Submitter : Mrs. Linda Gerber **Date:** 06/30/2006

Organization : Carestar

Category : Nursing Aide

Issue Areas/Comments

GENERAL

GENERAL

I see many problems in taking away the autonomy of patients. One major concern I have, as a nurse aide who works with someone who struggles daily to walk, is the concern that has been placed on my client that she won't have functioning braces in the future. Polio patients need to be individually fitted for braces. If the quality of these braces decreases, the support and aid that they offer to people will decrease. This will put them at risk of major injuries. In the long run, I don't see how there will be any financial advantage if money is saved regarding the orthotics and prosthetics only to turn around and spend more repairing broken limbs because the braces aren't capable of doing the job that they should be designed to do. Improperly fitted braces could significantly decrease quality of life and hasten placemant in a Nursing Home. What ever happened to 'an ounce of prevention is worth a pound of cure?'

Submitter : Dr. Joseph Sokolowski, Jr. MD **Date:** 06/30/2006

Organization : NAMDRC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

NAMDRC welcomes the opportunity to comment on numerous provsions of the proposed rule. We are attaching our detailed comments

Submitter : Mr. Gary Yeakle **Date:** 06/30/2006

Organization : Northport Health Service

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

June 30, 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 Case Manager for the Northport Health Service facilities in Missouri. An objective of my position is to ensure that our residents receive timely services during their stay.

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 our skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care interventions could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At our facilities, 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,

Gary Yeakle
Regional Case Manager-Missouri
Northport Health Service

Submitter : Mr. Jon Tiger **Date:** 06/30/2006

Organization : Nat'l Home Oxygen Patients Association

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

The National Home Oxygen Patients Association welcomes the opportunity to comment on proposed rules for competitive bidding. Our full comments are provided as an attachment.

Submitter : Ms. Lori Wolfe **Date:** 06/30/2006

Organization : Cardinal Health

Category : Other Health Care Provider

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Competitive Bidding Areas

" To eliminate confusion, once an MSA has been defined using the US Census Bureau data, it should not be redefined. How would you create a program in a given territory and then redefine it, especially since networks may only represent 20% of a market.

" We agree that the elimination of rural areas and those areas of low population density within urban areas is acceptable. However, mail order business should not enter into this discussion. Exclusion should be just that: exclusion!

" Mail order should only be allowed if they can provide the same level of training and education that the local supplier provides. To think that the physician, who does not and should not get involved in training on DME and supplies, would be capable of training and teaching is unrealistic. Therefore, the mail order should be expected to meet the same criteria as the local supplier. Further, physicians offices do not have access to the wide variety of equipment that is necessary (e.g. talking home blood glucose monitors). We would like to know what information CMS has gathered that shows that physicians can be responsible for beneficiary training and education of blood glucose supplies if the supplies were delivered via mail order.

Conditions for Awarding Contracts

Conditions for Awarding Contracts

" If a supplier does not successfully attain accreditation, we will suspend or terminate the supplier contract. This implies that the site visit is a formality because it takes 6-9 months at a minimum to become accredited. Further, not every applicant success achieves accreditation on the first evaluation. A grace period will not alleviate the issue of working with only accredited providers.

" You state that you will require accreditation agencies to place priority on those needing to submit bids in the first 10 MSAs. Understanding that accreditation organizations run businesses, we don t understand how CMS can require this. There are other payers and state license requirements that demand accreditation. Blue Cross of Maine, for example, is requiring that all providers become accredited by January 1, 2007. The state of Florida is requiring that all licensed DME suppliers also become accredited in 2007. Accreditation agencies must work to meet the needs of all their customers.

" We propose that a time frame be established for all Medicare providers who must meet Quality Standards through an accreditation organization in order to remain in the Medicare program. At a minimum, we propose that a concrete and realistic time frame be established once the standards are released. This will ensure that accredited providers can participate in the bidding process. Suppliers won t know their administrative costs of accreditation until they have successfully completed the process. Submitting a bid during a grace period prior to knowing these costs could create potential for a supplier to bid at a rate that they cannot uphold.

" When evaluating the financial condition of a supplier, why not evaluate a supplier s ability to collect their receivables? This will illustrate the financial health of a supplier and is a common measure used in the DME industry. Further, a retail pharmacy network s financial condition is impossible to measure since it has no track record. The network should not be required to meet a large company s financial reporting since it is made of many smaller entities.

Criteria for Item Selection

Criteria for Item Selection

Criteria for Item Selection

" While choosing the products that have the greatest potential for savings, beneficiary demographic information should be easier to access. Since a competitive bidding contract lasts 3 years, it poses an undue burden on the small supplier who would have to conduct extensive research on potential demographics of beneficiaries and their applicable disease states just to be able to bid. In the midst of running a business, it is unrealistic to expect small providers to have the time and resources to research this information prior to bidding.

" We propose that CMS further limit the number of product categories that will be included in the first round of competitive bidding. Selecting too many product categories is overwhelming and will impede the overall success of the program.

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

" How can a rebate option be legal? It is a financial incentive which is clearly prohibited under Medicare. We propose abandoning the rebate option.

Education and Outreach

Education and Outreach

Education and Outreach
" Additional ways to educate should include webinars and teleconferences (open door forums). We propose that these education and outreach programs start sooner rather than later. We would like to see education now for the suppliers and beneficiaries.

Issue

Issue

Conditions for Awarding Contracts (Cont)
When trying to establish a network s capacity potential, how would one know how small or large it can grow since there is no history or precedent? Moreover, the demonstration project did not have any networks because of the difficult logistics which include legal matters, capacity issues, administrative burdens and varying competitive business practices.

" As you evaluate capacity, keep in mind that businesses off all sizes can expand easily with a proper business plan. For example, when the DME MACS were chosen, many had to expand and train additional staff to process claims. In the same way, allow suppliers to expand their scope of business.

" If a supplier loses its good standing with Medicare or any other government agency we propose that the supplier receive a grace period in which to fix the problem before they are terminated or suspended from the program.

" Although you recognize that the way you determine the final bid price will leave out suppliers with very close but slightly higher bids, you do not seek a solution to this problem. Consider suppliers whose bids are one standard deviation off from the winning bid so that they are not unfairly eliminated from the market.

" We propose that the list of products eligible for competitive bidding be defined within each MSA and published before the Request for Bid is distributed. This will allow providers the opportunity to adequately assess those product categories before deciding whether or not to bid. We also suggest that a reasonable timeframe be provided to allow suppliers adequate time to evaluate their product offering and pricing before bidding. Keep in mind that the business demands of the holiday seasons be considered during these time frames.

" Selecting only as many suppliers as necessary to ensure CMS has enough capacity to meet the projected demand is not taking into account how far a beneficiary will have to travel in order to obtain their product. When making the decision to have only enough suppliers to meet the demand, we propose that those winning suppliers for each product category are spread as evenly as possible throughout the MSA and that a number of extra suppliers be selected to meet the changing market demands.

Opportunity for Networks

Opportunity for Networks

Opportunity for Networks
" Networks were an option included in the demonstrations but no networks were formed. This is because networks are logistically and operationally challenging. Further, by nature, small suppliers are proprietary. Additionally, if a network s market share can t exceed 20% of the Medicare market, this will be hard to monitor since this is a moving and fluctuating target (patients switch insurance and the market shrinks and expands readily). Finally, due to the short time frame in which competitive bidding is to roll out, it would be impossible for networks to be formed with all the criteria that are listed in the proposed rule. Forming a legal entity comprised of many suppliers to form a network would be very challenging and time consuming. Most independent pharmacies would be against sharing their business with a former competitor.

" If each member of the network must be accredited, this will ensure the small provider won t be able to participate, even if you allow them to form a network. Accreditation is cost prohibitive for many small suppliers.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers
" The SBA may define a small business as less than $6 million in annual receipts, but in the DME world, this is considered a large provider. We recommend that you redefine a small company as one with receipts of less than $1 million. CMS needs to consider that some businesses, like pharmacies, may aggregate their revenue and receipts for all of their business divisions. For many, their DME revenue is relatively small compared to their pharmacy revenue.

" Define opportunity to be considered for participation. Does this means that the small supplier should be included in the bid process but not necessarily to participate as a winning supplier? If this is true, this is unfair and unreasonable since as you state, small providers make up more than 90% of all suppliers.

" It states that we recognize the importance, benefits and convenience offered by the local presence of small suppliers. If this was true, you would take other steps to ensure their survival. Maybe you should first commit to a percentage of small suppliers as winning bidders.

" Further, as you impose accreditation on small suppliers (retail pharmacies) who furnish only diabetic supplies, for example, you are discounting the fact that they have been licensed and credentialed beyond what accreditation requires. If this holds true and these providers exit the market, you will force beneficiaries to use mail order companies. Now where will they go to get the training that the mail order companies neglect to provide? Don t expect their physicians to provide this training about which they know little. Their reimbursement is obtained through a different fiscal intermediary and the DME MACs have no impact on them.

" You met with only 44 beneficiaries in a focus group. This is hardly a representative sampling and would be discounted in any other environment as is it nowhere near a statistically significant sample.

" Becoming accredited and having financial practices that are up to GAAP standards, having a Human Resource Management team, and establishing an information management system is not realistic for a small provider who only provides diabetic supplies to beneficiaries. We propose that diabetic supplies be part of a pharmacy only benefit and be excluded from competitive bidding. The state of California has already adopted this measure.

Payment Basis

Payment Basis

Payment Basis
" We believe that a beneficiary who rents products through a grandfathered supplier should remain with the grandfathered supplier until the rental period is up. Giving the beneficiary the choice to switch to a contracted supplier is unfair to the contracted supplier, because they will be unlikely to recoup their cost of the product (depending on what month of rental the beneficiary is in). It should be the choice of the contracted supplier whether or not to accept the patient in the middle of a capped rental period. Further, as of June 30, 2006, oxygen patients will own their equipment after 36 months of rental. No provision has been made for transfer of these patients and their equipment in the latter months of this 36 month time frame. HME suppliers should not be expected to accept a patient in month 35 of an oxygen rental period. Finally, enforcing this provision is a challenge, at best.

" If beneficiaries often travel to visit family members or to reside in other states with a warmer climate during the winter months and they are subject to competitive bidding in their primary residence but not in the warmer climate, how do you suggest they determine where to go and how to obtain the contracted price from a noncontracted supplier? It would put an undue burden on the beneficiary to expect them to find a supplier in the warmer climate who would know the pivotal bid price in the CBA from the beneficiary s primary residence. Enforcing this would appear difficult if not impossible.

Physician Authorization/Treating Practitioner

Physician Authorization/Treating Practitioner

Physician Authorization/Treating Practitioner
" In attempts to separate high technology blood glucose monitors from the lower ones, we propose reclassifying blood glucose monitors into different HCPCS codes, which will require different pricing. Keeping one HCPCS code for all diabetic monitors provides a severe disservice to the beneficiary, physician and supplier. This will force suppliers to provide the cheapest model available forgoing the higher quality products (with better technology) in order to cut costs. There will be some patients that will have a special need for monitors with greater technology than the typical monitor the supplier carries (or based their bid on). We must ensure that patients still have access to those monitors with higher technology, while maintaining a fair price to the suppler for providing that item. The only way to accomplish this would be to establish separate HCPCS codes for the different blood glucose monitors that are available. This will help improve healthcare and the quality of life for the person, their doctor and lastly the supplier.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Suppliers
" To accredit all suppliers would take years. There won t be sufficient supply of accreditation agencies. Why not allow small suppliers to adhere to the quality standards without going through the formality of accreditation?

" What role will the NSC play if you give accreditation agency the charge of maintaining quality standards? Why not merge the supplier standards with the quality standards to eliminate redundancy?

Regulatory Impact Analysis

Regulatory Impact Analysis

Regulatory Impact Analysis

" It states not all suppliers will be affected directly by the competitive bidding program. This may be true but mandatory accreditation alone will force MANY small suppliers out of business.

" It states 10% of suppliers will not have received the necessary accreditation. How did you arrive at this figure? If 56,000 retail pharmacies give 2/3 of Medicare beneficiaries their diabetic supplies, how do you expect them to stay afloat and become accredited? Are they included in your 10%?

" How did you decide that an accountant or auditor would prepare the bid? What if the owner does it? Is $31.25 per hour still applicable? What if the preparer is a pharmacist earning more than $100,000 per year?

" Small suppliers are likely to have similar costs for submitting bids than are large suppliers. This is not necessarily true. Large suppliers have more experience with managed care contracts and may be bidding in multiple MSAs. This will cost them less than the small supplier bidding for the first time in one MSA.

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

Submission of Bids under the Competitive Bidding Program
" Under the MMA payment will not be made for items furnished under a competitive bidding program unless the supplier has been selected as a contract supplier to furnish those items. We propose that any willing and accredited provider be allowed to participate at the winning bid price. It would allow beneficiaries access to choice, something that the MMA would otherwise limit.

" How are you going to ensure that the administrative process used to select the winning bidders is fair and reasonable as well as accurate?

" For those items which are capped rentals (or oxygen equipment) after January 1, 2006 we propose that a separate HCPCS code be created for reasonable and necessary servicing and maintenance for each rental item. Maintenance rates vary widely among the different product lines. For example, labor and parts for a nebulizer repair would be significantly less than labor and parts for maintenance of a wheelchair and/or oxygen concentrator. Without the knowledge of an average acceptable charge for servicing of a rental item, a supplier would not be able to accurately include that charge in their bid.

Terms of Contracts

Terms of Contracts

Terms of Contract
" No new products should be added during a contract term. Suppliers may or may not have access to the goods and may or may not be able to provide the product.

CMS-1270-P-1117-Attach-1.DOC

CMS-1270-P-1117-Attach-2.DOC

Submitter : Ms. Sheba Wilburn **Date:** 06/30/2006

Organization : Wheel Chair Sales & Services (WS&S Medical)

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

My comment is being sent as an attachment. See Attachment

CMS-1270-P-1118-Attach-1.DOC

#1118

WS&S MEDICAL

June 30, 2006

RE: Competitive Bidding Comments
Submittal: www.cms.hhs.gov/eRulemaking

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

To Whom It May Concern:

As a DME provider, we are aware that the process of competitive bidding is inevitable. However, there is not enough clarity on the entire process in order for us to move forward in such a short period of time with such drastic changes that may effect not only a small business such as ours, but clients and patients who are dependant upon medical equipment and supplies. It is to our understanding that CMS intends on selecting items for the competitive bidding process that contain the highest cost and highest volume. We believe that this proposal poses a problem for those patients in urgent need of wheelchairs, hospital beds, patient lifts, oxygen supplies, diabetic testing supplies, etc. These supplies are vital to the physical condition of our clients.

Although we are already accredited by the Exemplary Provider Accreditation Program and remain in good standing with Medicare and are in respectable financial standing with our creditors; we are concerned about the jeopardy of our "small business". The fact, that Medicare proposes the idea of examining two years of past claims for each item on a monthly basis to determine the expected demand vs. how many suppliers are needed to meet the projected demand, is a major concern as a determining factor. To explain, we have been in business for almost 10 years and we are a growing company. The suppliers and clients that we have today are not comparable to what we had even in the past two years. If these determining factors abide, it seems as though the bigger corporations will "knock us out of the box", altogether.

According to the demographics described by CMS, New York, Los Angelos, & Chicago will be excluded from competitive bidding. Our office is located in New Lenox, IL approximately 30 miles outside of Chicago and we are unclear how this will affect our

company. Thus, a more thorough scrutiny and explanation of what "Competitive Bidding" entails is considered necessary in keeping us abreast as a small business.

Conclusively, in addressing the power mobility rule... physicians will have 45 days instead of 30 to provide us with a prescription and supporting documentation after a face-to-face exam with the patient. This rule affects the patient significantly because, in most cases, doctors hardly ever submit this information to us in a timely matter. We call repeatedly and these physicians "drag their feet". Our primary concern, must meet the needs of our patients/clients first and foremost. We must **NOT** cut corners with our client's health. It is our fiduciary duty to provide them with the best quality care possible. How are DME providers, such as our organization, able uphold our duty if we cannot afford to compete with the mass corporations? On behalf of our company, we trust that our concerns will be taken into careful consideration. Please do not hesitate to contact us, if you have any questions or concerns.

Respectfully submitted,

Sheba L. Wilburn, Admin. Asst.
Accounting Department

Submitter : Mr. Phillip Porte **Date:** 06/30/2006

Organization : Sleep Manufacturers Alliance

Category : Device Association

Issue Areas/Comments

GENERAL

GENERAL

The Sleep Manufacturers Alliance welcomes the opporutnity to comment on proposed regulations for competitive bidding. Our detailed comments are provided as an attachment.

Submitter : **Date: 06/30/2006**

Organization : **Multiple**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1120-Attach-1.DOC

1120

June 30, 2006

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 Administrator McClellan:

The undersigned organizations appreciate the opportunity to provide our views concerning the Centers for Medicare and Medicaid (CMS) Services' proposed rule *Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*, 71 *Fed. Reg.* 25,654 (May 1, 2006).

Under the DMEPOS proposed rule, CMS would implement a competitive bidding program for certain Medicare-covered items of DMEPOS. We have several important concerns about the proposed rule, which we raise to protect our patients from any unintended harmful effects of the new initiative.

EXEMPTION FOR PHYSICIANS AND NON-PHYSICIAN HEALTH CARE PRACTITIONERS FROM DMEPOS COMPETITIVE BIDDING PROGRAM

In accordance with the mandate under the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (MMA) to implement a DMEPOS competitive bidding program, CMS is proposing that physicians who supply DMEPOS must submit bids and be awarded contracts in order to furnish the items included in the competitive bidding program.

We urge CMS to exempt from the DMEPOS competitive bidding program physicians and certain other health professionals, *e.g*, podiatrists, optometrists, physical and occupational therapists, physician assistants (collectively referred to hereinafter as "practitioners"), who provide their own patients with DMEPOS. Instead, when these practitioners are licensed by their state board to practice in that state, they could be "deemed" as qualified to provide patients with DMEPOS, and current payment policy would apply to these practitioners for these items of DMEPOS.

Practitioners generally operate as small businesses (and small suppliers of DMEPOS), and the financial and administrative burden of complying with the new competitive bidding program, simply to supply DMEPOS to their own patients, likely will be too great. Yet, practitioners must be integrally involved in providing DMEPOS to their patients to ensure that (i) a particular item of DMEPOS meets the "size and fit"

specifications for that particular patient; and (ii) the patient is properly instructed concerning the use of that DMEPOS. This is necessary to provide patients with the highest quality of care, achieve patient compliance, reduce risk of further injury and avert liability concerns as well.

For example, if a patient is diagnosed with a foot fracture, a walking boot and crutches may be required upon leaving the physician's office. If the patient is unable to acquire the item from the treating physician and must obtain the item from another supplier due to the new competitive bidding program, serious adverse consequences could result, including a delay in care, continuous or exacerbated pain, or the patient could be at risk for additional, increased injury, which would increase costs to the Medicare program. This could also result in fragmented care, which could disrupt the patient-practitioner relationship. Moreover, in some cases, Medicare allows only one item of DMEPOS per patient. In this event, if the item is not initially properly fitted and sized, the patient may later have to pay out-of-pocket for a replacement item.

Further, the clinical judgment and expertise of the treating practitioner in selecting a particular item is essential and should be based on the evaluation of the patient at the time of dispensing. This would also be the appropriate time to instruct the patient and address any questions or concerns on the utilization of the item. If a patient is sent elsewhere to obtain an item and the fit is incorrect or the patient receives insufficient information about an item, the patient will likely return to the practitioner's office with questions or for assistance. This will result in increased costs to the Medicare program and will increase utilization under the sustainable growth rate (SGR). **Thus, practitioners should be exempt from the DMEPOS competitive bidding program for the purpose of providing their own patients with DMEPOS.**

In the alternative, if CMS does not provide this exemption, CMS, at the very least, should phase these practitioners into the bidding process after 2009. In accordance with the MMA DMEPOS mandate, CMS will phase-in this program with respect to certain Metropolitan Statistical Areas (MSAs) in 2007 and 2009, with additional competitive bidding occurring in other areas after 2009. A phase-in for certain areas, with an additional phase-in after 2009 for practitioners who provide their patients with DMEPOS would also conform to the spirit of the MMA mandate, which contains a provision to protect small suppliers of DMEPOS.

As discussed above, practitioners operate as small businesses and the cost of complying with the competitive bidding program and related requirements could effectively prohibit them from supplying patients with DMEPOS that is most appropriate when supplied at the time of the patient visit. Thus, these practitioners should have lead time before applying the competitive bidding program to them. If patients do not have access to enough suppliers who offer the needed product categories, this could seriously impact access to appropriate care. Finally, this phase-in time will allow practitioners time to identify those DMEPOS items that should not be part of the competitive bidding program, as further discussed below.

If practitioners are phased-in over time, however, CMS should provide a less burdensome process for practitioners, including an exemption from the accreditation standards that may be appropriate for a large regional or national DMEPOS supplier, but are much too burdensome for practitioners who merely provides DMEPOS to their patients.

EXEMPTION FOR CERTAIN ITEMS FROM THE DMEPOS COMPETITIVE BIDDING PROCESS

Under the proposed rule, as discussed above, physicians that are also DMEPOS suppliers must submit bids and be awarded contracts in order to furnish items included in the competitive bidding program for the area in which they provide medical services. The rule also states that physicians must ensure that any arrangement under which they refer for and furnish DMEPOS under a competitive bidding program must be in compliance with the physician self-referral law.

We understand that certain DMEPOS arrangements may be prohibited by the physician self-referral law. While we are not advocating for a repeal of this provision of the self-referral law, we, nevertheless, note that there is an exemption from the law for certain items of DME. Some items, such as canes, crutches, walkers and folding manual wheelchairs, were exempted because the patient requires the item to depart from the physician's office. In addition, there is a separate exemption from the physician self-referral law for implants furnished by an ambulatory surgery center (ASC), including, but not limited to, cochlear implants, intraocular lenses and other implanted prosthetics, implanted prosthetics devices and implanted DME that meet certain requirements. Certain other services and prosthetic devices, such as eye glasses or contact lenses following cataract surgery, were exempted to avoid significant inconvenience to Medicare patients and because they are already subject to frequency and payment limits.

Similar to this physician self-referral law, we urge CMS to apply current payment policy to and exempt from the competitive bidding program the above-listed and other similar items (including, but not limited to, wrist, ankle and finger splints; shoulder, elbow and hand splints; aircasts; cervical collars; orthotic inserts; spine stabilization braces; corsets; and rib belts) that practitioners provide to their patients. It is our understanding that prosthetics devices are not among the items covered in the MMA's competitive bidding provision. However, we note that even if prosthetics were covered under the law, there should be an exemption for physicians providing these devices to their patients. This will ensure quality of care and patient safety. We also urge CMS to work closely with the undersigned organizations to develop an appropriate list of exempted DMEPOS to ensure patient care is not impeded. To maintain transparency and equity in this process, CMS should provide an opportunity for review and public comment with regard to this list.

ELIGIBILITY TO PARTICIPATE IN THE DMEPOS COMPETITIVE BIDDING PROGRAM

The proposed rule states that "providers that furnish Part B items and are located in a competitively bidding area and are also DMEPOS suppliers" must submit bids in order to

furnish competitively bid items to Medicare beneficiaries (emphasis added). The proposed rule does not define the term "provider." In the event that CMS does exempt practitioners from the DMEPOS competitive bidding program as requested above, we urge CMS to clarify that certain health care professionals who are not MDs or DOs and who regularly provide their patients with DMEPOS would be considered "providers" for purposes of participating in the DMEPOS bidding process and could be awarded a contract as a DMEPOS supplier. Some of these practitioners may provide their patients with Medicare DMEPOS, and thus should be permitted to participate in the competitive bidding process.

QUALITY STANDARDS AND ACCREDITATION FOR SUPPLIERS OF DMEPOS

The proposed rule provides that DMEPOS suppliers will be required to meet applicable quality standards specified by the Secretary of the Department of Health and Human Services. Although quality standards are set forth under existing law, the Program Advisory and Oversight Committee (PAOC) was mandated by the MMA to advise the Secretary with respect to certain functions, including (i) the implementation of the Medicare DMEPOS competitive bidding program; and (ii) the establishment of quality standards for DMEPOS suppliers. In fact, the PAOC has already held meetings concerning the development of new quality standards for suppliers. In addition, draft proposed quality standards are posted on the CMS web-site.

We have strong concerns about implementing a regulation that requires suppliers to meet quality standards that are in transition and have yet to be finalized. Public comments can only focus on existing quality standards, yet, we understand that new standards will be applied on top of the existing standards. This creates confusion and does not provide physicians and other impacted parties an opportunity for meaningful review and comment, as required by the Administrative Procedures Act. **We urge CMS to clarify the quality standards that suppliers must meet under the DMEPOS competitive bidding program, and if new quality standards are developed, CMS should issue a formal proposed rulemaking before moving forward with the DMEPOS competitive bidding program to ensure proper notice and opportunity to comment on any new quality standards.**

OPPORTUNITY FOR NETWORKS

CMS proposes that suppliers may form networks for DMEPOS bidding purposes. Such networks would be comprised of several companies joined together through a legal contractual relationship to submit bids for a product category under competitive bidding. CMS notes in the proposed rule that although no networks submitted bids for the demonstration project, it may be a useful option for suppliers in some cases.

We believe that this option would be very unrealistic for physicians who supply patients with DMEPOS. It would require: (i) expensive legal resources to set up the network while guarding against anti-competitive and other antitrust concerns, as well as (ii)

additional, significant administrative resources. Thus, it is unlikely that physicians would be able to take advantage of this option.

PHYSICIAN AUTHORIZATION/TREATING PRACTITIONER

The MMA mandate for the DMEPOS competitive bidding program allows the Secretary to establish a process by 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. CMS is proposing that the physician or treating practitioner would be able to determine that a particular item would avoid an adverse medical outcome, and that the physician or treating practitioner would have the discretion to specify a particular product brand or mode of delivery. The proposed rule further states that when a physician or other treating practitioner requests a specific item, brand, or mode of delivery, contract suppliers would be required to furnish that item or mode of delivery, assist the beneficiary in finding another contract supplier in the competitive bidding area (CBA) that can provide that item, or consult with the physician or treating practitioner to find a suitable alternative product or mode of delivery for the beneficiary.

We agree with CMS that the physician or treating practitioner should have the sole discretion to make these kinds of determinations about the individual medical needs of their patients and that suppliers should be required to furnish the particular item requested by the physician or treating practitioner.

The proposed rule further states that if, after consulting with the contract supplier, the physician or treating practitioner is willing to revise his or her order, that decision must be reflected in a revised written prescription. However, if the contract supplier decides to provide an item that does not match the written prescription from the physician or treating practitioner, the contract supplier should not bill Medicare as this would be considered a non-covered item.

We urge CMS to aggressively monitor contract suppliers to ensure that they do not: (i) unilaterally provide a different item than that specified in the physician's or treating practitioner's written prescription, thereby depriving patients of access to the most appropriate care, as determined by their physician or treating practitioner; and (ii) burden physicians with unnecessary or repeated requests to revise their orders, thus delaying necessary care for a patient and leaving a patient at risk of further injury.

REBATE PROGRAM

CMS is proposing to allow contract suppliers that 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.

Although we appreciate that beneficiaries have the opportunity to benefit from system-wide savings, the rebate program, as structured, is unfair to physicians. This would allow some physicians, who win a supplier contract award, to provide patients with a rebate, while other physicians, who do not win a contract, may be unable to provide their patients with a particular item of DMEPOS. **The inherent inequity in this system underscores the need to exempt physicians who provide their own patients with DMEPOS from the competitive bidding program.**

OFF-THE-SHELF ORTHOTICS

Items subject to the DMEPOS competitive bidding program would include, among others, off-the-shelf orthotics (OTS). CMS sets forth a proposed definition of OTS in the rule and states that the agency will consult with a variety of individuals, including experts in orthotics, to determine which items and/or HCPCS codes would be classified as OTS orthotics. **We encourage CMS to include medical organizations that represent physicians who provide off-the-shelf and custom-made orthotics in that consultation process, and we look forward to further clarification of this issue.**

MONITOR IMPACT OF DMEPOS COMPETITIVE BIDDING PROGRAM

We urge CMS to aggressively monitor the impact of the DMEPOS competitive bidding program on patient access to care. This is an entirely new and complex program that will significantly change the market dynamics for supplying DMEPOS to patients, and CMS must ensure that these market changes do not unintentionally limit the current variety of DMEPOS available to patients, thereby adversely impacting patient access to these important Medicare items.

In addition, CMS should ensure that patients have adequate choice of suppliers within their locality, in addition to any mail order options. Patients (especially when injured) or their caretaker should not have to travel long distances to obtain needed DMEPOS as this could put patients at risk and increase Medicare costs. **Thus, we urge CMS to ensure that suppliers are available across competitive bidding areas, and not concentrated in one or a few areas of a locale.**

We appreciate the opportunity to comment on this new Medicare competitive bidding program for DMEPOS, and look forward to working with CMS to address the critical issues raised above.

Sincerely,

American Academy of Nurse Practitioners
American Academy of Ophthalmology
American Academy of Physician Assistants
American Academy of Sleep Medicine
American Association of Orthopaedic Surgeons

American College of Osteopathic Surgeons
American College of Surgeons
American Gastroenterological Association
American Medical Association
American Occupational Therapy Association
American Optometric Association
American Osteopathic Academy of Orthopedics
American Physical Therapy Association
American Podiatric Medical Association
American Society of Cataract and Refractive Surgery
American Society of Hand Therapists
American Society of Plastic Surgeons
American Urological Association
Child Neurology Society
Medical Group Management Association
National Association of Spine Specialists

Submitter : **Mr. Chuck Wilson** **Date: 06/30/2006**

Organization : **Target Corporation**

Category : **Private Industry**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Please see attachment.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Please see attachment.

CMS-1270-P-1121-Attach-1.PDF

#1121

TARGET

June 30, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-1850

Subject: Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and other Issues

To Whom It May Concern:

Target is an upscale retailer with a focus on high-quality, on-trend merchandise, plus everyday basics all at affordable prices. Target operates 1180 pharmacies in 45 states and employs over 338,000 team members across the country. We share the agency's goal for implementation of the Medicare Part B competitive bid law and offer our comments on the proposed Medicare competitive bidding program for Durable Medical Equipment (DME) and the establishment of new quality standards for DME suppliers.

DME Competitive Bidding

The National Association of Chain Drug Stores estimates that over 7 million current Medicare beneficiaries have diabetes and this number is likely to grow. We are concerned that the DME competitive bidding program will limit the scope of supplies available to diabetics, as well as access to products needed to manage their disease.

Currently, diabetic testing supplies are available at a wide range of community retail pharmacies throughout the country. No other DME covered item has as extensive a network of providers. Senior patients have come to expect the ease and constancy of national pharmacy chains carrying specific diabetic testing supplies throughout a nationwide chain. Senior patients have become more mobile, often traveling for a season at a time, and disruptions in access to diabetic testing supplies at national chains or a remote independent pharmacy could create health concerns.

People with diabetes are much healthier when they consistently use devices to monitor their blood glucose levels. Medicare beneficiaries need access to a full range of diabetic testing products in order to manage their diabetes. Blood glucose monitors come in a variety of forms including models tailored for visual impairments and ease of use models with error codes and automatic timing. Diversity of diabetic supplies and blood glucose monitors are important for a patient's health. Our pharmacy team assists patients with the selection of the most appropriate monitor to fit their needs. Specific test strips are used with certain monitors and limiting testing supplies and monitors could prevent diabetic patients from successful, accurate and timely testing.

A competitive bidding program could potentially reduce access to diabetic products in the market as well as professional advice from a patient's trusted pharmacist. Most diabetic patients also require prescription drugs. If a senior patient's pharmacy is not included in the competitive bidding program, a patient would be forced to go to multiple locations to obtain diabetic supplies and prescriptions. This creates a barrier to quality care by limiting access to a pharmacist that is familiar with the beneficiary's history. Retail pharmacies can offer a full range of products and medications that diabetic patients need.

Quality Standards

We believe that diabetic DME items should be excluded from additional accreditation requirements for the following reasons. First, pharmacists are licensed by each state's Board of Pharmacy after meeting high professional standards. Pharmacies and pharmacists must comply with rigorous standards of state licensure including inspection and compliance with state standards for pharmacy. While state laws differ slightly, all states have laws that establish provisions for patient counseling, professional responsibilities, consultation with prescribers and the scope of the pharmacy practice.

Second, pharmacies already require extensive education to practice including a six year Doctor of Pharmacy degree, a rigorous state pharmacy license exam, an intern rotation, and 30 hours of continued education every two years. This education and training makes pharmacists uniquely qualified to serve as medication and medical device use experts for advising and counseling Medicare patients and providing advice to other health care providers on the use of diabetic health care products.

Third, pharmacies and pharmacists are already subject to state and federal laws which require offering patient counseling. These laws also subject pharmacies and pharmacists to disciplinary actions by State Boards of Pharmacy if state laws are not followed.

Finally, the Centers for Medicare and Medicaid Services (CMS) has not tested diabetic testing supplies and blood glucose monitors in any pilot to measure the impact on patient care. There is no concrete evidence that there are any real savings by including these products in the competitive bid process. We believe CMS should exclude diabetic testing supplies and blood glucose monitors from the DME competitive bidding program.

We appreciate the opportunity to provide these comments. Please feel free to contact me at 612-696-3077 with any questions.

Sincerely,

Chuck Wilson
Vice President, Pharmacy Operations

Submitter : Mrs. Maria Ephraim

Date: 06/30/2006

Organization : Civic Center Health and Rehabilitation

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

I am writing to express concerns regarding CMS competitive bid proposal for certain durable equipment and other supplies.

I am the Administrator at Civic Center located in Bham AL with 95 beds duly certified for Medicaid and Medicare services. With 127 exceptional employees, services include wound care, rehabilitative and restorative, IV therapy, and many projects to promote a homelike environment.

The proposed rule is significant change to current 'any willing provider'environment. Requiring skilled nursing facilities to bid in order to receive Medicare Prt B reimbursementfor certain DMEPOS & other sprecialty items appears to be a method to disrupt existing care plans-jeopardizing health and safety of residents.

Medicare Part B residents often are among the frail and critically ill in skilled nursing facilities. This proposed rule has potential to compromise a resident's access to specific services and products, resulting in longterm 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 residents should not be threatened or compromised by a mandate whose impact, altough well-intended, is not conducive to the long term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,
Maria Brown Ephraim, MS, NHA, LD
Administrator

Submitter : Dr. Joseph Sokolowski, Jr. MD **Date:** 06/30/2006

Organization : NAMDRC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

NAMDRC welcomes the opportunity to comment on proposed rules regarding competitive bidding. See attachment

CMS-1270-P-1123-Attach-1.DOC

#1123

June 29, 2006

TO: The Centers for Medicare and Medicaid Services

RE: **CMS-1270-P**

FROM: The National Association for Medical Direction of Respiratory Care (NAMDRC)

The National Association for Medical Direction of Respiratory Care, NAMDRC, welcomes the opportunity to comment on proposed regulations for implementation of competitive bidding for certain items of durable medical equipment. All of our comments are premised on important principles related to patient care and patient access to devices prescribed by physicians as part of a plan of care coordinated with an equipment supplier –

- Competitive bidding must not inhibit or otherwise adversely affect patient care;
- Competitive bidding must not be an obstacle to for Medicare beneficiaries access to appropriate medical devices and supplies;
- Competitive bidding must permit physicians rather than suppliers to select devices that ensure quality healthy care;
- Competitive bidding must not impose unreasonable administrative costs/burdens on beneficiaries, physicians, suppliers or CMS and its contractors.

