HME referral community is a very small universe and for CMS to believe the "word" would not get out because a provider did not advertise his rebate program is completely naïve. And finally, the mere existence of a potential rebate program will set "heads a spinnin" on how the bid process might be gamed to create a legal kickback program endorsed by the Federal Government. CMS must eliminate any notion of a rebate program and create a system where all winning bidders are on a level playing field if they have any expectation of competitive bidding working over the long run.

► the position that CMS must approve a change in ownership goes way beyond its authority. Should a winning bidder choose to sell his company the only legitimate concern CMS should have is whether or not the new owner can meet the published quality standards. Market capacity is a dynamic concept at best. The ebb and flow of commerce dictates turnover in the inventory of organizations for many reasons. As an example, what if an owner dies in a tragic automobile accident and his estate is forced to sell his company to pay estate taxes. The very act of CMS denying the new owner winning status based on market capacity would so harm the value of the company that it would be tantamount to an illegal taking by the government. This is clearly believed to not be CMS's intend, but serves as just one more example of how poorly thought out most of the proposed regulations contained in this NPRM are.

The above referenced comments are by no means all inclusive to the issues surrounding this NPRM. At best they are an attempt to address the more pragmatic issues which are obvious to this author. Recognizing there are many more legal and procedural issues which need to be addressed I will leave it to the industry attorneys and associations to comment on them far more eloquently than I ever could.

In summary, CMS owes it to every stakeholder affected by this NPRM to withdraw these regulations in total. A complete and thorough reevaluation of the entire Competitive Acquisition program should then be undertaken considering all comments received with new regulations resulting. These new regulations should then be submitted for public comment in the Federal Register.

Respectively submitted,

Thomas E. Inman II
President
Virginia Home Medical

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June 26, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1270-P
P. O. Box 8013
Baltimore, MD. 21244-8013
<http://www.cms.hhs.gov/eRulemaking>

Re: File Code CMS-1270-P Notice of Proposed Rule Making on Competitive Acquisition

To Whom It May Concern:

Having reviewed the proposed rule making for competitive acquisition, I am confused by several issues which I would like to comment on.

1. It seems a bit like "putting the cart before the horse". National accreditation and previously proposed standard updates need to be established prior to beginning the competitive bidding process. Otherwise bids may be submitted by suppliers who cannot or will not be able to supply beneficiaries with quality products and/or service. The proposed quality standards will affect the cost of servicing beneficiaries, which will thereby, affect the bid itself. To the best of my knowledge not only have the proposed standards not reached final approval, but the accreditation process has not been established. Suppliers do not have a clue at this point in time what procedures will be acceptable by CMS. What establishes a supplier as a "qualified", or "eligible" bidder?

CMS should publish the quality standards in order to facilitate comment on them, before the implementation of such standards on the industry. Previously the proposed standard updates were available for comment, but again I have not seen anything since commenting on them. Accreditation firms, or processes, should be identified and time allowed for businesses to secure accreditation, or at a very minimum be in the process of receiving accreditation. It is my understanding the process can be quite lengthy and costly. For the small durable medical equipment business, I am concerned the research and cost would be prohibitive. However, some standard must be in place prior to soliciting bids to assure the bids made would be cost efficient for the Medicare program and still provide the beneficiary with quality of product and care.

In my opinion the first step should be creating the guidelines which establish a qualified or eligible supplier. This step is the most important. It is the foundation for all other elements of the process. Guidelines need to be created and implemented before the bidding begins to guarantee the continuity of care for Medicare beneficiaries currently receiving items which will come under the bidding process. It also ensures the quality of the bid itself. It would certify the bidding process by assuring only those bidders who can and/or do meet the specific guidelines for operation of their business.

2. "Competitive Bidding" should mean exactly what it says. Bidding should be based an amount the supplier is willing to provide a particular item/service for x number of customers. As I understand it, bids above the current fee schedule would be disqualified. However, some items within the current fee schedule are bare minimum with little or no profit margin for the supplier, especially small business owners who cannot afford to surplus order items. Businesses are expected to show a profit; if they do not show a profit, they will eventually be forced to close their doors.

If CMS received fifty bids for same or similar service, but only needed five contracted suppliers to provide for the beneficiaries within the metropolitan area, would bidder five have the "winning bid"?

What if bidder five's bid was substantially lower than the median of the fifty submitted bids? It appears the payment method would be the median of the contracted suppliers, or in the case of the above example the payment would be the median bid of the five suppliers. And what about the other 45 bidders, are they just out of luck? Will they be forced to eventually close their doors because they cannot accept new beneficiaries for these services? Suppose bidder #30 has several Medicare beneficiaries as customers, will the customers be transferred to another supplier? If so, how does the business make up for that lost revenue? Or what happens when the payment period has reached the maximum for those beneficiaries, but the company could not keep building its business?

Bidding should be truly competitive and affordable for all parties. Additionally, the "winning bid" should be the average bid for the group of products within the particular location. In other words, all bids from the metropolitan area should be taken into consideration and the median of those bids should be the amount of the "winning bid". As this trickles down to smaller cities and towns, the same would hold true. It makes a difference in the cost of service when you have a larger coverage area in terms of mileage. While a metropolitan area might be able to provide the service to its beneficiaries, a rural supplier who may drive 50 or more miles one way to make a delivery or service a beneficiary would have more cost involved for that service, especially when you factor in the rising cost of gasoline.

3. The "Rebate" program which would allow contract suppliers to choose whether to offer a rebate of the difference between their bid and the established payment amount to the beneficiary is also a point of great concern. What if the supplier chose not to rebate the customer? What happens to the additional payment amount then? The contracted supplier would not be allowed to advertise the rebate to potential customers. However, CMS would identify suppliers who offer rebates and the amount of the rebate in the materials it distributes to beneficiaries and referral sources! Isn't that a form of advertisement? Why can CMS advertise the information, but the supplier cannot?

How can this not be considered an inducement or "kickback" to the beneficiary? Kickbacks to physicians, beneficiaries, and other health organizations have always been forbidden! Providing the beneficiary a rebate is contrary to other laws applicable to the Medicare program such as the Anti-Kickback Statute and the Beneficiary Inducement Statute. I would think the rebate is illegal.

It also is opposite to the statutory requirement that beneficiary's incur a 20% co-pay. Rebates are given on automobiles, household items, and even as an incentive for early retirement. However, for the competitive bidding program to work - how could one supplier legally offer a rebate over another supplier? Would this lead to allegations of fraud and abuse from the beneficiary?

4. The process to determine the number of suppliers to meet the projected beneficiary demand in a given metropolitan area are vague, but seem to be weighted in favor or larger, higher volume regional suppliers even though small providers will have the opportunity to participate. Further more there are no guarantees that a small business, or a network of small businesses, will be chosen as the "winning bidders".

Additionally, new business would only be directed to contracted suppliers. I urge CMS to consider the negative impact the proposed competitive bidding process could have on small durable medical equipment companies, or companies specializing in the services they offer.

What happens to our company if a regional supplier receives the "winning bid" for beneficiaries in our local area? What happens to the beneficiary's service should regional care be the method of choice for CMS? How does the small durable medical equipment company stay in business without being able to assist beneficiaries living in the area? I think additional research should be done to ensure stability for the existing suppliers who have and would like to continue to do business with Medicare beneficiaries. Wouldn't this place an undue burden on the small company or specialty store?

5. Once competitive bidding has been implemented, beneficiaries who live in a metropolitan area will only be permitted to obtain supplies/service from contracted suppliers. What happened to the

patient's right of choice in selecting their supplier? And if the beneficiary permanent residence is outside of the metropolitan area but they are visiting, the beneficiary can only receive supplies/service from the contract supplier. What about those persons whose permanent residence is in one state, but the beneficiary spends 3-6 months in another state? How would they receive the supplies or service they need?

6. The proposal also allows for physicians to prescribe a specific brand or type of equipment. This could lead to a demand for premium or brand name items based solely on marketing or advertising. Often the "brand name" product has the same benefit as other products which carry a lesser known brand. Many of us in the durable medical equipment business tend to put quality product above the brand name issue. I know of several manufacturers of walkers, but I carry only two brands because based upon our experience with other brands of walker, the ones we handle hold up better over time. In my opinion the quality of the product (meaning how it lasts with beneficiary's extended use), ease of use for the beneficiary, and meeting the needs of the beneficiary are all more important than the brand name of the product.

The contracted suppliers will not be required to carry all brands/models of equipment, but if a physician orders a specific brand/model the supplier does not handle, the supplier must choose whether to fill the order, refer the beneficiary to another supplier, or ask the physician to change the order. This seems unnecessary because the statement is already true to basic day to day operations. Most suppliers do not carry all brands or models of any equipment. We select the products we want to carry in our store based upon our knowledge of the product, reliability, cost, etc. And most physicians do not prescribe items based upon brand, instead they use generic names if you will, such as hospital bed or wheelchair. Furthermore, the decision to select a certain product based upon brand name should ultimately be the choice of the beneficiary. He/she currently has the right to choose where they fill a prescription for any item the physician orders. If one supplier doesn't carry a particular brand, they may take the prescription to another supplier.

7. In addition to these specific quandaries, I have reasonable doubt left by the undefined MSA. What metropolitan areas will be the beginning of the competitive bidding process? To my knowledge a general list has been circulated which names various cities where the process could start, but nothing has been decided. I think CMS should be required to disclose the specific geographic areas as well as products that will be selected in the bidding process.

The issue of competitive bidding in my mind is a bit ridiculous to start with. The fee schedule sets a limit of what will be reimbursed for a given item or service. These fees are routinely update and/or reduced as is deemed necessary by CMS. Hence, one wonders why have competitive bidding, when there are already boundaries established regarding what charges will be allowed as "customary fee for service"?

Home care is the most cost-effective setting for healthcare. A simple fact amply documented and proven in medical research. It is much less expensive than care in the hospital, nursing home, or assisted living facility. Moreover, spending for home care represents a very modest portion of the Medicare budget. Demand for home care has and will continue to increase for several years along with the medical needs of a growing population of older Americans. The "baby boomer" generation has only begun to reach the age of a Medicare recipient. Spending for home care is clearly not the problem with Medicare. In fact, it's part of the solution! For these reasons, I encourage you to make wise and sound decisions regarding the implementation of competitive bidding for durable medical equipment.

Sincerely,
Ronnie & Teresa Grimsley

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Advanced MEDICAL CONCEPTS INC.
The Prescribed Fit

www.amcbaltimore.com

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATT: CMS-1270-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244

June 29, 2006

RE: 1270 P- Comments related to specific elements of the proposed regulation.
A) Competitive Bidding Areas - Pg. 13 B) Criteria for Item Selection – Pg. 17
C) Opportunity for participation for small suppliers. - Pg. 30

To Whom It May Concern:

Advanced Medical Concepts, Inc. is a durable medical equipment (DME) company specializing in mobility, seating and positioning, for those patients with complex medical needs. Located in Owings Mills, Maryland, Advanced Medical Concepts has served clients in Maryland for over fifteen years. A distinct and recognized strength of the company is the use of physical and occupational therapists as field sales representatives thereby giving the customer a clinical and professional interaction

A) Competitive Bidding Areas – Pg. 13

It was indicated in the proposed regulations, that this program would be implemented in the 10 largest markets initially. Arbitrarily, this was amended to exclude the three largest markets, Chicago, Los Angeles and New York. The adverse effect of this arbitrary decision is to have those providers who otherwise would have been excluded from implementation in the initial phase, suddenly do to no change in demographics, but just because the three largest markets create a challenge to CMS and implementation , that they would now 'move up the list' and have to be included. This is patently unfair. Firstly, if the program works, it should be implemented as mandated, including the ten (10) largest markets with no 'carve out' . Secondly, if the three largest markets create a delay that might be considered unreasonable, than the initial phase should be amended to begin implementation in the next seven (7) largest markets. This would insure that no provider is suddenly penalized, and included in the first phase, who would have otherwise been excluded but for CMS'S inability to devise an adequate system to address the needs of the three (3) largest markets.

In a free market system, companies are constantly being bought and sold, and the economic impact of this decision could be devastating to those who relied upon CMS'S representations as to which providers would be included in the initial phase.

B) Criteria for Item Selection – Pg. 17

This aspect of the proposed regulations is particularly disturbing to our industry, our company, especially our patients, and the services we provide. Page 17 indicates that Orthotics is included, but limited to only those that require 'minimal adjustment'. However, after indicating which items will be included and which will not, there is a chart which indicates that Power Wheelchairs is at the top of your list of those items which will be included! I would refer you to the following narrative, which hopefully will convey the incredible time, effort, detailed application and professional knowledge necessary, to properly deliver this service.

Our Rehabilitation Technology Specialists staff of licensed occupational and physical therapists offer expert evaluation, equipment selection, fitting and follow-up. Each of our RTS's has at least achieved a Bachelor of Science Degree, in Occupational Therapy and Medicine, and we have one who has a Masters Degree in Physical Therapy, and all have specialized training in ergonomics and kinesiology.

Advanced Medical Concepts focuses on custom manual and powered mobility, home medical equipment, as well as custom seating and positioning for proper fit and function with special emphasis on pediatric, adult and bariatric clients. Using accepted clinical guidelines and a systematic decision-making process, we provide the most suitable equipment for the patient. We create seating and mobility solutions designed to meet the unique needs of each individual.

The Advanced Medical Concepts' RTS (Rehabilitation Technology Specialists) provide assistive/rehabilitation technology in the areas of

- Wheeled mobility
- Seated and Alternative positioning
- Ambulation Assistance
- Activities of Daily Living

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We begin with a thorough patient assessment and evaluation performed by a licensed physical/occupational therapist. This includes medical history, work environment, current medical equipment, and family participation. Follow-up evaluation home visits are included in the process.

The RTS offers consumers product choices and meets basic standards of acceptable practice in the provision of equipment including ordering, assembling, adjusting, delivering and providing on-going individualized support and service. The RTS has specialized knowledge of musculo-skeletal anatomy, abnormal neurodevelopment, neuromuscular abnormalities, biomechanical principles, concepts and applications.

Moreover Advanced Medical Concepts substantiates the recommended durable medical equipment with documentation of the rationale as well as follow-up on the outcome after equipment has been delivered. Accurate information is recorded regarding measurements, wheelchair set-up, method of propulsion, patient objectives (posture/pressure relief/ function) and clinical assessment.

Advanced Medical Concepts' staff of licensed physical and occupational therapists offer patients cost-effective options for commercially available products and fabricated components with input from other health professionals such as physicians, nurses and social workers.

Clinical patient outcomes achieved through proper equipment fitting include:

- Increased functional status
- Increased mobility
- Greater independence
- Prevention of medical complications
- Decreased safety risks

In addition to assessment and provision of specialty seating, the RTS also trains the caregiver in how to help the patient into the chair correctly, how to properly move the chair, and elements of chair maintenance.

Providers that do not specialize in custom rehabilitation equipment including power wheelchairs can do patients an injustice through misapplication of positioning principles and poor product selection.

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We believe that the services that AMC and other similar providers provide to their patients with complex medical needs (not just those patients with MS or Spina Bifida), are incredibly specialized, and as such, must be excluded from this proposed regulation.

Providers that do not specialize in custom rehabilitation equipment, including power wheelchairs, can do their patient a serious injustice, through misapplication of positioning principles and poor product selection. The ultimate cost to correct these misapplications, as well as the potential acute care costs that would be required to attend to the needs of the patients because their condition worsened, would be far greater than any savings. This doesn't begin to factor in the adverse effect on the quality of life of the patient.