We must also express concern regarding the overall substance, or lack thereof, regarding key specifics of the competitive bidding rule. Locations for competitive bidding are not identified, devices and supplies subject to competitive bidding are not identified, supplier standards are not yet identified, and a specific timetable for these matters is not provided. As noted in several sections below, we are also not supportive of any effort that addresses these issues through program memorandum rather than the formal rulemaking process in the ***Federal Register***.

Quality Standards for Suppliers of DME: NAMDRC and its sister societies, the American College of Chest Physicians and the American Thoracic Society express serious reservations regarding recommendations from the Program Advisory and Oversight Committee (PAOC).. Based upon a recommendation from PAOC, the proposed rule indicates CMS will publish quality standards through program instructions rather than the more formal process of publication via the ***Federal Register***. First, we do not support a process that implements a statutorily mandated requirement through a manual instructions rather than the more formal mechanism of ***Federal Register*** rulemaking which permits physicians the opportunity to comment. Because these standards will impact directly on the care of our patients, the proposed process of rulemaking is not acceptable. Importantly, CMS must recognize that respiratory related devices, including oxygen, CPAP, RADs and ventilators, are the largest single group of devices likely to be competitively bid. Despite our efforts to participate as active members of PAOC, PAOC membership does not include a single representative from

either the pulmonary medicine community or the home oxygen/CPAP/RAD/ventilator patient community. Because we have not been afforded the opportunity to participate directly in PAOC despite the clear likelihood that our patients will be most affected by competitive bidding, we reject this PAOC recommendation on the basis that decisions were made by those who do not have primary responsibility for our patients.

Recommendation: CMS should establish a clearly transparent policy process for final promulgation of "product specific requirements" rather than the proposed approach through program instructions.

Implementation Contractor: Pulmonary physicians frequently interact with Medicare contractors to discuss various aspects of patient care. While we are not opposed to CMS' designation of competitive bidding implementation contractors (CBICs), we are unclear as to how the CBICs and DMERCs will interact in terms of development of policy. Pulmonary physicians should know precisely who to contact when issues arise regarding patient care, and adding another layer of contractors to the DME process can easily become confusing. We cannot help but believe that this additional layer of bureaucracy will be more cumbersome, and such a structure eventually affects a physician's ability to interact with contractors to ensure high quality patient care.

We also believe that CMS can improve dramatically the communication and interaction between its contractors to improve patient access and quality of care. Specifically, as noted below, physicians have a certain responsibility to prescribe devices in accordance with medical necessity and a plan of care, and on occasion must recertify that need. It seems prudent to us that such a Medicare requirement is reasonable, but should not be an unfunded mandate for a non-covered physician service. Contractors must work together, with CMS, to ensure that beneficiaries have access to all the recertification/retesting requirements that may be implemented as a result of competitive bidding.

Payment Basis:

Mail order programs under competitive bidding: CMS must be cautious as it considers implementation of this aspect of competitive bidding. Because there is such a wide range of devices, from hospital beds to life support ventilators that might be competitively bid items, simply permitting suppliers to drop ship life support devices without direct interaction between supplier and beneficiary regarding appropriate use is unacceptable – it signals to us a major shift in CMS' attitudes toward quality patient care. The Federal Register cites blood glucose test strips as an example of supplies that may be appropriate for drop shipping, but hopefully CMS will not permit drop shipping of oxygen cylinders, ventilators or respiratory assist devices to Medicare beneficiaries. In the broad arena of respiratory devices, one cannot signal any kind of parallel between canes and walkers on the one hand and use of a home ventilator, fitting a CPAP mask, or instruction related to supplementary oxygen on the other hand. We urge extreme caution and any pursuit of this process must include the opportunity for public comment prior to adoption of any Medicare policy that permits mail ordering of respiratory related devices that provide support for the management of chronic disease.

Submission of Bids:

We support the CMS proposal that establishes product categories for bidding purposes. This approach appears to ensure that beneficiaries can do one stop shopping for all of the needs related to oxygen therapy, including ongoing replacement supplies.

In terms of bidding for oxygen and oxygen equipment, it appears that CMS is dismissing the findings from its competitive bidding demonstration projects. CMS found that access to lightweight portable systems declined by approximately one-third during the pilot project, a finding that is extremely problematic unless it is appropriately remedied. In 2007 the availability of lightweight portable devices crosses several spectrums, from liquid systems manufactured by Puritan Bennett, to transfilling systems manufactured by Invacare and Chad, to portable oxygen concentrators manufactured by Inogen and AirSep making the potential for access issues even more acute.

To achieve that end, we strongly recommend that CMS use its authority to establish payment under competitive bidding based on classes of devices – a payment for ambulatory devices, a separate payment for portable (heavier than 10 pounds) systems, and a third payment amount for stationary devices. Maintaining a "modality neutral" system as Medicare currently uses will unquestionably exacerbate access issues to physician prescribed devices.

Education and Outreach:

NAMDRC supports CMS' efforts to commit to a process that will ensure that Medicare beneficiaries are thoroughly educated regarding competitive bidding. The sour experience of many Medicare beneficiaries regarding selection and enrollment in the Part D drug benefit indicates the critical importance of education regarding competitive bidding.

Physician Authorization/Treating Practitioner:

We strongly support CMS' proposal to permit physicians and other ordering practitioners to specify a particular item if the physician believes that particular device would avoid an adverse medical outcome. We have two examples where this provision will prove critical in a competitive bidding structure:

- Physicians should test/titrate new oxygen patients on the device that will be used by the patient in the home. Doing otherwise can easily create a situation that is less than optimal therapy. Knowing that physicians can titrate patients on a particular device with assurance the same device will be used in the home is a major step toward improving care.
- IN the treatment of sleep apnea, patients should be titrated and fitted with a mask that is identical to the devices used at home. As the example above, doing otherwise can easily create a situation that is less than optimal therapy.

If we can be of further assistance or clarification, please do not hesitate to contact our Executive Director, Phillip Porte, at 703-752-4359 or Phil@namdrc.org.

Sincerely,

Joseph Sokolowski, Jr. MD, FCCP
President

Submitter : **Sharmila Sandhu** **Date: 06/30/2006**

Organization : **American Occupational Therapy Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Comment is in two attachments.

CMS-1270-P-1124-Attach-1.DOC

CMS-1270-P-1124-Attach-2.PDF

#1124

AOTA The American Occupational Therapy Association, Inc.

Occupational Therapy: Skills for the Job of Living

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.

The American Occupational Therapy Association, Inc.
4720 Montgomery Lane
Bethesda, MD 20814-3425
301-652-2682
301-652-7711 Fax
800-377-8555 TDD
www.aota.org

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

#1124.

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

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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:

[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

Submitter : Mr. Dale Harris **Date:** 06/30/2006

Organization : City Drugs of Grove Hill

Category : Pharmacist

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

Patient care is severly hampered when patients lose their RIGHT to choose providers. This is especially true in patients with certain diseases such as diabetes who depend on their LOCAL pharmacist to lend advice and expertise when complications arise. A patient who is experiencing high or low glucose levels needs the pharmacist who filled their DME's such as strips and lancets and other diabetes related prescription drugs to observe them and suggest a course of action which will avoid life threatening outcomes such as severe hypoglycemia or diabetic coma. Please do not compromise patient care by limiting who can provide the service.

In addition, CMS must do more 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 be competitive in a large metropolitan area with large suppliers. After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment should by allowed to join the program as a contracted supplier. I urge CMS to take these steps tp preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established provider/patient relationships.

Thank you,
Dale D. Harris
City Drugs of Grove Hill
123 S Jackson St
Grove Hill, AL 36451

Submitter : Mr. Jon Tiger **Date:** 06/30/2006

Organization : Nat'l Home Oxygen Patients Association

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

The National Home Oxygen Patients Association welcomes the opportunity to provide detailed comments on proposed rules for competitive bidding. See attachment.

CMS-1270-P-1126-Attach-1.DOC

#1126

June 29, 2006

TO: The Centers for Medicare and Medicaid Services

RE: **CMS-1270-P**

FROM: The National Home Oxygen Patients Association (NHOPA)

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The National Home Oxygen Patients Association is glad to have the opportunity to comment on the proposed regulations that provide structure to competitive bidding, slated to begin some time in 2007. Our comments focus on a limited number of issues as we believe it is appropriate to comment only on matters directly affecting Medicare beneficiaries who utilize home oxygen.

Payment Basis:

Grandfathering: The proposed rule identifies a specific grandfathering process related to oxygen therapy. We support these provisions that –

- Permit beneficiaries the option to continue receiving services and supplies from their current supplier, assuming that supplier is willing to accept the competitively bid pricing amounts;
- Permit beneficiaries to transition to a contract supplier at any time
- Permit beneficiaries residing in a competitive bidding area but on travel status be allowed to obtain items from a supplier that has not been awarded a contract UNLESS the area being visited is also a competitively bid region. In the latter case, the beneficiary would be required to receive equipment and services from a contract supplier.

Competitive Bidding Areas:

We are concerned that CMS may unintentionally encourage mail order/drop shipping for oxygen and related equipment. We strongly oppose such an approach that might actually encourage suppliers to ship oxygen cylinders or other similar devices through methods other than direct delivery by the supplier. There are important safety issues that preclude such an approach in the arena of oxygen.

Submission of Bids:

We support the CMS proposal that establishes product categories for bidding purposes. This approach appears to ensure that beneficiaries can do one stop shopping for all of the needs related to oxygen therapy, including ongoing replacement supplies.

In terms of bidding for oxygen and oxygen equipment, it appears that CMS is dismissing the findings from its competitive bidding demonstration projects. CMS found that access to lightweight portable systems declined by approximately one-third during the pilot

project, a finding that is extremely problematic unless it is appropriately remedied. In 2007 the availability of lightweight portable devices crosses several spectrums, from liquid systems manufactured by Puritan Bennett, to transfilling systems manufactured by Invacare and Chad, to portable oxygen concentrators manufactured by Inogen and AirSep makes the potential for access issues even more acute.

To achieve that end, we strongly recommend that CMS use its authority to establish payment under competitive bidding based on classes of devices – a payment for ambulatory devices, a separate payment for portable (heavier than 10 pounds) systems, and a third payment amount for stationary devices. Maintaining a "modality neutral" system as Medicare currently uses will unquestionably exacerbate access issues to physician prescribed devices.

Selection of bidders: We recognize that there are complicated bidding considerations for suppliers, but CMS readily acknowledges that it will select only as many suppliers as necessary to ensure Medicare beneficiary needs are met. On the surface, that sounds reasonable, but it could create a scenario of only a few national chains receiving contracts to provide equipment if their collective capacity comes close to matching Medicare projected demand. We cannot help but ask the rhetorical question, "What harm is there in Medicare contracting with suppliers that exceed Medicare demand by 20-40% as long as those contractors agree to provide services and equipment for the Medicare contract price?" To go even further, we are not sure why the concept of "any willing provider" is rejected as long as aggregate savings targets are reached.

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Rebates: The rebate program appears attractive as it rewards beneficiaries financially if they choose certain suppliers. If this approach withstands legal considerations, we support it.

Physician Authorization/treating Practitioner:

We strongly support the proposed rule that permits a physician to prescribe a particular device. As long as the physician believes that providing a different device may trigger less than optimal care, we support this option for physician prescriptions for oxygen and related equipment.

If we can be of further assistance on this matter, please do not hesitate to contact me directly.

Jon Tiger, NHOPA President
Jon.M.Tiger@spiritaero.com
703-752-4353

Comment [b1]: Would this be a good place to address the relationship between the physician's perscrption and the claeese defined above?

Submitter : **Charlotte Sexton** **Date: 06/30/2006**

Organization : **Ozark Health and Rehabilitation**

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

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 Ozark Health & Rehab- 312 Bryan Dr. Ozark, Ala. 36360
We are 149 Bed Facility with 164 full time employees. Facility has 22 bed Dementia Unit. We also have long & short term rehabilitation, with full time, in house Physical Therapy, Occupational Therapy, 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 (facility name) 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,

Charlotte Sexton
Assistant Administrator

Submitter : Mr. Lewis Golinker **Date:** 06/30/2006

Organization : Assistive Technology Law Center

Category : Attorney/Law Firm

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

see attached comments

CMS-1270-P-1128-Attach-1.DOC

#1128

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MEMORANDUM

TO: **Lorrie Ballantine; Joel Kaiser; Michael Keane; Walt Reutemiller; Linda Smith, Centers for Medicare & Medicaid Services, United States Department of Health & Human Services**

FROM: **Lewis Golinker**

RE: **CMS 1270-P: Competitive Acquisition for Certain DMEPOS and Other Issues: Comments to Proposed Rulemaking**

Date: **June 30, 2006**

The Assistive Technology Law Center submits these comments in response to the Notice of Proposed Rulemaking related to competitive bidding for items of durable medical equipment.

Criteria for Item Selection

DME Product Categories Subject To Or Exempt From Competitive Acquisition

CMS has not identified which product categories of DME will be selected for competitive bidding. CMS also has not stated clearly the procedure by which it will make this determination.

An inclusion-exclusion selection procedure for DME product categories is necessary because Congress did not require all DME items to be subject to competitive acquisition. As the proposed rules acknowledge, the Medicare Act expressly authorizes the Secretary

to exempt "items and services for which the application of competitive acquisition is not likely to result in significant savings." 42 U.S.C. § 1395w-3(a)(3)(B).

The proposed rules are not clear regarding ***how*** the Secretary will make these inclusion-exclusion determinations pursuant to this authority.

We believe the Secretary must use great care regarding selection of DME product categories for competitive acquisition. Errors regarding product category selection can have profound adverse impacts on Medicare recipients. In addition, CMS acknowledges in the proposed rules that there may be no mechanism for administrative or judicial review of product category selections. 42 U.S.C. § 1395w-3(a)(10)(E). For this reason, preventing harm from errors in product category selections may be exceedingly difficult.

Sub-section E of the preamble to the proposed rules discusses only one criterion for excluding items: utilization volume. We believe this is an insufficient measure.

In a letter dated October 12, 2005 to Sean Dalenberg, the ATLC explained the basis for requesting an exception from competitive bidding for speech generating devices and related items (hereafter SGDs). In summary, the October 12, 2005 letter explained that the individual items comprising the product category known as SGDs are distinct physically, functionally, and operationally, and also in regard to follow-up service and support. For this reason, speech-language pathologists, SLPs, the professionals Medicare has made responsible for assessment of SGD need, make recommendations of a specific SGD model, and often a specific mount and access aids. By contrast, SLPs do ***not*** make determinations that a Medicare recipient requires only an SGD from a specific code. The differences in the needs and abilities of recipients and the functional, physical, operational and support characteristics of the specific SGD models are so significant that SGD recommendations are made on the basis of factors other than SGD cost.

The existence of product categories such as SGDs is not acknowledged in the CMS proposed rules for competitive bidding. Specifically, the existence of products that are selected for Medicare recipients' use based on a comparison of features and capabilities (both individual and device) and not based on a comparison of costs, requires an additional procedural step not yet contemplated by CMS. It is the opinion of the organizations on whose behalf the October 12, 2005 letter was submitted, that competitive bidding cannot effectively be applied to products that may be coded together but are so functionally and operationally dissimilar that they do not as a practical matter compete on the basis of cost.

For this reason, it is recommended that CMS adopt in its final rule a threshold procedure for determining the appropriateness of any DME code for the competitive bidding process. This procedure should enable CMS to determine that the items within the code are sufficiently similar in capability, function and other relevant characteristics that selection of specific models within the code is or reasonably can be made on the basis of device cost. If the answer to this threshold inquiry is in the negative, as it will be for SGDs and SGD related items, the items, code or product category should be exempt from the competitive bidding process.

This threshold step is both authorized and required, in our opinion, to ensure that the implementation of competitive bidding does not adversely affect DME *coverage.* Clearly, the greatest potential savings to the Medicare program can be achieved by eliminating coverage of specific DME items or of entire product categories. But "substantial savings" from coverage reduction or elimination is not what Congress enacted. Therefore, CMS must engage in a threshold inquiry to identify and exempt those DME items, codes and product categories where the implementation of competitive bidding will adversely affect coverage or beneficiary choice. Looking only at the items or product categories with the highest prices or highest utilization is not an adequate means to make this determination.

To simplify review and consideration of this comment, a copy of the letter dated October 12, 2005 is reprinted below.

Please contact me if you have any questions regarding this comment.

Thank you.

Lewis Golinker, Esq.
Director

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October 12, 2005

Mr. Sean Dalenberg
Centers for Medicare & Medicaid Services
Mailstop C5-08-27
7500 Security Boulevard
Baltimore, Maryland 21244

RE: DME Competitive Bidding
Exemption for Speech Generating Devices

Dear Mr. Dalenberg:

The Assistive Technology Law Center (ATLC) submits these comments in support of the exemption of Speech Generating Devices (SGDs) and related items from Medicare "competitive bidding."

These comments are submitted on behalf of all parties interested in Medicare coverage of SGDs: Medicare beneficiaries; the speech-language pathologists (SLPs) who determine patients' need for an SGD and who provide SGD treatment; the manufacturers of SGDs; and advocates. The organizations on whose behalf these comments are submitted include the:

American Speech-Language-Hearing Association (ASHA);
Assistive Technology Industry Association (ATIA);
Assistive Technology Law Center (ATLC);
Dynavox Technologies;
International Society for Augmentative & Alternative Communication (ISAAC);
Rehabilitation Engineering and Assistive Technology Society of North America (RESNA); and
United States Society for Augmentative & Alternative Communication (USSAAC).

Please take note that the individuals and organizations responsible for the comments that follow are the same as those on whom HCFA (now CMS) and the DMERC medical directors relied to develop the current Medicare SGD national coverage determination, and the current SGD Regional Medical Review Policy (RMRP).

Summary Statement of Position

The nine HCPCS codes that comprise the product family "speech generating devices and related items" E 2500-2599, should be exempted from the Medicare competitive bidding process and procedure. The basic assumptions underlying competitive bidding are false as applied to SGDs and related items.

First, SGD models, even within the same code, are not functionally and qualitatively equivalent, such that they are able to compete on the basis of price. To the contrary, SGD models are functionally and qualitatively distinct. SGD models do not merely copy each others' capabilities. Instead, different models seek their own niche: to address still-unmet needs among patients' enormous range of physical, cognitive, sensory and linguistic functioning. For this reason, SLPs make SGD recommendations on the basis of "feature-matching" between patients' abilities and needs and the distinct functional capabilities and limitations of various SGD models.

Second, the imposition of competitive bidding is not required to ensure that Medicare SGD and related items recommendations reflect the lowest cost, equally effective alternative. That standard represents the ***current*** basis for SLP decision making, imposed by the ***current*** Medicare SGD coverage criteria. It also represents the generally accepted current standard for SLP decision making for all third party SGD funding programs.

Third, the distribution of SGDs and related items is distinct from that of other DME items. Almost without exception, distribution is made directly by the SGD manufacturer. Unless all SGD manufacturers are allowed to compete in each geographic area subject to competitive bidding, some SGD models will cease to be available, and some patients will be unable to acquire an SGD appropriate to meet their needs.

Finally, imposition of competitive bidding for SGDs and related products cannot yield significant cost savings for Medicare. Overall utilization is exceedingly low: only approximately 1,220 SGDs per year are purchased by Medicare, divided among 6 HCPCS codes. SGDs and related items may well have the lowest utilization of any DME product category covered by Medicare.

Medicare Speech Generating Device Coverage

Medicare's coverage of Speech Generating Devices (SGDs) is based on a National Coverage Determination, NCD Manual, § 50.1, Coverage Issues Manual, CIM, § 60-23 (Jan. 1, 2001). This guidance is supplemented by a Regional Medical Review Policy (RMRP), jointly issued by all four DMERCs.

The National Coverage Determination defines SGDs as:

> Speech aids that provide an individual who has a severe speech impairment with the ability to meet his functional speaking needs.

The NCD also describes the functional characteristics of SGDs, which are reflected in the nine HCPCS codes that currently define SGDs and related items, such as software, mounting systems, and accessories:

E2500 SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, LESS THAN OR EQUAL TO 8 MINUTES RECORDING TIME

E2502 SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 8 MINUTES BUT LESS THAN OR EQUAL TO 20 MINUTES RECORDING TIME

E2504 SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 20 MINUTES BUT LESS THAN OR EQUAL TO 40 MINUTES RECORDING TIME

E2506 SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 40 MINUTES RECORDING TIME

E2508 SPEECH GENERATING DEVICE, SYNTHESIZED SPEECH, REQUIRING MESSAGE FORMULATION BY SPELLING AND ACCESS BY PHYSICAL CONTACT WITH THE DEVICE

E2510 SPEECH GENERATING DEVICE, SYNTHESIZED SPEECH, PERMITTING MULTIPLE METHODS OF MESSAGE FORMULATION AND MULTIPLE METHODS OF DEVICE ACCESS

E2511 SPEECH GENERATING SOFTWARE PROGRAM, FOR PERSONAL COMPUTER OR PERSONAL DIGITAL ASSISTANT

E2512 ACCESSORY FOR SPEECH GENERATING DEVICE, MOUNTING SYSTEM

The SGD NCD and RMRP represent the outcome of an 18 month policy review by HCFA staff. In June 1999, the HCFA administrator contacted the Assistive Technology Law Center to announce she was initiating a re-examination of Medicare coverage policy toward what were then called "augmentative and alternative communication" (AAC) devices. The Administrator asked the ATLC to coordinate the preparation of a "Formal Request" for Medicare coverage.

A work group of the nation's leading AAC researchers, educators, and clinicians was formed to prepare the *Formal Request for National Coverage Determination for Augmentative & Alternative Communication Devices*. This document was submitted to HCFA on December 30, 1999. It contains a comprehensive review of the medical literature related to AAC interventions and of current standards of clinical practice. It describes the neurological conditions most closely associated with SGD need and use; it outlines the speech-language pathology (SLP) assessment process, and the key clinical indicators that lead to a determination that an SGD is the appropriate form of SLP treatment; and it describes the most important characteristics of SGDs. (The *Formal Request* is posted for review at www.augcominc.com/funding.html (scroll to bottom of page))

After submission of the *Formal Request,* HCFA staff and the DMERC Medical Directors continued to work with the SLP work group for the next 16 months, until May 2001. At that time the final components of updated Medicare coverage policy were completed. This long-duration, positive working relationship shaped Medicare policy toward SGDs. Of greatest significance, it led to acknowledgement in the RMRP that the SLP is the key professional to determine the need for an SGD and to recommend the specific model of SGD and any related items. Indeed, SGDs and related items are the only category of Medicare covered items or services for which a non-physician is given primary responsibility for determination of medical need.

The *Formal Request* explained that SGDs and related items are used by individuals *with the most severe or complex* speech and language disabilities. Persons whose speech and language disabilities are less severe or less complex are served by other speech-language pathology treatment interventions. Those interventions allow the person to utilize natural communication methods, such as speaking, writing, signing or a combination of those methods to meet daily communication needs. *SGDs and related items are recommended* ***only*** *when the severity or complexity of the person's expressive communication disability makes it impossible for the person to meet daily communication needs using those natural communication methods.* RMRP, Coverage & Payment Rules, at ¶¶1(b); 3; and 4. This constitutes the "reasonable and necessary" standard for SGDs incorporated into the RMRP.

The Formal Request described the 7 most common neurological conditions that are associated with SGD need and use. These include:

Amyotrophic Lateral Sclerosis (ALS) (also known as "Lou Gehrig's Disease")
Cerebral Palsy

Locked In Syndrome
Multiple Sclerosis
Parkinson's Disease
Brain Stem Stroke
Traumatic Brain Injury

These diagnoses, however, do not equate to SGD need. Each of these conditions has a wide range of severity. As the RMRP acknowledges, the need for an SGD can only be determined upon completion of a comprehensive SLP evaluation.

The RMRP acknowledges that the SLP will play the central role in the assessment and decision making process related to SGD need. The SLP assessment is the centerpiece of the RMRP. It requires the SLP to gather data about and assess the significance of more than a dozen factors that affect both the person who ultimately will use the SGD as well as that person's primary communication partners, such as his or her spouse or primary caregiver. This broad-based inquiry is necessary because of the extraordinarily wide range of physical, sensory, cognitive, and linguistic functioning among people with severe speech and language disabilities. People with SGD needs range from having no physical impairment beyond their loss of speech, to being "locked in" to the point where "eye gaze" or "eye blinks" are their only volitional movements. Cognitively, people with SGD need range from having mental retardation or having aphasia, to having the abilities of Stephen Hawking. In addition, not only must the SLP assessment focus on the individuals involved in communication, it also must consider the primary environments in which communication with the SGD will occur. All of these factors can have SGD selection implications.

The assessment process required by the RMRP leads to a specific SLP recommendation. The SLP must determine SGD need, and recommend *a specific SGD model, plus all necessary related items, such as software, a mount, or accessories.* Moreover, it is a general element of SLP practice to recommend the least costly equally effective alternative. This applies to all Medicare SGD recommendations as well as the recommendations made to all third party funding programs.

Finally, the RMRP acknowledges the professional and financial independence of the SLP. SLPs who conduct SGD assessments have no connections to either the SGD manufacturers or suppliers. Their recommendations reflect solely their professional judgment about the most appropriate SGD and related items needed to meet the Medicare beneficiary's functional communication needs.

Viewed as a whole, the Medicare National Coverage Determination and RMRP for Speech Generating Devices supports Medicare SGD coverage without limitation.

As noted above, the *Formal Request* described *who* are the Medicare beneficiaries who will seek SGDs, and *how* their need for an SGD will be identified. In addition, the *Formal Request* described *how many* SGDs will be sought. Demographic research about persons with severe communication impairment support estimates that the need for SGDs will arise among 0.12 percent of the general population. Within a U.S. population as a whole of almost 300 million persons, the total "need" for SGDs is approximately

360,000. Within the approximately 38 million Medicare beneficiaries, approximately 46,000 have current SGD needs. The data presented in the *Formal Request* also made clear that SGD "need" and SGD "demand" are distinct. Annual SGD demand (and correspondingly, SGD costs to Medicare) will be an exceedingly small subset of SGD need.

Once again, the focus falls on the SLP. Every person seeking an SGD must first be assessed by an SLP, but SLPs who conduct SGD assessments are in exceedingly short supply. Many factors limit the number of SLPs working with this population. The patient population is exceedingly small, and represents individuals with the most severe and complex communication, physical, cognitive and sensory disabilities. SLPs require an extensive, ongoing commitment to continuing professional education. Moreover, other forms of SLP treatment receive higher levels of reimbursement. In addition, many SLPs with these skills are employed full time by schools and therefore are not available to serve the primarily adult Medicare beneficiary population. Another factor limiting SLP supply is that SLPs are not able to work independently as Medicare services providers. Taken together, these limitations will allow fewer than 3 percent of persons with SGD need to be able to seek Medicare reimbursement per year. Of 46,000 Medicare recipients with current needs, the *Formal Request* estimated that no more than 1,320 SGD claims will be submitted annually if Medicare adopted favorable SGD coverage policy.

These estimates are consistent with Medicare's actual claims experience. In the four years between 2001 and 2004, only approximately 1,211 Medicare recipients have acquired SGDs, per year, divided across 6 HCPCS codes. Total Medicare SGD expenditures, since coverage began four years ago, is less than $ 27 million. SGDs may well have the lowest utilization of any DME product family covered by Medicare.

Imposing Competitive Bidding On SGDs Will Have Significant Adverse Impacts On Medicare Beneficiaries

A competitive bidding process or procedure, if applied to SGDs and related items, will have significant adverse impacts on Medicare beneficiaries. The underlying assumption for competitive bidding is that Medicare beneficiaries now have access to multiple device choices that are sufficiently similar in function and quality, but which vary in price. Competitive bidding is intended to force these functionally and qualitatively equivalent items to compete on the basis of price. For SGDs, however, that fundamental assumption is not accurate: SGDs, even devices within the same HCPCS code, are not functionally or qualitatively equivalent.

Because SGD models are not functionally or qualitatively equivalent, imposing competitive bidding will substantively alter the scope of Medicare SGD coverage. As noted previously, the present scope of Medicare SGD coverage is *without limitation*, *i.e.*, any Medicare beneficiary will be able to acquire the SGD that will meet his or her functional communication needs. Imposing competitive bidding, however, will reduce the scope of SGD models available to Medicare beneficiaries. This will cause some Medicare beneficiaries to be able to access *no* SGD that will meet their needs. Other Medicare beneficiaries will not have access to the most effective SGD.

These results are not consistent with the Congressional purpose or intent for competitive bidding. Congress assumes competitive bidding will be applied under existing substantive DME coverage rules. For SGDs, this simply is not possible.

SGDs are organized into 6 HCPCS codes (with 3 others assigned to related items such as software, mounting systems and accessories). Upon review, the characteristics that define these codes are very broad. The four codes for digitized speech output devices consider only 2 factors: type of speech output (digitized) and amount of recording time. The 2 codes for synthesized speech output devices also consider only 2 factors: type of speech output (synthesized) and means of access (direct selection and spelling; or multiple methods).

By using only these pairs of characteristics to distinguish the SGD codes, the individual models that fit within each have very wide physical and functional variations. SGDs differ greatly in four ways. Within each code:

- **SGD models do not have the same features**; *E.g.*
  - SGDs have either dynamic or static displays (it is the SLP's responsibility to determine whether the client has the *physical* ability to use and the *cognitive* ability to understand the storage and organization techniques associated with a dynamic display; otherwise, only a static display SGD will be appropriate. If a client lacks the *physical* ability to change the paper overlays of a static screen display independently, a dynamic screen SGD is the only way the client can communicate independently. A client with limited support from caregivers or spouse for programming the SGD may be more appropriate for a dynamic display SGD because they enable messages to be added or deleted easily or easily moved from one page or level to another.);
  - Among the digitized speech output SGD models, only some support indirect access (scanning) while others require direct selection (activation by touch);
  - Some SGDs produce synthesized speech only, while others offer a mix of digitized and synthesized speech (an SGD with both types of speech output is particularly important for patients who communicate with partners who speak English during part of the day (*e.g.*, caregivers), and Spanish during another part of the day (*e.g.*, family members));
  - Only one model-family of SGDs offers visual output as well as speech output (this feature is especially important for communication partners who are hearing impaired, a relatively common factor considering the Medicare population and the effects of presbycusis, the normal age-related reduction in hearing ability);
  - Some patients require feedback from the SGD to ensure they are properly constructing their intended message. Some SGD models will provide auditory feedback, visual feedback, tactile feedback, but the models vary in which type of feedback, if any, they offer;
  - The most common access method for SGDs is direct selection by the client's finger. Other patients, however, require other means of access. This may include single switches, multiple switches, joysticks, optical

pointers. SGD models vary in regard to the types of alternative access methods they will support. (It is the SLP's responsibility to determine which is the most effective and efficient access method, and to identify the SGD model(s) that will support that access method.);

- Only two models of SGDs offer access to persons who must rely on eye gaze to activate their device (patients who require eye-gaze are the most severely physically disabled of all persons who require SGDs; no other SGD models will be of any benefit);
- Only a few SGD models allow messages to be produced by use of Morse code, an important tool for patients with severe mobility limitations and who must rely on a head-activated switch to activate their SGD;
- Some SGDs offer rate enhancement techniques to speed up the rate of message formulation. Pre-storage of messages; abbreviation expansion; letter, word or phrase prediction are common means of rate enhancement. Not all SGDs have this capability and not all SGD models offer the same rate enhancement techniques;
- For AAC accessories, mounts and software, Medicare acknowledged the wide inherent differences in their functional characteristics by abstaining from developing a fee schedule for any of these items. Instead, they are priced individually;

➢ **Even if the same components or features are present, they do not function in the same way**; *E.g.,*

- The cell or key sizes of many digitized speech output SGDs are distinct, ranging from ¾ inch to 1 1/8 inch square; some are fixed; others can be re-sized or shaped (an important consideration for a client who has limited fine motor control (the client must be able to hit (touch) a target with these dimensions, or s/he will not be able to produce messages accurately);
- The display of most SGD models is arranged in the form of a "grid," with multiple rows and columns of cells or keys from which messages are selected or produced. These grids vary in size from model to model: they include grids of 1x3; 2x4; 2x5; 2x10; 4x6; and 8x16. Some of these grids are fixed, while other models allow them to be resized. (The SLP must ensure the client has the physical ability to reach and accurately select all the cells on the grid, as well as have access to an efficient amount of vocabulary to be able to communicate effectively.);
- The layouts of new SGD models are arranged in other than grid format, based on the *cognitive* abilities and needs of patients (*e.g.* people with aphasia) to see their communication choices in specific contexts;
- Among the keyboard based devices, E 2508, one model-family is useful only for one or two finger typing, while the other 2 models allow touch-typing;
- Among the keyboard based devices, E 2508, one model-family has its speakers on the bottom of the device, which affects both loudness and speech clarity when the device is placed in the client's lap or on a solid surface; the other models have the speakers placed on the back of the device facing the communication partner. The size of the speakers also varies among these devices, which affects both speech output loudness

and clarity. As a result, even though all of these SGDs produce synthesized speech and access the same synthesis software, they produce sound of different loudness and clarity;

- Among the many SGD models that support indirect access (scanning), there are significant variations among SGD models in the degree to which the method of scanning can be controlled. Scanning methods and techniques include linear, row-column, block, automatic, inverted and step scanning, but not all SGD models support each, and not all models offer the same degree of control over scanning speed;

➢ **Among synthesized speech output devices are those that function very differently because their operating software is different;** *E.g.*,

- SGD speech synthesis software governs the operation of SGDs in the E 2508 and E 2510 codes. These software programs are unique to specific device models, and are not interchangeable.
- SLPs must make a precise "fit" between a client's most effective method of assembling or producing messages and the software program that supports that method. For example, software in specific SGD models will allow production of messages from a wide variety of inputs: letters, whole words, phrases, or fully formed messages; as well as picture symbols and actual photographs. But not all software will support all of these options. Also, only one software program will allow picture symbols to be assigned "multiple meanings," *i.e.*, they will produce different words and messages based on the combination of symbols used, and the order in which they are assembled in the message. All other software assigns picture symbols single meanings. The SLP must determine which of these input options is the most effective for the client, including whether combinations of methods is necessary;
- The SLP also must consider how the software operates, *i.e.*, how difficult or complex is the task of adding and storing new messages; and how other aspects of device operation controlled by the software, e.g., word pronunciation, and rate enhancement techniques operate. These functions will differ from program to program and correspondingly, among SGD models

➢ **The support offered by the SGD manufacturers is different**; *E.g.*,

- A necessary, close, and lifelong tie must exist between SGD users and the SGD manufacturer. Patients and their caregivers or spouses remain in periodic contact with the SGD manufacturers to address a wide range of issues. SLPs must consider how the manufacturers conduct this ongoing customer support as part of their SGD selection determination. The manufacturers vary in terms of the amount and quality of support offered by phone; through the manufacturer's web-site; the clarity of its written materials; the ease of use of search tools for access to on-line information; whether upgrades to software are distributed for free for the life of the product; whether narrower solutions to specific issues or operational

problems are circulated to existing owners of specific models; how repair is handled;

- The SGD manufacturers vary in the size and geographic distribution of their support staffs; for patients and communication partner who will need a lot of support in order to learn how to operate the SGD effectively, it will be very valuable to select an SGD model that can be readily supported by staff that is close at hand and able to make a home visit;
- The SGD manufacturers also vary in their reputations for repair, technical assistance and other aspects of device operation.