C) Opportunity for participation for small suppliers. – Pg. 30

It is clear that in its initial form, this proposal was to have ensured that small suppliers should have the opportunity to be considered for participation. Yet, in CMS'S own regulatory impact analysis, they indicate that 90% of suppliers affected by this regulation will be the small DME suppliers (pg.43)! This analysis is in direct conflict of CMS'S mandate. The lack of appreciation for the value that small DME suppliers provide is unconscionable. The following narrative will explain the value of the small specialized DME provider.

Qualified, small DME providers with credentialed staff offer high quality rehabilitation technology (custom manual wheelchairs, power wheelchairs, specialized walkers) to the consumer with medical and physical disabilities. The Rehabilitation Technology Specialist must establish optimal wheelchair fit without over-correction. The custom chair must address the normalization of muscle tone and inhibition of primitive reflexes often seen in stroke patients. Trunk control, leg length discrepancy and lumbar support must be addressed.

If the elderly patient is frail, they may require a tilt/recline wheelchair to provide position change and adequate pressure relief to prevent decubitus ulcers. Without an expert evaluation by a rehabilitation technology specialist, a typical DME company would provide a standard wheelchair ultimately causing the patient to develop pressure ulcers and remain in bed which leads to more complications of immobility.

Advanced Medical Concepts Rehabilitation Technology Specialists visit the patient in their home setting and assess their postural seating needs. It is not a simple procedure of providing a wheelchair or walker because the physician has ordered it. The physician expects the DME supplier to provide the most appropriate product. Our staff has had to

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point out to a physician that a scooter or power wheelchair is not appropriate for a patient who has cognitive or visual deterioration. This prevents the patient from injuring themselves and others as well as saving thousands of dollars for the payor.

Measurements are taken to determine the width, depth, seat to floor height and back height of a wheelchair and seating components. Our licensed personnel assess the flexibility and movement of the patient's hip, trunk, shoulders, neck, knees, feet, respiratory status, pain control, nutritional status, skin integrity and home environment before recommending the proper equipment.

Fitting a multiple sclerosis patient with a wheeled mobility system illustrates why a specialty provider with licensed clinical staff is required. A large DME supplier provides wheelchairs to this population often with deleterious effects.

Multiple Sclerosis is a progressive neurological disease with an unpredictable course. One of the most difficult assessments is figuring out the length of time the patient will be able to use their rehab equipment. For example if a manual wheelchair is purchased, will the patient be able to use it in six years or will it last less than 12 months? It takes an experienced rehabilitation technology licensed clinician to consider whether the patient may benefit most from a manual chair, powered mobility, powered mobility with a joy-stick, or in cases of advanced disease – a powered wheelchair with an alternative input such as head switches or chin control. The combination of physical and cognitive issues must be weighed to determine the most appropriate, cost-effective product. Advanced Medical Concepts is recognized as a reputable, exceptional provider by the Multiple Sclerosis Society of Maryland. We have a proven track record of meeting the complex seating needs of our MS clientele.

Seating and mobility interventions are very challenging because of the number of physical, functional, socio-economic, and environmental variables that must be taken into account. The "one-size-fits-all" mobility solution offered by large commercial DME suppliers can cause significant decreases in patient function. The freedom of movement made available by specialized DME mobility providers such as Advanced Medical Concepts is key to a patient's function, comfort and activity. It is imperative that the specialty provider survives in order to best match durable medical equipment parameters to the user.

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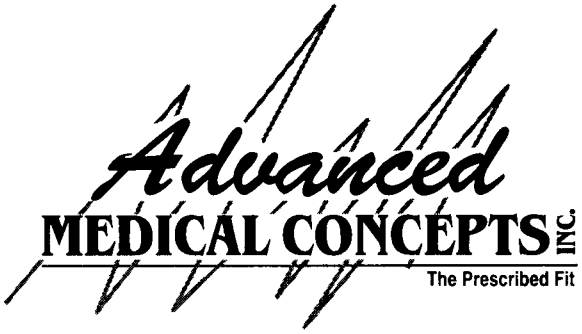

www.amcbaltimore.com

We respectfully request that CMS include these comments in the official record, and that CMS take a critical look at the potentially disastrous effects of this initiative. We recommend that CMS create a task force with Industry participation to develop a program that does not jeopardize the welfare of the very beneficiaries that we are servicing.

Yours very truly,

Ari P. Krupp, CEO
Advanced Medical Concepts, Inc.

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CHAPMAN HEALTHCARE CENTER, INC.
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ALEXANDER CITY, AL 35010
PHONE (256) 234-6366
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June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To Whom It May Concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the administrator at Chapman Healthcare Center, located in Alexander City, AL. We are licensed for 212 beds. I have 239 employees at the present time. We offer Physical, Occupational, and Speech Therapy at our facility.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Chapman Healthcare Center we have numerous residents whose care could be interrupted as a result of this implementation-jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,

Archie J. Chapman

Archie J. Chapman Administrator
Chapman Healthcare Center, Inc.

FOX MILL FOOT AND ANKLE CENTER, PLC

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Seth A. Rubenstein, DPM*
George D. Lane, DPM*
E. Kent Picklesimer, DPM

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Suite 220
Reston, VA 20190

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June 28, 2006

Mark B. McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Electronic Comments

Dear Dr. McClellan:

I am writing to voice my opposition to certain provisions of the proposed rule that would establish a competitive acquisition program for durable medical equipment, including prosthetics, orthotics and supplies (DMEPOS).

We currently provide CAM Walkers, night splints and various other DME's through our practice to patients who require such devices. In many cases, DME's are dispensed in an acute setting. This ensures delivery of the best possible care in the most expeditious manner. Most patients, and especially those in the Medicare age group, would not be well served by requiring them to drive from provider to supplier and back and forth again if the device were not fitted properly or needed adjustments.

Physicians represent 3.1% of all allowed dollars for DME. A competitive acquisition program that requires physicians to bid to supply items to patients will likely result in the elimination of most physician suppliers and ultimately result in delayed or diminished clinical outcomes.

I urge the Centers for Medicare & Medicaid Services (CMS) to exclude all physicians, including podiatric physicians, form the competitive acquisition program and to instead allow physicians to continue to supply DMEPOS items as part of the normal course of patient care.

Sincerely,

Seth A. Rubenstein, DPM

**Fellow: American College of Foot Surgeons*
**Diplomate: American Board of Podiatric Surgery*

Carolina Foot & Ankle Specialists, PA

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Physicians & Surgeons of the Foot & Ankle

Robert A. Liberatore, D.P.M.

Board Certified: American Board of Podiatric Surgery

Board Certified: American Board of Podiatric Orthopaedics

Fellow: American College of Foot & Ankle Surgeons

Fellow: American College of Foot & Ankle Orthopaedics and Medicine

E. Jason Plumley, D.P.M.

Associate: American College of Foot & Ankle Surgeons

Member: American Podiatric Medical Association

Kristine M. Strauss, D.P.M.

Associate: American College of Foot & Ankle Surgeons

Member: North Carolina Foot & Ankle Society

Member: American Diabetes Association

Specializing In:

Shockwave Therapy for Chronic Heel Pain

Diabetic Foot Care & Wound Management

Reconstructive Foot Surgery

Ingrown & Fungus Nails

Foot & Ankle Injuries

Chronic Foot & Ankle Ailments

Diabetic Shoes, Custom Molded Shoes & Foot Orthotics

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June 27, 2006

Mark B. McClellan, MD, PhD
Administrator f
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan:

I am writing to I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r) before finalizing the regulations for the competitive acquisition program. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

In my practice I use a variety of DME items. Some common problems I treat include fractures of foot and ankle, tendon injuries, severe foot and ankle deformities. In many cases it is imperative that my patients immediately be dispensed these items from my office. I feel patient care will be compromised if I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide

It is also important to make sure that the devices used fit the patient properly, that the patient understands how and why the device is needed and it is important for them to get the proper device. We are able to stock those devices that work best for my patient population. I fear that if the device is necessary and is not readily available by to the DMEPOS supplier a brand or item of lesser quality will be substituted.

I also employ a Certified Pedorthist and my staff is well trained in the specifics regarding my specialty.

Podiatrists are physicians who treat foot and ankle problems similar to an Orthopaedic surgeon. I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians. Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

As a podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. These individuals are my patients and they rely on me to use my best medical judgment and clinical skills in treating them. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to my patients only and the right to execute a physician authorization.

I prescribe and supply select DMEPOS items as part of patient care. I do not supply items to individuals who are not my patients and believe that requiring me to do so would not be appropriate to Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

Please change the physician definition from 1861(r)(1) to 1861(r) so that I am eligible to bid to supply items to my patients only and execute physician authorizations. I want to be able to continue to provide medically necessary and appropriate care to the patients I serve.

Sincerely,

Robert A. Liberatore, DPM
RAL:bon

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NEIGHBORHOOD Diabetes

Helping To Make A Difference.

Submitter: Thomas Cronin
Title: Chief Executive Officer
Organization: Neighborhood Diabetes
Category: Durable Medical Equipment Supplier
Reference CMS 1270-P
Issue/Areas for Comment: General

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1270-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

To whom it may concern:

Neighborhood Diabetes is a small business with about 50 employees that provides supplies for Self Monitoring of Blood Glucose (SMBG) to approximately 20,000 clients in the Boston area.

The large majority of our clients are covered by Medicare. Unlike other Medicare DME diabetes suppliers whose business model depends on consumer advertising to attract new clients, Neighborhood Diabetes receives its referrals from clinicians, over 1,500 of whom provided us with a referral over the last twelve months. These clinicians vary from nurse practitioners at overwhelmed urban health clinics to endocrinologists at Boston teaching hospitals such as Massachusetts General Hospital.

Our clinicians provide us with referrals because we offer services that help make their patients healthier. These services include: Home visits to new clients to ensure that they are properly trained on their glucose testing equipment in a comfortable environment, home delivery of testing supplies and prescription medications, live people answering the phone, creation of support literature to ensure that common barriers to glucose testing are overcome, and targeted follow-up calls geared toward ensuring not only that clients test their blood sugar, but that they obtain ADA recommended laboratory tests and physician visits as well. We perform these services in the client's native language. Our staff includes native speakers of English, Spanish, Portuguese, Haitian Creole, Khmer and Vietnamese.

Diabetes is different from other conditions because of the chronic nature of the disease, the number of people affected, and the important role that self-care plays in limiting downstream complications. Data

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Wakefield, MA 01880

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Fax: 781 246 1978

www.sugartest.com

clearly shows that better adherence to self-monitoring of blood glucose levels significantly improves quality of life and decreases the cases of complications related to diabetes. In addition to providing our clients with their testing supplies, Neighborhood Diabetes has taken on the responsibility of educating and supporting them in order to achieve better adherence to their testing regimens. Taking this extra step is expensive for us, but it has proven to be a successful educational supplement to what our clients are learning from their clinician. Compared to significant studies, our clients' adherence levels are far better than the average US diabetic population. (For instance, we did a study which found that 74% of our non-insulin dependent Type II diabetics regularly check their blood sugar, as opposed to 39% that were identified in a study[1]of insureds at Kaiser-Permanente of Northern California) .

My concerns with the proposed new rules can be summarized as follows:

Competitive Bidding on diabetes supplies will not save money in the long run:

Implementing a competitive bidding program for diabetes supplies will lead to a 'penny wise and pound foolish' situation. The ripple of short term cost savings from the program will be dwarfed by the tidal wave of costs that will come from diabetic complications suffered by Medicare participants who are not trained sufficiently or face language issues that leave them unable to adhere to their recommended treatment regimen. These complications include very expensive conditions such as heart disease, hypertension, neuropathy, retinopathy, and other conditions. A recent study[2] showed the following:

Average annual healthcare cost for a non-diabetic insured:	$2,560
Average annual healthcare cost for a diabetic insured:	$14,233
Average annual healthcare cost for a diabetic insured with heart disease and an HbA1c > 10.0 :	$46,879
Annual cost blood glucose testing supplies cost (est.)[3]	~$500

Using this data, if the changes caused by Competitive Bidding lead to even a 1% increase in the development of complications such as heart disease among insureds, the cost increase would be $326 per insured (($46,879-$14,233)*.01). This amounts to over sixty percent of the amount paid per year for supplies. Is it possible that being served by the lowest bidder (or a low bidder) as opposed to a company like Neighborhood Diabetes could lead to 1% of the insured population 'veering off track' from their glucose testing regimen and suffering these complications? Based upon our experience we would say "Absolutely". Is there any way that the competitive bidding program will save sixty percent of annual blood glucose testing supply costs? We would say "Absolutely not". Will this program be cash positive for the Medicare program? Again, we would say "Absolutely not".

Competitive Bidding is inequitable to Small Businesses

Clients and health care providers alike agree that Neighborhood Diabetes provides extraordinary service to diabetes patients. With this service level and our additional educational and support efforts, we have consistently helped to make our clients healthier. Our hard work over the years has built a strong business with 20,000 clients. The efforts we have made to build a company based on 'making a difference' to patients should be rewarded, not potentially cast aside by a new set of rules from

Washington.

If competitive bidding in diabetes were to take place in our market, we would essentially lose our entire client base. This is patently unfair to small, regional, single product line companies like ours. Unlike the 'national' companies in our business, we can not bid for contracts in several markets, offering a variety of prices in the hopes of winning some or all of them. To make small firms like ours essentially 'bet the company' on a single bid for our local area puts us at a significant disadvantage to larger concerns. Again, this is just not fair to small businesses.

Competitive Bidding will be bad for Patient Health

As I mentioned in my first point, having potentially low-cost providers offering generic glucose testing equipment and little training or support to patients would actually lead to higher long-term costs for the Medicare Program. This wouldn't just be bad for the program, it would be very bad for the patients covered by Medicare.

In the current reimbursement environment, Medicare suppliers of diabetes testing equipment such as Neighborhood Diabetes compete for clients based on the level of service they provide, rather than price (since the price is set by Medicare). Overall, this leads to better-educated patients, who receive information and training from their suppliers that supplements information received from sometimes overwhelmed clinicians, who face continuously declining reimbursable time with their patients.

To self monitor their blood glucose, seniors who often have difficulty seeing, hearing, or understanding English are being asked to use complex technological devices that are foreign to them. A company that has had to submit a competitive bid will have an incentive to provide the lowest cost product in the most efficient possible manner. We believe this will 'leave behind' Medicare participants who need the type of support or special products we routinely provide. For instance, one of the elements of service that our company takes great pride in is offering a client the glucose monitoring system that best fits the client's needs. We have products that are best for clients with dexterity issues, vision problems, and those for whom 'coding' a glucometer is difficult. In a 'provide a meter at the lowest possible cost' environment, with a limited number of suppliers to turn to, these Medicare patients will have more difficulty getting the meter and training they need to adhere to their treatment regimen, and could develop the terrible complications that diabetes routinely causes, such as heart disease, blindness, foot amputations and the like. The New York Times and other publications have described diabetes as an "epidemic" in the United States today. For CMS to consider instituting a competitive bidding program that could lead to more suffering for the victims of this epidemic, is, I believe, reprehensible.

Footnotes:

1) Karter, AJ et al, *American Journal of Medicine*, Volume 111, July 2001
2) Gilmer, TP et al, *Diabetes Care*, Jan 2005, 28(1): 59-64
3) Neighborhood Diabetes estimate

Following are a few of the testimonials that Neighborhood Diabetes has received concerning its services:

"My staff and I at the Massachusetts General Hospital Healthcare Center in Revere have utilized the programs and services offered by Neighborhood Diabetes. The feedback received from our patients has been extraordinary. My staff has been able to take advantage of a service that is an intangible asset, the home delivery and in-service training. Their unique services allow my staff to spend more quality time with our patients. The courtesy, professionalism, and knowledge of glucose monitors offered by ND gives our staff the utmost confidence in referring our patients to them for diabetic testing supplies.

The customer service exhibited by ND is proof positive that they are truly caring and cognizant of their client's needs. The attention to detail, prompt, accurate, and precise customer service makes ND the most competent diabetes equipment provider. Neither my staff nor I would even think of referring our current or newly diagnosed diabetics to any other company than ND.

Another wonderful feature that my patients have commented on is their ongoing telephone follow-up. This feature allows my patients to troubleshoot their monitor questions and avoid running out of testing supplies. The bottom line is that my patients do not feel 'lost' using ND. There are no voice-recorded messages when calling the office, you get answers immediately and my patients have developed a trust with ND."

Pat Roberge, LPN, *Massachusetts General Hospital - Revere*, Revere, MA

"They (ND) have been exemplary in their care of diabetic patients including in-home training and routine follow up and this has been unmatched by any of our other suppliers. The personal attention that they give patients helps to improve their heath and makes it more efficacious for us to treat patients in an excellent manner."

Dr. Eric Schreiber, Endocrinologist, *Riverside Healthcare Associates*, Medford, MA

"I just wanted to thank you for being so reliable, honest and consistent. I have never gotten one negative report from any of the clients I have referred to your agency. Only the following actual comments from my clients, heard on several occasions:

You get to talk to a real person.

Those boys were so patient with me.

I call them all the time because I forget how to use my machine but they keep helping.

I never run out of test things any more because they call me.

Thank you for making a difference in the lives of elders, and continuing to find new ways to accommodate and serve them as well as you do. Even after your expansion, you managed to offer the same quality customer service and you are setting a fine example for other growing small businesses to live up to. IMPRESSIVE!"

Melissa Manderson, Diabetic Care Case Manager, *SeniorCare, Inc.,* Gloucester, MA

"They (ND) will not only deliver diabetes product supplies in a timely manner but will educate clients on the use of the diabetes related equipment. They will actually visit the home of a client to demonstrate on the use of a meter. . . . It is most refreshing to have a local company, which offers personal care with unprecedented service."

Andrea Penney, RN/CDE, *Joslin Diabetes Center - Anna Jaques Hospital,* Newburyport, MA

"I am writing to sing the praises of Neighborhood Diabetes. They have been wonderful to work with. They are a class act that follows up on their word, a rarity in this present age. Our patients are very grateful for the personal care that they receive from ND, who go to the patient's home and give follow up calls. When we refer to ND I know that the patient will receive excellent care and quality products."

Nancy Perrault, RN,CCM, *South Shore Medical Center,* Norwell, MA

"In my thirty years as a healthcare provider, I can't top the service that this provider has supplied to us and our patients."

Margaret Davis, MS, RD, LDN, FADA, CDE, *Live Nutrition,* Brewster, MA

"I often recommend my clients contact Neighborhood for their diabetes supplies. I have used their services for about two years now and I have no complaints whatsoever about their service. They are responsible, courteous, and best of all, they are the only company I know that sends someone to the client's home to teach them how to use a meter. You can't imagine how valuable a service that is. Not only do they help the client, but they also help the nurses and the diabetes educator in the meter teaching process. As you may know, we have a shortage of time to spend with our clients, and sometimes do a quick review on how to use a meter, or sometimes don't even have time for a review. A quick phone call to Neighborhood enrolling the client with their services and making sure they review the meter usage with the client is a lifesaver."

Virginia Hernandez, RN, BSN, CDE, *Diabetes Management Center,* Dartmouth, MA

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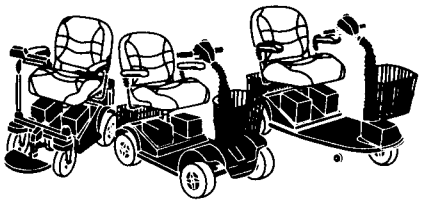

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June 27, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: File Code CMS-1270-P

VIA OVERNIGHT MAIL

Dear Sir or Madam:

Electric Mobility Corporation, DBA "The Rascal™ Company," has reviewed the "Proposed Rule for the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues" and is submitting the following comments pertaining thereto:

Payment Basis (proposed §414.408)

The following citation is of particular concern to our company:

> "We are proposing that if a non contract supplier located in a competitive bidding area furnishes an item included in the competitive bidding program for that area to a beneficiary who maintains a permanent residence in that area, the beneficiary would have no financial liability to the noncontract supplier..."[1]

We believe this provision unfairly restricts Medicare beneficiaries' choices if this applies to cash sales for which a claim would be submitted on a non-assigned

[1] Page 45

basis. Of note, when this question was proposed to representatives of the Centers for Medicare & Medicaid Services (CMS) at the Open Door Forum held in conjunction with the Program Advisory and Oversight Committee (PAOC) meeting on May 23, 2006, those representatives were unable to answer citing that they "hadn't thought of this scenario."

Many beneficiaries prefer the option of choosing a certain type or model of DMEPOS and to bill the Medicare program on a non-assigned basis. To limit, or indeed to eliminate, this option for beneficiaries in competitive bid areas seems an unfair restriction on those beneficiaries' freedom of choice.

Determining Single Payment Amounts for Individual Items: Rebate Program (proposed §414.416[c])

Electric Mobility Corporation is greatly concerned that this program is providing the opportunity for violations of the Antikickback Statute, the Stark Provisions, False Claims Act and runs contrary to the compliance guidance and opinions promulgated by Health and Human Services Office of the Inspector General (OIG). This provision appears to provide the potential for fraud and abuse in an industry that is still reeling from the violations brought to light by "Operation Wheeler Dealer."

Furthermore, the Proposed Rule states "Contract suppliers would also be prohibited from directly or indirectly advertising rebates to beneficiaries, referral sources, or prescribing health care professional."[2] However, at the PAOC meeting held on May 22, 2006, the presentation by representatives from CMS contained the information: "CMS will provide information on the suppliers who decide to offer rebates."[3] While the Proposed Rule clearly delineates that this program is *voluntary*, CMS disseminating information about suppliers who participate in the rebate program creates an unfair marketing advantage to those suppliers.

Terms of Contract: Repairs and Replacements of Patient Owned Items Subject to Competitive Bidding (proposed §414.422 [c])

The following citation is of particular concern to our company:

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[2] Page 102

[3] Page 1 of Presentation entitled "Rebate Program Proposed § 414.416 page 25701." Presented to Program Advisory and Oversight Committee (PAOC), May 22-23, 2006.

> "Repair or replacement of patient-owned DME...that are subject to the competitive bidding program, must be furnished by a contract supplier because only winning suppliers can provide these items in a competitive bidding area. The contract supplier cannot refuse to repair or replace patient-owned items subject to competitive bidding. This proposed policy will help to ensure that the beneficiaries will get the items from qualified suppliers, and it is consistent with the competitive bidding program in that it directs business to contract suppliers. Therefore, we propose that repair or replacement of patient-owned items subject to competitive bidding must be furnished by a contract supplier."[4]

Given the varying complexity in many areas of DMEPOS, it seems unduly burdensome to expect contract suppliers to service and/or repair patient-owned DME from all manufacturers. How can any supplier be expected to have all replacement parts for all units manufactured in their area of expertise? How can any supplier expect to have staff trained to service all units manufactured in their area of expertise? Rather than affording the benefit of having beneficiaries-owned DME repaired by qualified suppliers, if that supplier does not have the product/part or the knowledge to perform the repair, this will have the opposite of the desired effect. Those beneficiaries may very well receive substandard repairs if the contracted supplier in their area of permanent residence is unfamiliar with their particular piece of DME.

Electric Mobility Corporation appreciates this opportunity to comment on the Proposed Rule and hopes that its observations serve to illustrate our areas of concern.

Sincerely,

Michael Flowers
President

MF:jrb

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SUBMITTED ELECTRONICALLY
AND VIA OVERNIGHT DELIVERY

June 29, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1270-P – Notice of Proposed Rulemaking, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Invacare Corporation (Invacare) is pleased to submit comments on CMS' Notice of Proposed Rulemaking for Competitive Acquisition for Certain DMEPOS and Other Issues. As the global leader in the manufacture of the broadest product offering of innovative home medical equipment (HME) that promotes recovery and active lifestyles, Invacare manufactures and sells to HME (DMEPOS) suppliers a broad array of DMEPOS products, including manual and power wheelchairs, other mobility aides such as canes and crutches; respiratory products such as oxygen concentrators, portable oxygen systems, nebulizer compressors and respiratory disposables; sleep therapy products; home care beds; low air loss therapy products; bath safety products; and patient transport equipment. Much of this equipment falls under the definition of "durable medical equipment" as defined under Part B of the Medicare Program.

Invacare submits the following comments on CMS' Notice of Proposed Rulemaking published May 1, 2006 in the *Federal Register* (71 *Federal Register* 25654), Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues. As CMS requested, our comments are divided into sections with "headers" that correspond to the particular subject in the proposed rule.

1. Procedural Issues

A. Need for Additional Comment Period on Issues with No Proposal in NPRM

There are numerous times in the NPRM that CMS provides no specific proposal but instead asks for public comment on a particular issue. For example, under proposed 42

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CFR §414.408(e), "Authority to Adjust Payments in Other Areas," CMS invites comments and recommendations on this issue, without providing any proposed methodology to implement this section of the law. We strongly recommend that once CMS receives comments on this and other issues for which it has no proposal, that CMS issue these proposals in another proposed regulation. If CMS chooses not to do this, there will be absolutely no opportunity for comment on any proposal before CMS issues it in final regulation. This would be wholly inconsistent with the intent and substance of the Administrative Procedures Act. Therefore, we strongly recommend that CMS provide for an additional comment period particularly on issues for which CMS has no identified proposal in this NPRM.

B. Need to Address Competitive Acquisition in conjunction with DRA Issues

CMS' implementation of the DRA provisions on capped rental equipment and the "rent to purchase" of oxygen equipment will have a significant impact on the bid process and bid amounts. These new reimbursement provisions impact winning and losing bidders and beneficiaries. CMS should allow stakeholders to address these issues together when it publishes the DRA NPRM later this year. The information in the NPRM is inadequate to serve as a basis for public comments, especially with respect to the impact that the implementation of the Deficit Reduction Act of 2005 (DRA) will have on competitive bidding. Prior to implementing competitive bidding, CMS should issue an interim final rule to allow additional stakeholder comments. Further, because the NPRM raises more questions than it answers, does not identify the markets, or the products, and the final quality standards have not been published, CMS should also allow adequate time to schedule a meeting of the Professional Advisory Oversight Committee (PAOC) after it publishes an interim final rule. This will permit CMS to obtain industry input one more time before publishing a final rule and initiating program implementation.

C. Need for Public Comment on Final Quality Standards

Invacare applauds CMS for its apparent intent to ensure that all suppliers providing items and services under the competitive acquisition programs meet defined Quality Standards. At the time of this writing, however, CMS has not issued the final DMEPOS Supplier Quality Standards. We believe that these Quality Standards must be analyzed in the context of this proposed regulation, and therefore ***recommend that CMS either extend the comment deadline for this NPRM to 60 days after CMS issues the final Quality Standards, or allow for a formal comment period on the Quality Standards, for a period of at least 60 days once CMS issues the final Quality Standards.*** In addition, ***CMS should respond to public comments on the Quality Standards as part of its response to comments it receives on this NPRM.***

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CMS must allow stakeholders an opportunity to comment on the quality standards before they are finalized. We understand that CMS received comments from 5600 organizations and individuals on the draft supplier standards, and the final standards will likely differ significantly from the draft. If so, under principles of administrative law, CMS must give stakeholders another comment period. Furthermore, an additional comment period is appropriate inasmuch as CMS has chosen to by-pass the procedural protections of the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget that would otherwise be part of the rulemaking process applicable to the quality standards.

At the very least, CMS should schedule a PAOC meeting after it publishes the standards. Invacare strongly supports a requirement that all suppliers billing the Medicare program for DMEPOS must meet quality standards and be accredited. It is also critical that final supplier standards apply to any supplier desiring to submit a bid. Allowing an additional comment period is unlikely to significantly impact the overall implementation timeline. Even so, competitive bidding is a radical departure from traditional Medicare and this program is still mostly experimental; consequently, CMS should tolerate delays and not rush to implement the quality standards or any other aspect of competitive bidding.

D. Need for PAOC Meeting Once CMS Issues Final Rule

Due to the many issues that are not addressed in the NPRM, Invacare strongly recommends that CMS convene a meeting of the PAOC as soon as the final regulation is issued. At this point, CMS must ensure that the geographic locations (MSAs) and products to be included in the competitive bidding programs are known, as well as the detailed implementation schedule.

2. Creditor Issues

According to the CMS Regulatory Impact Analysis, about half of these suppliers will not be selected as contract suppliers, adversely affecting the majority of suppliers in this country. These non-contract suppliers will therefore not likely be able to sustain their businesses based upon the items not included in competitive bidding. We believe the proportion of adversely affected suppliers will be significantly greater for smaller suppliers, given the fact that price will be the key factor in determining which suppliers become contract suppliers.

As the largest worldwide manufacturer of home medical equipment, Invacare extends credit to literally thousands of entities that are Medicare DMEPOS suppliers in the United States. CMS's Regulatory Impact Analysis does not include the costs and impacts on creditors such as Invacare; probably the largest creditor to the HME industry. The stark reality is that competitive bidding will force about half of the current suppliers to go

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out of business. The direct financial impact on Invacare is potentially huge. As a creditor, Invacare has no information to understand which suppliers will be contract suppliers and which will not. As a result, Invacare will be significantly negatively impacted by the implementation of competitive bidding. Invacare strongly recommends that CMS consider and incorporate creditors' impacts in the Regulatory Impact Analysis.

3. Regulatory Impact Analysis

CMS' Regulatory Impact Analysis is, as noted above in the section on Creditor issues, limited in terms of the scope of the real economic impact to the United States. CMS has not considered the larger macroeconomic impacts of forcing half of the DMEPOS suppliers out of business; these impacts include lost jobs, lost personal and corporate taxes, and other direct losses to communities across the country that will result from a large number of small business entities being forced to close their doors.

Further, CMS' Regulatory Impact Analysis overstates the potential savings from implementing competitive bidding. CMS cannot assume that competitive bidding will achieve the same level of savings as were experienced in the demonstration projects in Polk County, FL, and San Antonio, TX. Since those demonstrations occurred, Congress has imposed a series of significant cuts on the major product categories. For example, the Medicare Modernization Act imposed significant cuts to oxygen (11-13%, hospital beds 20%, nebulizers 22%, etc.). Further, there have been CPI freezes imposed on the DMEPOS fee schedules, which are in reality a cut as labor, fuel and other costs have increased dramatically over the last few years. As a result of these series of significant cuts, we strongly recommend that CMS re-calculate the potential savings; and recommend that the Administration request Congress to request that the Congressional Budget Office revise its estimate of savings in light of these facts that will have a direct impact on the potential savings associated with implementing competitive bidding.

Finally, we believe that CMS has significantly under-estimated the administrative costs associated with developing and implementing the competitive bidding program. The administrative costs to review all bidders information to ensure compliance with quality, financial and other standards, physical site visits to potential contract suppliers, bid review, calculation of pivotal bids and single payment amounts, and ongoing oversight in the CBAs will be enormously complex and resource intensive. CMS should re-examine its assumptions, and based upon comments received, recalculate the anticipated costs of administering this program. CMS should then provide that information to the Congress, along with its revised estimate of the potential for savings associated with the program. Looked at together, the administrative costs will not be able to be rationalized, given the meager potential savings that the program might yield.

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4. Need For Product Standards

Without any quality, performance or technical standards in place for all items potentially included in competitive bidding except for power wheelchairs and power-operated vehicle, CMS is creating a program that will result in substantially inferior products. During PAOC meetings, CMS has identified a process whereby it would monitor on a retrospective basis the actual brand items of bid products that are provided to beneficiaries in a CBA. This burdensome process would be administratively impossible to monitor and, CMS has no measures to determine whether the items provided meet any particular standards.