Because the SGD models are so different, and the examples provided above are mere illustrations rather than a list of the extent of their differences, the SLP's role in the assessment process is to rule out models – not on the basis of price – but instead, on the basis of "feature-matching" between the device model and the needs and abilities of the intended user. SLPs who conduct SGD assessments must know the characteristics of the various device models within each code, and apply them to the myriad of individual facts gathered during the assessment process. Ultimately, the SLP must recommend the SGD model with the features that best match the characteristics of the individual, primary communication partner and communication environment. In other words, the physical and functional differences among the SGD models, even within a code, have important selection or recommendation implications. Moreover, often the SLP, the Medicare beneficiary and his or her primary communication partner must choose between competing functional characteristics of SGD models because the individual, partner or communication environment imposes needs that no one device most appropriately satisfies.

The leading treatise on AAC intervention, D. Beukelman & P. Mirenda, Augmentative & Alternative Communication (3d Ed.)(Baltimore: Brookes Publ. 2005), describes the feature matching process as one of the primary ways in which AAC assessment is conducted, and always has been conducted. Its roots date back to the mid-1980s. Beukelman & Mirenda describe it as follows:

> Several authors have suggested predictive profiling or *feature matching* as an extension of the criterion based approach (references omitted). In the predictive assessment approach, the team first assesses the capabilities of the individual using ***a number of carefully selected, criterion referenced tasks***. Based on the results of this assessment, the AAC team then predicts the efficiency with which the individual might utilize one or more devices or techniques. . . . Feature matching requires that the AAC team members be knowledgeable about the operational and learning requirements of a wide variety of AAC options. . . .

Id. at p. 161(emphasis supplied)

The SLP assessment mandated by the RMRP was based on extensive input from Dr. Beukelman and other leading AAC professionals, and consequently it incorporates this feature match process. It states "a number" – more than a dozen – "carefully selected, criterion referenced" sources of data must be collected during the assessment process. Included among these are:

- the Medicare beneficiary's impairment type and severity;
- the anticipated course of the person's physical and speech or language impairment;
- for the Medicare beneficiary and primary communication partner:
  - hearing status;
  - vision status;
  - physical status;
  - cognitive status;
  - language skills; and
- daily communication needs, including primary communication partners and communication environments.

Then, the assessment process requires the SLP to conduct a "feature match" to determine which SGD model, and if necessary, which related items of software, mounting system and accessories will be best able to accommodate all these abilities and needs. This task is spelled out in instructions for SLPs using the Medicare RMRP – whether for Medicare funding or SGD funding by other systems of health benefits – that were developed by the same SLP work group that prepared the *Formal Request* and advised HCFA and the DMERC medical directors. Those instructions state:

> V. Rationale for Device Selection
>
> This section [of the SLP report] will explain why certain device features are required based on the person's skills and abilities as described in Section II [complete functional assessment.] This section provides data that leads first to the selection of a specific device code and second to a specific device within that code, as well as specific accessories.

Medicare SLP Assessment Protocol, posted at http://www.aac-rerc.com/pages/medicare/MCAppProtocol.htm.

The instructions continue to state that matching of the individual's (and often the primary communication partner's) specific abilities or needs to the features of specific SGD models requires consideration of at least the following:

- **Selection technique**, *e.g.*, direct selection or scanning, including whether the display type should be dynamic or static, how many keys (cells) are on the display and how they are arranged; whether an electronic aid to direct selection will be used; whether eye gaze will be required; for scanning, how the scanning will be conducted – row column; linear; group-row; etc.; whether scanning will be directed by a joystick or trackball; for switches, how much pressure they require; must they provide feedback, such as tactile or auditory feedback; positioning of the switches and mounting for them;
- **Input features, and encoding**, *e.g.*, what will the user see and use to create or produce messages: will they be letters, words, phrases, picture symbols, actual photographs; will Morse code be used to produce messages; will semantic compaction be used; how must these items be arranged on the display

- **Message characteristics or features**, *e.g.* what is the message length needed; are many pre-formed messages needed; how are they to be stored and organized for retrieval;
- **Rate enhancement techniques**, *e.g.*, letter, word or phrase prediction; abbreviation expansion; screens or levels; other techniques;
- **Output features**, *e.g.*, type of voice output; loudness and clarity of speech output; visual output as well.
- **Characteristics of the visual display;** *e.g.*, size, contrast, color or black and white; and
- **Feedback needs**, *e.g.*, is visual or auditory or tactile feedback needed.

In short, the physical, sensory, cognitive and linguistic differences among people with SGD needs and their primary communication partners, the differences in the environments in which SGDs will be used, and the physical and functional differences among the device models themselves belie any suggestion that SGD models, even within a single code, are functionally or qualitatively equivalent, and therefore, can be subject to competitive bidding on the basis of price.

In addition to all of the foregoing, SGDs are distributed in a way that is distinct from almost all other Medicare DME product categories. SGDs are distributed almost exclusively by their manufacturers, and ***not*** by dealers or re-sellers. Some manufacturers, *e.g.*, Zygo, distribute nationally from their company headquarters and manufacturing facility, located in Portland, Oregon. The three largest SGD manufacturers, Dynavox Technologies, the Prentke Romich Company, and Assistive Technology, Inc., use re-sellers in six or fewer states, and distribute their SGD models directly to all other locations from their company headquarters and manufacturing facilities in Pittsburgh, Pennsylvania, Wooster, Ohio, and Dedham, Massachusetts, respectively.

The effect of this distribution system is that in almost all locations throughout the country, and for almost all SGD models, particularly in the E 2508 and E 2510 codes, there will be a sole source of supply. Imposing competitive bidding on this distribution framework will result in the elimination of Medicare coverage for specific device models, which as noted above, may be the only models that are effective for individuals with specific combinations of physical, sensory, linguistic or cognitive abilities and needs.

The repeated mention that people with SGD needs present an extraordinary range and great complexity of communication, physical, cognitive and sensory disabilities are not merely hypothetical statements. To the contrary, these are a reflection of the individuals who already have sought Medicare funding for SGDs. Upon request by the Assistive Technology Law Center, Dynavox Technologies, the largest SGD manufacturer, surveyed 47 files of Medicare beneficiaries who acquired Dynavox SGDs. The characteristics of these individuals reinforce the conclusion stated here that competitive bidding poses a great threat to the ability of people with SGD needs to acquire the SGD models that will fit their individual needs.

Among the 47 cases reviewed, all the most common neurological conditions associated with SGD need and use were represented, as were all the most common communication diagnoses (dysarthria, apraxia, aphasia; and aphonia). These patients also included

people whose communication disabilities were stable, and those that will become progressively worse.

Thirty-four of the patients used direct selection to access their device. Of that total, 10 are recognized as having progressive impairments that will necessitate a change in access method to scanning at a later time. Two patients currently used a combination of direct selection and scanning. Six patients relied on switch-based scanning, utilizing at least 8 different types of switches. Five patients used other access methods, including a joystick, and Head Mouse.

The patients' receptive language skills, cognitive skills, vision and hearing ability were all reviewed as well. These functional areas ranged from normal to moderately to severely impaired.

In sum, the matters discussed in this document reflect the accumulated knowledge and experience of the speech-language pathologists who conduct AAC and SGD clinical assessment; and are an actual reflection of the Medicare beneficiaries who have sought SGD funding.

Imposing Competitive Bidding on SGDs Will Not Generate Significant Savings to the Medicare Program

Fewer than 5,000 SGDs have been purchased by Medicare since 2001: on average, only 1,211 per year. The four-year total number of digitized speech output devices purchased by Medicare is only 576, or only 144 per year; only 822 keyboard-based synthesized speech output SGDs have been purchased, or 206 per year; and only 3,449 multiple-access, synthesized speech output SGDs have been purchased, or 862 per year.

Among software, mounts and accessories, the total purchases are similarly small. In 2004, for example, Medicare spent only $ 4,562 on SGD software (E 2511); less than $ 220,000 was spent on mounting systems (E 2512), and less than $ 280,000 was spent on all SGD accessories.

The foregoing data make clear that competitive bidding for the nine codes representing SGDs and related items will not generate significant savings to the Medicare program. That is not possible: this product category is not a source of significant Medicare outlays.

In addition, the current process by which SLPs determine whether an SGD is needed, and if so, which one, and what if any related items are required, assures that only the least costly equally effective items are being recommended. The previously discussed SLP assessment process leads to that result.

Moreover, the RMRP for SGDs requires that all SLPs involved in SGD recommendations have ***no*** financial relationship with an SGD supplier or manufacturer. RMRP for SGDs, Coverage and Payment Rules, ¶ 7.

Conclusion

For the reasons stated above, representatives of all parties interested in Medicare SGD coverage: patients and their families; speech-language pathologists; SGD manufacturers; and advocates, request that CMS exempt the nine speech generating device and related items codes from the competitive bidding process. The wide range of functional differences among the Medicare beneficiaries who rely on these devices; the differences in the device models; the distribution system for these devices and related items; the fiscally sensitive assessment and recommendation process; and the exceedingly low utilization of these items all justify this exemption.

Please contact the undersigned if you have any questions or require any additional information.

Thank you.

Sincerely,

Lewis Golinker
Director

On behalf of:

American Speech-Language-Hearing Association (ASHA);
Assistive Technology Industry Association (ATIA);
Assistive Technology Law Center (ATLC);
Dynavox Technologies;
International Society for Augmentative & Alternative Communication (ISAAC);
Rehabilitation Engineering and Assistive Technology Society of North America (RESNA);
United States Society for Augmentative & Alternative Communication (USSAAC).

And the members of the Medicare Implementation Team, *i.e.* AAC professionals who worked with HCFA staff and the DMERC Medical Directors to develop the Medicare SGD coverage criteria, and who subsequently developed the Medicare funding resources posted at www.aac-rerc.com. The individual members of the Medicare Implementation Team are identified at http://www.aac-rerc.com/pages/medicare/MCgeneral.htm#mit.

Submitter : **Mr. Phillip Porte** **Date: 06/30/2006**

Organization : **Sleep Manufacturers Alliance**

Category : **Device Association**

Issue Areas/Comments

GENERAL

GENERAL

The Sleep Manufacturers Alliance welcomes the opportunity to comment on proposed regulations for competitive bidding. See attachment.

CMS-1270-P-1129-Attach-1.DOC

#1129

June 29, 2006

TO: The Centers for Medicare and Medicaid Services

RE: **CMS-1270-P**

FROM: The Sleep Manufacturers Alliance

The Sleep Manufacturers Alliance[1] includes nine device manufacturers which, under approval from the Food and Drug Administration, produce and sell diagnostic and therapeutic devices in the United States for the diagnosis and treatment of sleep disordered breathing, most notably obstructive sleep apnea. We welcome the opportunity to comment on the proposed regulations published in the May 1, 2006 ***Federal Register*** that address competitive acquisition for durable medical equipment.

Overview: There are several principles that must be incorporated into a successful competitive bidding program. First, it must ensure that the quality of care Medicare beneficiaries receive is not adversely impacted by this program. Secondly, the program must ensure that Medicare beneficiaries have access to the devices and supplies that are medically necessary for effective implementation of the treatment plan established by the physician and others. Thirdly, its administration should be relatively seamless to ensure that suppliers not only have all the information necessary to participate in the program but can do so without administrative burden to the suppliers. Lastly, it should achieve cost savings without impacting on the three principles cited above.

Another principle that should be woven into this proposed rule is an appreciation that, particularly in the arena of respiratory related devices (oxygen systems, CPAP devices, ventilators, etc.) these devices provide critically needed therapy for treatment of chronic illness. Without appropriate concurrent services to manage such respiratory-related devices, morbidity and mortality increase and associated health care costs increase.

As there are major components of the competitive bidding program that are not addressed at all or are addressed without specificity, we strongly recommend that any final rule addressing competitive bidding be published as an "interim final rule" to allow appropriate public comment on policies that are being proposed for the first time.

Quality Standards for Suppliers of DME: The primary goal of quality standards must focus on ensuring that Medicare beneficiaries receive the device(s) and supplies that are appropriate for the management of their illness. The proposed rule indicates that on the basis of a recommendation from PAOC, CMS will publish quality standards through program instructions. On the one hand, we find it problematic that CMS would choose to implement a statutorily mandated requirement through a simple instruction rather than the more formal mechanism of rulemaking through the ***Federal Register*** which would afford interested parties ample opportunity to comment. However, as these standards will apply to our customers who participate in the competitive bidding program, it is of paramount importance that CMS permit ample opportunity for public comment, whether

it be through the Federal Register rulemaking process or the less formal program memorandum process. .

Specifically, the proposed regulation states, "These standards will measure the effect of suppliers' services on beneficiaries. The supplier quality standards will include product specific requirements that will focus on a consumer-directed model of service delivery for suppliers to improve beneficiary access to information about DMEPOS." The term "product specific requirements" clearly would affect our products, and therefore the development of standards not subject to input from manufacturers of devices that are likely to be bid competitively is problematic.

Recommendation: We recommend that CMS create a transparent policy process with ample opportunity for public comments for final promulgation of "product specific requirements."

Implementation Contractor: As device manufacturers, we maintain ongoing relationships and communications with the DMERCs and the SADMERC. While we are not opposed to CMS' designation of competitive bidding implementation contractors (CBICs), we are unclear as to how the CBICs and DMERCs will interact in terms of development of policy, implementation of each other's policies, and overall coordination by CMS central office. On the one hand, the CBIC(s) will prepare the requests for bids, perform bid evaluations, select qualified suppliers and set single payment amounts for all competitive bidding areas, and the CMS approach here seems logical. But the addition of "assist(ing) CMS and the DMERCs in monitoring program effectiveness, access and quality, " the mix of responsibilities could be confusing and repetitive due to overlap of responsibilities, and costly to taxpayers.

The proposed rule is unclear in delineating specific responsibilities of existing and new contractor responsibilities, and therefore, without extensive clarification, it is unlikely that manufacturers as well as suppliers, providers and beneficiaries will know where to turn to address the myriad of issues that will arise related to competitive bidding.

Recommendation: we urge CMS to provide specific contractor responsibilities so that manufacturers, providers, physicians, and beneficiaries know where to address concerns regarding access, quality of care, etc.

Payment Basis:

Mail order programs under competitive bidding: Our review of the proposed rule indicates that CMS will seek bids from mail order suppliers on ALL items of durable medical equipment, regardless of the fact those items might not be included in a nationwide or regional competitive bidding program. We strongly urge CMS to approach this aspect of competitive bidding very carefully to ensure that patient care, access to suppliers, etc., is not adversely impacted. In candor, we believe that because there is a wide range of items under the DME benefit, it would be wise to seek specific input from

the public and interested parties, including physicians, to determine what items can appropriately be distributed through mail order. Using the CMS example, items such as blood glucose test strips may be appropriate for mail order processing, but certainly CMS does not want to encourage shipping of oxygen cylinders or ventilators to Medicare beneficiaries. In the arena of respiratory related devices, one must not presume that, unlike a cane or walker, instruction on proper use is as simple as reading an instruction manual. In the case of CPAP, fitting of a proper mask is paramount to successful compliance with/adherence to a prescribed plan of care. To presume that the same mask is clinically appropriate ad infinitum and the patient's condition does not warrant a different kind of mask at some time during the ongoing course of treatment is extremely problematic.

It is also unclear as to the application of mail order in the context of initial order versus re-ordering of supplies. Clearly situations will arise where re-ordering via mail order may be appropriate, but this, too, must be carefully monitored to ensure that the beneficiary's needs have not changed. Ongoing involvement of health care providers is imperative to ensure that any mail order process does not adversely affect patient care.

Again, we urge extreme caution in selection of devices that can be handled through mail order and strongly request careful consultation with the respiratory medical community prior to any proposed rules related to mail order programs.

Criteria for item selection: We cannot help but seriously question the approach CMS has outlined for device selection for competitive bidding. Using CPAP as an example, Medicare data indicate that these devices account for 1.2% of all DME allowed charges, $204.7 million in 2003. Assuming for the sake of discussion that Medicare believes it can save 5-10% of that amount through competitive bidding **if implemented nationally,** this would be a national savings of $20 million. While we fully appreciate and support CMS' fiduciary role to act on the taxpayer's behalf in a responsible way, it is difficult to fathom that the costs associated with implementing the program would make the approach cost effective.

Specifically, CMS estimates that its aggregate savings in 2008 will be $110 million. Using CMS' tables for the top 10 eligible DME policy group allowed charges, with the allowed charges of $7.4 billion, savings of $110 million signals to us a savings of 1.4% in 2008. To us, creation of a new bureaucracy including new Medicare contractors, and other obvious related financial as well as social costs, very well may not justify the return. We do appreciate CMS' need to implement a Congressionally mandated competitive bidding program, but it seems infinitely more logical to focus on product categories that will ensure savings that truly justify the associated costs. It is also important to emphasize the correlation between effective disease management for sleep disorder breathing and corollary reductions in other associated health care costs. Therefore, when one looks at the broad financial perspective, CPAP is not an appropriate category for competitive bidding!

Opportunity for Networks:

We support the concept of permitting suppliers to form their own networks. However, the use of networks must be very carefully structured to ensure that Medicare beneficiaries have appropriate access to Medicare suppliers. In theory, under the current structure, a Medicare beneficiary in Miami has dozens of suppliers from which to choose, and the implementation of competitive bidding will unquestionably reduce that number. Because such networks already exist for group purchasing, it is only reasonable to permit willing suppliers to form legal entities that will function to pass such savings on to the Medicare program as well as Medicare beneficiaries.

Specifically, we do note, however, that there appears to be a problematic limit on the size of such networks, as CMS proposes to limit market share to 20%. In fact, this could be discriminatory in its very nature if in fact large national suppliers can exceed the 20% threshold in their capacity. For example, if two national chains, as winning bidders, account for 75% of the threshold capacity identified by Medicare, what logic exists in limiting the network's capacity to 20%? Simply, why is one company permitted to function above the 20% threshold while a legal network of companies must be limited to 20% capacity? To us, it appears to be questionable legally as it discriminates against small suppliers and their ability to participate in the program. To reiterate, we support the option for suppliers to create networks, but we do not believe that limiting the market share of such networks to 20% is reasonable and, if implemented as proposed, would likely inhibit beneficiary access to a reasonable number of choices of suppliers.

Education and Outreach:

We support the Agency's commitment to ensure that Medicare beneficiaries are thoroughly educated regarding this matter. Recent CMS experience unequivocally signals the need for aggressive, thorough, timely and accurate education of beneficiaries who will be impacted by competitive bidding.

Gap Filling:

CMS recognizes that the current system does not readily address pricing of new technologies in the DME arena. We can identify numerous specific examples in the broad respiratory category where dramatic advances in sleep technology as well as oxygen delivery technology have quickly surpassed CMS' ability to code, let alone price these new technologies. We also recognize that, on occasion, there are either statutory or administrative limitations to pricing of new technologies, and it would be appropriate for CMS to recognize those limitations as well rather than espousing detailed analytical processes that would apparently usurp or replace other pricing structures already in place. Our comments, therefore, focus on the specific arena of pricing for competitive bidding as well as the broader issue of gap filling for all devices covered by the Medicare program.

CMS's proposal for gap filling in the context of competitive bidding is especially problematic. If a new code is established during a competitive bidding

cycle, CMS has stated that payment will be made at the rate for the current code until the end of that competitive bidding cycle. However, that rate may not be adequate / appropriate for a newer, more advanced technology. The CMS approach is likely to be a barrier to access to new technologies.

Additionally, of great concern to us is the statement, "we can use the technology assessment process at any time to adjust prices on or after January 1, 2007 that were previously established using the gap filling methodology if it is determined that those pricing methods resulted in payment amounts that do not reflect the cost of furnishing the item." We interpret this to mean that technological assessment alone, to the exclusion of both price comparison and medical benefit assessment, can be used to re-price items that have payment rates established through the traditional gap filling methodology currently in place. We support use of those two assessment tools in the establishment of pricing for new technologies as well as re-pricing of existing technologies. Excluding those assessment tools is unacceptable.

To address "gap filling" in the broader context of Medicare outside of competitive bidding, we recommend that CMS develop a process that ensures Medicare contractors will solicit and review information from manufacturers that address product development as well as information from providers regarding costs associated with support, service and delivery of the device(s). Therefore, we believe it is more appropriate for CMS to promulgate a separate, free-standing rule addressing gap filling that would apply to devices in general, not just devices that may be subject to competitive bidding.

Concluding comments:

The Sleep Manufacturers Alliance believes that a competitive bidding program can be structured in such a way to ensure that the services associated with medical devices continues to be provided in a seamless, clinically appropriate manner. Likewise, we believe that such a program can achieve worthwhile savings to Medicare and, therefore, the taxpayer. We are not convinced, however, that the proposed program achieves those goals. Too much is left for decisionmaking through subsequent rulemaking, program memoranda, and processes that may not afford the public ample opportunity for comment. It is in that context that we have outlined the comments above. We are committed to working with CMS and would be glad to offer assistance in clarifying these matters for you if you so request.

If we can be of further assistance, please do not hesitate to contact Phillip Porte at 703-752-4353 or Phil@GRQConsulting.com.

[1] Embla, Fisher & Paykel Healthcare, Invacare Corporation, Pro-Tech Services, Puritan Bennett, ResMed, Respironics, Sunrise Medical, VIASYS Healthcare

Submitter : **Gail Bimbo** **Date: 06/30/2006**

Organization : **NHS Management**

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

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 Regional Administrator for, Ozark Health & Rehab, Opp Health & Rehabilitation,Florala Health & Rehabilitation, Georgiana Health & Rehabilitation, Luverne Health & Rehabilitation,Tallassee Health & Rehabilitation,Wetumpka Health & Rehabilitation, Prattville Health & Rehabilitation, Lineville Health & Rehabilitation,

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 our facilities 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,
Gail Bimbo
Regional Administrator

Submitter : **Kathy Griggs** **Date: 06/30/2006**

Organization : **NHS Management**

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

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 Regional Case Manager for, Ozark Health & Rehab, Opp Health & Rehabilitation,Florala Health & Rehabilitation, Georgiana Health & Rehabilitation, Luverne Health & Rehabilitation,Tallassee Health & Rehabilitation,Wetumpka Health & Rehabilitation, Prattville Health & Rehabilitation, Lineville Health & Rehabilitation,

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.

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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,
Kathy Griggs
Regional Case Manager

Submitter : **Mrs. Marianne Smith** **Date: 06/30/2006**

Organization : **TMDH, Inc. dba Arnold Drug Company**

Category : **Other Health Care Provider**

Issue Areas/Comments

Conditions for Awarding Contracts

Conditions for Awarding Contracts

We recommend that any qualified provider willing to accept the winning bid as reimbursement be allowed to participate as a Medicare provider. This process will allow participation for small businesses, more accessibility to products and providers for beneficiaries, more complete coverage for rural areas, all at no increased cost for products. It is, in fact, possible that faster response time and more complete individualized coverage will result in cost-savings due to fewer complications, hospitalizations, and emergency room visits.

Opportunity for Networks

Opportunity for Networks

The ability to bid as part of a network is unclear as the requirements for networks are not well defined. Network regulations and structure need to be clearly set forth. Also, CMS has stated that market share for networks cannot exceed 20%. This figure needs to be increased to allow for more small business participation.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

The process to determine the number of suppliers including the methodology to establish supplier capacity appear to heavily favor the large, regional suppliers. The Small Business Administration needs to be consulted on the impact to small businesses as employers, tax-payers, and components of their communities. Also, the negative impact on beneficiaries from the lack of readily accessible, personal care by local providers needs to be considered.

Payment Basis

Payment Basis

The rebate program brings several concerns to mind. Offering gifts, rebates, or inducements to beneficiaries to influence their choice of providers has been prohibited by the Medicare program. Inducements distort beneficiary decision making, undermine honest competition, and favor the use of cheaper goods or lower quality services. Offering rebates favors large providers with greater financial resources, once again slanting the program against small suppliers. The rationale of forbiding inducements in one geographical area while encouraging them in an adjacent area during the opening phases of competitive bidding is confusing at best. The rebate program needs to be omitted.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Our company is a small, independent pharmacy and durable medical equipment supplier serving a rural area in Georgia. We employ 12 people, serve a 15 county area, and have been a Medicare supplier for almost 20 years. We are currently in the accreditation process; however, the supplier standards which will apply have not been finalized nor have the accrediting bodies been named. Any supplier desiring accreditation should have the time and opportunity to accomplish this goal before the implementation of competitive bidding. To require accreditation of suppliers while allowing non-accredited suppliers to bid is counterproductive.

Submitter : **Sara Thompson** **Date: 06/30/2006**

Organization : **NHS Management**

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

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 Regional Nurse Consultant for, Ozark Health & Rehab, Opp Health & Rehabilitation,Florala Health & Rehabilitation, Georgiana Health & Rehabilitation, Luverne Health & Rehabilitation,Tallassee Health & Rehabilitation,Wetumpka Health & Rehabilitation, Prattville Health & Rehabilitation, Lineville Health & Rehabilitation,

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 our facilities 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,
Sara Thompson
Regional Nurse Consultant

Submitter : **Ms. Mary Newberry** **Date: 06/30/2006**

Organization : **Illinois HomeCare Council**

Category : **Home Health Facility**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1134-Attach-1.DOC

#1134

ILLINOIS HOMECARE COUNCIL
NATION'S FIRST HOMECARE ASSOCIATION

June 30, 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, MS 21244-1850

RE: CMS-1270-P

Dear Sir:

Thank you for this opportunity to comment on the proposed rule entitled "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues" published in the Federal Register (Vol. 71, No. 83, page 25653) on May 1, 2006. The Illinois HomeCare Council (IHCC) is a trade association representing approximately 200 home care providers and suppliers in Illinois. These comments were developed by IHCC's DME/HME Work Group and Regulatory and Reimbursement Committee.

General Comments

It should be noted that IHCC has grave concerns about the competitive bidding program in its entirety. IHCC members feel that competitive bidding restricts trade in that it allows some suppliers to participate in the Medicare program while others may not. IHCC understands that CMS must use some criteria to select the providers and suppliers with whom they do business. However IHCC members feel that the selection should not be based on price bidding.

Implementation Contractor (Proposed 414.406)

IHCC members believe that introducing another contractor into the DMEPOS purchasing process will only increase the administrative costs of the DMEPOS program for the Centers for Medicare and Medicaid Services (CMS). Noting that one of the primary purposes of the competitive bidding proposal is to reduce

CMS outlays in this area of the Medicare program, IHCC believes that the alternatives discussed on page 25662 of the proposed regulation are more cost effective.

Recommendation:

- Implement the competitive bidding program in the most cost effective way by either using current contractors or identifying alternate contractors who will be responsible for all of the bidding and payment functions.

Payment Basis (Proposed 414.408)
Grandfathering of Suppliers (Proposed 414.408(k))

IHCC members support provisions that enhance the experience of Medicare beneficiaries with the Medicare program. Therefore, IHCC agrees that beneficiaries should be able to choose between continuing an existing rental relationship established prior to competitive bidding and a new supplier under the competitive bidding program. In instances where beneficiaries choose to change to a new supplier, IHCC supports the provision of a transition period of not less than 60 days.

However, CMS' rule does not consider all of the potential complications that may arise from the continuation of these pre-competitive bidding relationships. For example, what will happen when a beneficiary who is receiving a product from a grandfathered supplier needs a new product? Will the beneficiary then be expected to maintain relationships with two suppliers? This is a difficult matter to resolve.

Finally, IHCC is concerned that the proposal to pay the grandfathered supplier single payment amounts for items that require substantial servicing and for oxygen and oxygen equipment may not provide sufficient reimbursement for the level of service required. IHCC believes that there should be a mechanism for increasing the reimbursement based on a higher than usual number of physical contacts the supplier may have with the beneficiary to meet his needs.

Finally, the proposed rule does not address the criteria or mechanism that the contractor will use to evaluate whether items remain medically necessary when a grandfathered supplier is involved in a situation involving substantial servicing. IHCC believes CMS should clarify how these determinations will be made.

Recommendations:

- Allow for a period of at least 60 days to complete the transition of a beneficiary with rental equipment from their current supplier to a new supplier under competitive bidding in instances when the beneficiary elects to change suppliers.

- Address the circumstances described above where the needs of a beneficiary in a relationship with a grandfathered supplier expand to require other products not included in the grandfathered relationship.
- Tie reimbursement of grandfathered suppliers providing items that require frequent and substantial servicing and oxygen and oxygen equipment to the frequency of beneficiary contacts.
- Publish the criteria and mechanism that will be used to evaluate the ongoing medical necessity of products provided by a grandfathered supplier.

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

IHCC finds these proposed provisions to be unrealistic. First, IHCC members believe that CMS should describe in the proposed rule how "travel status" will be defined and documented. Suppliers must be able inform beneficiaries of the exact type of documentation required to establish travel status.

It also seems unrealistic to expect that the single payment amount in the beneficiary's home MSA be paid, regardless of the costs involved in providing the supplier to the beneficiary where he is currently residing. Not only does this proposal appear to overlook the real differences in costs across the country, but it also will involve very complex administration as contracted suppliers will have to determine and verify the MSA of the beneficiary's permanent residence and the rate that contracted suppliers in that area are being paid.

Recommendations:

- CMS should develop and publish a definition of "travel status" and the documentation required to establish it.
- CMS should pay contracted suppliers the rates established via their local competitive bidding process even when beneficiaries are only receiving supplies from them while on travel status. Using the rates applicable to the beneficiary's home MSA carries too high an administrative burden.

Limitation on Beneficiary Liability for Items Furnished by Noncontract Suppliers (Proposed Section 414.408(f))

IHCC recognizes CMS' need to identify non-participating suppliers in a competitive bidding area (CBA).

Recommendation:

- To further facilitate use of contracted suppliers, IHCC believes that CMS should establish local toll free telephone numbers beneficiaries can use identify and access suppliers capable of furnishing needed items in the CBA.

Competitive Bidding Areas (Proposed Section 414.410)

IHCC members believe that implementation of competitive bidding in a large metropolitan area such as Chicago will be very challenging, and question whether CMS has conducted sufficient pilot projects to plan for these challenges. IHCC members are doubtful that experience in smaller cities in years 1 and 2 will provide the knowledge needed to implement competitive bidding in the nation's largest population centers without potentially destroying the capacity currently available in these communities. Once destroyed, this capacity will be quite difficult to rebuild.

IHCC also has concerns about the proposed use of nationwide or regional mail order suppliers as described in the preamble. The use of diabetic testing equipment such as blood glucose monitors is critical to the health and well-being of diabetic beneficiaries. Even though this equipment has become much simpler in recent years, the implications of misuse or lack of understanding of how to interpret the results is potentially profound. IHCC members believe strongly that the provision of diabetic supplies such as test strips and lancets should not be exclusively handled through national or regional mail-order companies. Beneficiaries should at least have the option of receiving these supplies from a local supplier.

Recommendation:

- IHCC feels that pilot projects in Chicago, New York or Los Angeles should be conducted prior to bringing them into the competitive bidding program in 2009, or at any other time.
- Maintain the option for beneficiaries to receive diabetic testing supplies from local suppliers.

Submission of Bids Under the Competitive Bidding Program (Proposed Section 414.412)

IIHCC members understand the need for some sort of product categorization as described in the preamble to the rule on pages 25672 and 25673, however there are concerns about the potential impact of specialization in limited product categories by some suppliers. While requiring bidders to offer all of the products in the category will help to reduce fragmentation for beneficiaries with only one illness, fragmentation may increase for beneficiaries with multiple diagnoses. This is a concern to IHCC members. IHCC believes that successful implementation of the program will require that detailed information be readily available to beneficiaries about where they may go to secure needed supplies. If access is too complicated, beneficiaries are likely to forgo needed supplies to their detriment.

IHCC is also concerned that provisions related to capped rental items that ultimately become the property of the beneficiary (see page 25673 of the

preamble) do not define reasonable and necessary servicing of the DME, even though this activity will be included in the competitive bidding program. This must be clarified in order for suppliers to determine whether or not to support this proposal.

Recommendations:

- Insure that detailed and easily understood local information is available to beneficiaries telling them which product categories are available from which contracted suppliers in order to reduce the potential for confusion and resulting non-compliance.
- Clarify reasonable and necessary servicing of DME owned by Medicare beneficiaries prior to requesting that bids be submitted for the provision of these services.

Conditions for Awarding Contracts (Proposed Section 414.414)

Quality Standards and Accreditation (414.414(c))

IHCC members support the proposed requirement that all suppliers participating in the competitive bidding program should be accredited by an independent, approved accrediting body. However, IHCC believes strongly that all of the details of the quality standards must be made available to suppliers at least six months in advance of the issuance of a request to submit bids. It is critical that suppliers know the standards they must meet in order to accurately calculate costs on which to base their bids, particularly in light of the three year life of the contract.

In addition, allowing financial standards to be included in the request for bids suggests that they will be variable across CBAs. IHCC feels strongly that standards should be the same nationwide and should be available for a significant period prior to the opening of the bidding process.

However, IHCC has concerns about the grace period for achieving accreditation that is proposed. IHCC members believe that suppliers should be accredited prior to submitting bids. Allowing unaccredited suppliers to enter the program and then removing them if they fail to achieve accreditation will be too disruptive for beneficiaries.

Recommendations:

- Publish quality standards at least six months in advance of the opening of the bidding period and insure that accreditation opportunities and financial standards are the same nationwide.
- Require that suppliers be accredited prior to bid submission.

Composite Bids (414.414(e))

Recommendation:

- IHCC members believe that the weighting of individual items within the product category be based on both volume and cost. Failure to consider either of these elements would result in a failure to adequately evaluate the market importance of the item under consideration.

Determine the Pivotal Bid (414.414(e))

IHCC members find CMS' proposal for determining the pivotal bid to be too extreme in its price cutting implications. By starting with the lowest bid CMS endorses the notion that only price is important and gives too much credence to the lowest bidder.

IHCC believes that a better method would be to consider both price and capacity when constructing the pivotal bid by starting at the mean bid price and moving both up and down equally until capacity is met or exceeded. Such an approach would support CMS' quality concerns and would help to assure that sufficient capacity is available to ensure that beneficiaries have access to the services that they need (see below).

Recommendation:

- Determine the pivotal bid by starting at the mean bid price and moving both up and down equally until projected capacity needs are met.

Selection of New Suppliers After Bidding (414.414(h))

IHCC is concerned about CMS' proposal to select only as many suppliers as are needed to insure capacity based on projected demand for supplies. IHCC members believe that CMS does not have sufficient experience on which to base such an expression of confidence. This approach makes no real provision for the failure of a supplier to meet its obligations under the program.

IHCC believes that CMS should insure that there is sufficient capacity among contracted providers to exceed projected demand, at least during the early years of the program. CMS could conceivably determine a percentage cushion by product category or geographic area based on past experience with DMEPOS purchasing. In addition, the approach to determining the pivotal price described above has the advantage of increased capacity since all of the lowest price bidders could also be included as contracted suppliers, even if "just enough" capacity was reached before the stepwise process reached their proposals.