As a way to ensure that beneficiaries are able to continue to receive quality items and related services, Invacare strongly recommends that CMS establish a process for each item subject to competitive bidding that ensures that products that contract suppliers provide are of similar quality compared to products provided in non-bid areas. Specifically, CMS needs to establish quality standards for products as CMS did for power wheelchairs and POVs. Regardless of the level of complexity, there will be durability, performance and other measures to ensure a certain level of product integrity and quality. As CMS did with power wheelchairs and POVs, CMS needs to work with the relevant manufacturers to establish these standards. Once the standards are established, manufacturers would apply for a code verification; the HCPCS code designation would require the product to meet those specific standards. This would ensure that beneficiaries only have access to items of acceptable integrity and quality standards; it would resolve the quality issue at the front end, obviating CMS' need to track from every contract supplier, an itemization of all the products provided to beneficiaries in the CBA.

5. Need for HCPCS Code Refinement

In order for DMEPOS suppliers to submit bids for individual HCPCS codes, there must be a narrow range of technology defined by each HCPCS code. That specificity simply does not exist with the majority of HCPCS codes. We therefore recommend that CMS refine its HCPCS code system for each product category it intends to include in a competitive bidding program. That refinement must be done in consultation with stakeholders, including manufacturers, suppliers, physicians and other clinicians, and consumers, to ensure that HCPCS codes are refined with sufficient specificity. If CMS fails to refine the HCPCS code system for product categories it intends to include in competitive bidding, suppliers will not be able to provide intelligent bid information for each code; because suppliers cannot anticipate the specific future needs of beneficiaries for specific items that will fall with one HCPCS code.

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6. Implementation Contractor

The proposed rule states that CMS will contract with a new entity, the Competitive Bidding Implementation Contractor (CBIC), whose primary functions will be to provide oversight and decision making, operation design functions, bidding and evaluation, access and quality monitoring. There is no further information regarding how CMS plans to choose the CBIC; but Invacare recommends that CMS ensure that any CBIC entity avoids any potential conflict of interest. For example, a conflict of interest would exist if a CBIC were also a private payor that negotiates directly with DME/HME providers in a managed care context.

7. Payment Basis

Payment for Supplies/Accessories for Items Subject to Grandfathering: Invacare supports CMS' proposal that accessories and supplies used in conjunction with an item furnished under the proposed grandfathering process can also be furnished by the grandfathered suppliers.

Payment Adjustment to Account for Inflation (Proposed 414.408(b)): Invacare supports CMS states that suppliers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U. Suppliers have no assurance that Congress will not override the update through subsequent legislation in any given year. CMS needs to address how it plans to assure providers that the inflation update to the competitive bid price will not be subject to subsequent freezes in the CPI-U. If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids.

Authority to Adjust Payments In Other Areas (Proposed 414.408(e)): Effective for items furnished on or after January 1, 2009, CMS has the authority to use payment information from the competitive bidding program to adjust payment amounts to items in an area not in a competitive bid area. CMS is proposing to use this authority, but has not proposed any specific methodology for doing so. Instead, CMS invites comments and recommendations regarding a methodology CMS should use to implement this authority. Invacare recommends that CMS issue a separate NPRM addressing this issue to allow for substantive comments on specific proposals.

Invacare recommends that CMS use criteria that CMS has established under its inherent reasonableness authority, under section 1842(b)(8) of the Social Security Act, to adjust payment rates for Part B items other than physician services. These criteria are in CMS' final regulation issued December 13, 2005 (70 *Federal Register* 73623). The IR methodology includes procedural steps to protect stakeholders and requires an analysis of the factors that influence a determination to make a payment adjustment. In using

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information derived from competitive bidding, at least one of these factors is the comparability of the CBA to the areas where CMS intends to make a payment adjustment. CMS should undertake an impact analysis before applying bid rates from a competitive bid area to items in a non-competitive bid area. That analysis should focus on the ability of suppliers to provide the item at that bid rate and the impact on beneficiaries and their ability to access quality items at that bid rate.

We cannot comment further because CMS has not identified a proposed methodology to address in comments. Therefore, CMS should initiate a separate notice and comment rulemaking to solicit comments on a specific proposal before implementing this authority in a final rule.

Requirement to Obtain Competitively Bid Items from a Contract Supplier (§414.408(f)):
The NPRM states that if the area that the beneficiary is visiting is not a competitive bidding area, or if the area is a competitive bidding area but the item needed by the beneficiary is not included in the competitive bidding program for that area, the supplier would be paid at the rate of the single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. This proposal will make it difficult for traveling beneficiaries to obtain products and services in some areas. While we recognize that this is the current Medicare policy, the maximum payment difference from one state to another is only 15%, while the difference between a single payment price under competitive bidding and the fee schedule amount in a non-bid area could be substantially more than that. Invacare recommends that CMS continue to pay the fee schedule amount that corresponds with the beneficiary's permanent residence when beneficiary's travel outside their competitive bid area.

There are a significant number of beneficiaries who are "snowbirds", who spend a good portion of the year in a more southern area of the country. This proposed requirement will have a significant and undue impact on suppliers providing items and services to snowbird beneficiaries. It is simply not equitable to impose a bid rate on an item on a supplier in a different area of the country, without any analysis regarding the appropriateness of that new lower price. This proposal will have an undue negative impact on suppliers serving "snowbird" beneficiaries, and CMS should reject this proposal in the final rule. We recommend that CMS modify its claims jurisdiction policy for these beneficiaries because these beneficiaries will likely find it difficult to obtain quality items and services when they are not at their permanent residence. This proposal needs to be changed to ensure that beneficiaries maintain appropriate access to medically necessary items.

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Further, CMS states that it will monitor the programs to ensure that this type of "abuse or circumvention of the competitive bidding process and requirements to obtain items from a contract supplier does not occur." If this "avoidance of competitive bidding contract suppliers" activity does occur, CMS should understand that it is likely a strong indication that the competitive bid program is not meeting physician and beneficiary needs in that area. Beneficiaries would only seek out non-contract suppliers if they, and their referring physicians, are dissatisfied with the quality of items and services available from contract suppliers. This activity should therefore be monitored as a measure of whether contract suppliers are providing beneficiaries with a suitable level of quality and access; there would be nothing nefarious about his activity.

Grandfathering Medicare Advantage Beneficiaries: The NPRM does not address the impact of competitive bidding on Medicare Advantage (MA) patients who leave their plan to reenter traditional Medicare. These patients may have a provider who is part of the MA plan network, but that may not be a contract supplier. What rules will apply to this patient population under competitive bidding? Will these patients have the opportunity to continue to use their existing supplier when they reenter the traditional Medicare program? We recommend that patients moving from an MA plan to traditional Medicare be given the option of remaining with their existing provider under the grandfathering provisions proposed in the NPRM.

Beneficiary Switch to Contract Suppliers: The NPRM states that a beneficiary can decide to use a contract supplier at any time. Contract suppliers will be required to furnish capped rental or oxygen equipment to beneficiaries in the competitive bidding area regardless of the rental months remaining on the equipment. CMS states that suppliers must factor these additional costs into their bids. Suppliers will be unable to include these additional costs into their bids because it is not possible to predict whether beneficiaries may decide to switch to a grandfathered supplier and how many rental months remain on a piece of equipment. Moreover, CMS also states that suppliers may not submit bids higher than the current fee schedule amount for an item. This artificial ceiling on the bids further complicates bidding under this scenario. We appreciate CMS' desire to preserve the beneficiary's freedom to change suppliers even under a competitive bidding program. We recommend that CMS initiate a new period of continuous use if a beneficiary decides to switch from a grandfathered supplier to a contract supplier.

Application of DRA to Oxygen Patients: It is unclear from the NPRM how CMS intends to apply the DRA provisions on oxygen to grandfathered suppliers and beneficiaries. Will the "grandfathered" relationship terminate at the conclusion of 36 months? The implementation of the DRA forced ownership provisions on oxygen and capped rental equipment have important ramifications for competitive bidding. Stakeholders cannot provide meaningful comments on many issues in the NPRM without understanding how

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CMS will administer the DRA requirements. Consequently, it is important that CMS publish an interim final rule before it publishes the final rule on competitive bidding.

8. Competitive Bidding Areas

Invacare recommends that CMS identify the initial ten MSAs in the final regulation implementing competitive bidding. The geographic location of the initial ten MSAs is the most critical information that must be made public as soon as possible, to allow suppliers as much time as possible to become accredited and be able to prepare to submit bids.

CMS should stagger the implementation of competitive bidding in the initial ten MSAs to allow for a more orderly roll out of the program. This would also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread or occur in all ten initial MSAs at once.

Establishing the CBAs for 2007 and 2009 (Proposed §414.410(b)): CMS is proposing to establish competitive bidding areas (CBAs) in ten of the largest MSAs in 2007 and 80 MSAs in 2009. However, CMS does not believe it is confined to areas within an MSA, and proposes specific criteria for when to include areas outside an MSA. The statute appears crystal clear that CMS does not in fact have the authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established ***"in"*** an MSA. Therefore, we strongly oppose any criteria CMS proposes to use to annex areas next to an MSA, and we urge CMS to reject its proposal to have the discretion to define a CBA to be larger than an MSA.

9. Nationwide or Regional Mail Order (proposed §414.410(d)(2))

CMS is proposing to establish a nationwide or regional competitive bidding program, effective January 1, 2010, for the purposes of awarding contracts to suppliers to furnish these items across the nation or a region to beneficiaries who elect to obtain them through the mail order outlet. Invacare recommends that the term "mail order" be replaced with "home delivery," since this more accurately describes the program.

It is unclear why CMS anticipates having a separate CB program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in CA in MSAs during 2007 and 2009, a separate program for them in 2010 would be unnecessary. In addition, many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes. A definition of "mail order supplies" needs to be established.

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10. Criteria for Item Selection

Items Included in Competitive Bidding: CMS identifies three categories of items that are subjective to competitive bidding consistent with the requirements of §1847(a)(2): "Covered items" *as defined under §1834a(13)* for which payment would otherwise be made under §1834(a) *and "supplies used in conjunction with durable medical equipment;"* enteral nutrition, equipment, and supplies, and off-the-shelf orthotics (OTS). Prosthetics and prosthetic devices and supplies were not included in competitive bidding by Congress. Under §1834(a)(13), a "covered item" means "durable medical equipment" as defined under §1861(n). Ostomy products and supplies are not "durable medical equipment" and consequently do not meet the definition of "covered items" as defined under §1834(a)(13). CMS should confirm that ostomy products and supplies are not included in competitive bidding under §1847(a)(2).

Potential for Savings: CMS should explain and clarify what specific measures will be used to decide an item's potential savings as a result of CB. Specifically, CMS should address the following:

- *Annual Medicare DMEPOS allowed charges*: Is there a threshold expenditure level that will trigger CA for a product category?
- *Annual growth in expenditures*: Is there a threshold growth percentage and does it vary by the dollar size of the category?
- *Number of suppliers*: How will CMS determine the appropriate number of suppliers for a product category in each MSA? What supplier capacity thresholds will be used to determine this and how were those thresholds determined?
- *Savings in DMEPOS demonstrations*: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects?
- *Reports & studies*: Which ones and types will be considered? Who will review the studies and determine their validity and applicability for modeling Medicare program savings?

Regarding CMS' proposed criteria for selecting items to including in competitive bidding, Invacare recommends that CMS add a critical step as it determines which products will be included in competitive bidding. Specifically, CMS should first identify the savings it believes may be attained by including the particular product category, and should compare those costs with the administrative costs related to implementing competitive bidding for that product category. We find it difficult to fathom that the costs associated with implementing the program would, in many product category cases, make the approach cost effective. Specifically, CMS estimates that its aggregate savings in 2008 will be $110 million. Using CMS' tables for the top ten eligible DME policy group allowed charges, with the allowed charges of $7.4 billion, savings of $110 million indicates a savings of 1.4% in 2008. That seems to be a waste of time and resources,

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including the creation of a new bureaucracy including new Medicare contractors, and other obvious related financial costs. We understand CMS is under a Congressional mandate, however, it would be far more logical for CMS to focus on product categories that will ensure savings that more than balance the associated administrative costs. Therefore, Invacare recommends that CMS first identify the savings it believes may be attained by including the particular product category, and should compare those costs with the administrative costs related to implementing competitive bidding for that product category.

Definition of "Product Categories": CMS should have included in the proposed regulation a definition of the product categories that it would potentially include in the initial ten MSAs, and we recommend that CMS identify in the final rule the definition of product categories that might be selected for the initial ten MSAs. Further, we strongly recommend that CMS define product categories only as subsets of the current policy groups; CMS should not combine products from more than one policy group. For example, CMS should not include items from oxygen and hospital beds in any definition of "product categories." This will benefit smaller suppliers, and simplify the administration of competitive bidding for suppliers as well as for CMS.

CMS Should Exclude Power Mobility Devices: The methodology that CMS proposes for item selection relies on historical data and does not take into account recent changes in a benefit that will affect utilization. For power wheelchairs, recent changes in the HCPCS codes, a new LCD, and new fee schedules will significantly change utilization for these items. Specifically, CMS will lack the cost and volume data required under the formula in the NPRM to select an item. CMS will be unable to determine which codes within this product category are the highest cost and highest volume for Medicare using current data. We recommend that CMS not include power wheelchairs in the initial rounds of competitive bidding because it would lack recent data from which to determine the HCPCS codes that represent the highest costs and highest volume for CMS. Moreover, assuming that the coding, pricing and coverage changes result in accurate utilization for these products, in future years there is not likely to be a rationale for including power wheelchairs in competitive bidding under the formula CMS has proposed. There must be ample time to analyze the true impact of the changes before determining if any of these products are appropriate for competitive bidding.

CMS Should Exclude High End Custom Manual Wheelchairs: Manual wheelchairs HCPCS codes will soon be the subject of a significant recoding process beginning in 2007. Due to its greater breadth as a category, manual wheelchair will probably cost more to bid categorically. Complex Rehab Technology patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the NPRM proposal, a supplier who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standards, ultra

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lightweight, bariatric or manual tilt-in-space. In many cases, complex Rehab manual wheelchairs require multiple components to achieve appropriate fit and function for the individual. Therefore, due to the complexity of certain manual wheelchair configurations and the new code process for these items, manual wheelchairs will not be suitable for competitive bidding in 2007, and we recommend that CMS exclude these items.

Further, if CMS were to include manual wheelchairs, including high end products, suppliers awarded the contract many not necessarily be awarded the contract for the associated seating items that are used in conjunction with the high end manual wheelchairs. This would lead to unnecessary complexity for consumers, physicians, therapists and suppliers; ultimately impacting beneficiary access to the appropriate items.

11. Submission of Bids Under the Competitive Bidding Program (Proposed §414.412)

Product Categories for Bidding Purposes: Under the proposed rule, each product category would also include all of the ancillary related supplies. Suppliers would be required to submit bids to reflect all items within the product category. We support this approach as it should allow Medicare beneficiaries a "one stop shopping" opportunity to receive all the necessary products and accessories from one contract supplier. Likewise, we support the proposal that would permit a supplier to bid for only the products and accessories they are seeking to furnish under competitive bidding as it permits suppliers to specialize if they so choose.

- CMS needs to be more specific about the information it will give bidders so that they can determine an appropriate bid in light of the requirement that they must accept any beneficiary in the MSA regardless of the number of rental months remaining on capped rental or oxygen equipment.

- Data suppliers will need to have to determine "worst case" scenario – how many beneficiaries using oxygen and capped rental items – that winners may be forced to take on.

12. Conditions for Awarding Contracts (Proposed §414.414)

Quality Standards and Accreditation (Proposed §414.414(c)): CMS is proposing to phase-in the accreditation requirement. Invacare strongly recommends that CMS explicitly require all suppliers submitting bids to demonstrate, as part of the bid submission, that they have already received accreditation status through an accreditation organization that has received "deemed status" from CMS. A "phase-in" approach is inappropriate because it leaves open the possibility that bids from suppliers who may not be successful in receiving accreditation status will be included in the single payment

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amount calculation, and would therefore taint the bid calculation and contract supplier selection processes.

Instead, once CMS announces the initial ten specific MSA geographic locations, CMS should allow sufficient time for all interested bidders to complete the accreditation process (receive notice from the approved accreditation organization that the organization has either met or not the Quality Standards). This would ensure that all suppliers submitting bids have become accredited, and would create a "level playing field" among all submitting bidders in that they have incurred the various costs that accreditation requires.

Therefore, Invacare disagrees with CMS's proposal in the NPRM where CMS states that it will allow a "grace period" during which unaccredited providers can participate in the bidding process. Invacare strongly recommends that CMS not allow unaccredited providers to complete accreditation during an unspecified grace period. If CMS allows unaccredited suppliers to submit bids, then bid information from bidders who do not become accredited during the grace period will be woven into the various calculations – including supplier capacity, pivotal bids and single payment amounts calculations, fundamentally tainting the validity of those calculations. CMS cannot eliminate this deficiency by simply later eliminating those bidders who do not become accredited. Instead of going through the administratively burdensome process of recalculating supplier capacity, pivotal bids, and single payment amounts, it will be far more efficient to allow a defined time period (consult accreditation organizations for what would be the appropriate period of time) to allow suppliers interested in submitting bids to go through the accreditation process.

CMS should allow additional time for suppliers to analyze the CMS final quality standards in conjunction with the NPRM. The quality standards will affect the cost of servicing beneficiaries and as such are an integral part of the bid process.

If CMS chooses to reject this recommendation and allow suppliers a grace period to meet the Quality Standards and obtain accreditation after bid submission, then if one of these suppliers subject to the grace period ends up not becoming accredited, CMS must re-calculate the single payment amount if any supplier is suspended or terminated from the program using the bid amount of the next supplier or suppliers needed to replace the stated capacity of the suspended/terminated supplier.

Finally, CMS should grandfather all providers accredited by organizations that meet the criteria CMS identifies.

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Eligibility (Proposed §414.414(b)): Invacare recommends that the proposed eligibility rules be expanded to require that each bidder must provide documentation in its bid submission that it has been accredited by an organization that has received "deemed status" with CMS.

Financial Standards (Proposed §414.414(d)): CMS should consider the following evidence of a supplier's financial stability:

- How long the company has been in business
- Dun and Bradstreet (D&B) report, particularly the paydex score (which measures how quickly the company pays their accounts payable)
- Insurance certificates
- Income/balance sheets
- Cash flow statements (would like to see a pattern of profitability over the last two years)
- Copy of the last two years' corporate tax return statements

Evaluation of Bids (Proposed §414.414(e)): Overall, the bid evaluation and the selection of winning bidders processes should be designed to result in pricing that is rationale and sustainable. CMS has not identified any process in its proposed evaluation of bids procedures that will enable CMS to determine that the submitted bids are rational. Once it receives bids, after CMS arrays suppliers' composite bids from low to high, CMS must conduct an analysis of the composite bids and discard any that are unreasonably low.

Logical Consideration of Criteria: The evaluation of the supplier's financial stability, accreditation status, and compliance with all requirements must take place before the bid prices are arrayed and the pivotal bid is selected. Bids from disqualified suppliers should not be considered in selecting the winning bid point or setting the payment amount.

a. Market Demand and Supplier Capacity (Proposed §414.414(e))

The NPRM states that CMS will evaluate market capacity and supplier capacity to determine the number of suppliers necessary to service beneficiaries in an MSA. We agree that CMS must carefully evaluate capacity issues to ensure adequate access to DMEPOS items in a competitive bidding area. Under the methodology proposed in the NPRM, CMS would array the composite bids from lowest to highest and count up from the bottom until it identifies the point where the bidders' cumulative capacity is sufficient to service the MSA. This will be the winning, or "pivotal" bid. This methodology does not include any mechanism to "rationalize" the bids to ensure that there are no unreasonably low bids. Although competitive bidding is premised on the theory that suppliers will submit their "best bid," in fact there will be suppliers with small individual

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capacity who may submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity.

We recommend that the bid solicitation and evaluation process include safeguards against this type of bidding strategy. At the very least, CMS should eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. If these safeguards are not part of the process, CMS can have no assurance that the competitive bidding payment amounts are sustainable over time.

Invacare recommends that CMS use 130% of anticipated Medicare volume as the threshold for the number of suppliers needed in a geographic area. This would promote increased competition in the market, ensure more (smaller) suppliers remain in the market to serve non-Medicare payors and ensure better competition for any future bidding rounds. In addition, this would minimize the need to recruit more suppliers (that bid above the pivotal bid) if one of the contracted suppliers is terminated or elects to drop out of the competitive bidding program.

The NPRM also states that if at least two suppliers are at or below the pivotal bid amount, CMS would designate the two suppliers as winning bidders. We urge caution in adopting this minimalist approach. CMS should select more suppliers than necessary to meet minimum capacity requirements in the competitive bidding area. Any number of circumstances, such as a natural disaster, could create unanticipated access problems for beneficiaries in the MSA. It is unlikely that CMS could address these types of access problems quickly enough to avoid serious disruption to patient care. Additionally, CMS should at least consider other variables beyond capacity that may affect the selection of winning bidders. For example, beneficiary convenience and proximity to contract suppliers would greatly diminish under a scenario where CMS selects only two or three contract suppliers.

b. Determine the Pivotal Bid (Proposed §414.414(e))

CMS states that ""During the demonstration, evaluating quality and financial standards was time-consuming for the bid evaluation panel....". This statement implies that CMS does not plan to evaluate the quality and financial standards of all suppliers that submit bids at the outset of the bid evaluation process. We are very disturbed by this implication. *(And CMS should not short-cut the procedures simply because it may be more administratively burdensome – such is the nature of this bidding process.)* Further, it is entirely unclear in the proposed regulation at what point CMS plans to evaluate whether bidders do in fact meet all the requirements, including quality standards (accreditation), financial standards, Medicare supplier standards, etc. It is imperative that CMS conduct this evaluation process at the outset before the bid evaluation process begins to ensure that bid information from a bidder that does not meet one or more of the requirements is

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not included in any part of the evaluation process. Otherwise, the entire bid calculation (including pivotal and single payment amount calculations) and contract supplier selection process will be fundamentally tainted with information from non-qualifying bidders.

c. Assurance of Savings (Proposed §414.414(f))

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Instead, CMS should adopt the methodology used in the demonstrations.

Invacare strongly opposes the proposal that suppliers cannot submit a bid that is above the current allowable. Section 1847(b)(2)(A)(iii) of the Act prohibits awarding contracts to any entity for furnishing items unless the total amounts to be paid to contractors in a competitive bidding areas are expected to be less than the total amounts that would otherwise be paid. To meet this requirement, CMS proposes not to accept any bid for an item that is higher than the current fee schedule. This would require that the bid amount be equal to or less than the current fee schedule. Invacare strongly disagrees with this proposal because it places artificial constraints on a process that is trying to be designed to harness market forces. If CMS is truly using competitive bidding as a way to understand the price the market will bear, then CMS must allow suppliers to submit their lowest possible bid. Given the many new requirements associated with providing the items and related services under the bid program, bids may rationally and realistically be greater than the current fee schedule amount for the particular item. Given the fact that the majority of suppliers will be incurring new costs of accreditation (compliance with quality standards), and the fact that in the last few years reimbursement has been cut for many of the major product categories (*e.g.*, FEHBP-based reductions), and some products have increased suppliers' documentation costs (e.g., power mobility device documentation requirements), it is highly likely that bids for certain product categories may realistically be at a rate that is higher than the current allowable.

CMS can still meet the "assurance of savings" requirement through alternative means. If bids received are higher than the current allowable, CMS should choose not to include that particular item or product category in the competitive bid program, because that is a strong indicator that savings are unlikely. Requiring that the bid be equal to or less than the fee schedule as a requirement of the RFB artificially restricts bidding. Instead, CMS should allow suppliers to bid based on the true costs associated with each bid item. CMS can then use this information to determine whether the savings is adequate to justify awarding contracts for these items. The "assurance of savings" requirement would be met when CMS only included items for which the winning bid amount were less than the current allowable.

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Selection of New Suppliers After Bidding (Proposed §414.414(h)): CMS proposes to select only as many suppliers as necessary to meet projected demand in a given MSA. However, CMS further suggests that if a supplier falls out of compliance with any of the requirements identified in the regulation and in the bidding contract, it may be necessary to suspend or terminate their contract. This could result in unmet demand. In these situations, CMS proposes to contact remaining contract suppliers to see if they could absorb the demand. If an unmet demand remains, CMS proposes then to refer to the list of suppliers that submitted a bid for that product category in that round of competitive bidding areas, use the list of composite bids that they arrayed in lowest to highest, and proceed to the next supplier on the list. This process would result in a single payment amount being developed using bids from suppliers that do not meet Medicare's standards. Instead, CMS should use 130% of capacity for the pivotal bid to provide greater assurance that the single bid price will be indicative of bids submitted by qualified suppliers in the event that a contract supplier is subsequently suspended or terminated from a competitive bidding program.

Determining Single Payment Amounts for Individual Items (Proposed §414.416): CMS proposes to determine the single payment amounts for individual items by using the median of the supplier bids that are at or below the pivotal bid for each individual item within each product category. A necessary prerequisite is that CMS must first eliminate from all calculations information from bidding suppliers who don't meet all the quality and financial standards, and other requirements. Next, CMS needs to apply a test of reasonableness to all bids, and eliminate unreasonably high or low bids. Therefore, the single payment amount calculation should be based upon a review of all "reasonable" bids. This should provide a better representation of what the market price actually should be, rather than median of the lowest bids.

Invacare disagrees that the single payment amount should be based upon the median of supplier bids that are at or below the pivotal bid for each item. One must assume that each bidder is submitting its lowest possible bid in order to increase its chances of becoming a contract supplier. This methodology ensures that half of the contract suppliers will be forced to accept a bid amount that is less than their submitted bid. This will significantly increase the possibility that these suppliers will choose not to be a contract supplier, or will not be able to sustain their businesses if they do become a contract supplier. No winning bidder should be paid less than the amount of its bid. Instead, the single payment amount should be set at the pivotal bid amount, to ensure that beneficiaries will have access to suppliers who are able to sustain their businesses, and provide quality items and services.

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13. Rebate Program (Proposed §414.416(c))

In the NPRM, CMS proposes to allow contract suppliers who submitted bids for an individual item below the single payment amount to provide the beneficiary with a rebate. The rebate would be equal to the difference between their actual bid amount and the single payment amount. CMS proposes that the rebate be voluntary but that contract suppliers cannot implement on a case-by-case basis. Contract suppliers would also be prohibited from directly or indirectly advertising these rebates to beneficiaries, referral sources, or prescribing health care professionals.

Invacare has serious concerns with this proposal and recommends that CMS eliminate the proposal in its entirety. This proposal is in direct conflict with the federal Medicare and Medicaid Anti-Kickback and Beneficiary Inducements laws, and we cannot understand how CMS can reconcile a rebate program with the clear statutory prohibition on beneficiary inducements under Section 1128A(a)(5) of the Social Security Act.

Specifically, §1128A(a)(5) prohibits the offering or transfer of remuneration when an individual or entity knows or should know that it is likely to influence the beneficiary's selection of a provider or supplier. Remuneration includes anything of value and would apply to the rebate proposed by CMS. While the statute contains exceptions to the definition of the term "remuneration," the rebate program proposed in the NPRM does not fit any of the statutory exceptions. For example, "remuneration" does not include unadvertised waivers of coinsurance or deductible amounts for individuals who have been determined to be in financial need. The rebate offered by contract suppliers under the CMS program would not fit into this exception. We are also unaware of any guidance from the Office of Inspector General (OIG) of the Department of Health and Human Services that would authorize the program CMS proposes. In light of the statutory prohibitions of §1128A(a)(5), CMS lacks the authority to implement a rebate program. Consequently, CMS should withdraw the proposal.

This practice would clearly be illegal under this law if the supplier were to directly communicate a rebate to the beneficiary. The illegality is not corrected simply because the contract supplier is not the entity directly communicating with the beneficiary.

If CMS is attempting to provide beneficiaries with information to make more informed decisions about their health care, then CMS should provide beneficiaries with information that is more relevant to that decision-making process. For example, CMS should provide beneficiaries with information related to consumer satisfaction surveys, which are a current requirement of accreditation organizations. This would enable beneficiaries to make qualitatively informed decisions. Health care decisions are never made purely on price; rather, consumers are interested in the quality of the items and services.

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Finally, allowing an illegal practice in the context of the competitive bidding program will only perpetuate the industry's cloud of fraud and abuse; CMS should not be fostering that perception through illegal means.

14. Terms of Contract (Proposed §414.422)

CMS states that the length of the contracts may be different for different product categories. Invacare strongly urges CMS to have the same length contract for all products in a particular competitive bid area to minimize confusion among beneficiaries, referring physicians and suppliers. As it is, there are numerous variables that these stakeholders will have to understand (which products are part of the competitive bid; the boundaries of the competitive bid, etc.), it will simply add significantly more confusion if there are different lengths of contracts for different product categories in the same geographic area.

Repairs and Replacements of Patient Owned Items Subject to Competitive Bidding: CMS proposes to require that repairs or replacement of patient-owned items subject to competitive bidding must be furnished only by a contract supplier. Given the new Deficit Reduction Act provisions that will result in beneficiaries owning significantly more items of DME than currently, Invacare strongly recommends that CMS develop detailed repair and replacement codes that would be part of the bid process. This has not been necessary when many items of DME had been rental items. With increased beneficiary ownership, specific codes for repair of specific items will be necessary to submit bids for repairs, as well as to facilitate claims processing.

Change in Ownership (Proposed §414.422(d)): It is reasonable for CMS to review a change of ownership to determine whether the buyer meets the quality standards before granting the new company contract supplier status. However, CMS cannot unreasonably withhold its approval of a change of ownership and should not deny winning supplier status to a new owner on the basis that its capacity is not necessary within the competitive bidding area. CMS should approve a change of ownership if the new entity will meet applicable quality standards and other requirements of competitive bidding. CMS approval should not be withheld based on a determination that the supplier's capacity was not necessary.

The proposal to restrict the acquisition of a winning supplier unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the supplier's property rights. While it is appropriate for CMS to consider the buyer's quality and financial stability, CMS should not make approval of the acquisition contingent on the need to preserve capacity within the MSA.

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Termination of Contract: CMS must include procedural safeguards for contract suppliers prior to terminating their contract. Minimum requirements for the process are notice that CMS believes the supplier is in breach, an opportunity for the supplier to cure the breach, and a review or appeal mechanism if the supplier is terminated.