IHCC feels it is critical that CMS plan to have sufficient capacity available to insure that beneficiaries can secure the supplies and equipment they need even if a contracted supplier fails to deliver on its promises.

Recommendation:

- Plan for product capacity among contracted suppliers that exceeds projected demand in order to have an appropriate safety net for beneficiaries.

Determining Single Payment Amounts for Individual Items (Proposed 414.416)

Setting Single Payment Amounts for Individual items (Proposed 414.416(b))

IHCC members believe that CMS' proposal for setting single payment amounts will cripple the DMEPOS program by potentially paying many suppliers considerably less than their bids. In addition, it encourages suppliers to inflate their bids, knowing that their chances of receiving the bid price are remote. At a minimum, CMS should employ an adjustment factor to bring all contracted suppliers up to their own bid, use an adjustment factor to bring all contracted suppliers up to the pivotal bid, or use verifiable information about the true costs of the items being supplied and the services that must be provided to insure that the equipment and supplies are used safely and properly.

Though IHCC understands the legislative mandate under which CMS is operating, IHCC is concerned that such a draconian method for setting single payment amounts will severely damage the DME/HME supplier industry. And, it suggests that the bidding process will not be undertaken by suppliers in good faith, while at the same time almost insuring an inflated approach.

Recommendation:

- Abandon the current proposal and use an approach like those described above.

Rebate Program (Proposed 414.416(c))

IHCC is unequivocally opposed to the proposed rebate program. First, any rebate that exceeded the co-pay amount would be 20% below the single payment amount. IHCC believes that if the bidders show that level of variation, something is seriously wrong in the way they are pricing their bids.

CMS appears to have mixed feelings about this proposal themselves since they would allow suppliers to offer the rebates but would not allow them to advertise them. IHCC believes that this is an unworkable prohibition—suppliers who are primed to compete on price will find advertising rebates compelling and will search for loopholes that will allow them to get the word out. It will also encourage the less scrupulous supplier to offer inducements for referrals or commits other types of fraud.

IHCC finds evidence of CMS' recognition that a modest profit is appropriate in the Medicare program in the payment system that applies to most of its members—the home health prospective payment system. Suppliers that compete appropriately on price should be able to take their profits and use them to enhance service delivery, expand their product offerings or reward their shareholders.

Recommendation:

- Eliminate the rebate program proposal.

Physician Authorization/Treating Practitioner (Proposed 414.420)

IHCC members believe that two phrases used in this section need further clarification in order to provide suppliers with the guidance they need to achieve compliance with the proposed regulations. The first is language in 414.420(a) that states that a physician or treating practitioner can prescribe a particular brand or mode of delivery if he believes that its use will "avoid an adverse medical outcome" for the beneficiary. IHCC members find this language to be too general. An adverse medical outcome could be anything from mild discomfort to death or disability.

Similarly, Section 414.420(b)(1) states that the supplier must make a "reasonable effort" to furnish the particular brand or mode of delivery that is prescribed. The preamble (see page 25684) describes a series of alternatives the supplier might pursue, including providing the specified item, assisting the beneficiary in finding another local contracted supplier who offers the particular item, and working with the physician to modify the order. Is this what CMS considers to be a reasonable effort?

Recommendation:

- Clarify the terms "avoid an adverse medical outcome" and "reasonable effort" in the interests of facilitating supplier compliance.

Terms of Contract (Proposed 414.422)

IHCC members are concerned about the non-discrimination requirement stating that exactly the same products must be provided to Medicare beneficiaries as are provided to other customers. It seems in this instance that CMS wants to have the advantages of a competitive bidding program without the disadvantages. If a supplier must compete on price then it is likely the company will stock lower priced brands in a particular product type or category. Other payers with more generous reimbursement may receive a higher priced brand. As long as the product meets the definition under the ordered HCPCS code, and the physician has not ordered a specific brand, then the supplier should be free to furnish the lower cost brand.

IHCC is also concerned about the repair and replacement requirements for patient-owned items that will fall on contracted suppliers. Ultimately, the acceptability of this requirement will depend on the payments arrived at by the price-setting mechanism. IHCC members believe that the rates should be generous enough to insure that beneficiaries receive an appropriate level of response.

CMS' proposed regulation fails to address the circumstances under which the supplier may terminate the contract. IHCC believes that contracted suppliers must have the right to exit the program with adequate notice being given to CMS, perhaps 90 or 120 days.

Recommendations:

- Allow suppliers to provide lower-cost brands to Medicare beneficiaries since the products are acquired via a competitive bidding program designed to restrict costs.
- Revise the regulation to allow suppliers to voluntary terminate their contract with appropriate notice.

Administrative or Judicial Review (Proposed 414.424)

IHCC objects to CMS' proposed refusal to allow suppliers access to the administrative review structure in relation to competitive bidding processes and decisions. Though allowing for appeals of claim denials is appreciated, IHCC members believe that suppliers should be able to appeal the contractors' adherence to CMS' process and regulations and CMS implementation of its own rules.

Recommendation:

- Allow bidding and contracted suppliers access to administrative and judicial review processes just as other entities participating in Medicare are allowed.

Opportunity for Participation by Small Suppliers

IHCC recognizes and appreciates CMS' efforts to facilitate the participation of small suppliers in the competitive bidding program, but unfortunately believe that they are not sufficient. A small supplier winning a specialized bid may not have the capital required to expand as quickly as the proposed program will require. Rapid expansion increases debt and can place both the financial health and quality of service delivery at risk.

In addition, even with CMS' efforts to meet their needs, many small suppliers will not be able to compete as stand-alones. A number will close while others will merge or seek to sell themselves to larger operations. As a result, community resources will be reduced and a significant amount of DMEPOS capacity

nationwide will be lost. Ultimately, prices may rise because fewer suppliers will be available to bid in the program.

Recommendation:

- Delay implementation of the competitive bidding program until 2010, allowing CMS to assess the savings afforded by the new capped rental guidelines.

Sincerely,

Mary Newberry
IHCC Vice-President

Submitter : Kevin McKee **Date:** 06/30/2006

Organization : Brick Hand & Rehabilitative Services

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am an occupational therapist also certified as a hand therapist by the Hand Therapy Certification Commission. I am writing to voice my concerns about proposed implementation of the "Proposed Rule for Competetive Acquisition of Certain DMEPOS", CMS-1270-P. As an occupational therapist specializing in the provision of hand therapy services to many Medicare beneficiaries I frequently provide prefabricated orthotic devices to these patients. I am concerned that implementation of a competetive bidding process would be detrimental to the treatment process and overall health of my patients. The process of an established therapy program with a Medicare beneficiary gives the therapy provider an in depth understanding of the unique needs of each patient as they progress toward recovery. Other providers of orthotic services who are not involved in every aspect of the occupational or physical therapy treatment program of a patient will not have the optimum perspective to help choose and provide the most effective orthosis to meet each patient's needs. CMS-1270-P will permit a mechanism for such less prepared and involved providers of prefabricated orthotics to make decisions regarding specific orthoses to be provided and I anticipate that this will result in instances of less than optimally effective orthosis provision to beneficiaries. I have seen this interference with the therapeutic progress of patients in other patients being managed by private sector "managed care" insurance companies. Therapists specializing in an area such as upper extremity dysfunction usually have a broad knowledge of specific individual orthotic devices which differ significantly between brands of product and variations in design which effect the best choice decision of the orthosis to be selected for a patients needs. Some non-therapist orthotic suppliers may only supply a small variety of orthotics which they choose to help them stay profitable within the competetive bid amount they were awarded for that device billing code. The Medicare beneficiary will be the loser in these instances. I am also concerned about the potential legal and ethical issues imposed by introduction of another providers choice of orthotic within my overall treament program for a patient. If the other provider gives the patient a less effective or even detrimental orthosis that I would not have provided and the patient does poorly as a result, will the poor outcome reflect on my therapeutic program? I think that may be a problem that I don't want to ever have and what a shame for the patient. I suspect that I will not be able to compete with many orthotic providers in successfully securing a bid for prefabricated orthotics because I will always put the patient first by providing a wide variety of specific orthotic devices based on my patient's needs. The more choices I offer, the higher by bid submission must be. So to remain ethical in my provision of the best services and products, I will probably have to pay the price of being denied the opportunity to provide prefabricated orthotics if CMS-1270-P provisions are implemented as proposed. If CMS does proceed with implementation of CMS-1270-P, and I hope this will not occur, I would like to propose that occupational and physical therapists be exempt from the competitive bidding process if they choose, and be permitted to provide prefabricated orthoses based on the current geographic fee schedule allowances particularly for patients they are currently treating in an established therapy program. If that is not feasible I would still propose that therapists be permitted to provide prefabricated orthoses and be reimbursed for them by Medicare at the prevailing competetive contractor's established rate.

Submitter : **Dr. Richard Gosnay** **Date: 06/30/2006**

Organization : **West Connecticut Podiatry**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Richard Gosnay, DPM
West Connecticut Podiatry, LLC
235 Main St.
Danbury, CT 06810-6606

June 30, 2006

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

I am writing to strongly object to having podiatrists submit bids for our regions in order to dispense durable medical equipment to our patients. This would be comically inappropriate and would interfere with my ability to treat my patients.

Items of durable medical equipment are essential for the care of foot and ankle medical and surgical practices. Our patients need to be braced, or splinted, or otherwised treated by the podiatric physician who is diagnosing and directing care. It is absurd to think that a surgeon would send a patient off to find the best Ankle-Foot orthosis for post operative healing. My patients require that I personally dispense the appropriate devices because I am best qualified to dispense exactly what they need.

CMS seems to understand this when it exempts MD s and DO s from the bidding process. But podiatrists need to be exempted by the same logic.

The competitive bidding model may be reasonable for store-front medical supply businesses. But durable medical equipment is also essential to the practice of podiatry. I have an x-ray machine here in my office. Yet some patients present with trauma, and I must refer them out with a prescription for x-rays before I treat them. This is dictated by their insurance plans. Meanwhile, I can treat other patients with fractures immediately because their insurances allow me to x-ray. This would be analagous to making my medicare patients seek out durable medical equipment elsewhere. I need to provide durable medical equipment if I am going to be able to treat my patients appropriately.

Sincerely,

Richard, Gosnay, DPM

Submitter : **Dr. Brian Homer** **Date: 06/30/2006**

Organization : **Dr. Brian Homer**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 30, 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:

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.

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.

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

Sincerely,

Dr. Brian Homer

Submitter : Mr. Todd Gillenwater **Date:** 06/30/2006

Organization : California Healthcare Institute

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Attached are the comments of the California Healthcare Institute (CHI) on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding competitive bidding for certain items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), published in the Federal Register on May 1, 2006 (the Proposed Rule).

CMS-1270-P-1138-Attach-1.PDF

#1138

C·H·I CALIFORNIA HEALTHCARE INSTITUTE
WWW.CHI.ORG

June 30, 2006

SUBMITTED ELECTRONICALLY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

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

Dear Administrator McClellan:

The California Healthcare Institute (CHI) welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding competitive bidding for certain items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), published in the Federal Register on May 1, 2006 (the Proposed Rule). 1/ CHI represents the full biomedical sector of the California economy and unites more than 250 of California's leading biomedical firms, universities, and private research institutes in support of biomedical science, biotechnology, and pharmaceutical and medical device innovation. California is the global leader in biomedical R&D, with more than one-third of all U.S. biotechnology and medical device firms turning scientific discoveries into medical products at an unprecedented rate. California companies lead the nation in bringing to market frontline therapies for diseases such as AIDS, breast cancer, stroke, and diabetes.

As a representative of an industry that is dedicated to improving patients' lives through technology, CHI believes that CMS should be guided by the following key principles as it finalizes its proposed rule:

- The Competitive Bidding Program (the Program) must ensure that Medicare beneficiaries can continue to access the full range of appropriate DMEPOS items.

- The Program must permit Medicare beneficiaries to access needed products and services within their local communities.

- The Program should not provide disincentives for continued innovation and therapeutic advances for DMEPOS items.

1/ 71 Fed. Reg. 25653 (May 1, 2006).

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- The competitive bidding process and resulting program should be transparent to bidding suppliers and beneficiaries.

- Beneficiaries' access to DMEPOS items promotes self-sufficiency, reduces morbidity and costly hospitalizations, and saves lives. As a result, CMS should calculate cost savings in the Program by evaluating costs for a course of therapy across all Medicare payment systems, including Part A.

With these principles in mind, CMS should revise and clarify key provisions of the Proposed Rule relating to access to and quality of care for Medicare beneficiaries suffering from diabetes. Diabetes is an increasingly prevalent disease threatening the health and lives of Medicare beneficiaries. From 1997 through 2004, the incidence of diabetes increased 43% among individuals aged 65-79. 2/ In California alone, recent data show that over 1.7 million adults suffer from the disease, and the prevalence among Californians over the age of 65 has increased from 15.1% to 16.5%. 3/

Nationwide, the Medicare program has the highest share of potentially preventable diabetes-related costs, with at least $1.3 billion attributable to hospitalization costs alone. 4/ But evidence shows that these costs can be controlled if patients comply with a self-monitoring regimen and carefully control their glycemic levels. 5/. For these reasons, CHI strongly believes that blood glucose monitors and related supplies should be excluded from the Program. In particular, CMS lacks the experience necessary to implement the Program in a way that will adequately protect beneficiary access to quality care. The stakes are just too high to risk launching an experimental program that could limit beneficiaries' ability to obtain diabetes supplies appropriate to their needs and reduce full compliance with their self-care regimen.

If CMS decides to include diabetes supplies in the Program, it must ensure that beneficiaries can continue to access quality supplies. To this end, CMS should revise its proposed implementation of the Program so that beneficiaries can obtain supplies within a reasonable geographic proximity to their home. Further, the Proposed Rule creates unfortunate incentives for suppliers to stock only certain low-cost items within a product category, without sufficient protections to ensure that a beneficiary can obtain the most clinically appropriate item for his or her condition.

CHI also believes that infusion pumps and related drugs should be excluded from the Program because these therapies have unique characteristics, and CMS lacks sufficient experience to ensure that beneficiaries will continue to access vital, life sustaining therapies. If CMS determines

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2/ Centers for Disease Control and Prevention (CDC), National Diabetes Surveillance System, http://www.cdc.gov/diabetes/statistics/incidence/index.htm (last visited Jun. 26, 2006).
3/ California Department of Health Services, Prevalence of Diabetes in California Counties, 2003 Update, www.dhs.ca.gov/chs/OHIR/reports/countyhealthfacts/diabetes2003.pdf#search='california%20diabetes%.
4/ Agency for Healthcare Research and Quality (AHRQ), Economic and Health Costs of Diabetes, http://www.ahrq.gov/data/hcup/highlight1/high1.htm (March, 2005).
5/ National Diabetes Information Clearinghouse, National Diabetes Statistics, http://diabetes.niddk.nih.gov/dm/pubs/statistics/#14 (last visited Jun. 26, 2006).

that infusion pumps and related drugs should be included in the Program, CHI believes that CMS should narrowly define the product categories and establish protections to ensure that beneficiaries can access each brand of drug from at least one supplier in each area. Further, CHI is concerned that CMS' interpretation of the Medicare statute requiring payments under the Program to be lower than the current fee schedule amount will harm beneficiary access to needed care and reduce incentives for manufacturer innovation. Instead, we recommend that CMS analyze the aggregate savings offered under each bid.

The Proposed Rule also lacks clear quality standards and accreditation requirements for suppliers. CMS should publish a new proposed rule clarifying these standards so that suppliers can prepare bids that accurately reflect their costs under the Program. In addition, CMS should work to educate beneficiaries, providers, and suppliers to reduce disruptions in care and assist them in transitioning to the Program. CMS should also continuously monitor beneficiary access to care throughout implementation of the Program.

Finally, CHI is very concerned that CMS' proposed use of the gap-filling methodology for new DME items and drugs and biologicals provides disincentives for innovation and could lead providers to decline to provide new therapies because they cannot cover their costs. CMS should put forward a new proposed rule setting reimbursement for new therapies at a rate that appropriately rewards innovation and protects beneficiary access to state-of-the-art care.

I. CMS Should Ensure Beneficiary Access to Quality Diabetes Supplies

A. The Competitive Bidding Program Must Ensure Beneficiary Access to Local Suppliers (Payment Basis; Competitive Bidding Areas)

CHI strongly urges CMS to exclude diabetes supplies from the Program. Diabetes supplies were not included in the Medicare Competitive Bidding Demonstrations, meaning that CMS lacks necessary experience with competitive bidding for these products. Implementation of the proposed Program on a widespread basis should not include diabetes supplies until CMS can fully evaluate what works and what doesn't work. The stakes are simply too high for those beneficiaries who suffer from diabetes and require access to daily monitoring and complex treatment.

If diabetes supplies are included in the Program, CHI is concerned about the potential disruptions in beneficiaries' access to these supplies. For example, many Medicare beneficiaries traditionally have obtained their diabetes monitoring systems and related supplies through their local pharmacy or other supplier. These beneficiaries often access other necessary pharmaceuticals and supplies through "one-stop shop" pharmacies for diabetes patients' health care needs. But if a beneficiary's local pharmacy does not bid to be a contract supplier, or does not win a bid, that beneficiary will have to obtain his or her diabetes supplies from a different supplier and may have to find yet a third supplier to fulfill other health care needs. This change represents a potential barrier to care, and, if CMS includes diabetes supplies in the Program, CHI recommends that CMS promulgate rules similar to those under TriCare and Medicare Part D to ensure that beneficiaries have access to suppliers within a reasonable geographic proximity.

CHI is concerned about CMS' statement that it has the authority to expand the competitive bidding area beyond the boundary of the Metropolitan Statistical Area (MSA). 6/ The MSA may be an imprecise proxy for a service area, but CHI believes that Section 1847(a)(1)(B)(II) of the Social Security Act should be interpreted to require MSAs to be the exclusive venue for competitive bidding areas. 7/ To the extent CMS is concerned about manipulating natural markets for DMEPOS, CHI urges that the competitive bidding areas be made smaller, not larger, to ensure that beneficiaries do not have to travel too far from home to access their supplies.

Beneficiaries deserve the freedom to choose the retail outlet that is most appropriate to their needs. As in the Medicare Part D program, beneficiaries should have a choice whether to obtain items through a mail order program or through their local pharmacy or retail outlet. Further, any mail order program must include adequate safeguards to ensure that the beneficiary has access to face-to-face counseling and assistance. In addition, the impact of a national or regional mail order program on beneficiary compliance with diabetes monitoring and self-care is unknown and may be negative for patients who are elderly or who do not adapt well to the use of a mail order product.

B. CMS Must Ensure that Beneficiaries Have Access to the Appropriate Diabetes Supplies for their Medical Needs (Criteria for Item Selection; Physician Authorization/Treating Practitioner)

CHI is concerned that CMS' Proposed Rule does not adequately recognize the diversity of items within each product group, particularly those related to blood glucose monitoring systems. These monitoring systems are not interchangeable, and there is a significant amount of differentiation and innovation among them. In addition, we note that CMS has provided little clarity about the standards it will use to select items, as well as how bid selection will ensure the item quality. If a particular brand of monitoring system is a fundamentally better option for Medicare beneficiaries, but is more expensive than other products within a HCPCS code, CHI is concerned suppliers will have an incentive to supply only lesser-quality items in order to ensure a greater profit margin. Such incentives could effectively override a physician's decision about the appropriate product for a particular beneficiary.

CHI is pleased to see that CMS has proposed allowing a physician or treating healthcare provider to prescribe a particular brand of product if he or she determines that use of the product would avoid an adverse medical outcome for the patient. 8/ CMS' proposed rule mandates that the contract supplier provide the required item or therapy, assist the treating provider in finding another contract supplier who can provide the item, or consult with the treating provider to find an appropriate alternative. 9/ If the supplier furnishes an item that is different from the treating provider's prescription, CMS will not reimburse the supplier. 10/

Although this provision helps provide some assurances that beneficiaries will not be forced to use items that could result in adverse outcomes for them, it is not sufficient to guarantee that patients can access the care they need. Within an individual HCPCS code there is a wide variance of

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6/ 71 Fed. Reg. at 25667.
7/ 42 U.S.C. § 1395w-3(a)(1)(B)(i).
8/ 71 Fed. Reg. at 25684.
9/ Id.
10/ Id.

brands available. If the suppliers chosen in the Program only carry some of the brands of a necessary item, the beneficiary may face hurdles to accessing the brand that is right for them. The physician authorization provision only protects a beneficiary when the doctor has determined that other available products would result in an adverse medical outcome. 11/ But if a physician orders a particular brand, he or she has presumably determined that it is the best brand for the patient. For example, when selecting a self-monitoring blood glucose system for a patient, the physician makes a choice based on many factors, including, but not limited to: (a) strip size and ability of the patient to handle the strip (i.e., dexterity issues, tremor, vision problems, ability to touch reagent pad without affecting the result); (b) the impact on a blood test of any co-morbidities; (c) the ability of the patient to read the results on the display panel; (d) the amount of blood sample the patient is able to draw (i.e., if the patient has bleeding issues such as being on a blood thinning regimen or having thick skin); (e) monitoring glycemic levels; (f) ease of calibration; and (g) auto on/off features. All of these factors can contribute to patient compliance and improved health outcomes. But if the contract suppliers do not provide the system the physician recommends, the Proposed Rule effectively overrides the physician's judgments about what is medically indicated for their patients. This could result in decreased patient compliance and increased complications or morbidity. Such a result not only puts beneficiaries' health at risk, but could cost the Medicare program more overall.

C. CMS Should Do More to Ensure the Participation of Small Suppliers (Opportunity for Participation by Small Suppliers)

Many small companies sell blood glucose monitoring supplies through mail order and pharmacies, but the Proposed Rule does not provide sufficient assurances that they successfully can compete in the Program. Although CMS states that they will have the opportunity to participate in networks with other small suppliers, 12/ many of the smallest suppliers are likely to lack the resources to establish networks. CHI urges CMS to create a technical assistance program to help small suppliers engage – and compete – in the competitive bidding process. If small suppliers are left out of the Program, beneficiaries will lose a valuable avenue for obtaining necessary supplies.

II. CMS Must Ensure that Beneficiaries Continue to Access Quality Infusion Pumps and Related Drugs

A. CMS Should Exclude Infusion Pumps and Related Drugs from the Competitive Bidding Program (Criteria for Item Selection)

CHI urges CMS not to include drugs and biological products in the Program. In just the past year, Medicare coverage and reimbursement of drugs has undergone radical changes, stemming from the introduction of Medicare Part D and the launch of the Medicare Competitive Acquisition Program (CAP). To add a dramatically new method of reimbursement for drugs and biological products through a competitive bidding program will result in confusion for beneficiaries and their providers, and potential disruptions in access to care.

In addition, drugs and biological products have unique characteristics that make them unsuited to a competitive bidding program. First, every drug and biological product has distinct

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11/ Id.
12/ Id. at 25701.

pharmacology and handling processes. A number of infusion drugs are single source therapies with no therapeutically equivalent or bioequivalent products. Some infusion drugs also share a Healthcare Common Procedure Coding System (HCPCS) code with other drugs that have the same active ingredient but have varying therapeutic effects on patients. Further, many drugs are manufactured by only one company, potentially with a limited distribution network. CHI believes that CMS should include not only every HCPCS code in a product category, but also every formulation of covered drugs to ensure adequate beneficiary access to appropriate therapies.

CHI also is concerned that CMS lacks necessary experience with the competitive bidding process for infusion pumps and related drugs. The Medicare Competitive Bidding Demonstrations conducted for other types of DME did not include any competitive bidding for infusion drugs and biological products. Although the demonstration tested nebulizer drugs, these drugs are very different from infusion drugs and biological products. Nebulizer drugs are primarily multiple source therapies, and do not present the same concerns about therapeutic equivalence. Often there is a large number of manufacturers that produce a particular nebulizer drug. This allows participating suppliers to choose from a wide range of therapies, while continuing to obtain appropriate drugs for Medicare beneficiaries. Further, the demonstration project was able to obtain lower prices for nebulizer drugs in large part because of the competition among multiple manufacturers. When suppliers are bidding on single source drugs, or drugs with only two or three manufacturers, it would likely be more difficult to generate the same cost savings.

CHI does not believe that the Medicare CAP is a sufficiently mature program to provide adequate guidance on competitive bidding for drugs and biological products. The program has not yet been fully implemented, and there have been no studies to determine the effect of CAP's bidding and distribution requirements on beneficiary access to care. Further, the CAP has additional protections for beneficiaries that are lacking in CMS' proposed competitive bidding program for DMEPOS. For example, the CAP allows physicians to choose to participate or to continue with the traditional buy and bill method for obtaining drugs. Under the proposed rule for the Program, Medicare beneficiaries and providers only could access the covered products through contract suppliers. 13/ But if those suppliers are unable provide an infusion drug or biological product because of an inadequate single payment amount, beneficiaries could lose access to critical therapies.

CMS should obtain significantly more experience in the implementation and oversight of a competitive bidding program before infusion pumps and related drugs are included. CMS needs to take time to ensure that the program is appropriately designed to guarantee that beneficiaries continue to receive necessary care.

B. If CMS Includes Infusion Pumps and Related Drugs, It Should Publish a New Proposed Rule to Clarify Categories for these Products (Criteria for Item Selection; Submission of Bids Under the Competitive Bidding Program; Regulatory Impact Analysis)

CHI believes that CMS has not provided adequate information on how product categories will be selected for competitive bidding, limiting stakeholders' ability to comment constructively.

13/ Id. at 25699.

CMS proposes to define "product category" as a "group of similar items used in the treatment of a related medical condition." 14/ Although the Proposed Rule identifies 20 DME policy groups, CMS indicates these are for illustrative purposes only, and the competitive bidding product categories may be different. 15/ From these statements, we cannot determine whether CMS intends to establish narrow or broad product categories, and the preamble to the Proposed Rule is ambiguous. For example, one of the 20 illustrative policy groups is broadly characterized as "Infusion Pumps and Related Drugs." 16/ But CMS also states that it will try to encourage specialization among suppliers. 17/ Although this latter statement suggests that CMS might define the product categories narrowly, the Proposed Rule does not provide sufficient information for stakeholders to know how categories will be defined or to comment appropriately. CMS' choice of categories will heavily influence the bidding process, as well as patient access to care.

CMS should issue an additional proposed rule to clarify and narrow the product categories. We believe a narrow definition of product categories will help increase the number of potential bidders and preserve beneficiaries' access to needed therapies. To illustrate, the Proposed Rule requires suppliers to submit a separate bid for all the items within a product category. 18/ Physicians who are DMEPOS suppliers who submit bids, as proposed by CMS, 19/ will want to supply drugs related to their practice. If CMS defines the product categories broadly, so that these physicians must supply all DME infusion drugs, they are less likely to participate in the Program. In the same fashion, specialty suppliers who cater to particular diseases or conditions may have a disincentive to bid if the categories are too broad. These physician and specialty suppliers are often trusted resources for infusion pumps and related drugs for Medicare beneficiaries. If they decline to participate in the Program, these beneficiaries could lose access to an important source of care. CMS should define the product categories more narrowly, increasing the likelihood these specialty and physician suppliers will participate. CHI recommends that CMS issue a second proposed rule defining these product categories, so that affected entities and individuals can provide meaningful comment.

C. If CMS Includes Infusion Pumps and Related Drugs in the Program, It Should Ensure that Beneficiaries Have Access to Needed Therapies (Physician Authorization/ Treating Practitioner)

Although drugs and biological products may be grouped within a single HCPCS code, many patients respond only to a particular formulation or brand within that HCPCS code, and the Proposed Rule recognizes this reality. As with the CAP's "furnish as written" protections, physicians should make decisions about necessary treatments for their patients and not be second guessed by the suppliers.

CHI believes this provision conflicts with CMS' proposal to allow contract suppliers to choose the brands of products within a HCPCS code that they will provide. 20/ As currently drafted,

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14/ Id. at 25672.
15/ Id. at 25670-71.
16/ Id. at 25671.
17/ Id. at 25673.
18/ Id. at 25672.
19/ Id.
20/ Id.

if the contract supplier only provides certain brands, Medicare beneficiaries and their providers will have no guarantee that a medically necessary therapy will be available in the area. CHI urges CMS to consider assessing contract suppliers' bids based in part on whether they can furnish each brand of a product within a category. At the very least, CMS should ensure that there is at least one contract supplier within a competitive bidding area that provides each brand of product within each HCPCS code.

CHI also recommends that CMS exercise its authority under section 1847(b)(7) of the Social Security Act to create separate categories for products within a HCPCS code, if indicated by "clinical efficiency and value of specific items." 21/ Specifically, CMS should use this authority to ensure continued beneficiary access to infusion drugs and biological products. Although CMS states that the HCPCS codes appropriately separate products based on their function, 22/ CHI believes that the current HCPCS process inappropriately groups together therapies that can have different pharmacologic effects as well as infusion pumps that have unique properties and attributes such as alarm systems and patient safety mechanisms. As we have stated in previous communications with CMS, we believe that each brand drug or biological product should have its own HCPCS code. 23/ If CMS chooses not to provide unique HCPCS codes for these medicines, CMS should ensure that all contract suppliers maintain an inventory of at least one National Drug Code (NDC) for each brand name drug or biological product, even if the claims for reimbursement use the same HCPCS code. Similarly, suppliers should be required to include a broad range of pumps to administer all necessary drugs safely to all types of patients.

D. CMS Should Refine Its Process for Analyzing Bids and Setting Payment Amounts (Conditions for Awarding Contracts; Determining Single Payment Amounts)

CHI believes that CMS is interpreting the statute creating the competitive bidding program in a way that could discourage supplier participation in the Program and reduce beneficiary access to quality care. The Medicare statute bars CMS from awarding a contract to a supplier unless the Secretary finds that "the total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts than would otherwise be paid." 24/ CMS' interpretation of this provision is that the bid amount for each item must be below the current fee schedule amount for that item. 25/ This interpretation could set inappropriately low reimbursement amounts for items, giving suppliers a disincentive to participate in the Program and reducing patients' access to care. CMS should not attempt to garner savings on each item, but should instead follow the model of the CAP for physician administered drugs. The CAP allows the single payment rate for a drug to be more than its Average Sales Price (ASP) based rate, if the total expected spending for the product category is below the ASP-based payment for those products. In addition, the competitive bidding demonstration program only was able to achieve savings for 16 out of 27 nebulizer drugs, yet the Medicare program still garnered aggregate savings. 26/ Further, many drugs administered through

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21/ 42 U.S.C. § 1395w-3(b)(7).
22/ 71 Fed. Reg. at 25684.
23/ CHI, Comments to Healthcare Common Procedure Coding System Public Meetings, April 2006.
24/ 42 U.S.C. at § 1395w-3(b)(2)(A)(iii).
25/ 71 Fed. Reg. at 25678.
26/ Tommy G. Thompson, Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, 2004, http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMS_rtc.pdf

DME are reimbursed at less than their ASP-based rates. 27/ As a result, CHI is concerned that CMS' proposed requirement for cost savings in the competitive bidding program will be impossible to satisfy for many of these therapies.

CHI also urges CMS to apply an expansive view of cost savings generated by the Program. Specifically, CMS should assess costs over a complete course of care for a Medicare patient. Often a less costly version of a drug infusion pump will require the purchase of high-cost, dedicated supplies and tubing, while a more costly pump may be used universal tubing and lower cost supplies. Similarly, the universal tubing often used with more sophisticated pumps also can be used for gravity drip, potentially eliminating additional costs during the course of care. Moreover, a high cost pump may contain certain advancements, improving overall performance and drug delivery, reducing the risks to the patient, improving compliance with a drug regimen, and potentially reducing costly hospitalizations or other treatments. For example, some drug infusion pumps include alerts or safety protocols that could be life-saving for a Medicare beneficiary, particularly one with cognitive impairments. Medicare beneficiaries deserve access to high quality infusion pumps that meet their needs, and CMS should consider all the costs relating to a patient's course of treatment when it evaluates cost savings under the Program.

Moreover, CHI urges CMS to follow the methodology it used in the Medicare Competitive Bidding Demonstration to set the single payment amount for items in the Program. This methodology should include the use of an adjustment factor. CHI notes that although CMS is proposing to set the single payment amount for each item at the median of the winning bids, 28/ this was not the method CMS used in the demonstration projects. 29/ Further, CMS provides no evidence that rates set under this methodology will be adequate to ensure an adequate number of suppliers to protect beneficiaries' access to care. The methodology used in the demonstration projects, with an adjustment factor, would bring all bids up to the level of the pivotal bid, to ensure that no winning bidder will be paid at a level below their bid price. If CMS chooses not to use this methodology, it also could set the single payment to equal a certain fraction of the highest winning bid, such as the 90th percentile of the winning bids or no lower than 5 percent below the highest winning bid. Either of these methodologies greatly will enhance the likelihood that a sufficient number of suppliers will choose to participate in the Program, protecting patient access to care.

Finally, CMS should have a system in place to protect against suppliers who submit winning bids but then decide to drop out of the Program. Some suppliers may submit unreasonably low bids in order to garner a contract but subsequently may decide not to participate. CMS should ensure that a process is in place to revisit the bidding process in the event this occurs.

27/ See April 2006 ASP Pricing File, http://www.cms.hhs.gov/MCrPartBDrugAvgSalesPrice/02_aspfiles.asp.
28/ 71 Fed. Reg. at 25679.
29/ Tommy G. Thompson, Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, 2004.

III. CMS Should Publish a New Rule to Clarify Quality and Financial Standards (Conditions for Awarding Contracts)

CMS' Proposed Rule requires a winning contract supplier to meet unspecified quality and financial standards. 30/ CMS states that it will establish the quality standards through program instructions published on the CMS website, and will continue to develop financial standards. 31/ We believe that the quality and financial standards must be completed before competitive bidding is implemented. Suppliers considering bidding for a competitive bidding contract need to know the cost of their obligations under the quality, financial, and accreditation standards at the outset in order to accurately reflect those costs in their bid. CMS should consider following the model of the CAP in setting the quality and financial standards for the Program, including requiring suppliers to have at least three years' experience in supplying these items.

In addition, we are concerned that CMS' proposed evaluation of bids creates incentives for suppliers to game the system by submitting low bids on certain items and high bids on others to generate a good composite score. Further, there is no differentiation on quality among bidding suppliers in the evaluation process, and CMS does not provide sufficient incentives for suppliers to provide quality service. CHI believes that the bid process should take into account quality measures such as "customer service" to Medicare beneficiaries.

CHI also recommends that CMS allow suppliers of home dialysis equipment and supplies to be exempt from these quality standards, because these entities currently must meet exhaustive quality standards. Suppliers of home dialysis equipment and supplies must have a relationship with a dialysis facility to provide direct patient training. CMS surveys these facilities to ensure compliance with conditions for coverage, and these facilities must participate in End Stage Renal Disease (ESRD) networks that monitor and document quality. In addition, CMS is working to improve quality monitoring for dialysis through pay-for-performance in the pending ERSD demonstration program. Suppliers of home dialysis equipment and supplies must meet extensive quality standards, and requiring them to comply with an additional set of standards is unduly burdensome.

IV. New Items Must be Reimbursed Appropriately (Gap-Filling)

CMS has proposed revising its gap-filling process to set a payment amount for a new DME HCPCS code that is introduced in the middle of the billing cycle. As proposed, CMS would set a payment amount for a new item of DME using the applicable rates for items determined to be comparable. 32/ CHI is concerned that this proposed process will provide a disincentive for innovations in care.