15. Administrative or Judicial Review (§414.424)

We recommend that CMS ensure that procedures are in place for bidders to ensure that calculation related to its bids are reviewed for accuracy, and that there are appropriate procedures in place for suppliers to redress issues such as simple calculation errors. Further, CMS should include a procedure for debriefing suppliers who did not win a bid and an opportunity for a review to determine at a minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

16. Opportunity for Participation by Small Suppliers (Proposed §414.418)

The statute states: "In developing procedures relating to bids ***and the awarding*** of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program...."[1] (emphasis added). Congress, therefore, desired CMS to take steps in the bid process as well and the awarding of contracts process, to take into account the particular needs of small business. This proposed regulation provides no meaningful implementation of this Congressional mandate. CMS defines a small business consistent with the Small Business Administration's definition of small business, but then has not identified one procedure relating to bids or the awarding of contracts that are specific to or geared to accommodate the particular needs of small business.

The one proposal CMS puts forth to try and address small business issues is networks. This network proposal, however, is not limited to small businesses, and, due to its cumbersome administrative and legal requirements, is not likely to be a realistic option for small business.

During PAOC meetings, PAOC members recommended a number of ways to address small business issues. For example, small suppliers should be subject to less costly financial standards requirements; but the proposed rule makes no mention of this.

Invacare recommends that CMS adopt concrete measures to address the needs of small business. Specifically, CMS should establish a certain volume in each geographic area to "set-aside" a meaningful volume of business dedicated for small business, as do many other federal agencies such as the Veterans Administration.

[1] 42 U.S.C. §1395w-3(b)(6)(D).

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17. Opportunity for Networks

CMS is proposing to allow suppliers the option to form networks for bidding purposes, with several criteria that would have to be met to be a recognized and valid network. Invacare has a number of concerns regarding this proposal; primarily that the proposal is complex and will be very difficult for small suppliers to be able to have the time to form a network and comply with all the requirements, given the aggressive implementation timeline CMS has indicated. We understand that it may take close to a year for a small group of suppliers to form a network. As a result, CMS's network proposal is not a practical option for small suppliers who want to participate in competitive bidding, unless CMS provides significantly more time between its announcement of the initial ten selected MSAs and the date by which suppliers will have to submit bids.

18. Physician Authorization/Treating Practitioners

CMS proposes to allow physicians and other treating practitioners to request a specific item, brand, or mode of delivery. When this occurs, contract suppliers would be required to furnish that item or mode of delivery, assist the beneficiary in finding another contract supplier in the CBA that can provide that item, or consult with the physician or treating practitioner is to find a suitable alternative product or mode of delivery for the beneficiary. While we understand this requirement is based in the Medicare Modernization Act, CMS should understand that this requirement is likely to increase suppliers' costs; as often the physician will be requiring the supplier to provide an item that is more costly than what the supplier may typically maintain in its inventory.

19. Gap Filling

Invacare applauds CMS' recognition of the inadequacies of CMS' current gap-filling methodology used to determine fees when new HCPCS codes are created. The gap filling formula has become less and less relevant, as the market prices for many home medical products have simply not kept pace with inflation in other economic sectors. We agree with CMS, "there is an inherent responsibility to pay enough for beneficial new technologies to ensure beneficiary access to care, while also being a prudent payer".

Procedural Issues: Invacare strongly recommends that CMS separate its proposal for changing its current gap fill methodology from its proposed regulation on competitive acquisition for certain DMEEPOS items. The gap-fill methodology and its replacement pertains to all new codes that are created outside of CMS' implementation of competitive acquisition; and deserves appropriate separate consideration, public comment and related procedures.

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Regarding a proposed replacement to the current gap fill methodology, Invacare recommends that CMS follow defined procedural rules when exercising this authority, similar to the process CMS has developed for its National Coverage Determination process. For example, CMS should ensure that the public is informed at the time CMS initiates the process, there is a formal opportunity for public input and a formal opportunity for CMS to respond to public comment; and that all of these processes occur during a defined time period. Importantly, CMS needs to establish meaningful appeal rights for affected parties. Finally, the process for determining fees for new codes needs to be transparent (e.g., CMS must disclose all sources of data it relies upon in its determination), and CMS must be accountable to affected parties. In addition, the process should include a process to "lookback" and determine whether CMS pricing decisions have impacted beneficiary access

CMS proposes to discontinue the practice of deflating supplier prices and manufacturers' suggested retail prices to the fee schedule base period. When fee schedule amounts are established based on pricing information, prices in effect at the time that the fee schedule amounts are established would be used. Invacare agrees with this proposal. When manufacturers establish pricing information, it is based upon a multitude of factors that contribute towards the cost of manufacturing and distributing that product. Invacare recommends that CMS must demonstrate why it believes MSRP information is inappropriate before it would be able to abandon MSRP information as a significant factor in establishing new reimbursement amounts.

We are encouraged to know that CMS recognizes that the current gap-filling methodology can have arbitrary results. We also agree that CMS should depart from the practice of "deflating" current MSRP to arrive at a gap-filled amount and that CMS should use the median current retail price for new items to establish the payment amount. We remain concerned, however, because the proposal for a technology assessment process is vague and lacks any opportunities for stakeholder participation. More importantly, CMS' only authority to adjust payment amounts for an item or a category of items is the IR authority under §1842(b)(8) and (9). Further, a number of stakeholders asked CMS to allow an expanded comment period for this issue specifically so that we can provide CMS with thoughtful recommendations on how to proceed. We reiterate that request.

The IR methodology established by Congress requires CMS to make a determination that using the "standard rules for calculating payment" results in a payment amount that is not inherently reasonable. Congress directed the Secretary to identify the factors that it would use to determine when a payment amount is not "inherently reasonable" because it is either grossly excessive or grossly deficient. In determining whether a payment amount is not inherently reasonable, and in establishing a new payment amount, CMS or its contractors must use "valid and reliable data" that meets specific criteria applicable to the

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data collection and analysis. 42 C. F. R. §405.502 (g). Importantly, the IR methodology contains specific procedural safeguards that apply to any determination to adjust a payment amount by more than 15%. For payment adjustments greater than 15%, one factor CMS must consider (among others) is the "potential impact of such a determination on quality, access, and beneficiary liability, including the likely effect on assignment rates and participation rates." §1842b (8) (C).

CMS' proposal to use a technology assessment process to adjust payment amounts would allow CMS to avoid the explicit requirements under §1842b and its implementing regulations simply by migrating existing products into new HCPCS codes. Congress included the requirements for notice and comment and the use of valid and reliable data under the IR methodology in order to protect the interest of beneficiaries and providers from poorly conceived payment reductions that can affect access. CMS cannot use a technology assessment to make a payment adjustment based on a determination that a payment amount does not "reflect the cost of furnishing the item" as the proposed rule states because those factors cannot serve as the basis for a special payment adjustment under §1842b (8) and (9).[2]

We strongly oppose CMS' proposal to use a technology assessment process to establish fees for new HCPCS codes. This process inappropriately combines coding, coverage and payment issues; processes that have for good reason been separate. However, to the extent that CMS intends to use the technology assessment to establish a payment amount or a new HCPCS code for new products, we recommend that CMS include notice to affected stakeholders and an opportunity to participate in the process.

We agree that CMS should establish fee schedule amounts for new products using the median retail price for the item or the fee schedule amounts for comparable items. Moreover, we recommend that if CMS believes retail prices are inappropriate, then CMS must demonstrate why it believes that is the case, before it employs an alternate methodology to establish pricing. Retail pricing is probably the best indicator of the appropriate market price.

CMS proposes that when revisions to HCPCS codes for items under a competitive bidding program occurs in the middle of a bidding cycle and a single HCPCS code for two or more similar items is divided into two or more separate codes, the payment

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[2] It is important to note that the technology assessment CMS proposes does not and cannot include any information to assess the cost of furnishing an item to a beneficiary. The criteria proposed for the technology assessment focus on a cost benefit analysis of the technology relative to other similar products. This analysis is different from an analysis of provider costs to furnish the product which would include not only the acquisition cost of the product, but also the cost of servicing the beneficiary, the cost of accreditation and other regulatory compliance, as well documentation, billing, and other costs.

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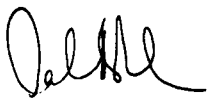
amount applied to these codes will continue to be the same payment amount applied to the single code until the next competitive bidding cycle. Invacare strongly opposes this proposal because it is based on the unfounded assumption that the items in the two new HCPCS are comparable with comparable appropriate prices. When a HCPCS code is divided into two or more codes, the most likely rationale is that there exist significant enough differences in the technology to warrant different codes and hence different prices.

* * * * *

Thank you for the opportunity to provide comments on this important proposed regulation. Invacare is happy to discuss these issues in further detail. Please contact Cara Bachenheimer at 440-329-6226, or via electronic mail at cbachenheimer@invacare.com.

Sincerely,



Cara C. Bachenheimer

Vice President of Government Relations

Invacare Corporation

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BURLINGTON PODIATRY ASSOCIATES
DAVID J. CARROLL, D.P.M.
BOARD CERTIFIED - AMERICAN BOARD OF PODIATRIC SURGERY

6-27-06

Dear Dr. Mc Clellan,

I write today to urge CMS to allow podiatrists to competitively bid to supply DMEPOS only to their patients. As a physician in the medicare program I ask the same rights afforded an MD or DO. With this in mind I urge CMS to use the 1861(r)(3) definition of physician.

My patients deserve the access to DME's in my office. It affords them prompt, appropriate, professional care for a wide variety of problems that can be treated in the out-patient setting.

ex. Simple Hammer toe repair can be safely performed in the office. As you know, this saves thousands of dollars, compared to out patient surgery at the Hospital. I should be able to dispense crutches and a surgical shoe for these patients.

Please do the right thing!! Sincerely,

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BURLINGTON, MA 01803
781-272-1040

955 MAIN STREET
WINCHESTER, MA 01890
781-729-6773

500 SALEM STREET
WILMINGTON, MA 01887
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Crowne

June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Crowne Health Care of Montgomery, LLC, located in Montgomery, AL. Crowne Health Care of Montgomery is a 185 facility with approximately 220 employees, our services include skilled nursing services as well as therapy services.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Crowne Health Care of Montgomery we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,
Wanda Suggs

Crowne Health Care of Montgomery, LLC • 1837 Upper Wetumpka Road • Montgomery, Alabama 36107 • (334) 264-8416

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American Academy of Physical Medicine and Rehabilitation

aaPM&R

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June 28, 2006

Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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7500 Security Blvd.
Baltimore, MD 21244-1849

Re: Competitive Acquisition for Durable Medical Equipment, Prosthetics, Orthotics and Supplies; CMS-1270-P.

Dear Dr. McClellan:

The American Academy of Physical Medicine and Rehabilitation (AAPMR) appreciates this opportunity to comment on the proposed rule establishing a competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). The AAPM&R is the national medical society representing over 7,000 physiatrists, physicians who are specialists in the field of physical medicine and rehabilitation.

Crutches, Canes and Walkers

Physicians specializing in physical medicine and rehabilitation (also known as physiatrists) often treat patients with musculo-skeletal conditions many of whom have injuries or mobility impairments. Often these patients have difficulty walking and may have considerable pain. It is common practice for physiatrists treating such patients to dispense directly from their office items such as crutches, canes, and walkers. This saves the patient the inconvenience and possibly extra pain and suffering of having to obtain these products elsewhere. We are extremely concerned that the proposed rule will make it impossible for physiatrists to continue to provide these items to patients who need them and instead patients will be required to travel to vendor sites. For the frail elderly Medicare population, this would indeed be a disservice. [1]

In order to preserve patient access to these low cost but essential items, AAPM&R urges that CMS establish an exception from the competitive bidding program. In this regard, we point out that CMS has already recognized the importance of allowing physicians to dispense these items directly to patients in the context of the exceptions to the physician self-referral or "Stark" law. The Stark law regulations specifically permit physicians to self-refer for crutches, canes, walkers and folding manual wheelchairs. 42 C.F.R. Section 411.355. We believe it is essential that a similar exception apply to the competitive bidding rule.

[1] Although we understand that physicians are permitted to submit bids to be DMEPOS vendors, most physician practices would not want to provide all the items that the proposed rule would require of potential vendors and, moreover, would be constrained from doing so under the Stark law.

aaPM&R

Orthotics

AAPM&R also believes an exception must be made for certain low cost off-the-shelf orthotics including splints for fractures and sprains, spinal stabilization braces, corsets, rib belts cervical collars and other similar low cost items. Currently, many physiatrists dispense these items directly to the patient. This not only saves the patient the burden and inconvenience of having to travel elsewhere, but has the added benefit of allowing the physician to exercise some quality control over the product and, more importantly, to ensure that it is properly fitted. This reduces the possibility that the patient will obtain a product that does not fit properly and is therefore ineffective. For example, if a physiatrist sees a patient who has been in a motor vehicle accident and has a neck spasm, the patient should be able to receive a cervical collar directly from the physician and not be required to drive around looking for one. Similarly, if a patient needs a wrist splint, by dispensing it directly from the office, the physiatrist can ensure that it fits properly and does not cause pain. This would be a particular hardship for patients in rural areas who may have to drive considerable distances to find their Medicare approved DME vendor; it would also be a hardship for low-income Medicare beneficiaries who may not have access to a car or other readily accessible means of transportation.

If an exception is not made for these relatively low-cost items for which there is acute need, Medicare beneficiaries will undergo needless suffering and inconvenience. For this reason, we strongly urge that the proposed regulations be amended.

Vendor/Physician Arrangements

AAPM&R also requests that CMS clarify that there is nothing in the rule that prohibits DMEPOS vendors from providing physicians with these items as inventory which the physician can then dispense directly to the patient with billing to be done by the vendor. Assuming such arrangements are consistent with other Medicare laws such as the anti-kickback law, they should be permitted. We ask that CMS clarify that this is the case.

We appreciate the opportunity to submit these comments. If you have any questions please contact Dawn Brennaman, MPA, AAPM&R's Director of Health Policy and Practice Services at 312-464-9700.

Sincerely,

Steven M. Gnatz, MD
AAPM&R President

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June 29, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Comments to Proposed Rule CMS-1270-P: Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

Recommendation: In the Final Rule implement an additional program safeguard requirement that is likely to increase assurance that all DME items provided are *reasonable and necessary* to treat the beneficiary.
Rationale Summary: Competitive bidding will reduce the overpayment driver of waste, abuse, and fraud. Mandatory compliance will increase effective program safeguards.

Dear CMS:

I propose the following additions (**bold**) to the Final Rule under the following comment headings:

- Conditions for Awarding Contracts (Proposed §414.414)
- Terms of Contract (Proposed §414.422)

Recommendations for Incorporation into Final Rule CMS-1270:

1. §414.414: Conditions for awarding contracts.: (c) Quality standards and accreditation.
    a. Recommendation: Add an additional section **(3) *Compliance program.* All bidding suppliers must include in their bid a compliance program designed to assure that the items provided to beneficiaries are *reasonable and necessary* consistent with the purpose for which the item is prescribed by the referring (treating) practitioner.**
    b. CMS should consider whether to specify in the regulation that --- **CMS reserves the right to consider factors other than price to award a contract (e.g. the quality of a compliance program: the likelihood that**

a bidder's compliance program will assure services provided are *reasonable and necessary*).

2. §414.422: Terms of contracts.:
Recommendation: Add to *(a) A contract supplier must comply with all terms of its contract, including any option exercised by CMS,* **including but not limited to contract award conditions specified in §414.414(c),** *for the full duration of the contract period.*

Rationale: These proposals may further effectuate the intent the following goals articulated in the regulation:

- Improve the efficient interaction among manufacturers, providers of services, suppliers, and individuals;[1]
- Increase oversight of product provision[2] in an efficient manner that includes provider innovations consistent with sound business practices and recommendation of the OEI/OIG;[3]
- In addition to requiring specified quality standards and accreditation[4], provide for additional accountability and business integrity through a readily auditable program to assure that the items supplied to beneficiaries are *reasonable and necessary*;[5]
- Encourage DME suppliers to optimize information management techniques that meet these goals;[6]
- Encourage and reward DME suppliers that contribute to an improvement of net health outcomes by facilitating the communication of the results of diagnostic tests (performed with DME supplies) to the referring practitioner to support superior decision-making;[7]
- Assure that DME supplier eligibility fulfills the OEI/OIG recommendations that CMS supports: those that are likely to help assure DME items supplied to beneficiaries are *reasonable and necessary* (i.e. are not compromised by fraud, abuse, or waste);[8]

In order to assure savings under the Medicare DMEPOS Competitive Bid Program, CMS should consider whether a bidder's robust compliance program, fully effectuated and proven effective by independent audit, may substantially assure the affected DME items provided are *reasonable and necessary*, even when the payment for a few individual items within a product category is higher than the allowable established by the *Pivotal*

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[1] CMS-1270-P page 25658
[2] CMS-1270-P page 25659
[3] OEI-03-98-00230; June 2000; OEI-03-98-00231; June 2000
[4] CMS-1270-P §414.414 (c)(1) and (c)(2) page 25700
[5] CMS-1270-P page 25659
[6] Ibid.
[7] CMS-1270-P page 25671: "compete on quality for business"
[8] CMS-1270-P page 25675: "bidders must meet eligibility rules"

Bid.[9] If CMS agrees with this intent, the Final Rule should permit CMS to consider the value of a provider's compliance program designed to assure statutory *reasonable and necessary* requirements are met[10]. CMS may wish to consider non-price variables when awarding contracts for certain DMEPOS items.

For example, the Final Rule should allow CMS to consider the value of innovative business models that are likely to assure that DME supplies provided to beneficiaries are *reasonable and necessary*[11], including:

a. Assurance that DME supplies for self-administered tests are used by the beneficiary for illness management;
b. Assurance the practitioner who orders the supplies is regularly informed of the beneficiary's self-management test activity; and
c. A method by which DHHS agencies may readily audit the activities of the DME supplier to assure its compliance with contract requirements.

ABt Associates recommended parameters of (1) business quality standards and (2) product quality standards.[12] I believe the ABt recommendations do not go far enough to meet the needs of program integrity outlined by the OEI/OIG and agreed upon by the Agency.[13] The OEI/OIG recommends a voluntary DME compliance program. My suggestion is that CMS makes the compliance program mandatory. The Agency would promote concurrence and cooperation with the OEI recommendations by requiring a DME supplier to provide a *compliance program* as part of its bid. In addition, CMS should retain the authority to measure the value of the compliance program based on the likelihood compliance is assured, the ease with which CMS may audit the compliance, and other additional benefits the compliance proposal can bring to the Program to reduce cost and improve health outcomes. Bids by suppliers who adopt such approaches would offer CMS the opportunity to create net savings from factors other than a low-bid based model alone.

Specifically, the value could be measured by evaluating whether

- The supplies are delivered to the beneficiary;
- The supplies are *reasonable and necessary*;
- The supplies are used as part of medical decision making by the patient and/or practitioner;
- All documentation requirements are met;
- Other recommendations promulgated by OEI/OIG/DHHS and agreed upon by the Agency are met;

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[9] CMS-1270-P page 25678: "During the demonstration, several product categories received overall savings, whereas payment amounts increased for a few individual items within those product categories."
[10] Section 1862(a)(1)(A) of the Act.
[11] Under §1862(a)(1)(A) of the Social Security Act of 1965 and related statutes and regulations.
[12] Quality Standards for Suppliers of Durable Medical Equipment, Prostehtics, Orthotics, Supplies (DMEPOS) and Other Items and Services: Draft of Proposed Recommendations, September 26, 2005, page 1.
[13] OEI-03-98-00230; June 2000; OEI-03-98-00231; June 2000

- The method the DME supplier will use will assure compliance;
- The DHHS agencies may easily audit the DME supplier for compliance; and
- The DME proposal can measure and report to appropriate stakeholders the contribution the DME supplies make to improve health outcomes of the beneficiaries.

For example, if a non-insulin diabetic self-tests his/her blood glucose the following data would be helpful to determine whether ongoing test supplies are *reasonable and necessary*:

1. How often is self-testing performed?
2. Is the referring practitioner aware of the results and patient self-management?
3. Are the test results used to help diabetes management?

Taxpayers through Congress provide a comprehensive medical benefit to those who are over 65 or disabled. The cost of the program is substantial. Some taxes for the Program are paid by working individuals without illness and injury insurance and young children to rear. All providers who are paid by the Medicare Program enter into a legal contract as well as a social covenant to respect the Program and adhere to its statues, regulations, and rules—both explicit provisions and implicit expectations. The fraud, abuse, and waste documented in the OEI/OIG reports are unacceptable. All providers are expected to comply with Medicare rules, and agree to do so at the time of provider enrollment. Therefore, a voluntary compliance program seems insufficient, as opposed to a mandatory program. I suggest a robust compliance program is a reasonable additional requirement for a DME company that enjoys guaranteed payment for an item or service covered by the Program. By requiring compliance and a compliance program for all bidders, the cost of compliance will be part of the payment. The field of competition will remain level, with greater likelihood of compliance. A rationale objection to a mandatory compliance requirement applicable to all DME suppliers escapes me.

By assuring payment will be made only for *reasonable and necessary* items and services, compliance may assure savings greater than that achieved by price reductions alone. CMS should retain the discretion to determine the likely value a particular supplier's compliance program brings Medicare and consider its value as an independent variable for contract award.

Respectfully Submitted:

Gerald N. Rogan, MD
Medicare Consultant

About the commenter:

In my role as the Medical Director for the largest Part B carrier in the country, NHIC CA (1997-2003), I was honored to focus carrier resources to help identify practical safeguard solutions to reduce Program vulnerability to fraud, waste and abuse; and underscore to practitioners the unique value the Program brings to their practices and their patients. From this experience I found that Medicare's total cost for a particular benefit was directly proportional to the amount by which a payment exceeds the reasonable cost to provide an item or service and indirectly proportional to the effectiveness of the program safeguard activity associated with the benefit. I found the "pay and chase" method to protect the Program is suboptimal. For DME, competitive bidding will reduce the overpayment driver. Mandatory compliance will increase effective program safeguards.

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June 28, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Dr. McClellan:

Option Care of Camilla, Inc. is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

Option Care of Camilla, Inc. is located in Camilla, Georgia and has been in business for 20 years. We specialize in durable medical equipment, orthotics, infusion therapy, enteral nutrition therapy, and supplies. We provide equipment & these therapies to thousands of patients in the rural area of South West Georgia. This proposal would severely restrict beneficiaries' access to needed items and supplies and may compromise patient health outcomes. The new competitive bidding initiative will put my business and many other companies on the brink of bankruptcy.

CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

We urge you to carefully consider and adopt the detailed recommendations being sent to you under separate cover by our national organization, the National Home Infusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for infusion and enteral therapies, but urge CMS to recognize that Medicare payments both within and outside the competitive bidding program need to be at a level sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. CMS should affirm this point in the final rule.

3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

4. The preamble to the proposed rule indicates that Medicare expenditures for DME infusion pumps and related drugs in 2003 were approximately $149 million. This number appears to include expenditures made for insulin and insulin pumps for patients with diabetes, which are not provided by infusion pharmacies and is largely a different market than infusion. It also includes drugs that have sole or limited national distribution arrangements with particular pharmacies, where there would appear to be little savings to be gained from the imposition of competitive bidding. In addition, it includes drugs that are administered to the "sickest of the sick" patients who are very compromised and which require extraordinary expertise for safe and effective provision. These drugs should never be subject to a competitive bidding regimen. The more accurate amount of Medicare expenditures for 2003 for DME infusion pumps and related drugs was approximately $87 million.

5. Similarly, enteral nutrition is not a good candidate for competitive bidding. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services. It creates serious policy and operational issues for nursing homes as well as for CMS. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

   If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for DME patients. CMS should also modify the proposed payment structure for enteral pumps and, consistent with current law, ensure that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

6. The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 229-336-7758.

Sincerely,

J. Harris Morgan, RPh
President

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

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KENDALL P. TABOR, D.P.M., F.A.C.F.S.

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June 26, 2006

Mark B. McClellan, M.D., PhD
Administrator
Centers for Medicare & Medicaid
Dept. of Health & Human Services
7500 Security Blvd.
Baltimore, MD 21244

Attention: CMS-1270-P

Dear Dr. McClellan:

I am writing in opposition to the proposed rule that would establish a competitive acquisition program for durable medical equipment.

This rule, if implemented, would limit my ability to supply rapid, quality care to my patients. I urge the Centers for Medicare & Medicaid Services to at least exclude physician services from the competitive acquisition program.

If a patient presents with a fracture, we can immediately dispense a fracture walker, rather than having to send him 50 miles to another supplier (we are in a rural area). Diabetics with ulcers on their feet and/or deformities can obtain therapeutic shoes in our office without a third-party involved, which makes obtaining adjustments and repair difficult.

Sincerely,

Kendall Tabor, D.P.M.

KPT:s

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Rec'd 6/29/06

June 26, 2006

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1270-P

Re: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Dear Administrator McClellan:

Empi, Inc. ("Empi") is pleased to have the opportunity to comment on the proposed rule, CMS-12710-P, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") and Other Issues. Empi is the leading Medicare provider of transcutaneous electrical nerve stimulation ("TENS") device which are used to relieve pain and promote recovery. Empi respectfully requests that the Centers for Medicare and Medicaid Services ("CMS") exercise its statutory discretion to not select TENS devices as one of the initial product categories that will be subject to the 2007 phase-in of the Medicare DMEPOS competitive bidding program. As we explain below, including TENS devices in the 2007 phase-in would force CMS to try to configure a competitive bidding program best suited for commodity type products into one dealing with differentiable products, which could compel many beneficiaries to use inferior TENS products without achieving measurable savings for the Medicare program. Since we understand the policy directive you have been charged with, which is to attempt to lower health care costs while preserving quality, we look forward to working with CMS on the continued implementation of the competitive bidding program and the specifics of the TENS market.

Background: TENS and Empi

TENS is an FDA Class II medical device that employs low-level electrical stimulation to relieve pain and promote recovery. TENS is most commonly used to treat back pain, but is also effective for the treatment of arthritis, strains and sprains, and neuralgia, among other conditions. TENS is frequently prescribed as an adjunct to physical therapy for conditions related to chronic pain and post-surgical or post-trauma acute pain. TENS works in two ways: first, by using

599 Cardigan Road • St. Paul, MN 55126-4099 Tel: 651.415.9000 FAX: 651.415.8535 www.empi.com

electrical stimulation to disrupt the body's transmission of pain messages; and second, when the stimulation is sufficiently intense to cause mild muscle twitching, by inducing the body to produce its own natural pain reliever, a neurohormone called endorphin.

TENS provides patients and clinicians with a safe and cost-effective alternative to drugs for the relief of pain. And, given the removal of Vioxx™ and Bextra™ from the market during the latter part of '04 and early '05, physicians are faced with an increasingly limited armentarium of pain interventions. The result is a national health care crisis resulting from physical dependence and addiction to opiates and narcotics. In the U.S., more than 200 million prescriptions are written for opiates such as Oxycontin™ each year (Dendrite International 2004). The direct and indirect cost associated with these medications can be reduced by increased reliance on non-systemic interventions such as TENS.

Empi is a market-leading manufacturer of electrotherapy devices based in St. Paul, Minnesota, with facilities in South Dakota, Kentucky and Florida, and is the leading Medicare provider of TENS devices. Empi's digital Epix VT uses a microprocessor to store twelve distinct pre-programmed electrotherapy regimens, thus affording clinicians the flexibility to tailor treatment to the needs of individual patients and to make the devices easy to use by patients. The Epix VT is the only available TENS device to incorporate this feature. The Epix VT is also the only TENS device on the market to feature biosourced, biaphasic waveform, which ensures the constancy of the electrical stimulus, and provides an additional measure of patient comfort and safety. These unique features make the Epix VT the most popular TENS device on the market.

Finally, Empi is the only TENS manufacturer to provide periodic post-sale monitoring of its devices, an essential product support service. Empi provides TENS devices to over 187,300 patients per year with an effective, low cost pain therapy treatment, which is in many cases a preferred alternative to prescription drugs which have systemic side effects and potentially higher costs. In addition, to support these devices and this service level, Empi has developed nationwide service capabilities and a robust and on-going research and development program to continue to improve the products.

The Proposed Rule: Selection of DMEPOS Product Categories

As the Proposed Rule observes, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") "mandates a larger role for competitive bidding within the Medicare program," including the establishment by the Secretary of Health and Human Services ("HHS") of "competitive bidding programs for the furnishing of certain DME and associated supplies."[1] Section 1847(a)(1)(B)(ii) of the Social Security Act (the "Act") gives CMS the authority to phase in the competitive bidding program with its direction to focus, "first among the highest cost and highest volume items or those items that the Secretary determines have the largest savings potential."[2]

Among the factors that CMS proposes to weigh in "making determinations about an item's potential savings as a result of the application of competitive bidding," are different items'

[1] 71 Fed. Reg. 25657 (May 1, 2006).
[2] 42 U.S.C. 1395w-3(a)(1)(B)(ii).

annual Medicare DMEPOS allowed charges.[3] CMS estimates that "approximately 10 product categories will be selected for competitive bidding for 2006 and as many as 7 or 8 of the selected product categories will be among the 10 largest in terms of allowed charges. The remaining 2 or 3 product categories will come from the top 20 eligible DMEPOS policy groups and their 2003 allowed charges."[4]

TENS Devices Should not be Subject to Competitive Bidding in 2007

CMS should exercise its discretion under Section 1847(a)(1)(B)(ii) of the Act to exclude TENS devices from the 2007 phase-in of the competitive bidding program for several reasons. First, TENS devices in fact constitute a miniscule percentage of Medicare charges. Second, because until CMS has a better understanding of how to do competitive bidding in a non-commodity environment, the competitive bidding program defies the wide variation in quality—and, accordingly, price—within the TENS device market. By grouping all TENS devices within a single product category for the purpose of competitive bidding this will induce many patients to purchase inferior devices. Third, some TENS device manufacturers, including Empi, include within the cost of their devices a post-sale periodic monitoring services to ensure that the device is functioning properly. Low-cost providers generally do not. This would further complicate the nature of competitive bidding since not every medical device company would be offering similar products when they were to make their bid.

1. TENS Devices are a Low-Volume Product Category Relative to Other DME

The total allowed Medicare charges for TENS devices is very small relative to other DME products, with annual expenditures of approximately $10 to $15 million. Indeed, as Table 4 in the Proposed Rule indicates, TENS devices constituted less than one-tenth of one percent of allowed Medicare charges for DMPOS. Nor are TENS devices among the twenty-four highest volume DME items listed in Table 3 of the Proposed Rule.[5] Moreover, the overwhelming majority of DMEPOS reimbursed by Medicare are compressed into a very few high-volume product categories. According to the Proposed Rule, the top five categories alone account for a full 77% of allowed Medicare charges, with proportionate volume declining dramatically thereafter. Several policy groups, such as oxygen, wheelchairs, and diabetic supplies have charges in excess of $1 billion. Indeed, TENS devices, at number 20 on the list, account for only .4% of the charge volume of the fifth-ranked product category, Hospital Beds/Accessories, and about 12% of the charge volume of the tenth-ranked product category, Lower Limb Orthoses. As such numbers suggest, TENS devices are not among Medicare's "highest cost and highest volume" DMEPOS items, and do not offer the program substantial "savings potential," as required by the Act.

2. Including TENS Devices Within the First Phase of the Medicare Competitive Bidding Program Will Compel Many Patients to Purchase Inferior Devices

[3] 71 Fed. Reg. at 25671.
[4] *Id.* at 25691.
[5] *Id.* at 25670.