CHI strongly believes that DME, drug and biological products should be reimbursed in a manner that recognizes their unique qualities and costs to providers. Providers that cannot be sure of an appropriate payment rate for a new item may decline to provide it, thereby denying beneficiaries

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30/ 71 Fed. Reg. at 25700.
31/ Id. at 25659, 25675.
32/ Id. at 25688.

access to innovative therapies. CHI is opposed to CMS' proposed revisions to its gap-filling process. For new DME items, CMS should keep in mind that there often are no comparable products on the market and provide reimbursement at a level that reflects an accurate cost of the item. For new drugs and biological products, CHI suggests that CMS reimburse new drugs at 95 percent of average wholesale price (AWP), the current reimbursement methodology for DME infusion drugs, or 106 percent of wholesale acquisition cost (WAC) or 106 percent of ASP, as in the physician office or hospital outpatient setting, for new drugs added to the CAP in the middle of a bidding cycle. CHI is concerned that if prices are subject only to the discretion of CMS, the price established may be too low and have a negative impact on innovation. CHI requests CMS to reject this proposal in its final rule and put forward a new proposed rule that rewards innovation and protects beneficiary access to state-of-the-art medicine.

V. CMS Should Educate Stakeholders and Monitor Patient Access (Terms of Contract)

CMS should closely monitor patient access to DMEPOS items as the Program is implemented to protect against any disruptions in patient care. This is particularly necessary for patients who are in the middle of a course of treatment. For example, CMS should appoint an ombudsman in each competitive bidding area to respond to beneficiary complaints. CHI urges CMS to provide details on the elements of a monitoring program, as well as a program for responding to complaints, in its final rule.

In addition, CHI urges CMS to provide clear and regular educational and training materials to Medicare beneficiaries, Part B providers, contract suppliers, and non-contract suppliers, to ensure that beneficiaries and the professionals who care for them know how to access needed supplies and to ensure that suppliers communicate effectively with beneficiaries on these issues. Such communication is particularly important for beneficiaries undergoing infusion therapy and for individuals with diabetes to avoid disruptions in the continuum of monitoring and self-care.

VI. Conclusion

CHI thanks CMS for the opportunity to comment on the Proposed Rule, and we hope to work with CMS to ensure that Medicare beneficiaries continue to access innovative products and therapies that meet their medical needs. We hope our suggestions will help CMS address these important issues in the final rule. In brief, we urge CMS to:

- Exclude diabetes supplies from the Program.
- If diabetes supplies are included, ensure that beneficiaries can continue to access them through a local supplier by implementing a geographic proximity rule similar to the Medicare Part D and TriCare programs.
- Include protections to ensure that beneficiaries can access the item most clinically appropriate for their condition.
- Publish a new proposed rule to narrowly define the product categories, and give stakeholders an opportunity to comment.
- Exclude infusion pumps and related drugs from the Program.
- If infusion pumps and related drugs are included, ensure patients can access each brand of drug from at least one supplier in the area.

- Analyze cost savings resulting from the Program over a complete course of care for a Medicare beneficiary.
- Publish a new proposed rule clarifying quality standards and accreditation requirements for contract suppliers.
- Educate beneficiaries, providers, and suppliers about the Program and actively monitor its implementation.
- Publish a new proposed rule to set reimbursement for new DME and therapies at a rate that accurately reflects costs and rewards innovation.

If you have any questions, or need additional information, please contact Todd Gillenwater, Vice President, Public Policy at (858) 551-6677. Thank you for your attention to our comments.

Sincerely,

David L. Gollaher, Ph.D.
President & CEO
California Healthcare Institute

Submitter : Mr. Andrew Lenick **Date:** 06/30/2006

Organization : Avanced Healthcare Solutions

Category : Other Health Care Professional

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

This process should not elimate any providers. If costs need to be adjusted, then there should be an adjustment in the fee schedule

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

If a program goes into place that is restricted by region, it will cut my business significantly.I am a smaal customer orient business that focuses on service. I provides services in all regions. There needs to be the opportunity for small busniesses to compete with everyone else and be restricted to just one geographical area.

Submitter : Mr. Chris Hendrickson **Date:** 06/30/2006

Organization : UnitedHealthGroup

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1140-Attach-1.DOC

OVATIONS
A UnitedHealth Group Company

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To: Centers for Medicare & Medicaid Services
Submitted via email to http://www.cms.hhs.gov/eRulemaking.

From: Chris L. Hendrickson, President – Consumer Health Products, Ovations

Date: June 30, 2006

RE: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

We have reviewed the 42 CFR Parts 411, 414 and 424 Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues. We are providing the following attached comments. The comments are provided on behalf of Ovations and United HealthCare Products, LLC.

We greatly appreciate the opportunity to comment, and we look forward to continuing to provide medical supplies and services to Medicare Part B beneficiaries.

If you have any questions or concerns on our comments, please contact Jill Grell at 952.936.3952 or via email jill_a_grell@uhc.com.

Product Categories for Bidding Purposes: §414.412

Comment: We suggest that clear definition of the product categories be outlined and all HCFA Common Procedural Coding System (HCPCS) codes and their typical quantities 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. Additionally, certain clinical features need to be taken into consideration. For example, 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.

Appropriate Products for Beneficiaries' Needs: §414.408

Comment: The Notice of Proposed Rule Making (NPRM) proposes to allow physicians and practitioners to prescribe a specific brand or type of equipment. Such a provision will preserve beneficiary access to equipment. The availability of product that meets the clinical needs of Medicare beneficiaries is essential. We are concerned that competitive bidding based solely on price will result in the reduction of choices and brand availability to this vulnerable segment of society. Providers that are focused on serving the clinical needs of the patient often offer a wide variety of choice and often have higher product cost than those who restrict choice to a few or low cost manufacturers. Therefore, we recommend that product requirements take into consideration clinical needs. Thus, Medicare beneficiaries will retain the ability to purchase supplies that meet their respective needs. For example, certain Medicare beneficiaries with diabetes have different product needs which include:

- Visual Impairments that affect the ability to see information displayed on monitor
- Dexterity required to operate monitor
- Mobility issues that may dictate home delivery as opposed to retail purchase
- Requirement of monitor to store testing history and ability to download history to compatible systems of health professionals

Market and Supplier Capacity: §414.414

Comment: 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.

We recommend that the bid solicitation and evaluation process include safeguards against this type of bidding strategy. We recommend that CMS eliminate outlier bids to discourage suppliers who might submit irrational bids. An alternative may be to require justification for bids that appear artificial. If safeguards are not part of the process, there is no assurance that the competitive bidding payment amounts are sustainable over time.

Single Payment Determination: §414.414

Comment: 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. We believe that 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.

Rebate Program: §414.416(c)

Comment: 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 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. Additionally, the OIG has published guidance in the form of advisory opinions and fraud alerts and consistently held that inducements distort beneficiary decision making and undermine competition among providers. Consequently, we believe CMS should reconsider this proposal.

Quality Standards and Accreditation: §414.414

Comment: 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 a grace period. Winning bidders who do not become accredited during the grace period will loose the contract supplier status. With a large number of DME suppliers being 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. We recommend that CMS not proceed with competitive

bidding until suppliers who may want to submit bids have the opportunity to get accredited.

We also recommend that the evaluation of the supplier's financial stability 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.

Timeline: §414.406

Comment: The NPRM is unclear 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 any unforeseen challenges and provide remedies prior to the broader roll-out

Summary

We favor quality standards and fair competition in healthcare. But without safeguards for quality and fair competition, competitive bidding will threaten quality of service, discourage competition and restrict patient access. We suggest the development of quality standards before implementation of restrictive contracting so standards for necessary clinical support services are in place to ensure quality of care. Additionally, we believe CMS should allow any qualified provider to compete and should not limit the number of providers if they can meet prescribed prices and quality standards.

Submitter : Ms. Sharon Hildebrandt **Date:** 06/30/2006

Organization : NCART

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1141-Attach-1.DOC

#1141

NCART
National Coalition for Assistive and Rehab Technology

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June 30, 2006

Department of Health and Human Services
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Mail Stop C4-26-05
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Baltimore, MD 21244-1850

The National Coalition for Assistive and Rehab Technology (NCART) is pleased to have this opportunity to submit the following comments in response to the Centers for Medicare and Medicaid Services' (CMS') Notice of Proposed Rulemaking (NPRM) for Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues. NCART is a coalition of suppliers and manufacturers of assistive and rehab technologies. The Coalition's mission is to ensure proper and appropriate access to rehab and assistive technologies, which CMS classifies under durable medical equipment (DME). NCART members are committed to raising the level of professionalism and quality in regards to the assessment, service and delivery of complex rehab and assistive technology.

General Comments

NCART acknowledges that CMS and its contractors have given extensive consideration to the many proposals within this NPRM. However, NCART remains concerned that the only reason identified for products to be excluded from the competitive bidding program are purely based on potential savings. NCART believes that Congress intended for consideration to be given to clinical outcomes for Medicare beneficiaries. NCART 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 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 competitive bidding. The precedent for this has already been established with the exemption of prosthetics and customized orthotics from competitive bidding as enacted in the Medicare Modernization Act. Complex rehab and customized orthotics and prosthetics share similar processes and outcome requirements (mobility and function). Only the physical products and the diagnosis and prognosis of the beneficiaries differ. **While NCART 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 any way intended to offer alternatives to an exemption.**

II. Provisions of the Proposed Regulation

C. Payment Basis (§ 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. NCART 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 power wheelchairs. Under a capped rental scenario, accepting a new beneficiary transfer after several months of rental would be unrealistic. NCART 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. NCART recommends that CMS start the rental period over if beneficiaries are transferring to a contract supplier and payment is under capped rental. NCART 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.

5. Authority to Adjust Payments in Other Areas 414.408 (c) (P.43)

NCART 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 use the payment information determined under that competitive bidding program to adjust payment amounts for the same DMEPOS in areas not included in the competitive bidding program. CMS is proposing to use this authority but provides no detailed methodology for doing so. NCART recommends that CMS issue a separate Interim Final Rule addressing payment issues that have broad implications outside of the competitive bidding program. It is critical for the industry to have specific proposals on which to develop commentary and be allowed ample time to develop substantive written comments. We further recommend, absent the ability to comment on a specific proposal, that CMS complete a comparability analysis of each MSA before being able to adjust the payment amount for that area. 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.

6. 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. NCART believes this proposed plan will make it difficult for beneficiaries to obtain products and services in some areas. While NCART recognizes that this is the current Medicare policy, the maximum fee schedule 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. NCART 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.

D. Competitive Bid Areas

Proposed Methodology for MSA selection for 2007 and 2009 Competitive Bidding Programs (§ 414.410)

In this section, CMS proposes to use a formula driven methodology for selecting MSAs for competitive bidding in 2007 and 2009. CMS proposes to score the MSAs based on combined rankings of DMEPOS allowed charges per FFS beneficiary and the number of DMEPOS suppliers per beneficiary receiving DMEPOS items in CY 2004, with equal weight being given to each factor. CMS further states that the number of suppliers would be based on suppliers with at least $10,000 in allowed charges attributed to them for DMEPOS items furnished in the MSA in CY 2004. NCART believes it is important for CMS to understand the number of DMEPOS suppliers that provide the specific items targeted for a specific MSA. NCART believes that the proposed dollar amount is too low. In addition, the $10,000 threshold may be too small for some items of DME. For higher cost items, $10,000 would not indicate an adequate level of experience with a product to appropriately meet the needs of Medicare beneficiaries. NCART suggests that CMS look at total allowed charges and allowed charges for the items being bid. In addition, we recommend that CMS set an appropriate dollar threshold for each product category that would demonstrate that the supplier has adequate experience with the particular product category before counting that supplier for MSA selection purposes.

CMS also proposes, in a situation where more than one MSA receives the same score, to use the total DMEPOS allowed charges for items that CMS has the authority to include in competitive bidding in each MSA as the tiebreaker. NCART suggests that CMS instead consider the FFS charges for the items proposed for bidding in each MSA and the total number of accredited suppliers in each MSA to break ties

NCART agrees with CMS' proposal to exclude the three largest MSAs from inclusion in a competitive bidding until 2009. However, CMS indicates that an alternative is being considered that would establish a CBA that may include portions of one or more of these MSAs. NCART understands the desire to phase-in portions of the extremely large MSAs. However, NCART recommends that CMS not consider bidding portions of these complex MSAs in 2007.

NCART agrees with CMS' proposal to have at least one CBA in each DMERC region. It is critical for each region to gain experience in competitive bidding. This will allow CMS to monitor each DMERC's performance to ensure that any issues are identified and rectified before larger scale competitive bidding is implemented. 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. NCART recommends that CMS phase-in the first 10 MSAs. We suggest beginning with one MSA in each DMERC region and then phasing in the remaining 6 MSAs. A staggered implementation would allow CMS to identify and address problems as competitive bidding commences and avoid widespread problems...

1. b. MSAs for 2009

CMS proposes to use the same criteria to score MSAs for 2009 as would be used for 2007. However, the proposal also indicates that CMS is considering an option that would modify the rankings based on allowed DMEPOS charges per beneficiary so that it focuses on charges in each MSA for items that experienced the largest payment reduction or savings under the initial round of competitive bidding in 2007. NCART recommends that CMS not modify the criteria for 2009. There are many differences that may impact costs in various MSA. Focusing in on those items that provided the highest savings in the first round may not be indicative of future savings in round two of the same area, much less round one in a new area. NCART recommends using the same criteria in 2009.

E. Criteria for Item Selection

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. NCART understands that the goal of competitive bidding is to reduce costs. NCART does not believe that competitive bidding complex rehab and assistive technology would result in significant savings. Moreover, NCART does assert that competitive bidding of

complex rehab and assistive technology would have a negative impact on clinical outcomes for the population of Medicare beneficiaries with disabilities.

The portion of Medicare beneficiaries who utilize these technologies are primarily people with disabilities that qualify for Medicare based on eligibility for Social Security benefits for 24 consecutive months or diagnosed with Amyotrophic Lateral Sclerosis (ALS). This represents about 15 percent (6 million) of the 41 million total Medicare beneficiaries. Adequate access to a range of complex rehab and assistive technologies that increase functional abilities is vital to promote independence and self care. The service/delivery costs associated with complex rehab and assistive technology as it is provided today is higher than what is required for standard items of DME. These costs will only increase under new quality standards and accreditation. Provision of this technology requires assessments performed by experienced and knowledgeable staff to ensure that the proper technology is being recommended that will meet the medical needs of the beneficiary and frequently includes, but is not limited to, measuring, fitting, adjusting, and programming. 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. Often times, suppliers must use various components from multiple manufacturers to assemble the most appropriate system for a beneficiary. This requires substantial knowledge of the compatibility of the various options. NCART believes that CMS should establish a savings threshold including on-going administrative costs to access the appropriateness of competitive bidding for each product category. NCART 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, NCART 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. NCART 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 medical needs and anticipated 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. NCART provided comments regarding the draft supplier standards that encourage CMS to create specific standards for Complex Rehab and Assistive technology. We believe 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, NCART 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. NCART 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. In addition, we feel it necessary to point out that it is our belief that inappropriate growth in utilization in power wheelchairs did not occur as a result of the complex rehab and assistive technology segment. 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.

NCART 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.

F. Submission of Bids Under the Competitive Bidding Program (proposed §414.412)

3. Product categories for bidding purposes

In this section, CMS indicates, "We believe 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". NCART does not believe this would be appropriate in the case of wheelchairs and wheelchair accessories. We strongly believe that complex rehab products should not be competitively bid. However, the accessory codes are the same for accessories whether they are provided on a standard wheelchair or a complex mobility system. While NCART believes this is an inadequacy in the HCPCS code set, there is not time to address this issue. NCART 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.

4. Bidding Requirements (§414.408)

d. Capped rental items

CMS proposes that the lump sum purchase option in §441.229(d) for power wheelchairs be retained under the Medicare DMEPOS Competitive Bidding Program. NCART 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.

G. Conditions for Awarding Contracts

1. 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 this unspecified grace period. If they fail 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.

4. Evaluation of Bids (proposed §414.414(e))

a. Market Demand and Supplier Capacity

CMS proposes to compare expected capacity and Medicare volume to determine how many suppliers would be needed in an area. NCART 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 payers 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. NCART also recommends that CMS should not count the projected capacity of suppliers that do not have a proven track record of providing a bid item for purposes of determining the pivotal bid. Additionally, suppliers should be capped at 120% of their past 12 months of billing history for purposes of assigning supplier capacity to each bidder.

c. Determining the Pivotal Bid

NCART recommends using 130 % of anticipated demand. In addition, when determining the pivotal bid, capacity of suppliers that have not previously provided the bid items should not be included. In addition, a maximum of 120% of a supplier's previous 12 months billing for the bid items should be used for purposes of assigning supplier capacity to each bidder.

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d. Assurance of Savings (proposed §414.414(f))

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. 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. NCART acknowledges 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 of the RFB in our opinion artificially restricts bidding. NCART believes that CMS should allow suppliers to bid based on the true costs associated with each bid item. We believe this would provide CMS more accurate information by which to accurately determine potential savings. NCART believes that concerns stated in the NPRM about a shift in utilization to higher priced items could be eliminated through appropriate coverage policies. NCART believes that the use of payment to control utilization is inappropriate. Medicare beneficiaries must have adequate access to appropriate equipment that will meet their medical needs.

f. Selection of New Suppliers After Bidding (proposed §414.414(h))

CMS proposes to select only 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. NCART believes this process would result in a single payment amount being

developed using bids from suppliers that do not meet Medicare's standards. NCART's recommendation that CMS use 130% of capacity for the pivotal bid better ensures the single bid price will be indicative of bids submitted by qualified suppliers in the even that a contract supplier is subsequently suspended or terminated from a competitive bidding program. In addition, NCART recommends that CMS establish a timeframe in which a supplier will be allowed to correct issues that have caused them to be out of compliance with the current requirements.

H. Determining Single Payment Amounts for Individual Items (proposed §414.416)

b. Setting Single Payment Amounts for Individual Items (proposed §414.416(b))

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. NCART believes that no supplier should be paid less than their bid amount. It is also important that CMS analyze deviations among bid amounts to determine whether these deviations may indicate extremely high or extremely low bid prices. CMS must ensure that inappropriate bids do not influence the single bid price. 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.

c. Rebate Program (proposed §414.416(c))

In the NPRM, CMS proposes to allow contract suppliers that submit 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. However, CMS proposes to publish a list of contract suppliers denoting those that offer rebates.

NCART believes that the offering of rebates (even when not advertised by the supplier) violates anti-kickback laws. We further believe that having a program like this sanctioned by CMS in its competitive bidding program would encourage similar offerings outside of this program. NCART

respectfully recommends that CMS not include a rebate program within the competitive bidding program.

I. Terms of Contracts (proposed §414.422)

1. Terms and Conditions of Contracts

CMS proposes "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. Given that payment for the same HCPCS code can vary from payer to payer, NCART believes that competitive bidding will by necessity limit the devices available to Medicare beneficiaries. We do not feel it is appropriate for CMS to mandate that access be limited to individuals outside the Medicare program. Suppliers should be allowed to provide higher levels of technology when higher reimbursement is available. NCART does not see this as discrimination, but simply free trade.

3. Repairs and Replacements of Patient Owned Items Subject to Competitive Bidding (proposed §414.422(c))

NCART believes that this proposal is problematic for many reasons. In many situations suppliers actually lose money when repairing patient owned equipment under Medicare reimbursement. This is due to the low fee schedule amount associated with repairs and the need for replacement parts HCPCS codes. Therefore, requiring that contract suppliers repair all patient owned equipment inside an MSA is a disadvantage for those suppliers.

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.

4. Furnishing Items to Beneficiaries Whose Permanent Residence is Within a CBA

CMS is proposing that a supplier must agree to accept a beneficiary who began renting the item from a different supplier regardless of how many months the item has already been rented. In light of changes to capped rental payment pursuant to the deficit reduction act of 2005, this provision is extremely onerous. As already stated earlier in these comments, NCART recommends that CMS must start the rental period over if beneficiaries are transferring to a contract supplier and payment is under capped rental. NCART believes it would be impossible for suppliers to accurately estimate their financial loss in these situations. Therefore, suppliers cannot accurately account for this type of loss in a bid amount.

7. Change in Ownership (proposed §414.422(d))

CMS proposes that contract suppliers must notify CMS in writing 60 days prior to any changes of ownership, mergers or acquisitions being finalized. CMS states they have the discretion to allow a successor entity after a merger with or acquisition of a contract supplier to function as contract supplier when, among other things, there is a need for the successor entity as a contractor to ensure Medicare's capacity to meet expected beneficiary demand for a competitive bid item. NCART recommends that as long as the successor company meets all other requirements, and is willing to agree to assume the contract supplier's contract, including all contract obligations and liabilities that may occur after the awarding of the contract to the previous supplier, CMS should allow the successor company to function as a contract supplier.

K. Opportunity for Participation by Small Suppliers

Section 1847(b)(6)(D) of the MMA requires CMS to take appropriate steps to ensure that small suppliers of items have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. Under the current proposal, the only possibility a small supplier has of participating is by submitting one of the lowest bid prices. The fact that capacity is a key element in the selection process, if small suppliers don't under bid suppliers with higher capacity they have very little hope of being included in the Program. In order to better ensure participation by small suppliers, NCART recommends that any supplier that bids within 105% of the pivotal bid should be allowed to participate if they are willing to accept the payment amount and meet all other requirements

M. Education and Outreach

2. Beneficiary Education

NCART recognizes that being involved with beneficiary education allows suppliers to develop relationships with beneficiaries and to market their services. However, NCART 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, NCART 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. NCART 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.

O. Physician Authorization/Treating Practitioner and Consideration of Clinical Efficiency and Value of Items in Determining Categories for Bids

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.

For many items of DME there are not sufficient differences between products to justify specifying a particular brand. This however is not the case for rehab and assistive technology. Here, products not only have to meet the beneficiary's medical needs, where multiple items are required, they may also have to be compatible with each other. NCART believes that the level of specificity that goes into selecting the appropriate technology that will meet the individual needs of a beneficiary that this proposal is insufficient to ensure appropriate access. Clinical evaluations and technology assessments routinely result in brand specific recommendations. This in fact is part of what makes competitive bidding of this technology problematic. NCART feels that this proposal by CMS falls short of ensuring access to appropriate technology for those in need or complex rehab or assistive technology devices.

HCPCS Codes

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 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 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.

R. Establishing Payment Amounts for New DMEPOS Items (Gap-filling) (proposed §414.210(g))

NCART applauds CMS' recognition of the inadequacies of the gap-filling methodology. The gap-filling formula has become more and more problematic due to fee schedule freezes mandated by Congress. In addition, the problem is intensified by the growing trend toward testing requirements and SADMERC code verification of products to HCPCS codes. NCART further agrees with CMS that "there is an inherent responsibility to pay enough for beneficial new technologies to ensure beneficiary access to care, while also being a prudent payer".

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.

CMS further proposes in some situations to use the functional technology assessment process in part or in whole as another method for establishing payment amounts for new items. Based on the results of the technology assessment, the fee schedule amounts would be established using fee schedule amounts for items determined to be compatible to the new item or an amount determined to be appropriate for the new item based on the cost comparison. CMS also proposes to use the technology assessment process at any time to adjust prices on or after January 1, 2007 that were previously established using the gap-filling methodology if it is determined that those pricing methods resulted in payment amounts that do not reflect the cost of furnishing the item.

It is important to note that the inherent reasonableness (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%, one 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).

NCART recommends that CMS identify the factors it would consider in deciding to initiate a technology assessment. NCART further recommends that CMS allow participation in the technology assessment by interested stakeholders. Allowing manufacturers access to the contractor would allow them 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. Additionally, NCART recommends that CMS develop an appeals process in situations where the manufacturer disagrees with the recommendation of a contractor and has data to support its 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, NCART recommends that CMS initiate a separate rulemaking proceeding to solely address changes to the pricing methodology for DME.

Adjustments to competitively bid payment amounts to reflect changes in the HCPCS codes- §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. NCART strongly opposes this proposal.

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 supplier must furnish the items in accordance with the new codes. NCART disagrees with this proposal.

The reasons that CMS would determine that new HCPCS are needed are 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. NCART 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 that are appropriate for competitive bidding.

Summary Statement

NCART strongly recommends that CMS exempt rehab and assistive technology devices from the competitive bidding program. As stated previously, we believe the precedent for such an exemption has already been established with customized orthotics and prosthetics. In addition, it is important to ensure that the implementation of competitive bidding does not impact the clinical outcome of Medicare beneficiaries.

Respectfully submitted,

Rita S. Hostak, President
National Coalition for Assistive and Rehab Technology

Submitter : **Mrs. patsy friedlander** **Date: 06/30/2006**

Organization : **traverse bay hand therapy**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Concerning DMEPOS CMS 1270 P,I would like to go on record saying this is a very bad idea. I have been an Occupational Therapist for 23 years and have done hand therapy most of that time. Making splints is a very important part of the unique nature of hand therapy. I make custom, short term use splints that often are adjusted at every treatment session. These splints protect healing tissues, rest inflamed tendons, substitute for weak muscles, and aide in hand function/prehension. These splints are made immediately for the patient; sometimes immediately after the first post-operative Physician visit; and often require multiple, precise adjustments as the patient progresses. I have seen lots of Orthotist's splints down through the years and they are more expensive, take longer for the patient to get, and are quite frankly not of the quality that I can provide in the Hand Therapy setting. This bill will only hurt the patient in terms of money, time, and the ultimate quality of their rehabilitation. Sincerely, Patsy Friedlander, OTR Traverse Bay Hand Therapy, 214 N Division, Traverse City, 49686.

Submitter : **Mrs. Michelle Jarboe** **Date: 06/30/2006**

Organization : **Williamsburg Nursing Home**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Re: Competitive Acquisition Program for certain DMEPOS
1. Nursing facility residents are more vulnerable and require a higher acuity and level of care. Residents that reside in nursing facilities are more clinically complex. They have established care plans which could be interrupted as a result of competitive bidding. Resident access to quality products and services, like disease-specific enteral nurtrition 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 well suited for competitive bidding as other products tested.
3. Competitive bidding puts resident safety at risk. Suppliers of enteral nutrition products and services to nursing home residents are highly specialized. The potential for a facility to lose their choice of a preferred supplier or to have the ability to provide products on their own puts resident's health and safety at risk.

Submitter : Mr. Brian Lagana **Date:** 06/30/2006

Organization : Pedorthic Footwear Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1144-Attach-1.DOC

#1144

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June 30, 2006

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

The Pedorthic Footwear Association appreciates the opportunity to provide its views concerning the Centers for Medicare and Medicaid (CMS) Services' proposed rule *Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*, [CMS-1270-P] (May 1, 2006).

Under the DMEPOS proposed rule, CMS would implement a competitive bidding program for certain Medicare-covered items of DMEPOS. PFA has identified several important concerns about the proposed rule which are noted below in an effort to protect our patients from any unintended harmful effects of the new initiative.

1. Exempt non-physician healthcare practitioners - Certified and/or Licensed Pedorthists - from the DMEPOS Competitive Bidding Program.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandates the implementation of a DMEPOS competitive bidding program by CMS. The proposed rule would require DMEPOS suppliers to submit bids and be awarded contracts in order to furnish the items included in the competitive bidding program.

Certified and Licensed Pedorthists (C. Peds. and L. Peds.) generally operate as small businesses (and small suppliers of DMEPOS), and the financial and administrative burden of complying with the new competitive bidding program, simply to supply DMEPOS to their own patients, likely will be too great. Yet, C. Peds. and L. Peds. must be integrally involved in providing DMEPOS to their patients to ensure that a particular item of DMEPOS meets the "size and fit" specifications for that particular patient and the patient is properly instructed concerning the use of that DMEPOS. This is necessary to provide patients with the highest quality of care, achieve patient compliance, reduce risk of further injury and avert liability concerns as well.

Furthermore, the judgment and expertise of C. Peds. and L. Peds. in selecting a particular item is essential and should be based on the evaluation of the patient at the time of dispensing. This would also be the appropriate time to instruct the patient and address any questions or concerns on the utilization of the item. If a patient is sent elsewhere to obtain an item and the fit is incorrect or the patient receives insufficient information about an item, the patient will likely return to the C. Ped's. or L. Ped's. office with questions or

for assistance, such as a proper refiting or repair of an item. Medical ethics and customer service would dictate that the practitioner assist these patients, with our without the possibility of reimbursement.

If CMS does not provide this exemption, in the alternative, CMS should phase C. Peds. and L. Peds. into the bidding process after 2009. In accordance with the MMA DMEPOS mandate, CMS will phase-in the this program with respect to certain Metropolitan Statistical Areas (MSAs) in 2007 and 2009, with additional competitive bidding occurring in other areas after 2009. A phase-in by area and by practitioner type, with practitioners who provide their patients with DMEPOS phased into the process after 2009, would also conform to the spirit of the MMA mandate, which contains a provision to protect small suppliers of DMEPOS.

As mentioned, C. Peds. and L. Peds. operate as small businesses, and the cost of complying with the competitive bidding program and related requirements could effectively prohibit them from supplying patients with DMEPOS that is most appropriate when supplied at the time of the patient visit. Also, by virtur of their being small businesses, C. Peds. and L. Peds. naturally have a quicker response time in ordering special items. Unlike larger suppliers who more than likely would order from a single central location with a limited variety of options once a week to exercise as much economy as possible, smaller providers often have more sources and a wider range of options for their patients. The unintended consequences of larger operations in this scenario is the cost and inconvenience to the patient. Thus, these practitioners should have lead time before applying the competitive bidding program to them. If patients do not have access to enough suppliers who offer the needed product categories, this could seriously impact access to appropriate care. Finally, this phase-in time will allow practitioners time to identify those DMEPOS items that should not be part of the competitive bidding program, as discussed in #3 below.

2. Section 302(a)(1) of the MMA added Section 1834 (a)(20), requiring the Secretary to establish and implement quality standards for suppliers of DMEPOS. Quality Standards for Suppliers of DMEPOS Must Recognize Board for Certification in Pedorthics Certified Pedorthists and State Licensed Pedorthists

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) changed the status of Medicare's Therapeutic Shoes for Persons with Diabetes benefit from being a standalone benefit to one included in the broader orthotics and prosthetics category. Certified and licensed pedorthists, along with podiatrists, orthotists and prosthetists are currently allowed to fit and dispense shoes and inserts under this benefit. To maintain consistency with existing medical policy and ensure that only qualified providers are accessing the benefit, it is imperative that the Board for Certification in Pedorthics' (BCP) be recognized as a certifying and accrediting body, along with the American Board for Certification in Orthotics and Prosthetics (ABC) and the Board for Orthotist/Prosthetist Certification (BOC), to fully encompass the range of practitioners who provide items and services under the broad heading of customized orthotics and prosthetics.

BCP is the sole certifying agency for the pedorthic profession, establishing and maintaining the standards and scope of practice for approximately 2,200 certified pedorthic practitioners. In addition, BCP maintains and administers pedorthic facility accreditation standards for almost 100 pedorthic facilities.

Additionally, Supplier Specialty Codes and their tie to state licensure need to be addressed to maintain consistency with existing CMS requirement. Recently, the National Supplier Clearinghouse released Change Request 3959 (implemented as of October 1 and effective as of October 3, 2005) that puts new edits in the DMERC claims processing system that will look for Specialty Codes 51, 52, 53, 55, 56, 57 (including pedorthists), 65, 67 and all Physician Specialty Codes listed in the *Medicare Claims Processing Manual, Chapter 26, Section 10.8.2*, in order to ensure that only those who specify P&O on their Enrollment Application Forms (Form CMS-855S) are reimbursed for P&O supplies. This impacts only

certified/licensed pedorthists and orthotists and prosthetists in the states of Alabama, Florida, Illinois, New Jersey, Ohio, Oklahoma, Rhode Island, Texas, or Washington.

Certified/Licensed Pedorthists in the states that have pedorthic licensure (Ohio, Oklahoma, Florida and Illinois) were required to contact the National Supplier Clearinghouse to inform NSC that they should be under code 57. Certified pedorthists in the remaining five states (AL, NJ, RI, TX and WA) that have orthotic and prosthetic (O & P) licensure but not pedorthic licensure are unable to bill Medicare for certain orthotic devices as well as the L5000 and L5999 as listed in Transmittal 656.

The real issue remains with those orthotic, prosthetic and pedorthic (O P &P) practitioners in the remaining 41 states without any form of O P & P licensure. With CMS and NSC refraining from establishing uniform national qualified provider regulations for DMEPOS suppliers, or mandating that the remaining 41 states establish O P & P licensure requirements, the potential for waste, fraud and abuse committed by less-than-qualified (i.e. non-certified, non-licensed or non-Specialty Code 57 providers) will remain. PFA believes that it is incumbent upon CMS, during this standards setting project, to establish uniform national qualified provider requirements.

A Government Accountability Office (GAO) report [GAO-05-656] released in September supports PFA's contention that CMS and NSC need to take the lead in establishing and effectively enforcing federal qualified provider standards, and acting as lead advocate to advance state licensure requirements. The GAO report highlights the serious deficiencies in NSC's current efforts at verifying compliance with the 21 supplier standards, noting that NSC is weak in checking state licensure and conducting on-site inspections.

3. CMS is seeking a methodology to determine which off-the-shelf orthotics, requiring minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the beneficiary, should be included in competitive bidding.

PFA recommends to CMS that it should subject only those off-the-shelf orthotics that are considered dual use items – that is – have both retail *and* medical applications, to competitive bidding. Those items that have only medical applications, and are thus considered 100% medical grade items, would not be subjected to competitive bidding.

Again, PFA appreciates the opportunity to comment on this important rulemaking. If you should have any questions regarding these comments, do not hesitate to contact me on (410) 381-7278.

Sincerely,

Brian K Lagana

Brian K. Lagana
Executive Director

Submitter : Mr. THOMAS EPKE **Date:** 06/30/2006

Organization : SUPERIOR HOME HEALTHCARE

Category : Health Care Professional or Association

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

WE AT SUPERIOR HOME HEALTHCARE ARE A FEW DEDICATED RESPIRATORY THERAPISTS THAT TAKE GREAT PRIDE IN HELPING THE ELDERLY BREATHE. OUR EDUCATION PROVIDED US AN ENVIROMENT TO HELP AND IF BIDDING IS TO BE CUT THROAT WITH LARGE CORPARATIONS OUT BIDDING US, THEN YOU WILL DEFINATELY SEE LESS AND LESS RESPIRATORY THERAPISTS CARING OR POSSIBLY NOT EVEN IN THE HOME SETTING. PLEASE HELP SUPPORT THOSE OF US IN SMALL COMPANIES THAT SUPPORT THE CARE FOR THE SICK,WHILE YOU
CAN.

Submitter : **Date: 06/30/2006**

Organization : **American HomePatient, Inc.**

Category : **Other Health Care Provider**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Please see attached comment from American HomePatient, Inc.

CMS-1270-P-1146-Attach-1.RTF

#1146.

FILE CODE CMS-1270-P
COMMENTS FROM AMERICAN HOMEPATIENT, INC.