Available TENS device vary widely in quality and technological sophistication; accordingly, the market is properly stratified by price. We are concerned that the competitive bidding program is not yet structured to take into account these variances and we believe that it will require a significant amount of planning and development to design the program to be effective in achieving the dual goals of saving money while providing consumers with appropriate high-quality healthcare. As we described above, Empi's digital Epix VT uses a microprocessor to store twelve different pre-programmed electrotherapy regimens, thus affording clinicians the flexibility to tailor treatment to the needs of individual patients. This kind of customization is unavailable on the typically imported non-digital devices with which Epix VT competes. The same features that make the Epix VT the most popular TENS device, however, even with the advances in technology, also make it more costly to manufacture, and hence, by necessity, more expensive. Empi simply cannot and should not compete on price with the low-cost, technologically inferior, imported devices. To require Empi to do so by including TENS devices in the 2007 phase-in of competitive bidding before the sophistication of competitive bidding processes can be developed after seeing how the market reacts to competitive bidding in the easier commodity product categories would be to treat as fungible products that, in reality, are highly differentiated in terms of clinical efficacy. Inferior devices will prevail in a poorly designed competitive acquisition process, and as a result patients will receive sub-optimal therapy.

3. Many TENS Device Manufactures do not Provide Periodic Service and Monitoring of Their Devices

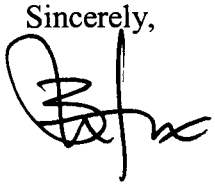
Finally, Empi provides post-sale periodic service monitoring of its Epix VT devices in order to ensure that they continue to function properly. By contrast, many of the low-cost TENS device manufacturers do not offer this important service. As in the case of pre-programmable therapy regiments, this feature contributes to the relatively higher cost of the Epix VT. Again, by treating as fungible TENS devices, such as the Epix VT, that include this important monitoring service and less expensive devices that do not, a competitive bidding process that is not properly designed to take into account this service component would ensure that many Medicare patients are deprived of a superior product.

For the reasons outlined above, primariliy that including TENS devices in the 2007 phase-in portion of the competitive bidding program would not result in measurable savings to the Medicare program, TENS devices should not be part of the phase-in program. Including TENS could also put in place a competitive bidding system that could have as an unintended consequence of an appropriate policy initiative, the result that many beneficiaries would be compelled to use inferior TENS product. CMS should therefore exercise its statutory discretion to not select TENS devices as one of the ten product categories that will be subject to the 2007 phase-in of the Medicare DMEPOS competitive bidding program.

We look forward to working with CMS over the next two years on refinements to the Competitive Bidding Program to ensure that beneficiaries will have access to high quality TENS devices and that a competitive bidding scenario can be developed that works in a non-commodity marketplace. We would be happy to meet with your staff to discuss TENS products and their Medicare market in more detail and to continue to provide assistance in developing ways to

lower Americans' healthcare cost while providing the high-quality, technologically advanced medical devices Americans deserve and desire.

Sincerely,



Barry Hix, MBA, MPH
Vice President – Marketing and National Accounts

Harry L. Zimmerman
Executive Vice President – General Counsel

cc: Laurence Wilson, Director, Chronic Care Policy Group

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Responsive Solutions Inc.
HOME INFUSION SERVICES™

June 28, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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File Code CMS-1270-P: Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan:

Responsive Solutions, Inc. is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

We are a small to medium sized home infusion pharmacy that offers infusion devices (infusion pumps) for patients we serve in our geographical area. We have a high density of retirees in our area since we are a resort / retirement destination. The Medicare population that we serve continues to grow yearly as more retirees move to our area and thus our negative exposure to competitive bidding. We have been in business in this area since 1994.

CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

We urge you to carefully consider and adopt the detailed recommendations being sent to you under separate cover by our national organization, the National Home Infusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for infusion and enteral therapies, but urge CMS to recognize that Medicare payments both within and outside the competitive bidding program need to be at a level sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. CMS should affirm this point in the final rule.

3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

4. The preamble to the proposed rule indicates that Medicare expenditures for DME infusion pumps and related drugs in 2003 were approximately $149 million. This number appears to include expenditures made for insulin and insulin pumps for patients with diabetes, which are not provided by infusion pharmacies and is largely a different market than infusion. It also includes drugs that have sole or limited national distribution arrangements with particular pharmacies, where there would appear to be little savings to be gained from the imposition of competitive bidding. In addition, it includes drugs that are administered to the "sickest of the sick" patients who are very compromised and which require extraordinary expertise for safe and effective provision. These drugs should never be subject to a competitive bidding regimen. The more accurate amount of Medicare expenditures for 2003 for DME infusion pumps and related drugs was approximately $87 million.

5. Similarly, enteral nutrition is not a good candidate for competitive bidding. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services. It creates serious policy and operational issues for nursing homes as well as for CMS. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

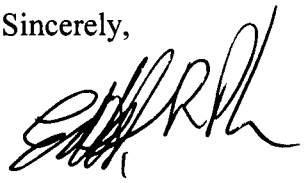
   If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for DME patients. CMS should also modify the proposed payment structure for enteral pumps and, consistent with current law, ensure that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

6. The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 843-497-5433.

Sincerely,



Ed Hewitt, RPh
Co-owner

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

RX Pharmacy Services

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Main Office
540 Seco Road
Monroeville, PA 15146

June 28, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

File Code CMS-1270-P: Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan:

RX Pharmacy Services and Mosso's Medical Supply Company are pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

RX Pharmacy Services is a Home Infusion Company with approximately 100 employees and 1,200 patients. Mosso's Medical Supply is a RT/DME Company with 140 employees and Approximately 7,000 patients. Both businesses are owned by Air Products Healthcare and are located in Western Pennsylvania. As a business leader, I am proud to tell you that my organization and it's employees provide only the highest level of clinical services to the patients that are under our care. Implementation of the competitive bidding is an indicator that CMS is looking for the cheapest price without concern for the clinical services provided to the patient. There are many companies in our area that provide lower service levels to patients in an effort to increase there profits. We however, consistently search for opportunities to become more efficient and maintain our level of services to the patient. While CMS has considered the quality standards in its process, there are different levels of quality in our industry. The competitive bidding process gives an edge to the providers that provide less services (commodity) with lower costs resulting from less service

CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging

undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

We urge you to carefully consider and adopt the detailed recommendations being sent to you under separate cover by our national organization, the National Home Infusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for infusion and enteral therapies, but urge CMS to recognize that Medicare payments both within and outside the competitive bidding program need to be at a level sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. CMS should affirm this point in the final rule.

3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

4. The preamble to the proposed rule indicates that Medicare expenditures for DME infusion pumps and related drugs in 2003 were approximately $149 million. This number appears to include expenditures made for insulin and insulin pumps for patients with diabetes, which are not provided by infusion pharmacies and is largely a different market than infusion. It also includes drugs that have sole or limited national distribution arrangements with particular pharmacies, where there

would appear to be little savings to be gained from the imposition of competitive bidding. In addition, it includes drugs that are administered to the "sickest of the sick" patients who are very compromised and which require extraordinary expertise for safe and effective provision. These drugs should never be subject to a competitive bidding regimen. The more accurate amount of Medicare expenditures for 2003 for DME infusion pumps and related drugs was approximately $87 million.

5. Similarly, enteral nutrition is not a good candidate for competitive bidding. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services. It creates serious policy and operational issues for nursing homes as well as for CMS. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

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6. The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 412-702-0209.

Sincerely,

Jeffrey Kreutzer
Division President, RX Pharmacy Services & Mosso's Medical Supply

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

NHC
NATIONAL HEALTHCARE CORPORATION

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June 29, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") and other issues (42 CFR Part 411, 414, and 424).

To Whom It May Concern:

On behalf of National HealthCare Corporation (NHC) (a multi-facility long-term care company), as Senior Vice President of Patient Services, I am writing to comment on the Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") and other issues (42 CFR Part 411, 414, and 424).

We strongly believe that Skilled Nursing Facilities (SNFs) should be excluded from the Competitive Acquisition Program. There are very strong practical issues from a nursing and facility perspective that must be considered. As a nurse, I can only imagine the confusion that the competitive acquisition rules will cause and how this confusion will disrupt care and services for nursing home residents.

1. The rules do not address the monitoring of multiple beneficiaries as occurs in a nursing facility; furthermore the rules are incompatible with plan of care requirements imposed on nursing homes:
    a. First and foremost, home patients have individual caretakers that monitor and communicate with suppliers, thus protecting the privacy of **one** patient and monitoring the quality of the service and equipment for **one** patient. This is a fairly easy process.
    b. SNFs, in comparison, have limited personnel to communicate for **many** patients in the facilities and must monitor the quality of supplies and privacy of **multiple** patients. The place of service the supplies are delivered makes a significant difference in the ease of monitoring the supplier.

2. Our SNFs use **one** supplier that furnishes enteral, urological, tracheostomy, ostomy, and, sometimes, surgical dressings. Nurses, bookkeepers, purchasing staff, and administration communicate with this one supplier about multiple patients. Competitive Acquisition might result in multiple suppliers furnishing limited supplies to multiple patients. Multiple suppliers furnishing to multiple patients would each have procedures for ordering and handling exceptions; this would cause an unnecessary burden on the center nursing staff.

3. I would expect confusion if we must fax new orders for supplies to multiple suppliers for multiple patients. This would be similar to faxing prescriptions to multiple pharmacies, depending on the drug ordered.

4. SNFs may experience increased liability as new suppliers may furnish unfamiliar products (different manufacturers) using unfamiliar personnel that may, or may not train on all three shifts in the SNFs. Training multiple caregivers on multiple shifts may present a new challenge for suppliers that have only provided home care.

5. Currently NHC centers dealing with one supplier receive all supplies in one delivery on a periodic basis that is convenient for the SNFs. With the introduction of several suppliers and different delivery schedules, SNFs will be required to spend more time monitoring the suppliers' activities in their facilities and the availability of products from multiple vendors.

6. Patients in SNFs have a higher acuity than patients at home. Our suppliers must have a wide variety of disease-specific enteral products available on short notice, and must be able to communicate knowledgeably with the professionals providing the care.

We think it will be mutually beneficial to CMS and to SNFs to manage these services differently than the way you propose in the regulations. SNF/NF settings are different than the home setting. Will you please consider excluding SNF/NF settings from the competitive bidding process?

Thank you for allowing me to voice my concerns. I hope we will avoid unintended consequences for SNF staff.

Sincerely,

Julia W. Powell, BSN, MA
Senior Vice President, Patient Services

cc: Mike Ussery

Board for Orthotist/Prosthetist Certification
THE ADVANTAGE IS EXPERIENCE™

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June 30, 2006

Mark McClellan, M.D., Ph.D.
Centers for Medicare & Medicare Services
Department of Health and Human Services
Attn: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments on Proposed Rule CMS-1270-P

Dear Dr. McClellan:

We are writing on behalf of the Board for Orthotist/Prosthetist Certification (BOC) in order to expand upon and clarify the points made by Donald O. Fedder in his letter to you dated June 13, 2006, regarding the proposed Competitive Bidding Rule. We appreciate this ongoing opportunity to dialogue with CMS and to provide comment regarding the proposed rule.

Off-the-Shelf (OTS) Orthoses

In Dr. Fedder's letter, he discussed the provision of certain off-the-shelf (OTS) devices in relation to the services of Certified Orthotic Fitters (COF) and Certified Mastectomy Fitters (CMF). While the BOC generally stands by the points outlined within the letter, we would like to clarify certain terms and issues addressed by Dr. Fedder.

In keeping with the language in the proposed rule, the term off-the-shelf (OTS) should be used to describe only those items that are ready-made and may be provided to a patient with minimal or no adjustment or customization for appropriate use. Such items may be literally taken from the box and provided to the patient "as is", and require no expertise for fitting or dispensing. While all OTS orthoses are "prefabricated", not all prefabricated orthoses are OTS. The proposed terms "Fitted High" and "Fitted Low" do not apply to OTS orthoses; rather, these terms refer to prefabricated orthoses that require the expertise of a trained, credentialed practitioner in order to properly fit and dispense. Prefabricated orthoses are not *custom made* for a specific patient, they are *customized* and intimately fit based on an individual patient's measurements. Custom fitted (high and low) prefabricated orthoses require varying degrees of customization and are appropriate only when properly customized by a trained and credentialed individual.

The Certified Orthotic Fitter (COF) credentialed practitioner is qualified to provide professional service to patients in need of custom fitted prefabricated devices. Secondarily, the BOC's Certified Orthotic Fitters (COFs) have been determined by National Commission for Certifying Agencies (NCCA) standards to be independent practitioners specializing in the dispensing of prefabricated custom fitted devices. Custom Fitted orthotic services require the COF to assess the patient's condition, determine the appropriateness of the prescription and custom fit prefabricated device.

The BOC has an overriding belief that OTS orthoses should be exempt from the competitive bidding program completely. The minimal savings that might be gained cannot offset the administrative burdens associated with the inclusion of OTS orthoses in the competitive bidding program.

The Medicare Modernization Act of 2003 (MMA), granted CMS the authority to exempt certain items from a Medicare competitive bidding program that were not likely to result in significant savings. We urge CMS to categorically exempt all OTS orthotics from the Medicare competitive bidding program on the basis that inclusion of OTS orthotics in a competitive bidding program will not produce significant savings to the Medicare program.

Actual data from the competitive bidding demonstration related to certain orthotics provides support for this position. For the 23-month period during which competitive bidding for certain orthotics was tested in San Antonio, TX, the Medicare program saved a total of $89,462, or less than $45,000 per year. CMS determined through its proposed scoring methodology that San Antonio is one of the ten largest MSAs with the highest potential for DMEPOS savings. We believe that other MSAs would likely yield even less savings than the original San Antonio demonstration. Statistics such as these lend little support to the use of competitive bidding in the provision of OTS orthotics.

Additionally, Section 1847(a)(1)(B)(ii) of the Social Security Act gives CMS the authority to phase-in competitive bidding "first among the highest cost and highest volume of items or those items that the Secretary determines have the largest savings potential." OTS orthoses are not high-cost or high-volume items nor do OTS orthoses have the largest potential for savings based on what was learned in the San Antonio demonstration.

The BOC does, however, support the use of quality standards and accreditation as a requirement for the provision of all DMEPOS. We maintain it is only through these avenues that CMS can ensure that Medicare beneficiaries receive the best possible care from highly qualified suppliers, while at the same time protect the Program by limiting unnecessary expenditures for OTS orthoses. To that end, we believe that CMS' focus should be aimed at designing, implementing and enforcing effective quality standards and mandatory accreditation requirements.

Privileging

In Dr. Fedder's letter, he expresses strong opposition to the proposed process for privileging non-credentialed or non-licensed professional staff. While we acknowledge the basis for Dr. Fedder's concerns, the BOC understands that allowing qualified, credentialed suppliers the authority to "privilege" or authorize an employee to perform certain functions is critical to ensuring cost-effective access to quality prosthetic and orthotic care. The process of privileging

entails documenting the qualifications of an individual to perform certain functions while under the supervision of an orthotist, and is an accepted documentation methodology in the majority of healthcare accreditation programs. The practice of granting privileges to healthcare paraprofessionals to allow for them to perform certain services under the supervision of a credentialed professional is a common practice in healthcare delivery, and is an avenue that the BOC supports in the provision of orthotics and prosthetics care.

Again, we appreciate this opportunity to expand upon and clarify the issues Dr. Fedder previously addressed. If we can provider any further information, please do not hesitate to contact us at (512) 965-8968 or the BOC office at the number listed above.

Respectfully Submitted,

Kay L. Zehms, BOCO, LO
Chairman of the Board
Board for Orthotist/Prosthetist Certification (BOC)