On May 1, 2006, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule in the *Federal Register* entitled "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues," **file code CMS-1270-P.** Although CMS requested suppliers comment on the proposed implementation provisions of competitive bidding, we find that the proposed rule lacks sufficient specificity about the competitive bidding program. As such, it is challenging, if not impossible, for suppliers to submit substantive comments relative to this NPRM.

Generally, we find that the proposed implementation provisions lack the necessary safeguards to ensure that the competitive bidding process is equitable for ALL bidders. We also find that it fails to ensure the beneficiary will continue to have access to needed durable medical equipment in a competitive bidding program.

In addition, we find the competitive bidding program has as a major shortcoming a process that selects the winning bidder based on low pricing (even unreasonably low pricing) before consideration is given to the selected bidder's financial capabilities and ability to provide quality services.

Specifically, CMS provides little or no information relative to the following:

1. **Submission of Bids Under the Competitive Bidding Program.**
   Product Categories for Bidding Purposes (Proposed § 414.412)

   The winning bidder is required to provide ALL products in the established product categories. CMS did not provide a list of product categories, therefore the supplier is unable to provide comments on the reasonableness of including certain items in a specific product category. Because of the complexity of certain equipment, a special category or a "carve-out" might be reasonable and necessary. For example, under the proposed program, suppliers that do not employ highly trained clinician would be permitted to provide invasive ventilators. This could result in possible harm to the beneficiary.

2. **Conditions for Awarding Contracts.**
   Quality Standards and Accreditation (Proposed § 414.414(c))

   Without specific information about the required Medicare quality standards, the supplier is unable to evaluate and comment on how compliance with the quality standards should be incorporated into the bid process. Likewise, without information as to the selected accrediting agencies, the supplier is unable to factor regulatory compliance into the bid process.

3. **Conditions for Awarding Contracts.**
Evaluation of Bids (Proposed § 414.414(e))

As outlined in the proposed program, all bids (including unreasonably low bids) are accepted and are used in determining the implementation "pivotal" bid. The pivotal bid is used in determining pricing as well as the number of suppliers selected as providers in a MSA.

4. **Determining Single Payment Amounts for Individual Items.**
Rebate Program (Proposed § 414.416(c))

Considering advisements provided by the Office of Inspector General relative to beneficiary kickbacks, it is uncertain as to how a rebate program could be constructed that would provide the supplier protection from civil and criminal anti-kickback enforcement actions.

5. **Terms of Contract.**
Furnishing Items to Beneficiaries Whose Permanent Residence Is Within a CBA

The winning bidder is required to accept, at any time, a patient wishing to transition from an existing supplier. This provision is applicable if the existing supplier chooses not to become a "grandfathered" provider or if another winning bidder is later disqualified and dropped from the competitive bidding program.

Certainly, CMS understands that for certain items of durable medical equipment where the reimbursement has a capped rental provision, the supplier will be disadvantaged by patients transitioning near the end of the capped rental period.

The implementation of a national competitive bidding program is a sweeping transformation of the existing durable medical equipment fee-for-service system. Therefore, CMS should publish an interim final rule that contains substantive information relative to the implementation of the competitive bidding program. This would allow the industry an opportunity to adequately evaluate the program and provide relevant comments to ensure fairness for the suppliers and access for the beneficiaries.

Submitter : Ms. Cheryl Meyer **Date:** 06/30/2006

Organization : Advocate Home Care Products

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1270-P-1147-Attach-1.DOC

CMS-1270-P-1147-Attach-2.DOC

#1147

June 30, 2006

Submitted electronically to http://www.cms.hhs.gov/eRulemaking

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

Re: CMS-1270-P

Dr. Dr. McClellan,

Advocate Home Care Products, Inc., ("*AHCP*") is a wholly-owned subsidiary of Advocate Health and Hospitals Corporation ("*Advocate* "). Advocate is a leading faith-based not-for-profit health system consisting of eight hospitals, home health services, and medical groups located in an eight county region around Chicago, Illinois. AHCP is one of the larger suppliers of durable medical equipment, prosthetics, orthotics, supplies and services ("*DMEPOS*") in the State of Illinois, serving approximately 5000 Medicare patients annually discharged from hospitals, nursing homes, and referred from the community at large. AHCP is a supplier providing general home medical equipment and specializing in home respiratory and sleep disorder equipment. AHCP is proud to play in important role in the formation of the final competitive bidding regulation and appreciate the opportunity to provide feedback.

I. Background

On May 1, 2006, the Centers for Medicare and Medicaid Services ("*CMS*") proposed rules implementing competitive bidding programs for certain covered items of DMEPOS, in accordance with Section 1847 of the Social Security Act ("*Act*"), 42 U.S.C. § 1395w-3. *See* 71 Fed. Reg. 25,654 (May 1, 2006) (hereinafter, the "proposed rules"). Under the proposed rules CMS proposes to initiate competitive bidding in ten of the nation's largest metropolitan statistical areas, including Chicago, in 2007. As the largest provider of DMEPOS in the Chicago metropolitan statistical area, AHCP is concerned with several provisions of the proposed rules that may have the effect of ultimately ensuring that home health patients receive medically-appropriate, high-quality DMEPOS from reputable suppliers. In particular, AHPC is concerned that CMS has not yet developed and published quality standards for bidders. As we set forth in greater detail herein, we are also concerned that (1) the mechanics of operating under the competitive bidding program need further refinement, and that (2) elements of the bidding process itself must be altered to protect Medicare beneficiaries. We discuss our concerns in greater detail, below.

II. AHCP's Proposed Modifications

II. B. Implementation Contractor

The proposed rule provides that CMS would designate one or more competitive bidding implementation contractors ("*CBICs*") to implement the Medicare competitive bidding program. *See* 71 Fed. Reg. 25,661. The rule notes that the CBIC's would conduct certain functions, such as preparing requests for bids, evaluating bids, selecting qualified suppliers, and setting single payment amounts in all competitive bidding areas. However, the existing durable medical equipment regional carriers ("***DMERCs***") would continue to provide outreach and education to beneficiaries and suppliers, processing claims, and continuing to be responsible for complaints related to claim processing. In the proposed rule,

CMS indicated its position that this approach would result in "economies of scale" and "ensure regional consistency in that the responsibility would not be divided between various entities."

AHCP is concerned that the purported benefits of using CBIC's may not materialize. In particular, AHCP is concerned that CMS is unlikely to achieve cost savings by creating yet another organization with responsibilities associated with the Medicare DMEPOS benefit, particularly given that the DMERCs have considerable experience in this area and will continue to have a variety of on-going responsibilities related thereto. Moreover, if CMS is truly concerned about "regional consistency," then it should revisit the notion that four separate regional entities the DMERCs, are (in the aggregate) responsible for processing and paying all DMEPOS claims. Thus, AHCP believes that the two alternatives considered by CMS (having each DMERC conduct competitive bidding and having the CMS Consortium Contractor Management Officer/Regional Offices and DMERCs implement the competitive bidding program) are superior to the proposed use of a CBIC.

II. C. Payment Basis – Special Rules (Grandfathering of Suppliers)

The proposed rule provides that beneficiaries who rent covered items and supplies prior to the competitive bidding program from an entity that is not awarded a contract under the bidding process may continue to rent the item from the supplier (a process called "grandfathering"). It further requires that if the grandfathered supplier is not willing to provide the item or if the beneficiary requests a new supplier, then a contract supplier would assume responsibility for furnishing the item and be paid based upon the single payment amount for that item under the competitive bidding program.

While we support the grandfathering process, we believe that it is likely that a significant number supplier changes may arise as a result of the competitive bidding process. We are concerned that patient safety may be compromised if there is an abrupt change in supplier. To alleviate this concern, we suggest that suppliers who are not contractors under the competitive bidding program be given a reasonable amount of time to arrange for transfers to contracted entities. We believe that this time frame should be no less than sixty (60) days.

We are also concerned that the proposal that grandfathered suppliers be paid single payment amounts for items that require substantial servicing and for oxygen equipment, instead of the current fee schedule amounts may not adequately reimburse suppliers for beneficiaries that require frequent home visits and deliveries to meet their needs. Given that these entities will not be contractors, it is unfair to impose competitive bidding rates upon them.[1] Instead, we would suggest that when these items are provided by a grandfathered supplier, either (i) the grandfathered supplier should continue to receive the fee schedule rate for that item, or (ii) the reimbursement rate received by the supplier should directly tie to the number of physical contacts the grandfathered supplier has with the beneficiary.

In the proposed rule, CMS indicates that some beneficiaries may continue to receive items from grandfathered suppliers "as long as the items remain medically necessary." Many of the items in question require a certificate of medical necessity signed by the patient's physician, and these certificates must be periodically renewed. Given these factors, we would like clarification concerning whether, and by what

[1] We fully understand CMS' position that "it is not reasonable to continue paying the fee schedule amounts for these items and services and that payment at the competitively determined rates will comport with an overarching goal of competitive bidding to achieve savings for the Medicare program." 71 Fed. Reg. 25,663. However, the unilateral imposition of competitively bid rates upon entities that are not contracted with CMS would be patently unfair, particularly for suppliers associated with charitable organizations that might either (i) lack the financial wherewithal to participate at rates established by the competitive bidding process, or (ii) have costs in excess of competing, proprietary entities arising because of their charitable mission, employee benefit costs, etc. Such organizations are motivated, at least in part, by factors other than pure profits, and hence, might view transitioning patients as proposed as being tantamount to abandonment of their mission. The proposed payment methodology could unnecessarily force such entities to make difficult decisions between financial solvency, on the one hand, and providing compassionate care to their patients, on the other hand.

methods, CMS proposes a new process to evaluate whether an item of DMEPOS is medically necessary when provided by a grandfathered supplier.

In addition, the proposed rule does not address how the grandfathering process would apply in the situation of a beneficiary who has rented equipment (such as CPAP) from a grandfathered supplier and whose physician has ordered additional equipment. Such a situation could arise, for example, where a patient who has received CPAP equipment from a grandfathered supplier now requires home oxygen. Under this scenario, if the beneficiary does not have the option of receiving additional DMEPOS from the grandfathered supplier, he or she will have to contend with multiple (competing) suppliers. This may be unduly confusing and time-consuming to many beneficiaries, and ultimately, we are concerned that such situations could pose a significant safety risk.

II. C. 6. Payment Basis: Requirement to Obtain Competitively Bid Items from Contract Supplier

The proposed rule indicates that a beneficiary who is traveling will be allowed to obtain items that he or she would ordinarily obtain from a contract supplier from either (i) another contract supplier, if the beneficiary is in another competitive bidding area and the item is part of the competitive bidding program in that area, or (ii) another suppler, if the beneficiary is not in a competitive bidding area.

We respectfully ask how a supplier can furnish equipment and supplies to beneficiaries on "travel status." We ask the CMS define documentation required for travel status to protect the interests of the supplier. We realize CMS currently has provisions for travel of patients and agree they should continue. We suggest clarification on how to document and substantiate travel status.

II. C. 7. Payment Basis: Limitation of Beneficiary Liability for Items Furnished by Non-contract Suppliers

As proposed, beneficiaries permanently residing in competitive bidding areas may have no liability to non-contracted suppliers who provide DMEPOS to them unless the non-contracted suppliers are grandfathered (as discussed above). Although this provision is reasonable and necessary, we believe that it is possible some beneficiaries may receive DMEPOS from non-grandfathered, non-contracted suppliers. The transition to contracted suppliers would be facilitated if beneficiaries received a local toll free number that beneficiaries can access to easily find suppliers who can furnish an item included in the competitive bidding area in which the beneficiary permanently resides.

II. D Payment Basis, Competitive Bidding Areas

As noted in the proposed rules, Section 1847(a)(1)(B) provides that competitive bidding must be phased in for ten of the largest MSA's in 2007. AHCP is concerned that the two previous demonstration projects involving competitive bidding took place in Polk County, Florida, and San Antonio, Texas. Implementing competitive bidding in a large metropolitan area such as Chicago will be very challenging given the greater geographical area, number of suppliers currently operating in the area, sheer number of Medicare beneficiaries, etc. To reduce the burdens associated with this process, we suggest that competitive bidding in one of the ten MSA's in question be selected for implementation first; thereby allowing the other MSA's to benefit from the lessons learned there. We believe that this process would substantially reduce the burden on both beneficiaries and suppliers, while still allowing CMS to meet the requirement that it implement competitive bidding during 2007. We suggest that a demonstration project be implemented specifically to test the program in a large MSA that allows modifications to be made in these areas. NOTE: the Act does not permit another demonstration project, and it requires implementation during 2007.

II. E. Criteria for Item Selection

We are concerned about the inclusion of home infusion therapy in the competitive bidding proposal. 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 billing at this time. We feel the 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. We recommend exclusion of infusion therapies from competitive bidding at this time.

Similarly, enteral nutrition is not a good candidate for competitive bidding. The quality standards for the home care settings may vary differently from the nursing home setting for example. Variance in quality standards among sites may make fair and competitive bidding extremely difficult.

If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for other DME items. CMS should also modify the proposed payment structure for enteral pumps, and ensure that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

II. F. 3. Submission of Bids Under the Competitive Bidding Program: Product Categories

Under the proposed rule, CMS will conduct bidding for items that are grouped in product categories, and suppliers would be required to submit a separate bid for all items in a product category. Although grouping DMEPOS into product categories will allow participation by specialized providers, such groupings may also create a fragmentation of services for beneficiaries who require DMEPOS items that fall into a variety of product categories. For example, consider the not-unlikely situation of a beneficiary who requires oxygen, blood glucose reagent strips, a wheelchair, and an air mattress. One single provider may not be a contracted provider for the services. We are concerned that such a situation may be unduly time-consuming and confusing for many beneficiaries, and ultimately, that it may impact patient safety.

II. F. 3. Submission of Bids Under the Competitive Bidding Program: Bidding Requirements

As noted in the preamble to the final rule, payment will not be made to suppliers for items furnished under a competitive bidding program unless the supplier has submitted a bid to furnish those items and has been selected as a contracted provider. *See* 71 Fed. Reg. 25,672. In this regard, the proposed rule directs suppliers to look at the existing regulations in 42 C.F.R. Part 414, subparts C and D, to determine whether a rental or purchase payment would be made of a particular item and whether other requirements, such as on-going maintenance, would apply to the furnishing of that item.
In item 4d we are concerned there is no explanation or definition of reasonable and necessary maintenance and servicing for beneficiary- owned DME, any limitations or exclusions that may apply.

II.G.1. Conditions for Awarding Contracts – Quality Standards and Accreditation

As noted in the proposed rule, Act § 1847(b)(2)(A)(i) specifies that CMS may not award a contract under the competitive bidding process unless the bidder meets applicable quality standards specified by Act § 1834(a)(20), which instructs CMS to establish and implement quality standards for all DMEPOS suppliers, not just suppliers in the competitive bidding areas.

As noted elsewhere in the proposed rule, CMS has not yet developed these quality standards. *See* 71 Fed. Reg. at 25,659. When developed, the proposed rule indicates that the quality standards will address a number of significant areas, including financial management, human resource management, beneficiary

services, performance management, environment and safety, beneficiary rights/ethics, and information management.

AHCP believes that the establishment and implementation of quality standards is an important step in ensuring the quality of services provided by DMEPOS suppliers. However, AHCP is concerned that the proposed rule contemplates that organizations would be able to win contracts under the competitive bidding process and would receive a "grace period" during which they would need to receive accreditation, after which the organization's contract would be terminated or suspended. This proposed structure raises two concerns for AHCP, related to the quality of care to be provided to Medicare beneficiaries and the costs associated with meeting CMS' accreditation criteria.

Permitting non-accredited bidders to provide services to Medicare beneficiaries may jeopardize patient care in two ways: first, because the supplier will not be reviewed for compliance with standards that CMS has determined are necessary to ensure quality services, and second, because if a supplier is suspended or terminated, their patients may need to be transitioned to another supplier. It is likely that for these reasons, the Act unambiguously states that CMS may not award a contract under competitive bidding unless the bidder meets applicable quality standards. Thus, we are concerned that provisional acceptance of unaccredited suppliers is contrary to the Act and could impede patient safety.[2]

AHCP's second concern is that suppliers may be unable to participate fully in the competitive bidding process if they are unable to determine the costs associated with accreditation and compliance because CMS has not published its quality standards and established an accreditation process. As noted above, the standards will address a number of different areas, and organizations could face significant, presently unquantifiable administrative costs in complying. This could result in some bidders under-pricing their bids, which might ultimately impede the quality of care provided to patients as winning bidders seek to "cut corners" to recoup their accreditation costs. In the alternative, bidders might overprice their bids if they over-estimate their costs, resulting in unnecessary increased costs to the Medicare program. Both of these possibilities undercut Congress' intent in establishing the competitive bidding process.

AHCP believes the full detail of the accrediting process, including the standards CMS will apply and the organizations that will be able to credential suppliers, needs to be available at least six months in advance to submitting a competitive bid.

II.G.4.b. Conditions for Awarding Contracts – Evaluation of Bids – Composite Bids

As discussed above, the proposed rule calls for the creation of "product categories" that include individual items for which CMS will require competitive bidding. Suppliers will be required to submit bids for each individual item within each product category they are bidding on, but they are not required to bid on all product categories. *See* 71 Fed. Reg. at 25,675. In the preamble to the proposed rule, CMS notes that when suppliers are bidding for multiple items in a product category, the lowest bid for each item will not always be submitted by the same supplier. To address this situation, CMS proposes to multiply a supplier's bid for each item in a product category by the item's "weight" and sum the numbers. The "weight" of an item would be based upon the utilization of the item computed to the other items within the product category, based upon historic Medicare claims.

We believe the composite bid should continue to be weighted on both the volume and payment amounts of the item as these both indicate the market importance of the item. It is not a true reflection of market importance to weight the item by just volume or payment amount alone.

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[2] In the proposed rule, CMS solicited comments concerning the length of any grace period. *See* 71 Fed. Reg. 25,675. To be clear, AHCP's position is that there should be no grace period for bidders. Instead, CMS should publish standards and identify accrediting organizations within a reasonable time before implementing the competitive bidding process in order to permit prospective participants to comply with the letter of Act § 1834(a)(20).

To ensure that CMS contracts with a sufficient number of suppliers to meet anticipated demand, the proposed rule involves calculating a "pivotal bid," which is point at which the aggregate capacity of the lowest bidders meets projected demand.

[In Section 4 item c, we propose a different calculation for the pivotal bid. The proposed process would determine that the array of bids be determined from the lowest bidder up. We believe it is in the best interest of the program to arrive at the bid price versus capacity from the mean bid price moving up and down equally until capacity is met and or exceeded. By 'setting' the price from the middle the bid process attempts to assure adequate funding for services with assumed quality standards and not on a 'lowest bidder' model.]

In the proposed rule, CMS indicates that it will select only as many suppliers as are necessary to ensure sufficient capacity to meet projected demand. CMS acknowledges that it may have to suspend or terminate a contract with a supplier that falls out of compliance with contract requirements, in which case, if there is excess demand, CMS will contact remaining contract suppliers to see if they can absorb the unmet demand. If the remaining contract supplier cannot absorb the unmet demand in a timely manner, CMS would refer to the list of suppliers that previously submitted bids, and contact the closest unsuccessful bidder with in invitation to participate at the already determined contract payment amount. CMS would go down the list until it satisfies expected demand. In the preamble to the final rule, CMS asserts that "After consultation with the DMEPOS industry and PAOC, CMS was told that additional capacity should not be a problem, as suppliers would be willing and able to handle the expected demand."

AHCP is concerned about the dearth of reliable information available to determine the number of suppliers who may fail to successfully bid during the competitive bidding process. Moreover, as discussed in our comments entitled "II.G.1. Conditions for Awarding Contracts – Quality Standards and Accreditation," CMS has not determined accreditation standards for participating suppliers yet, and this may result in some successful bidders being suspended or terminated from participation. Presumably, given Medicare's disproportionate impact upon the DMEPOS industry, some unsuccessful bidders may phase out product lines or even go out of business altogether. Moreover, it may be unrealistic for suppliers to assume unplanned volume on short notice, as that could involve significant additional outlays of fixed and working capital.

II.H. Determining Single Payment Amounts for Individual Items

Pursuant to the proposed rules, the method for determining single payment amount for and individual items will be the median of the suppliers' bids that are at or below the pivotal bid. We feel the median bid will set artificially low reimbursement for suppliers who submitted their bids based on their actual costs. An adjustment factor should be used to ensure that the overall payment amounts that contracted suppliers receive are at least as much as their bids.

Section II.H.2 also proposes to allow contract bids for an individual item below the single payment amount to provide beneficiaries with a rebate equal to the difference between their actual bid amount and the single payment amount. AHCP is concerned that encouraging rebates to patients based upon their selection of a particular supplier may unduly influence supplier selection to the detriment of other factors, such as quality, customer service, etc. Such rebates may within the scope of conduct presently proscribed by the anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and they may not qualify for protection under the existing scope of the statutes existing "safe harbor" for discounts and rebates, 42 C.F.R. § 1001.952(h). Moreover, we are concerned that entities providing rebates as proposed may violate the Act's proscription against offering inducements to Medicare beneficiaries. *See* 42 U.S.C. § 1320a-7a(a).

Moreover, we are concerned that by proposing such rebates, CMS is providing tacit support to the notion that beneficiaries should gauge their selection of providers upon an expectation of financial reward. Such expectations, if allowed to continue, could have a corrosive effect upon the entire artifice of the Medicare anti-fraud laws, leading providers to engage in impermissible conduct under the belief that such

laws lack legitimacy because of their selective application. Simply stated, such rebates could encourage widespread fraud and abusive referral practices.

We are adamantly opposed to the notion of any rebate directly back to patients. Instead, providers who have lower costs should use this operating margin to expand their services and or improve patient education, quality, and service. In any event, no rebate should be considered until the bidding provider has been adequately measured for compliance to measurable quality standards within their accrediting body's performance measures reporting.

II.I. Terms of Contract

As proposed, contracts with participating suppliers will contain a number of provisions, including a minimum length of participation and 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 supplier would provide to other customers).

We believe contracted bidders must have the ability to exit the program after delivery of written notice specifying that they will no longer participate. The notice should be sufficient to allow transition of patients with minimal disruptions. This will allow the bidders who may have failed to meet the quality standards or market expectations for the patient to exit while providing adequate transition for beneficiaries and business operations.

In addition, we are concerned that the non-discrimination provision discussed above is unfair to suppliers who may be unable to maintain a constant inventory of particular items at all locations. As long as a product is reimbursed under a particular HCPCS code, the manufacturer of that product should be irrelevant, and the supplier should be free to furnish the item, irrespective of brand. The net effect of the proposed "non-discrimination" provision may be to inappropriately limit regional differences in product selection, to the detriment of overall patient satisfaction, or to force contracted suppliers to overstock particular items simply because comparable products are demanded elsewhere. Moreover, the proposed non-discrimination rule does not take into account temporary shortages or supply disruptions.

III. Conclusion

In general, AHCP supports CMS in its attempt to implement the competitive bidding process. However, AHCP is concerned that previous demonstration projects were undertaken in geographies that were substantially smaller than the 10 MSA's in which the proposed competitive bidding process will be undertaken in 2007. We believe it would be prudent for CMS to carefully consider the complexity that will be entailed in undertaking this process and weigh the benefits of any proposed savings against the potential of harm to Medicare beneficiaries. In particular, we are concerned that, if implemented improperly, the competitive bidding process could limit access to medically necessary DMEPOS and create unnecessary complexity and confusion.

AHCP welcomes the opportunity to provide comments concerning the proposed rules. In particular, we believe that our role as part of a leading, faith-based health system in one of the MSA's that is to be subject to competitive bidding gives us a unique perspective. If you would like to discuss this matter further, please do not hesitate to contact me, Cheryl Meyer, Director of Quality and Risk Management for Advocate Home Health Services and Advocate Home Care Products at 630-368-6623 or Cheryl.Meyer@advocatehealth.com.

Sincerely,
Cheryl A. Meyer, MS, APRN, BC

#1147

June 30, 2006

Submitted electronically to http://www.cms.hhs.gov/eRulemaking

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

Re: CMS-1270-P

Dr. Dr. McClellan,

Advocate Home Care Products, Inc., ("*AHCP*") is a wholly-owned subsidiary of Advocate Health and Hospitals Corporation ("*Advocate* "). Advocate is a leading faith-based not-for-profit health system consisting of eight hospitals, home health services, and medical groups located in an eight county region around Chicago, Illinois. AHCP is one of the larger suppliers of durable medical equipment, prosthetics, orthotics, supplies and services ("*DMEPOS*") in the State of Illinois, serving approximately 5000 Medicare patients annually discharged from hospitals, nursing homes, and referred from the community at large. AHCP is a supplier providing general home medical equipment and specializing in home respiratory and sleep disorder equipment. AHCP is proud to play in important role in the formation of the final competitive bidding regulation and appreciate the opportunity to provide feedback.

I. Background

On May 1, 2006, the Centers for Medicare and Medicaid Services ("*CMS*") proposed rules implementing competitive bidding programs for certain covered items of DMEPOS, in accordance with Section 1847 of the Social Security Act ("*Act*"), 42 U.S.C. § 1395w-3. *See* 71 Fed. Reg. 25,654 (May 1, 2006) (hereinafter, the "proposed rules"). Under the proposed rules CMS proposes to initiate competitive bidding in ten of the nation's largest metropolitan statistical areas, including Chicago, in 2007. As the largest provider of DMEPOS in the Chicago metropolitan statistical area, AHCP is concerned with several provisions of the proposed rules that may have the effect of ultimately ensuring that home health patients receive medically-appropriate, high-quality DMEPOS from reputable suppliers. In particular, AHPC is concerned that CMS has not yet developed and published quality standards for bidders. As we set forth in greater detail herein, we are also concerned that (1) the mechanics of operating under the competitive bidding program need further refinement, and that (2) elements of the bidding process itself must be altered to protect Medicare beneficiaries. We discuss our concerns in greater detail, below.

II. AHCP's Proposed Modifications

II. B. Implementation Contractor

The proposed rule provides that CMS would designate one or more competitive bidding implementation contractors ("*CBICs*") to implement the Medicare competitive bidding program. *See* 71 Fed. Reg. 25,661. The rule notes that the CBIC's would conduct certain functions, such as preparing requests for bids, evaluating bids, selecting qualified suppliers, and setting single payment amounts in all competitive bidding areas. However, the existing durable medical equipment regional carriers ("***DMERCs***") would continue to provide outreach and education to beneficiaries and suppliers, processing claims, and continuing to be responsible for complaints related to claim processing. In the proposed rule,

CMS indicated its position that this approach would result in "economies of scale" and "ensure regional consistency in that the responsibility would not be divided between various entities."

AHCP is concerned that the purported benefits of using CBIC's may not materialize. In particular, AHCP is concerned that CMS is unlikely to achieve cost savings by creating yet another organization with responsibilities associated with the Medicare DMEPOS benefit, particularly given that the DMERCs have considerable experience in this area and will continue to have a variety of on-going responsibilities related thereto. Moreover, if CMS is truly concerned about "regional consistency," then it should revisit the notion that four separate regional entities the DMERCs, are (in the aggregate) responsible for processing and paying all DMEPOS claims. Thus, AHCP believes that the two alternatives considered by CMS (having each DMERC conduct competitive bidding and having the CMS Consortium Contractor Management Officer/Regional Offices and DMERCs implement the competitive bidding program) are superior to the proposed use of a CBIC.

II. C. Payment Basis – Special Rules (Grandfathering of Suppliers)

The proposed rule provides that beneficiaries who rent covered items and supplies prior to the competitive bidding program from an entity that is not awarded a contract under the bidding process may continue to rent the item from the supplier (a process called "grandfathering"). It further requires that if the grandfathered supplier is not willing to provide the item or if the beneficiary requests a new supplier, then a contract supplier would assume responsibility for furnishing the item and be paid based upon the single payment amount for that item under the competitive bidding program.

While we support the grandfathering process, we believe that it is likely that a significant number supplier changes may arise as a result of the competitive bidding process. We are concerned that patient safety may be compromised if there is an abrupt change in supplier. To alleviate this concern, we suggest that suppliers who are not contractors under the competitive bidding program be given a reasonable amount of time to arrange for transfers to contracted entities. We believe that this time frame should be no less than sixty (60) days.

We are also concerned that the proposal that grandfathered suppliers be paid single payment amounts for items that require substantial servicing and for oxygen equipment, instead of the current fee schedule amounts may not adequately reimburse suppliers for beneficiaries that require frequent home visits and deliveries to meet their needs. Given that these entities will not be contractors, it is unfair to impose competitive bidding rates upon them.[1] Instead, we would suggest that when these items are provided by a grandfathered supplier, either (i) the grandfathered supplier should continue to receive the fee schedule rate for that item, or (ii) the reimbursement rate received by the supplier should directly tie to the number of physical contacts the grandfathered supplier has with the beneficiary.

In the proposed rule, CMS indicates that some beneficiaries may continue to receive items from grandfathered suppliers "as long as the items remain medically necessary." Many of the items in question require a certificate of medical necessity signed by the patient's physician, and these certificates must be periodically renewed. Given these factors, we would like clarification concerning whether, and by what

[1] We fully understand CMS' position that "it is not reasonable to continue paying the fee schedule amounts for these items and services and that payment at the competitively determined rates will comport with an overarching goal of competitive bidding to achieve savings for the Medicare program." 71 Fed. Reg. 25,663. However, the unilateral imposition of competitively bid rates upon entities that are not contracted with CMS would be patently unfair, particularly for suppliers associated with charitable organizations that might either (i) lack the financial wherewithal to participate at rates established by the competitive bidding process, or (ii) have costs in excess of competing, proprietary entities arising because of their charitable mission, employee benefit costs, etc. Such organizations are motivated, at least in part, by factors other than pure profits, and hence, might view transitioning patients as proposed as being tantamount to abandonment of their mission. The proposed payment methodology could unnecessarily force such entities to make difficult decisions between financial solvency, on the one hand, and providing compassionate care to their patients, on the other hand.

methods, CMS proposes a new process to evaluate whether an item of DMEPOS is medically necessary when provided by a grandfathered supplier.

In addition, the proposed rule does not address how the grandfathering process would apply in the situation of a beneficiary who has rented equipment (such as CPAP) from a grandfathered supplier and whose physician has ordered additional equipment. Such a situation could arise, for example, where a patient who has received CPAP equipment from a grandfathered supplier now requires home oxygen. Under this scenario, if the beneficiary does not have the option of receiving additional DMEPOS from the grandfathered supplier, he or she will have to contend with multiple (competing) suppliers. This may be unduly confusing and time-consuming to many beneficiaries, and ultimately, we are concerned that such situations could pose a significant safety risk.

II. C. 6. Payment Basis: Requirement to Obtain Competitively Bid Items from Contract Supplier

The proposed rule indicates that a beneficiary who is traveling will be allowed to obtain items that he or she would ordinarily obtain from a contract supplier from either (i) another contract supplier, if the beneficiary is in another competitive bidding area and the item is part of the competitive bidding program in that area, or (ii) another suppler, if the beneficiary is not in a competitive bidding area.

We respectfully ask how a supplier can furnish equipment and supplies to beneficiaries on "travel status." We ask the CMS define documentation required for travel status to protect the interests of the supplier. We realize CMS currently has provisions for travel of patients and agree they should continue. We suggest clarification on how to document and substantiate travel status.

II. C. 7. Payment Basis: Limitation of Beneficiary Liability for Items Furnished by Non-contract Suppliers

As proposed, beneficiaries permanently residing in competitive bidding areas may have no liability to non-contracted suppliers who provide DMEPOS to them unless the non-contracted suppliers are grandfathered (as discussed above). Although this provision is reasonable and necessary, we believe that it is possible some beneficiaries may receive DMEPOS from non-grandfathered, non-contracted suppliers. The transition to contracted suppliers would be facilitated if beneficiaries received a local toll free number that beneficiaries can access to easily find suppliers who can furnish an item included in the competitive bidding area in which the beneficiary permanently resides.

II. D Payment Basis, Competitive Bidding Areas

As noted in the proposed rules, Section 1847(a)(1)(B) provides that competitive bidding must be phased in for ten of the largest MSA's in 2007. AHCP is concerned that the two previous demonstration projects involving competitive bidding took place in Polk County, Florida, and San Antonio, Texas. Implementing competitive bidding in a large metropolitan area such as Chicago will be very challenging given the greater geographical area, number of suppliers currently operating in the area, sheer number of Medicare beneficiaries, etc. To reduce the burdens associated with this process, we suggest that competitive bidding in one of the ten MSA's in question be selected for implementation first; thereby allowing the other MSA's to benefit from the lessons learned there. We believe that this process would substantially reduce the burden on both beneficiaries and suppliers, while still allowing CMS to meet the requirement that it implement competitive bidding during 2007. We suggest that a demonstration project be implemented specifically to test the program in a large MSA that allows modifications to be made in these areas. NOTE: the Act does not permit another demonstration project, and it requires implementation during 2007.

II. E. Criteria for Item Selection

We are concerned about the inclusion of home infusion therapy in the competitive bidding proposal. 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 billing at this time. We feel the 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. We recommend exclusion of infusion therapies from competitive bidding at this time.

Similarly, enteral nutrition is not a good candidate for competitive bidding. The quality standards for the home care settings may vary differently from the nursing home setting for example. Variance in quality standards among sites may make fair and competitive bidding extremely difficult.

If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for other DME items. CMS should also modify the proposed payment structure for enteral pumps, and ensure that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

II. F. 3. Submission of Bids Under the Competitive Bidding Program: Product Categories

Under the proposed rule, CMS will conduct bidding for items that are grouped in product categories, and suppliers would be required to submit a separate bid for all items in a product category. Although grouping DMEPOS into product categories will allow participation by specialized providers, such groupings may also create a fragmentation of services for beneficiaries who require DMEPOS items that fall into a variety of product categories. For example, consider the not-unlikely situation of a beneficiary who requires oxygen, blood glucose reagent strips, a wheelchair, and an air mattress. One single provider may not be a contracted provider for the services. We are concerned that such a situation may be unduly time-consuming and confusing for many beneficiaries, and ultimately, that it may impact patient safety.

II. F. 3. Submission of Bids Under the Competitive Bidding Program: Bidding Requirements

As noted in the preamble to the final rule, payment will not be made to suppliers for items furnished under a competitive bidding program unless the supplier has submitted a bid to furnish those items and has been selected as a contracted provider. *See* 71 Fed. Reg. 25,672. In this regard, the proposed rule directs suppliers to look at the existing regulations in 42 C.F.R. Part 414, subparts C and D, to determine whether a rental or purchase payment would be made of a particular item and whether other requirements, such as on-going maintenance, would apply to the furnishing of that item.
In item 4d we are concerned there is no explanation or definition of reasonable and necessary maintenance and servicing for beneficiary- owned DME, any limitations or exclusions that may apply.

II.G.1. Conditions for Awarding Contracts – Quality Standards and Accreditation

As noted in the proposed rule, Act § 1847(b)(2)(A)(i) specifies that CMS may not award a contract under the competitive bidding process unless the bidder meets applicable quality standards specified by Act § 1834(a)(20), which instructs CMS to establish and implement quality standards for all DMEPOS suppliers, not just suppliers in the competitive bidding areas.

As noted elsewhere in the proposed rule, CMS has not yet developed these quality standards. *See* 71 Fed. Reg. at 25,659. When developed, the proposed rule indicates that the quality standards will address a number of significant areas, including financial management, human resource management, beneficiary

services, performance management, environment and safety, beneficiary rights/ethics, and information management.

AHCP believes that the establishment and implementation of quality standards is an important step in ensuring the quality of services provided by DMEPOS suppliers. However, AHCP is concerned that the proposed rule contemplates that organizations would be able to win contracts under the competitive bidding process and would receive a "grace period" during which they would need to receive accreditation, after which the organization's contract would be terminated or suspended. This proposed structure raises two concerns for AHCP, related to the quality of care to be provided to Medicare beneficiaries and the costs associated with meeting CMS' accreditation criteria.

Permitting non-accredited bidders to provide services to Medicare beneficiaries may jeopardize patient care in two ways: first, because the supplier will not be reviewed for compliance with standards that CMS has determined are necessary to ensure quality services, and second, because if a supplier is suspended or terminated, their patients may need to be transitioned to another supplier. It is likely that for these reasons, the Act unambiguously states that CMS may not award a contract under competitive bidding unless the bidder meets applicable quality standards. Thus, we are concerned that provisional acceptance of unaccredited suppliers is contrary to the Act and could impede patient safety.[2]

AHCP's second concern is that suppliers may be unable to participate fully in the competitive bidding process if they are unable to determine the costs associated with accreditation and compliance because CMS has not published its quality standards and established an accreditation process. As noted above, the standards will address a number of different areas, and organizations could face significant, presently unquantifiable administrative costs in complying. This could result in some bidders under-pricing their bids, which might ultimately impede the quality of care provided to patients as winning bidders seek to "cut corners" to recoup their accreditation costs. In the alternative, bidders might overprice their bids if they over-estimate their costs, resulting in unnecessary increased costs to the Medicare program. Both of these possibilities undercut Congress' intent in establishing the competitive bidding process.

AHCP believes the full detail of the accrediting process, including the standards CMS will apply and the organizations that will be able to credential suppliers, needs to be available at least six months in advance to submitting a competitive bid.

II.G.4.b. Conditions for Awarding Contracts – Evaluation of Bids – Composite Bids

As discussed above, the proposed rule calls for the creation of "product categories" that include individual items for which CMS will require competitive bidding. Suppliers will be required to submit bids for each individual item within each product category they are bidding on, but they are not required to bid on all product categories. *See* 71 Fed. Reg. at 25,675. In the preamble to the proposed rule, CMS notes that when suppliers are bidding for multiple items in a product category, the lowest bid for each item will not always be submitted by the same supplier. To address this situation, CMS proposes to multiply a supplier's bid for each item in a product category by the item's "weight" and sum the numbers. The "weight" of an item would be based upon the utilization of the item computed to the other items within the product category, based upon historic Medicare claims.

We believe the composite bid should continue to be weighted on both the volume and payment amounts of the item as these both indicate the market importance of the item. It is not a true reflection of market importance to weight the item by just volume or payment amount alone.

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[2] In the proposed rule, CMS solicited comments concerning the length of any grace period. *See* 71 Fed. Reg. 25,675. To be clear, AHCP's position is that there should be no grace period for bidders. Instead, CMS should publish standards and identify accrediting organizations within a reasonable time before implementing the competitive bidding process in order to permit prospective participants to comply with the letter of Act § 1834(a)(20).

To ensure that CMS contracts with a sufficient number of suppliers to meet anticipated demand, the proposed rule involves calculating a "pivotal bid," which is point at which the aggregate capacity of the lowest bidders meets projected demand.

[In Section 4 item c, we propose a different calculation for the pivotal bid. The proposed process would determine that the array of bids be determined from the lowest bidder up. We believe it is in the best interest of the program to arrive at the bid price versus capacity from the mean bid price moving up and down equally until capacity is met and or exceeded. By 'setting' the price from the middle the bid process attempts to assure adequate funding for services with assumed quality standards and not on a 'lowest bidder' model.]

In the proposed rule, CMS indicates that it will select only as many suppliers as are necessary to ensure sufficient capacity to meet projected demand. CMS acknowledges that it may have to suspend or terminate a contract with a supplier that falls out of compliance with contract requirements, in which case, if there is excess demand, CMS will contact remaining contract suppliers to see if they can absorb the unmet demand. If the remaining contract supplier cannot absorb the unmet demand in a timely manner, CMS would refer to the list of suppliers that previously submitted bids, and contact the closest unsuccessful bidder with in invitation to participate at the already determined contract payment amount. CMS would go down the list until it satisfies expected demand. In the preamble to the final rule, CMS asserts that "After consultation with the DMEPOS industry and PAOC, CMS was told that additional capacity should not be a problem, as suppliers would be willing and able to handle the expected demand."

AHCP is concerned about the dearth of reliable information available to determine the number of suppliers who may fail to successfully bid during the competitive bidding process. Moreover, as discussed in our comments entitled "II.G.1. Conditions for Awarding Contracts – Quality Standards and Accreditation," CMS has not determined accreditation standards for participating suppliers yet, and this may result in some successful bidders being suspended or terminated from participation. Presumably, given Medicare's disproportionate impact upon the DMEPOS industry, some unsuccessful bidders may phase out product lines or even go out of business altogether. Moreover, it may be unrealistic for suppliers to assume unplanned volume on short notice, as that could involve significant additional outlays of fixed and working capital.

II.H. Determining Single Payment Amounts for Individual Items

Pursuant to the proposed rules, the method for determining single payment amount for and individual items will be the median of the suppliers' bids that are at or below the pivotal bid. We feel the median bid will set artificially low reimbursement for suppliers who submitted their bids based on their actual costs. An adjustment factor should be used to ensure that the overall payment amounts that contracted suppliers receive are at least as much as their bids.

Section II.H.2 also proposes to allow contract bids for an individual item below the single payment amount to provide beneficiaries with a rebate equal to the difference between their actual bid amount and the single payment amount. AHCP is concerned that encouraging rebates to patients based upon their selection of a particular supplier may unduly influence supplier selection to the detriment of other factors, such as quality, customer service, etc. Such rebates may within the scope of conduct presently proscribed by the anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and they may not qualify for protection under the existing scope of the statutes existing "safe harbor" for discounts and rebates, 42 C.F.R. § 1001.952(h). Moreover, we are concerned that entities providing rebates as proposed may violate the Act's proscription against offering inducements to Medicare beneficiaries. *See* 42 U.S.C. § 1320a-7a(a).

Moreover, we are concerned that by proposing such rebates, CMS is providing tacit support to the notion that beneficiaries should gauge their selection of providers upon an expectation of financial reward. Such expectations, if allowed to continue, could have a corrosive effect upon the entire artifice of the Medicare anti-fraud laws, leading providers to engage in impermissible conduct under the belief that such

laws lack legitimacy because of their selective application. Simply stated, such rebates could encourage widespread fraud and abusive referral practices.

We are adamantly opposed to the notion of any rebate directly back to patients. Instead, providers who have lower costs should use this operating margin to expand their services and or improve patient education, quality, and service. In any event, no rebate should be considered until the bidding provider has been adequately measured for compliance to measurable quality standards within their accrediting body's performance measures reporting.

II.I. Terms of Contract

As proposed, contracts with participating suppliers will contain a number of provisions, including a minimum length of participation and 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 supplier would provide to other customers).

We believe contracted bidders must have the ability to exit the program after delivery of written notice specifying that they will no longer participate. The notice should be sufficient to allow transition of patients with minimal disruptions. This will allow the bidders who may have failed to meet the quality standards or market expectations for the patient to exit while providing adequate transition for beneficiaries and business operations.

In addition, we are concerned that the non-discrimination provision discussed above is unfair to suppliers who may be unable to maintain a constant inventory of particular items at all locations. As long as a product is reimbursed under a particular HCPCS code, the manufacturer of that product should be irrelevant, and the supplier should be free to furnish the item, irrespective of brand. The net effect of the proposed "non-discrimination" provision may be to inappropriately limit regional differences in product selection, to the detriment of overall patient satisfaction, or to force contracted suppliers to overstock particular items simply because comparable products are demanded elsewhere. Moreover, the proposed non-discrimination rule does not take into account temporary shortages or supply disruptions.

III. Conclusion

In general, AHCP supports CMS in its attempt to implement the competitive bidding process. However, AHCP is concerned that previous demonstration projects were undertaken in geographies that were substantially smaller than the 10 MSA's in which the proposed competitive bidding process will be undertaken in 2007. We believe it would be prudent for CMS to carefully consider the complexity that will be entailed in undertaking this process and weigh the benefits of any proposed savings against the potential of harm to Medicare beneficiaries. In particular, we are concerned that, if implemented improperly, the competitive bidding process could limit access to medically necessary DMEPOS and create unnecessary complexity and confusion.

AHCP welcomes the opportunity to provide comments concerning the proposed rules. In particular, we believe that our role as part of a leading, faith-based health system in one of the MSA's that is to be subject to competitive bidding gives us a unique perspective. If you would like to discuss this matter further, please do not hesitate to contact me, Cheryl Meyer, Director of Quality and Risk Management for Advocate Home Health Services and Advocate Home Care Products at 630-368-6623 or Cheryl.Meyer@advocatehealth.com.

Sincerely,
Cheryl A. Meyer, MS, APRN, BC

Submitter : Mr. Nicholas Opalich **Date:** 06/30/2006

Organization : Strategica Health Partners, LLC

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1270-P-1148-Attach-1.DOC

CMS-1270-P-1148-Attach-2.DOC

1148

Department of Health and Human Services
Centers for Medicare and Medicaid

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.

In Re: Electronic Comments to CAP/DME
On behalf of independent retail Pharmacies

Date: June 28, 2006

Submitter: Nicholas Opalich Managing Partner
Strategica Health Partners, LLC
216-469-7859
njopalich@aol.com

Location: http://www.cms.hhs.gov/eRulemaking

Mark McClellan, M.D., PhD.
Administrator
Centers for Medicare and Medicaid
Room 314 G
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

On behalf of retail pharmacy and affiliated mail order clients we respectfully submit these general comments and guiding principles 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.

By way of information, I've worked very closely with CMS and BioScrip, Inc., the solo vendor for the CAP Medicare Part B Infusion and Injectable program scheduled to implement July 1, 2006. We have learned a great deal by working closely and effectively with CMS to implement this program and we further believe that we'll be a great asset in bringing similar synergies toward the implementation of the CAP/DME. We look forward to working with CMS on launching the

Competitive Acquisition Program for Durable Medical Equipment, Orthotics and Supplies. Additionally, there are several exceptional and unique qualities of the CAP B Infusion program that we believe applies under the CAP/DME proposed guidelines.

Diabetes care management is a growing concern for the Medicare population and all of our retail pharmacy clients (29,000+ strong) are focused on providing the highest quality of care through many face-to-face patient encounters. It is our single focus as we approach the anticipated CAP/DME program with our comments, that CMS envisions a strong network of retail pharmacy and affiliated mail order partners, which will offer a hybrid of care to our significant diabetic patient population.

Thank you for your time in consideration of our comments and guiding principles. We welcome the opportunity to work with CMS on the implementation of the CAP/DME.

Kind regards,

Nicholas Opalich, Partner
Strategica Health Partners, LLC

Essentially, our comments surround several Major points of interest in the Proposed Rule:

1. CMS should study the CAP Infusion & Injectable Program recently implemented by CMS on July 1, 2006 for Medications Administered in the Physician's office as a guidepost for implementing Competitive Bidding on Diabetic Supplies. In similar fashion --- CMS modeled the CAP "Part B" Infusion program to resemble a nationwide Pharmacy Dispensing Program, as opposed to using the old buy & bill distribution model. CMS in its wisdom recognized the difference between a distributor and a dispensing pharmacists - - Pharmacies across the country employ registered pharmacists accustomed to patient training, medication therapy management and working with Medicare beneficiaries, in CAP/DME, patients with diabetes. CMS decided to phase-in the CAP B program on a nationwide basis and we believe that CMS could achieve similar synergies within the national, regional or local MSA markets it intends to implement the DME program;

2. Access to the Appropriate Care must be continued (414.414 d,e).Whatever CMS chooses to implement access to the appropriate levels of quality care must be guarded for all Medicare beneficiaries, whether the supplier is a retail pharmacy or mail order supplier. Diabetic patients require additional care for monitoring and testing and we believe at all times Medicare Diabetic patients should always have access to this care in their local communities. We envision the importance of daily self-monitoring without any disruptions to this practice. The retail pharmacy industry has a long history of providing excellent point of care service and training to diabetic patients and strongly believes that the retail pharmacy model will continue to achieve and exceed a higher level of standards simply because they have a greater access to face-to-face encounters with the patients. We are not suggesting that a national or regional mail order companies should be precluded from participating in the CAP/DME however, we would like to stress that the retail pharmacy industry should not be circumvented to believe that mail order pharmacies could replace the face-to-face encounters enjoyed by local retail pharmacists and pharmacies. Our clients are 29,000 retail pharmacies strong and have a very powerful reach into the large, medium and small MSA's. Additionally, in conjunction and complimentary to our retail clients. Additionally, CMS suggested throughout the Proposed Rule that more suppliers mean increased competition. However, how are we supposed to interpret CMS intent to launch a nationwide mail order program. We recommend that CMS become more consistent in what it desires to implement and once again there should not be anything that becomes an obstacle to the current status of face-to-face patient retail pharmacy encounters, specifically within the diabetic marketplace;

3. The proposed methodology for selecting the 10 MSAs for 2007 and additional MSAs in 2009. We suggest that CMS does have the experience of establishing the criteria for the selection of MSA's and this is demonstrated by the CAP B Infusion program. How would CMS propose to use this process currently underway for the benefit of the CAP/DME. We would suggest that it would be more feasible in the

case of diabetic supplies that CMS select certain markets to phase-in a retail pharmacy distribution system before it launches a nationwide program without the benefit or what it may learn from a demonstration;

4. Opportunity for Networks (414.418). My client represents approximately 29,000 independent retail and chain pharmacies throughout the United States and in every MSA across the country. Accordingly, there are 56,404 retail pharmacies outlets supplying blood glucose monitors and test strips. Therefore, my client has a strong interest in forming a solid network among its retail pharmacy clients and judging by the numbers we represent over half of the supplying diabetic pharmacy suppliers. Most patients who obtain their diabetic supplies from a local retail pharmacy visit their pharmacy and incur a face-to-face encounter. Patients depend on their local pharmacist to obtain their supplies as well as training and the opportunity to have their questions answered. The Proposed Rule permits suppliers to form networks for bidding purposes. The time period that CMS allows to form a network and have its bid in place plus accreditation --- the timeline appears on its surface to be aggressive and we must have the ability and the time to evaluate the diabetic distribution among our retail pharmacy partners to ensure that there are no disruptions to their care. Additionally, we would like the opportunity to fully understand what you're attempting to propose about the formation of a network we understand that you offered this alternative during the San Antonio and Polk County markets and that no networks were developed. However, we believe that will not be the case should CMS add diabetic supplies and monitors to the CAP/DME. CMS stated that each member of the network must be independently eligible to bid, the network will be notified and given 10-business days to bid; what does CMS mean by eligible to bid. Each member must meet any accreditation and quality standards that are required; what are the requirements? Each member is equally responsible for the quality of care, service and items that it delivers to Medicare beneficiaries; what are these standards of quality of care;

5. Very few specifics on particular products to which CB will be applied in the selected MSAs, and only general methodology on how product categories will be chosen (414.412). Provided our read of the Proposed Rule Diabetes care is a prime candidate for expansion into the CAP/DME program. How does CMS propose to group together the methodology for product selection in this category. Until such time it is difficult to comment fully;

6. Alternatives to defining CB areas and standards for exempting particular rural areas from CB;

7. Methodologies for setting the single payment amount and determining the Pivotal Bid amount (414.414 e). In the CAP B Infusion program CMS used claims data from 2003 to establish what items, volume and payments it would draw its product selections from and to provide an incentive for suppliers to become interested in

bidding. Again as we stated in the financial section Pivotal Bid should be driven through a balance between volume and reimbursement data from a selected period;

8. Single Payment Amount (414.416 b). In addition, to using the bid price as a selection tools of suppliers it would be advisable to establish what the financial criteria, quality criteria and accrediting criteria will be prior t selecting a supplier. This would then eliminate unsophisticated suppliers attempting to game the system by achieving contractor status and then develop a strategy as a contractor to obtain supply status with the diabetic manufacturers;

9. Gap-filling 414.21 (g). These procedures in combination with HCPCS coding procedures have not been thoroughly discussed in the Proposed Rule. Either CMS should delay this subject for further review or at the minimum CMS should visit how it implemented adding new HCPCC codes to the CAP/B;

10. Rebates (414.416 C) CMS raised the specter of sharing rebates with Medicare Beneficiaries in the proposed rule. This is a distortion of law. There are severe penalties that effect suppliers who violate several laws that deal with inducements to force over utilization of Medicare reimbursed services. Simply stated this is an idea we do not like and would rather we not go down this road. The OIG has no opinion letter on record suggesting sharing rebates they would be approved and it is our further opinion sharing of rebates would eventually lead to suppliers perhaps cheating on service since rebates would drive prices too low or beyond what was bid which ignore how they could financially survive under such tactics;

11. The proposed approach for calculating market demand and estimating supplier capacity (414.414 d, 414.414 g). CMS stated that it is possible they could choose two suppliers to carry out the functions of the Proposed Rules for DME suppliers and went on to further state that in fact they believed that two suppliers could carry out the responsibilities of the suppliers of the Proposed Rule. We do not believe that this was the intent of the MMA or the Social Security Act and we strongly believe that a network of contracted pharmacies (suppliers) made up of a hybrid model (Retail Pharmacies & Mail Order) would best serve Medicare Beneficiaries and serve the intent of the Social Security Act, which meant multiple suppliers does not or could not be construed as the number two;

12. Best method of weighting individual items within a product category to determine the composite bid (414.414 e) as CMS has learned from the CAP B Infusion weighted methodology high volume items which are heavily weighted could create a lower composite bid. We suggest on higher weighted volume items CMS should consider a blended approach balanced between reimbursement and volume;

13. Financial standards evaluation criteria and required documentation (414.414(d)). Does CMS intend to submit a CAP/DME vendor enrollment form and does each vendor interested in bidding have to complete a new 855(B) or 855 (A) applications to be considered for CAP qualifications. CMS should develop and publish what will be the key financial standards and quality bid requirements;

14. Does CMS intend to explain to the vendor community how the Implementation contractors intend to process claims and will CMS propose to use a claims matching process with a written prescription;

15. Additional options to ensure that small suppliers have opportunities to be considered for participation in CB. CMS intended to have competition and proposed language as to how small suppliers could participate in the CAP/DME program. Effectively, retail pharmacies form the largest segment of suppliers for diabetic supplies and the most face-to-face patient encounters. Yet, CMS intends to implement a nationwide mail order diabetic program, which has not developed the level of face-to-face patient encounters. CMS somewhat described its intent to permit smaller suppliers to form networks and outlined in cursory format how to qualify to form and bid as a network. As we have stated we do not have enough information about forming networks and the stated criteria CMS published-accreditation standards, quality and financial standards are not yet fully understood;

16. Grandfathering of existing providers/suppliers what is the quality criteria that will be used to Grandfather existing Medicare Providers with a current Medicare Provider number which is in good standing. Again, I'd like to raise the issue that CMS didn't use Grandfathering to implement the CAP B Infusion & Injectable program. CMS used a very carefully outlined and articulated process by which interested bidding vendors must conform. These standards were outlined in the application for vendor status. Is there any reason why CMS could or should not adopt a similar strategy for CAP/DME;

17. Have Accreditation and Standards in place before starting (414.414(c)). We are unaware of any accrediting agency with prior experience or programs directed at Retail Pharmacies, a large source of diabetic supplies to patients. Most accrediting agencies have experience with accrediting homecare companies, durable medical equipment companies, home health agencies and others. A large source of diabetic supplies originates with retail pharmacies, independent and chain. As indicated we are uncertain as to how CMS plans to proceed with its accreditation process for the retail pharmacy industry and to conform to standards not yet developed for a retail pharmacy, or mail order pharmacy. Applying accrediting standards used for home health agencies and models similar do not apply to a

retail pharmacy. It was indicated in the proposed rule that all bidders must be accredited before they can participate as a vendor; how does CMS intend to implement. Additionally, we would like to know how any accrediting standards would be implemented within the timeframe necessary for the competitive acquisition program. How many accrediting agencies will be used by CMS to accomplish the enormous task of qualifying and accrediting interested bidding companies;

18. Diabetic supply patients typically must confront other related disease states, such as heart disease and other circulatory problems. Has CMS considered how it intends to coordinate disease management programs among its vendors involved in CAP/DME? It is feasible that diabetic patients may have to use more than one supplier to manage the disease? What will be the impact on patient compliance and total cost for their therapy regimen? We must examine the assumptions outlined in the MMA to drive costs lower and to provide savings to the Medicare program by using the Competitive bid process and look at what would happen if diabetic patients did not follow medication regimes under the competitive bid process only because the process itself drove the price of diabetic supplies downward in order to win a bid and the result might end with increased patient hospitalization because of the lack of therapy compliance.

#1148

Department of Health and Human Services
Centers for Medicare and Medicaid

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.

In Re: Electronic Comments to CAP/DME
On behalf of independent retail Pharmacies

Date: June 28, 2006

Submitter: Nicholas Opalich Managing Partner
Strategica Health Partners, LLC
216-469-7859
njopalich@aol.com

Location: http://www.cms.hhs.gov/eRulemaking

Mark McClellan, M.D., PhD.
Administrator
Centers for Medicare and Medicaid
Room 314 G
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

On behalf of retail pharmacy and affiliated mail order clients we respectfully submit these general comments and guiding principles 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.

By way of information, I've worked very closely with CMS and BioScrip, Inc., the solo vendor for the CAP Medicare Part B Infusion and Injectable program scheduled to implement July 1, 2006. We have learned a great deal by working closely and effectively with CMS to implement this program and we further believe that we'll be a great asset in bringing similar synergies toward the implementation of the CAP/DME. We look forward to working with CMS on launching the

Competitive Acquisition Program for Durable Medical Equipment, Orthotics and Supplies. Additionally, there are several exceptional and unique qualities of the CAP B Infusion program that we believe applies under the CAP/DME proposed guidelines.

Diabetes care management is a growing concern for the Medicare population and all of our retail pharmacy clients (29,000+ strong) are focused on providing the highest quality of care through many face-to-face patient encounters. It is our single focus as we approach the anticipated CAP/DME program with our comments, that CMS envisions a strong network of retail pharmacy and affiliated mail order partners, which will offer a hybrid of care to our significant diabetic patient population.

Thank you for your time in consideration of our comments and guiding principles. We welcome the opportunity to work with CMS on the implementation of the CAP/DME.

Kind regards,

Nicholas Opalich, Partner
Strategica Health Partners, LLC

Essentially, our comments surround several Major points of interest in the Proposed Rule:

1. CMS should study the CAP Infusion & Injectable Program recently implemented by CMS on July 1, 2006 for Medications Administered in the Physician's office as a guidepost for implementing Competitive Bidding on Diabetic Supplies. In similar fashion --- CMS modeled the CAP "Part B" Infusion program to resemble a nationwide Pharmacy Dispensing Program, as opposed to using the old buy & bill distribution model. CMS in its wisdom recognized the difference between a distributor and a dispensing pharmacists - - Pharmacies across the country employ registered pharmacists accustomed to patient training, medication therapy management and working with Medicare beneficiaries, in CAP/DME, patients with diabetes. CMS decided to phase-in the CAP B program on a nationwide basis and we believe that CMS could achieve similar synergies within the national, regional or local MSA markets it intends to implement the DME program;

2. Access to the Appropriate Care must be continued (414.414 d,e).Whatever CMS chooses to implement access to the appropriate levels of quality care must be guarded for all Medicare beneficiaries, whether the supplier is a retail pharmacy or mail order supplier. Diabetic patients require additional care for monitoring and testing and we believe at all times Medicare Diabetic patients should always have access to this care in their local communities. We envision the importance of daily self-monitoring without any disruptions to this practice. The retail pharmacy industry has a long history of providing excellent point of care service and training to diabetic patients and strongly believes that the retail pharmacy model will continue to achieve and exceed a higher level of standards simply because they have a greater access to face-to-face encounters with the patients. We are not suggesting that a national or regional mail order companies should be precluded from participating in the CAP/DME however, we would like to stress that the retail pharmacy industry should not be circumvented to believe that mail order pharmacies could replace the face-to-face encounters enjoyed by local retail pharmacists and pharmacies. Our clients are 29,000 retail pharmacies strong and have a very powerful reach into the large, medium and small MSA's. Additionally, in conjunction and complimentary to our retail clients. Additionally, CMS suggested throughout the Proposed Rule that more suppliers mean increased competition. However, how are we supposed to interpret CMS intent to launch a nationwide mail order program. We recommend that CMS become more consistent in what it desires to implement and once again there should not be anything that becomes an obstacle to the current status of face-to-face patient retail pharmacy encounters, specifically within the diabetic marketplace;

3. The proposed methodology for selecting the 10 MSAs for 2007 and additional MSAs in 2009. We suggest that CMS does have the experience of establishing the criteria for the selection of MSA's and this is demonstrated by the CAP B Infusion program. How would CMS propose to use this process currently underway for the benefit of the CAP/DME. We would suggest that it would be more feasible in the

case of diabetic supplies that CMS select certain markets to phase-in a retail pharmacy distribution system before it launches a nationwide program without the benefit or what it may learn from a demonstration;

4. Opportunity for Networks (414.418). My client represents approximately 29,000 independent retail and chain pharmacies throughout the United States and in every MSA across the country. Accordingly, there are 56,404 retail pharmacies outlets supplying blood glucose monitors and test strips. Therefore, my client has a strong interest in forming a solid network among its retail pharmacy clients and judging by the numbers we represent over half of the supplying diabetic pharmacy suppliers. Most patients who obtain their diabetic supplies from a local retail pharmacy visit their pharmacy and incur a face-to-face encounter. Patients depend on their local pharmacist to obtain their supplies as well as training and the opportunity to have their questions answered. The Proposed Rule permits suppliers to form networks for bidding purposes. The time period that CMS allows to form a network and have its bid in place plus accreditation --- the timeline appears on its surface to be aggressive and we must have the ability and the time to evaluate the diabetic distribution among our retail pharmacy partners to ensure that there are no disruptions to their care. Additionally, we would like the opportunity to fully understand what you're attempting to propose about the formation of a network we understand that you offered this alternative during the San Antonio and Polk County markets and that no networks were developed. However, we believe that will not be the case should CMS add diabetic supplies and monitors to the CAP/DME. CMS stated that each member of the network must be independently eligible to bid, the network will be notified and given 10-business days to bid; what does CMS mean by eligible to bid. Each member must meet any accreditation and quality standards that are required; what are the requirements? Each member is equally responsible for the quality of care, service and items that it delivers to Medicare beneficiaries; what are these standards of quality of care;

5. Very few specifics on particular products to which CB will be applied in the selected MSAs, and only general methodology on how product categories will be chosen (414.412). Provided our read of the Proposed Rule Diabetes care is a prime candidate for expansion into the CAP/DME program. How does CMS propose to group together the methodology for product selection in this category. Until such time it is difficult to comment fully;

6. Alternatives to defining CB areas and standards for exempting particular rural areas from CB;

7. Methodologies for setting the single payment amount and determining the Pivotal Bid amount (414.414 e). In the CAP B Infusion program CMS used claims data from 2003 to establish what items, volume and payments it would draw its product selections from and to provide an incentive for suppliers to become interested in

bidding. Again as we stated in the financial section Pivotal Bid should be driven through a balance between volume and reimbursement data from a selected period;

8. Single Payment Amount (414.416 b). In addition, to using the bid price as a selection tools of suppliers it would be advisable to establish what the financial criteria, quality criteria and accrediting criteria will be prior t selecting a supplier. This would then eliminate unsophisticated suppliers attempting to game the system by achieving contractor status and then develop a strategy as a contractor to obtain supply status with the diabetic manufacturers;

9. Gap-filling 414.21 (g). These procedures in combination with HCPCS coding procedures have not been thoroughly discussed in the Proposed Rule. Either CMS should delay this subject for further review or at the minimum CMS should visit how it implemented adding new HCPCC codes to the CAP/B;

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11. The proposed approach for calculating market demand and estimating supplier capacity (414.414 d, 414.414 g). CMS stated that it is possible they could choose two suppliers to carry out the functions of the Proposed Rules for DME suppliers and went on to further state that in fact they believed that two suppliers could carry out the responsibilities of the suppliers of the Proposed Rule. We do not believe that this was the intent of the MMA or the Social Security Act and we strongly believe that a network of contracted pharmacies (suppliers) made up of a hybrid model (Retail Pharmacies & Mail Order) would best serve Medicare Beneficiaries and serve the intent of the Social Security Act, which meant multiple suppliers does not or could not be construed as the number two;

12. Best method of weighting individual items within a product category to determine the composite bid (414.414 e) as CMS has learned from the CAP B Infusion weighted methodology high volume items which are heavily weighted could create a lower composite bid. We suggest on higher weighted volume items CMS should consider a blended approach balanced between reimbursement and volume;

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15. Additional options to ensure that small suppliers have opportunities to be considered for participation in CB. CMS intended to have competition and proposed language as to how small suppliers could participate in the CAP/DME program. Effectively, retail pharmacies form the largest segment of suppliers for diabetic supplies and the most face-to-face patient encounters. Yet, CMS intends to implement a nationwide mail order diabetic program, which has not developed the level of face-to-face patient encounters. CMS somewhat described its intent to permit smaller suppliers to form networks and outlined in cursory format how to qualify to form and bid as a network. As we have stated we do not have enough information about forming networks and the stated criteria CMS published-accreditation standards, quality and financial standards are not yet fully understood;

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17. Have Accreditation and Standards in place before starting (414.414(c)). We are unaware of any accrediting agency with prior experience or programs directed at Retail Pharmacies, a large source of diabetic supplies to patients. Most accrediting agencies have experience with accrediting homecare companies, durable medical equipment companies, home health agencies and others. A large source of diabetic supplies originates with retail pharmacies, independent and chain. As indicated we are uncertain as to how CMS plans to proceed with its accreditation process for the retail pharmacy industry and to conform to standards not yet developed for a retail pharmacy, or mail order pharmacy. Applying accrediting standards used for home health agencies and models similar do not apply to a

retail pharmacy. It was indicated in the proposed rule that all bidders must be accredited before they can participate as a vendor; how does CMS intend to implement. Additionally, we would like to know how any accrediting standards would be implemented within the timeframe necessary for the competitive acquisition program. How many accrediting agencies will be used by CMS to accomplish the enormous task of qualifying and accrediting interested bidding companies;

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Submitter : **Ms. Jessica Brodey** **Date: 06/30/2006**

Organization : **Assistive Technology Industry Association**

Category : **Device Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1270-P-1149-Attach-1.DOC

#1149

ATIA Innovation Cooperation
Assistive Technology Industry Association

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Dr. Mark McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
7500 Security Boulevard
Baltimore, MD 21244-8013

Re: Comments on Use of Terms and Low Vision Aid Exclusion in Proposed Rule Regarding Medicare's Competitive Acquisition for DMEPOS and Other Issues (CMS-1270-P)

Dear Dr. McClellan:

On behalf of the Assistive Technology Industry Association (ATIA), we submit the following comments in response to the Notice of Proposed Rulemaking on Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues, File Code CMS-1270-P (May 1, 2006, Vol. 71, No. 83). ATIA's comments will focus on two issues: 1) an exemption from the competitive acquisition program for high-tech rehab and assistive technology, including speech generating devices and accessories; and 2) the Low Vision Aid Exclusion.

The Assistive Technology Industry Association (ATIA) is a not-for-profit membership organization of approximately 100 manufacturers, sellers and providers of technology-based assistive devices and or services for individuals with disabilities. The majority of our members qualify as small businesses. ATIA's mission is to serve as the collective voice of the Assistive Technology industry so that the best products and/or services are delivered to people with disabilities.

Use of Terms: High-Tech Rehab, Assistive Technology, and Accessories Exception

ATIA objects to the definition of "certain DMEPOS items" as set forth in the Notice of Proposed Rulemaking. Indeed, the Notice merely states that the competitive acquisition program will be implemented for "certain DMEPOS items" as required under the sections 1847 (a) and (b). This language is overbroad, and could include DMEPOS items that would not be appropriate for the competitive acquisition program. ATIA urges CMS to include a carve-out in the definition of covered items as defined in these regulations for high-tech rehab and assistive technology products and services, including speech generating devices and accessories, from the competitive acquisition program.

Of particular concern to our membership are the nine HCPCS codes that comprise the product family "speech generating devices and related items" E 2500-2599, computer access products and accessories that are currently funded under Medicare. Speech generating devices (SGDs), also known as augmentative and alternative communication (AAC) devices, are electronic and non-electronic devices that help persons with speech and/or hearing disabilities communicate. Examples of these devices include communication boards, speech synthesizers, and text to voice software. Because individuals using these devices often have multiple disabilities, many speech generating/AAC device users rely on accessories to

assist them in utilizing these devices. These accessories may include mounting devices to attach them to wheelchairs, headsticks, light pointers, eye trackers, modified or alternate keyboards, switches activated by pressure, or touch screens.

ATIA requests that CMS further define "certain items of DMEPOS" and include an exception for high-tech rehab and assistive technology, including speech generating devices and accessories, in these regulations. It is critical for the high-tech rehab and assistive technology community to understand whether these regulations will apply as we move forward and prepare for the future. Congress specifically delegated the authority to the Secretary to determine classes of products to exempt from the competitive acquisition program, and it is critical that the Secretary exercise this authority. Indeed, as the Secretary begins to implement the competitive acquisition program, these types of decisions must be made clearly and decisively so that there is no confusion for vendors, customers, and medical practitioners.

Section 1847(a) allows the Secretary to waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of the program, and Section 1847(a)(3) specifically allows the Secretary to exempt items and services for which the application of competitive acquisition is not likely to result in significant savings. The market for speech generating devices/AAC devices is relatively small in the United States, particularly when compared to the market for other DME. Overall utilization is exceedingly low: only approximately 1,220 SGDs per year are purchased by Medicare, divided among 6 HCPCS codes. SGDs and related items may well have the lowest utilization of any DME product category covered by Medicare. Indeed, fewer than 5,000 SGDs have been purchased by Medicare since 2001; on average, only 1,211 per year. The four-year total number of digitized speech output devices purchased by Medicare is only 576, or only 144 per year; only 822 keyboard-based synthesized speech output SGDs have been purchased, or 206 per year; and only 3,449 multiple-access, synthesized speech output SGDs have been purchased, or 862 per year. Among software, mounts and accessories, the total purchases are similarly small. In 2004, for example, Medicare spent only $4,562 on speech generating/AAC device software (E 2511); less than $220,000 was spent on mounting systems (E 2512), and less than $280,000 was spent on all SGD accessories. The foregoing data make clear that competitive bidding for the nine codes representing SGDs and related items will not generate significant savings to the Medicare program.

There are only a few manufacturers of these devices, and most of these manufacturers would likely qualify as a "small businesses." Perhaps the most important fact is that these manufacturers are often not even direct competitors because each company has developed its device(s) based on its perception of their users' needs. SGDs are not interchangeable; they vary greatly in size, weight, style, accessibility and functionality. Different consumer needs have driven these dissimilarities. Some clients have good cognitive ability with limited physical ability, while others are the exact opposite. If one manufacturer's product is right for a particular individual, then it might be the only SGD product that is appropriate for that individual. Consequently, competitive acquisition is not likely to result in significant savings, since the price point of one company's product is not likely to drive down the price point of other companies' products as their products are different, work in different ways, and satisfy different needs. For example, some SGDs work with a keyboard for those who have dexterity in their hands but no ability to speak.

Other devices combine keyboards with frequently used words and a "memory" for mostly commonly typed words on a larger keypad with keyguards or a touchpad for those with high language functioning but more limited physical dexterity (such as someone with cerebral palsy). Still other devices have pictures in lieu of a traditional keyboard to produce communication for younger children or for those with autism or other limited language functionality. While most devices are word based, at least one device is phrase based. One device may include a remote control capability, while another may include a wireless phone, or a CD/DVD drive and a modem, or even a digital camera. The range of devices is just as broad and specialized as the range of disabilities, thus competitive bidding is unlikely to have an impact on setting the price point for these products. Rather, the price of these products is set by the cost of researching the product, the expense of manufacturing the product, the expected size of the market for the product, and the anticipated life of the product. Moreover, competitive bidding only affects consumer choice where the products or services supplied are similar enough that the client would opt for the lower priced item as an acceptable substitute for the higher priced item. With SGDs, the devices are so dissimilar as to undermine that premise, and the needs of the client and the specific functionality offered by the particular product drive the decision to purchase a product rather than the final price.

SGDs are also inappropriate for competitive acquisition because of the highly specialized nature of the products. The users of speech generating devices, computer access products and accessories are individuals with no ability to speak, often with other disabilities such as spinal cord injuries, cerebral palsy, amyotrophic lateral sclerosis, multiple sclerosis and other disabilities and diseases that are often progressive in nature. Because of the diversity in capabilities and communication needs, speech generating devices and accessories provided to such beneficiaries are highly individualized. The products must be assembled, fitted, adjusted, programmed, modified, serviced and monitored to accommodate each person's individual medical needs. Due to the uniqueness of the individual beneficiary, a high degree of specialized service is required in matching the beneficiary to the existing technology. As with speech generating devices, orthotics are often highly individualized. Section 1847(a)(2)(C) excludes orthotics that require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual from the competitive acquisition program. ATIA urges the Secretary to treat high-tech rehab and assistive technology devices, including speech generating devices, in the same manner as these orthotics that require expertise in trimming, bending, molding, assembling, and/or customizing to fit the individual and exclude these products from the competitive acquisition program.

As set forth in the Notice of Proposed Rulemaking, one of the stated purposes of the competitive bidding program is "to assure beneficiary access to quality DMEPOS as a result of the program." ATIA believes that the competitive acquisition of high-tech rehab and assistive technology products would inhibit access to these products for individuals with disabilities without any significant increase in savings. Competitive bidding of high-tech rehab and assistive technology products and services will have a serious negative impact on individuals with disabilities who require these products and services. Speech generating devices, computer access technologies and accessories are quite unique, because each individual's requirements affect the mode and type of equipment that is appropriate to address the disability. For example, an individual who cannot speak but has full utilization of hands and arms requires a different type of device and mode of access to the device than a quadriplegic with no ability to speak. Because the mode through which each individual can access these devices varies significantly from person to person,

and the specific language and communication needs of each individual likewise varies with the type of disability, technology assessments and home evaluations performed by independent professional clinicians to match the appropriate technology to the beneficiary are critical to the successful implementation of speech generating devices. ATIA believes that competitive bidding would undermine the current system because it would eliminate the specialized fitting of appropriate technologies and modes of access to the needs of the individual. A competitive bidding system would eliminate the ability of individuals to choose from a range of products that appropriately address their needs, and have the selected product fitted and adjusted to maximize value for the individual.

The current system encourages the adoption of speech generating devices, and helps allow more individuals with disabilities to participate in and contribute to society. Changing the rules to allow for competitive bidding would make it far more difficult for individuals to get the appropriate devices they require in order to fully access and participate in society. Such action would also have the long-term detrimental impact of establishing a harmful precedent of portraying speech generating devices and other assistive technology as one-size-fits-all. Consequently, ATIA strongly encourages CMS to adopt a carve-out for high-tech and rehab assistive technologies that includes speech generating devices, computer access devices, and accessories.

Low Vision Aid Exclusion

ATIA joins in the comments of the ITEM Coalition and the American Foundation for the Blind and similarly objects to the proposed low vision aid exclusion. The proposed exclusion states that 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" will be hereafter excluded from Medicare coverage based on the statutory "eyeglass" exclusion. As articulated by the ITEM Coalition, ATIA believes that this language is overbroad and would decrease access to important assistive technology for people with vision impairments now and in the future, and establish a harmful precedent that would limit access to assistive technology for all people with disabilities.

ATIA believes that this proposal will have a significant impact on beneficiaries with vision impairments who depend on assistive technology that incorporates one or more lenses to aid in their vision. The eyeglass exclusion prevents access to devices such as hand-held magnifiers, video monitors, and other such technologies that utilize lenses to enhance vision. These tools are often essential for individuals with low vision who, without the aid of assistive technology, cannot read prescriptions, financial documents, mail, recipes, and other important materials. While initially, this regulation may merely be a statement of current reimbursement practices, the proposed regulation will have a detrimental impact in the long term to the extent that it would exclude *any* technology that uses "one or more lens for the primary purpose of aiding vision." In essence, this regulation serves as a preemptive and unwarranted coverage denial for any new or future technologies designed to assist individuals with vision impairments. Such a preemptive coverage denial serves as a tremendous disincentive to manufacturers and innovators to develop new and progressive vision technology. If Medicare establishes this broad coverage exclusion for low vision aids, we would undoubtedly see a decrease in innovation in this area – harmful effects on those currently experiencing vision impairments or who will experience such impairments in the future. We believe that

there will be technologies that will be invented in the future involving lenses (much in the way that artificial lenses are now implanted as part of cataract surgery) that will be eligible for Medicare coverage that we cannot predict or anticipate now that would be wrongly prohibited by this exclusion.

ATIA believes that if Congress had originally intended the eyeglass exclusion to apply to *all* devices with "one or more lens" to aid in vision, it would have explicitly expressed that with statutory language. However, nowhere in the statute or legislative history does Congress suggest anything but a plain reading of the term "eyeglasses." Instead, we believe that Congress' use of the term "eyeglasses" was simply meant to apply to traditional eyeglasses. This interpretation has been supported by several federal courts. In one relevant case, *Currier v. Thompson,* 369 F. Supp. 2d 65 (D. Me. 2005), the U.S. District Court for the District of Maine found that a video monitor is *not* excluded from Medicare coverage based on the "eyeglass" exclusion and remanded the case back to the Secretary of Health and Human Services (HHS) to determine if a video monitor is considered under the Medicare benefit "durable medical equipment" or as a "prosthetic device."

Consistent with this decision, ATIA joins with the ITEM Coalition to argue that all vision aids with one or more lens, other than traditional eyeglasses, should be considered for a Benefit Category Determination (BCD). We recommend that the agency consider not just the common features between eyeglasses and other devices with lenses, but the differentiating features as well that may lend themselves to coverage under the program for specific populations with low vision needs. Some of these devices may use a power source or a video screen to augment vision. These are features that Congress was clearly not addressing in the statutory language regarding eyeglasses when this language was included in the statute years ago. After such an individualized evaluation, if it is determined that the device falls under a Medicare benefit category, coverage criteria should be established by CMS.

For example, a video monitor used to aid extremely low vision clearly meets Medicare's four-pronged definition of durable medical equipment (DME) in that it can withstand repeated use, is primarily and customarily used to serve a medical purpose, generally is not useful to an individual in the absence of an illness or injury and is appropriate for use in the home. Therefore, Medicare should develop a set of coverage standards for video monitors allowing appropriate individuals with low vision access to this medically necessary technology. CMS should assess other technologies through a similar process for purposes of Medicare coverage.

ATIA strongly recommends that CMS reconsider its proposal to preemptively disqualify all low vision aids which utilize a lens from Medicare coverage. Many of these types of devices could assist individuals in completing activities of daily living, thereby improving their health and independence. This proposed coverage exclusion will prevent access to currently available vision aids for people with vision impairments as well as decrease the development of new and innovative vision technologies for people with disabilities. We encourage CMS to evaluate the medical/functional purpose of each assistive device and technology at issue and establish individualized coverage decisions.

Conclusion

Additionally, ATIA would like to strongly echo the comments of the ITEM Coalition that CMS does not adequately weigh the real-life value of assistive technology for people with disabilities against the cost of covering such technology for appropriate beneficiaries. For almost all people with disabilities, assistive technology is often an essential factor in improving or maintaining one's health status, maintaining independence, living safely, returning to work or school, and participating in community activities.

Indeed, in many cases, assistive technology is akin to a medically necessary prosthetic device to the extent that it replaces a body part or functional system for an individual with a disability. Just as an individual with a missing limb is not given limitations in how they are permitted to use their prosthetic device, ATIA believes that individuals with an inability to communicate should not be limited in how they use their speech generating devices. Many of CMS' policies, such as the restrictions on speech generating devices that prohibit using these devices for functions in addition to speech generating functions, severely inhibit technology innovation and thereby diminish the quality of life for individuals with disabilities. By eliminating these restrictions and allowing 21st century technology to be used to its full communication capacity, people with disabilities could reduce the numbers of devices they would need to purchase, and could increase their health status, independence and quality of life with negligible or no additional cost to the program.

Respectfully submitted,

Jessica Brodey, Esq.

Submitter : **Ms. Deborah Buck** **Date: 06/30/2006**

Organization : **Association of Assistive Technology Act Programs (**

Category : **Other Association**

Issue Areas/Comments

Conditions for Awarding Contracts

Conditions for Awarding Contracts

Proposed '414.414 Conditions for Awarding Contracts
ATAP agrees that only accredited providers should be eligible to submit bids. However, we strongly urge CMS to identity the criteria that will be used to select potential accrediting bodies before implementing the competitive bidding process. It appears that CMS is willing to implement provisions for procurement of DME before a mechanism for establishing quality standards and accredited programs and providers is in place. We feel that this approach has inherent risks that will not benefit consumers, providers or CMS. ATAP encourages CMS to accept programs that have established recognized quality standards that are deemed equitable by CMS without requiring the agency to go through an additional approval process that will require additional resources and time. In addition, it does not seem prudent to implement the competitive bidding process without first including the associated costs of accreditation and quality standards in the bids. Assuring quality comes with associated costs and these costs should be factored as an integral part of bid process.
Recommendation:
ATAP recognizes that a section on Quality Standards and Accreditation for Suppliers of DMEPOS is proposed, we would encourage CMS to establish the system of standards and accreditation first, prior to implementing the bidding process.

GENERAL

GENERAL

see attachment

Low Vision Aid Exclusion

Low Vision Aid Exclusion

Proposed '414.15 Low Vision Aid Exclusion
ATAP strongly opposes the exclusions being proposed for essentially all lens for aiding sight except those with specific statutory language attached (i.e., section 1861 (s)(8) of the Medicare Act. Technology exists today that enables people with disabilities and elders to use whatever functional sight they may have. In many instances the ability to read written print can make the difference between living in the community or being moved into a more restrictive placement. This is counter productive to the stated Administration s goals contained in the New Freedom Initiative.

This narrow interpretation of vision aid will have other far reaching implications. It has long been accepted in the industry that Medicare drives policy decision for the private insurance industry. If insurance coverage, both public and private, is non-existent for a specific type of technology, the incentives for technological innovations in the area virtually disappear.

Recommendation:
ATAP encourages CMS to evaluate the medical/functional purpose of each assistive device and technology at issue and establish individualized coverage decisions rather than preemptively disqualifying all low vision aids which utilize a lens from Medicare coverage.

In closing ATAP strongly believes that it is more important to establish an appropriate system as opposed to hastily implement a procedure that is not founded on a thoughtful process of the anticipated outcomes and implications of requirements and processes or lack thereof.. If you have any questions or would like additional information, please feel free to contact me directly.

Opportunity for Networks

Opportunity for Networks

Proposed '414.418 Opportunities for Networks
Networks are a viable alternative to including small businesses in this bid process. Logistics of the present situation are not favorable for the establishment of networks. Due to the proposed timeline issued by CMS for implementing this bidding process, the small vendor will not have the time to form networks. The inability to form these networks and the requirement that all providers in the network meet any accreditation and quality standards (yet to be defined) eliminates them, for all practical purposes from the process at least initially. The timeframe under consideration could essentially limit the participation of small businesses and could have long-term ramifications. Small businesses may not have the capacity to sustain their operations until the system is aligned to enable their inclusion, thereby potentially contributing to the reduction of options over the long term.

Recommendation:
CMS should reconsider the potential impacts of this strategy. Many of the individuals particularly those in more rural areas, procure their DME and supplies through small, local mom and pops shops. While surely not intended, access to medically necessary equipment and supplies could be negatively affected in the current proposal.

CMS-1270-P-1150-Attach-1.DOC

#1150

Association of Assistive Technology Act Programs

Dr. Mark McClellan, MD, PhD
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, MD 21244-1850

June 30, 2006

Re: CMS-1270-P Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule.

Dear Dr. McClellan,

The Association of Assistive Technology Act Programs (ATAP) appreciates this opportunity to comment on the DMEPOS Competitive Acquisition Proposed Rule issued May 1, 2006 in the Federal Register. ATAP, a national, member-based organization, represents 54 of the 56 Assistive Technology Act programs located in the states and territories throughout the country. ATAP's mission is to promote the collaboration of state AT Programs with state and national level entities and to promote availability, access and acquisition of assistive technology, which includes DME, for individuals with disabilities of all ages in the United States and its Territories. Thank you for the opportunity to comment on the proposed rules for Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics Orthotics, and Supplies (DMEPOS) and other Issues.

Proposed §414.414 "Conditions for Awarding Contracts"
ATAP agrees that only accredited providers should be eligible to submit bids. However, we strongly urge CMS to identity the criteria that will be used to select potential accrediting bodies before implementing the competitive bidding process. It appears that CMS is willing to implement provisions for procurement of DME before a mechanism for establishing quality standards and accredited programs and providers is in place. We feel that this approach has inherent risks that will not benefit consumers, providers or CMS. ATAP encourages CMS to accept programs that have established recognized quality standards that are deemed equitable by CMS without requiring the agency to go through an additional approval process that will require additional resources and time. In addition, it does not seem prudent to implement the

competitive bidding process without first including the associated costs of accreditation and quality standards in the bids. Assuring quality comes with associated costs and these costs should be factored as an integral part of bid process.

Recommendation:
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Networks are a viable alternative to including small businesses in this bid process. Logistics of the present situation are not favorable for the establishment of networks. Due to the proposed timeline issued by CMS for implementing this bidding process, the small vendor will not have the time to form networks. The inability to form these networks and the requirement that all providers in the network meet any accreditation and quality standards (yet to be defined) eliminates them, for all practical purposes from the process at least initially. The timeframe under consideration could essentially limit the participation of small businesses and could have long-term ramifications. Small businesses may not have the capacity to sustain their operations until the system is aligned to enable their inclusion, thereby potentially contributing to the reduction of options over the long term.

Recommendation:
CMS should reconsider the potential impacts of this strategy. Many of the individuals particularly those in more rural areas, procure their DME and supplies through small, local "mom and pops" shops. While surely not intended, access to medically necessary equipment and supplies could be negatively affected in the current proposal.

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ATAP strongly opposes the exclusions being proposed for essentially all lens for aiding sight except those with specific statutory language attached (i.e., section 1861 (s)(8) of the Medicare Act. Technology exists today that enables people with disabilities and elders to use whatever functional sight they may have. In many instances the ability to read written print can make the difference between living in the community or being moved into a more restrictive placement. This is counter productive to the stated Administration's goals contained in the New Freedom Initiative.

This narrow interpretation of vision aid will have other far reaching implications. It has long been accepted in the industry that Medicare drives policy decision for the private insurance industry. If insurance coverage, both public and private, is non-existent for a specific type of technology, the incentives for technological innovations in the area virtually disappear.

Recommendation:
ATAP encourages CMS to evaluate the medical/functional purpose of each assistive device and technology at issue and establish individualized coverage decisions rather than preemptively disqualifying all low vision aids which utilize a lens from Medicare coverage.

In closing ATAP strongly believes that it is more important to establish an appropriate system as opposed to hastily implement a procedure that is not founded on a thoughtful process of the anticipated outcomes and implications of requirements and processes or lack thereof.. If you have any questions or would like additional information, please feel free to contact me directly.

Sincerely,

Deborah V. Buck
Executive Director

Submitter : **Mr. Francis Straub IV** **Date: 06/30/2006**

Organization : **Saint Marys Pharmacy Inc.**

Category : **Other Health Care Professional**

Issue Areas/Comments

Conditions for Awarding Contracts

Conditions for Awarding Contracts

see attachment 1

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

see attachment 2

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

see attachment 3

Payment Basis

Payment Basis

see attachment 4

CMS-1270-P-1151-Attach-1.DOC

CMS-1270-P-1151-Attach-2.DOC

CMS-1270-P-1151-Attach-3.DOC

CMS-1270-P-1151-Attach-4.DOC

"Conditions for Awarding Contracts"

Under the current proposed rule, CMS "would not accept any bid for an item that is higher than the current fee schedule amount for that item." This is included in order to assure savings from the program. It would be reasonable to consider, if not accept, bids that are in fact higher than the current fee schedule amount, if such data shows that there are not reasonable savings to be realized on such items. In this case, such items could be excluded from the program in order to allow more resources to be devoted to those items on which reasonable savings can be achieved.

The method of calculating composite bids in the proposed rule is not specific as to whether the supplier will have foreknowledge of the item weight of such items as are included in the category being bid. This method could also be disadvantageous to both small, specialized suppliers and the Medicare program itself; to illustrate this properly, see the following example.

> A supplier with approximately three million dollars in gross revenue specializes in providing CPAP disposable supplies. The price that this supplier bids for providing each of the CPAP supplies is lower than that of any other bidder, due to the company's focus on this specific product line. In order to bid on these items, however, the supplier is required to bid on all items in the same category, which may include items such as the CPAP machine and humidifiers, that the supplier has never before carried or supplied, and therefore has no knowledge of the costs involved. This results in the supplier's composite bid being higher than the determined pivotal bid. As such, the Medicare program has lost those savings that could have been realized by contracting with this provider, and the provider has lost those revenues that could have been realized by continuing to service Medicare patients.

CMS should ensure that quality standards are in place and fully enumerated prior to beginning the bidding process. Without knowledge of all standards and procedures that are to be involved with the provision of an item or service, a supplier cannot submit an accurate bid that takes into account all of these factors. Unless these standards are published in full prior to the bidding process, bids that are artificially low and economically unsustainable may be submitted, leading to a financial burden on the supplier and an administrative burden on the Medicare program if and when this supplier must be replaced with the next highest bidder.

"Determining Single Payment Amounts for Individual Items"

The "Rebate Program" enumerated in the current proposed rule should be eliminated. As it is currently stated, such a program may serve as an inducement for beneficiaries to choose one supplier over another. Said program may also serve to increase utilization of those items on which a rebate is offered, especially in those cases in which the rebate amount would be larger than that of the calculated co-payment amount; from the beneficiary's point of view, he or she would be paid to receive an item or service from the supplier, which can be nothing but detrimental to the Medicare program.

"Opportunity for Participation by Small Suppliers"

In order to guarantee that small providers are given a fair chance to compete under the competitive acquisition program, CMS should make an allowance that all such suppliers in the affected MSAs that fall under the SBA definition of a small business be entitled to provide items and services under bid at the competitively bid price arrived at through the bidding process, as long as such suppliers have participated in the bidding process. As these suppliers will not have the resources at their disposal that larger suppliers may have, such as detailed costing and dedicated legal and accounting departments, they will likely be less able to truly determine the price point at which they should bid. It is probable that they will therefore include costs not directly related to the services being bid and submit a bid higher than they otherwise should have. As a result, any such supplier would not be a "winning bidder" under the current proposed rule. If these suppliers are not able to truly provide these services at the new price, they will be forced economically to not participate in the program. Through this cost savings will still be realized while allowing small suppliers a fair chance to participate in the program.

"Payment Basis"

Although CMS is provided with the authority to use the payment amounts determined in competitive bidding areas to adjust payment amounts in areas not included in a competitive bidding program, any such action should be approached with trepidation. Although competitive bidding areas are to be MSAs that, statistically, will have higher costs to the supplier in wages and other areas, suppliers in more rural areas will have higher costs in delivery, item cost, and similar areas, due to the lower population density of these areas. This situation has been further exacerbated recently, with the higher cost of fuel across the nation. Any such "across-the-board" application of payment amounts determined in competitively bid areas should be preceded by extensive research into the comparative costs of suppliers in differing areas.

Submitter : **Dr. Paul Eckstein** **Date: 06/30/2006**

Organization : **Dr. Paul Eckstein**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 30, 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,

Paul E. Eckstein, DPM

Submitter : **Mr. Jason Dixon** **Date: 06/30/2006**

Organization : **Dixon Medical**

Category : **Other Health Care Provider**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

See Attached

CMS-1270-P-1153-Attach-1.DOC

June 30, 2006

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

Re: Centers for Medicare & Medicaid Services (CMS)
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

VIA: **www.cms.hhs.gov/eRulemaking**

Dear Colleagues:

As a Billing Service for Home Medical Equipment Suppliers, we welcome the opportunity to comment on this proposed rule which would implement competitive bidding programs for certain 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.

As a Billing Service, we represent the home care industry in 5 states, for stand alone and hospital based providers of home medical equipment. The following comments reflect the our collective years of experience and our assessment of the impact the above rule would have upon beneficiaries of the Medicare/Medicaid program, in addition to the impact on the providers of home medical equipment, their employees and our employees.

COMMENTS/ISSUES/QUESTIONS:

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. Along with this comes the fact that the majority of beneficiaries are supplied by small businesses. These small businesses are our clients. Due to their size, which diminishes their ability for affording accreditation, their minimal service locations and size of delivery area many of them will be excluded from the bidding process. This exclusion will in the end result in the closing of many providers r esulting in the increase in Unemployment throughout the United States. It is important to mention at this point that the United States was founded on freedom and entrepreneurship. This basically eliminates the freedom from the Medicare Beneficiary. This eliminates the entrepreneurship from the American Public as small business involvement in the Home Medical Equipment industry will be virtually eliminated.

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. The bottom line, 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..

On this point, we ask that CMS concur in the general understanding that any potential product cost savings gained through National Competitive Bidding for DMEPOS---including oxygen, wheelchairs, beds, respiratory equipment, wound care, diabetic supplies etc.---will ultimately be offset by increased costs in both the tertiary inpatient and outpatient care settings.

As the experience of DMEPOS providers demonstrates, these costs are recognized through increased administrative, oversight and program management expense, and often prevent patients from getting the most efficient and optimal health care available.

RECOMMENDATIONS: We recommend that CMS should stagger the bidding in MSAs in 2007 to allow for an orderly rollout of the program. This will actually allow CMS to identify problems that occur in the competitive bid areas and to work with providers and patients alike to help correct them before the problems become even more widespread. In addition to this staggering, CMS should move back implementation of the 2007 date, due to the questions remaining about the program, e.g. accrediting bodies and MSA's involved.

The initial MSA's and products selected should be clearly and distinctly identified in the final rule. Unfortunately however, under the current proposed CMS timeline, it appears that small DMEPOS providers will not have enough time to create legitimate and functional networks, which will ultimately eliminate, as mentioned above, "small" DMEPOS providers that want to participate, regardless of their industry knowledge, experience, and/or specialized expertise

CMS' process to determine the number of suppliers to meet projected demand in an MSA, along with its defined methodology to estimate supplier capacity, appears to heavily favor the large, high volume regional suppliers, rather than the smaller, independent DMEPOS providers, again as stated earlier, eliminating the small business and entrepreneurship of the American Public.

CMS' assertion that the NPRM provides an "equal" opportunity for small suppliers to participate is questionable, and there appears to be no guarantee that any of the winning bidders might be a small business, or even a network of small business providers.

We would urge that CMS consider the significant and potential negative impact that the NPRM may/will ultimately have on small DME businesses and upon the actual, "true" competitiveness of the second and third rounds of the competitive bidding process.

CMS should consult with the Small Business Administration to better assess the impact the NPRM will have on small businesses as both tax-paying members and constituents of the communities that they serve. Again, as mentioned above, the impact on Unemployment in those areas should be considered as well.

CMS should further explain and clarify the specific methodology that will be used to determine whether an MSA is "competitive" during the 2008 - 2009 bid expansion process.

CMS Bid scoring still needs to be improved, and more clearly defined. Suppliers need to know exactly what factors are/will be utilized and what weights will be given to these factors, especially if/when providers are attempting to bid subsets of a major product category.

CMS should explain and clarify what specific measures will be used to decide and how much an item's potential savings could be as a result of competitive bidding.

QUESTIONS: Annual Medicare DMEPOS allowed charges - Is there a specific volume/quantity, or simply a dollar threshold expenditure level that will trigger "competitive acquisition" for a particular product and/or product category? Alternatively, is there a specific threshold growth percentage in a product category that will determine whether it will be subject to competitive acquisition and/or will it vary by the overall dollar expenditures within the product category?

How will CMS determine the appropriate number of suppliers for a product category in each MSA? What specific supplier capacity thresholds will be used to determine this and how will those "capacity" thresholds be specifically determined?

How will potential "cost savings" through Competitive Acquisition be statistically determined and/or validated by actual data for the vast majority of products and categories that were not included in the two initial Demonstration Projects in FL and TX? What reports and/or types of data will be reviewed and considered when evaluating potential cost-savings? Who (either within or outside of CMS) will review the studies and determine their actual statistical validity and applicability for modeling potential future Medicare program savings? Anticipating roll out of the bid price to all areas, not just the MSA's, has CMS considered that the rural provider has significantly higher costs due to the distances traveled to deliver product to the Medicare Beneficiary?

Lack of Established Quality Standards and/or qualified "Accrediting Bodies"

The NPRM clearly states that providers must meet "quality standards," yet the proposed "final" versions of the DMEPOS provider quality standards have not yet been released. It is, therefore, difficult at best, if not impossible, to fully articulate and provides clear comments on these proposed rules for competitive biding when these rules refer to quality standards that have not been fully defined and released.

Ultimately, in the interest of establishing and providing some type of a baseline "provider standard," only accredited providers should be eligible to submit and be awarded "winning bids". In addition, accreditation MUST be affordable for the small provider. Current accrediting bodies' standards are significantly higher than those expected from CMS and their cost reflects that. CMS should not proceed with competitive bidding until it is certain that all of this is possible. CMS needs to clearly identify and establish both the objective and subjective criteria that it will use to identify and deem the accrediting bodies now, before proceeding with trying to implement the actual competitive acquisition processes.

We agree that Accreditation is and should be required, yet affordable, for any provider to service patients under the proposed rules, but again, no final, specific accreditation standards and criteria and/or approved accrediting bodies have yet been clearly identified. The proposed rule appears to still allow non-accredited organizations to bid and be awarded a bid prior to being accredited.

It remains unknown if any of the accreditation bodies will even be interested and/or have the functional accrediting capacity to undertake the standards and criteria which are yet to be specifically defined and established by this proposed rule. Therefore, accreditation organizations, as well as the associated standards, should be in place prior to any further movement towards any competitive bid. Only providers that have attained accreditation should be allowed to bid or be awarded any bid, without these organizations being named, the time constraint to meet this is clearly faulty. Patient safety and care dictates that providers should not be awarded a bid and be able to provide equipment and supplies without first demonstrating competency and proficiency in this area.

CMS should however, grandfather any/all providers that are already accredited by organizations that meet the new criteria that CMS identifies. However, CMS should then allow additional time for providers to analyze the quality standards in conjunction with the overall NPRM rule. The quality standards and cost of accreditation will ultimately affect the overall cost of servicing beneficiaries and are an integral part of the bid process. Therefore, CMS should consider further extending the NPRM comment period and any subsequent implementation plan(s), at least until those "definitive" quality standards are available and have completed the actual rule making process.

It is unrealistic to classify this process as a competitive bid when bidders are ultimately being encouraged, and essentially being forced to bid below a pre-determined price level. The result of this rule could result in bid awards that are established at unrealistic and unsustainable pricing levels. To maintain the integrity of the bidding process, CMS should have some way to objectively evaluate bids for statistical validity, sustainability and overall economic reasonableness. A mechanism for unreasonable bids needs to be incorporated in the final rule to weed out and eliminate purely "lowball" bids.

The prohibition on entities' ability to change ownership during specific periods of the bid award seems overly intrusive and an infringement on an entity's basic business rights.

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, 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.

<u>REBATE COMMENTS/ISSUES:</u>

The NPRM mentions a rebate option that contracted providers may choose to underbid and utilize based upon the idea of increasing patient volume...We believe that the potential use of "rebates" to beneficiaries in health care delivery is ultimately an unwise and potentially fraud-encouraging concept

that is without clear or reasonable legal precedent. The provision of rebates to beneficiaries is actually contradictory to other laws and regulations applicable to the Medicare program, including the Anti-Kickback Statute and the beneficiary inducement statute.

We therefore strongly encourage the elimination of this proposed "rebate" provision. Rebates could and would potentially encourage an increase in over utilization and could result in beneficiaries placing pressure on their healthcare providers to order unnecessary products and services. It is fairly certain that Congress did not intend competitive biding to include cash rebates to consumers with the potential of increasing unnecessary product utilization. We question as to whether this feature is consistent with the law.

RECOMMENDATION: The actual items that will be put up for bid should be identified now to solicit and allow further provider-based discussions and comments. 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 are 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.

The bid process needs to allow for economically r ealistic and sustainable bids, rather than simply encouraging "lower priced" bids. In the demonstration projects, some items were bid higher than the current Medicare allowable at that time. Mandating that all "winning" bids below the current Medicare level is ultimately short-sighted and unrealistic in that it effectively could negate reasonable and sustainable pricing levels which are based upon actual activity-based operational costs.

A statistically valid and accurate screening mechanism needs to be developed to completely remove and eliminate unreasonably low and ultimately unsustainable bids. The proposed rule appears to have a loophole where bidders can "low ball" their bid to grantee inclusion, yet not have to honor that "low ball" bid as their actual price paid. The use of statistical models to prevent this situation should be clearly established, defined and implemented prior to the actual biding process.

The determination of supplier's potential service capacity also needs to be better defined. It is still somewhat unclear exactly how CMS will determine a supplier's potential capacity. The proposed rule appears to discriminate and favor the large, regional providers, while the small and medium providers will effectively be shut out of the bidding process as it is currently proposed.

The process for the establishment of networks needs better definition. It is unclear as to the required corporate structure, the responsibilities of the network providers to the network administrator, the patient and CMS. The accreditation requirements for potential established or new provider networks are also still very unclear.

The two initial Competitive Acquisition demonstration projects in TX and FL ultimately neglected to look at the overall impact and costs that NCB will place on other areas of the healthcare continuum.

What economic provider relief is being considered for other areas of the healthcare continuum that will ultimately be exposed to increased costs and administrative burdens posed by NCB? Since none of these impacts were apparently evaluated or studied during the demonstration projects, there is certainly

additional potential negative care and cost implications that will likely be the result of the implementation of widespread NCB.

The NPRM in effect will result in an unfunded federal mandate for other associated members of the healthcare continuum as they seek to move and transition patients to the most clinically appropriate and cost-effective setting of care, not to mention decreased Tax Revenue due to decreased providers and employees and increased Unemployment. To rapidly facilitate acute-care inpatient and/or outpatient facility discharges, the implementation of an NCB mandate has the potential to disadvantage patients within physicians networks, hospitals, integrated healthcare delivery systems, home health, hospice, outpatient and long term care settings who will simply have to employ detrimental cost-shifting.

This concludes our comments. We value our partnership with CMS in our common mission to provide quality health care services and products for Medicare beneficiaries.

Sincerely,

Jason Dixon
President
Dixon Medical
16633 Livernois
Detroit, MI 48221
(313) 341-2100

Submitter : **Ms. Jennifer Smith** **Date: 06/30/2006**

Organization : **University Orthopedics**

Category : **Occupational Therapist**

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

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 effect the quality of service that I provide to Medicare beneficiaries as an Occupational Therapist.

My name is Jennifer Smith and I specialize in the treatment of upper extremity disorders. I have been in practice for over 20 years and have maintained certification as a hand therapist since 1991. I am currently working in an orthopedic setting and frequently treat Medicare beneficiaries that require custon and/or off the shelf orthoses.
As a hand therapist, providing orthosis is a critical component of the overall services that I provide to patients. Selecting the appropriate orthosis is based on presentation of the UE disorder, patient ADL needs, work requirements, precautions, and fit. This is usually done as part of an overall treatment plan with the aim of restoring as much UE function as possible.

I feel that the proposed competitive bidding system will compromise my ability to effectively treat these patients for several reasons. Often times the patients that I see have acute conditions or
have just had operations. This necessitates immediate fitting and adjustment of orthosis for a good outcome. Our clinic stocks a number of orthotics appropriate to upper extremity rehabilitation and commonly requested by the referring physicians. Sending a patient elsewhere for an orthotic device may result in a delay in their treatment. Oftentimes a patients needs adjustments to orthosis during the course of treatment because of edema, changes in functional status etc. Having to send patients to another facility for these services would cause a delay, possibly resulting in complications such as nerve compression. I also wonder about the legal ramifications of adjusting an orthotic that someone else has provided.

I am also concerned about the bidding process. There is a very small margin of profit received from prefabricted orthoses. In our hand therapy clinic upper extremmity orthosis are the only type of DMEs that we provide. It would be very difficult to compete with a larger supplier with a high volume of multiple items.

In conclusion I request that Medicare revise the proposed regulation to allow therpists to continue to supply critical OTS orthoses without the limitations that a competitive bidding process would provide. Therapist input and expertise in the supply of upper extremity orthoses is critical for effective treatment resulting in good outcomes for our patients.

Thank you again for this opportunity to comment on this proposed regulation.

Sincerely,

Jennifer Smith OTR/L,CHT
401-457-1581

Submitter : **Mr. James Howard** **Date: 06/30/2006**

Organization : **IRB Medical Equipment, LLC**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1155-Attach-1.DOC

CMS-1270-P-1155-Attach-2.DOC

June 30, 2006

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

Re: Centers for Medicare & Medicaid Services (CMS)
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

Dear Colleagues:

As a Home Medical Equipment Supplier here in Michigan, we welcome the opportunity to comment on this proposed rule which would implement competitive bidding programs for certain 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.

As a Supplier, we represent the home care industry in south east Michigan , as a stand alone provider of home medical equipment. The following comments reflect our collective years of experience and our assessment of the impact the above rule would have upon beneficiaries of the Medicare/Medicaid program.

COMMENTS/ISSUES/QUESTIONS:

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. At bottom, we believe that creation of a "limited provider panel" through t he p roposed n ational c ompetitive b idding (NCB) p rogram is bad p olicy f or a ll inv olved, 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.

On this point, we ask that CMS concur in the general understanding that any potential product cost savings gained through National Competitive Bidding for DMEPOS---including oxygen, wheelchairs, beds, respiratory equipment, wound care, diabetic supplies etc.---will ultimately be offset by increased costs in both the tertiary inpatient and outpatient care settings.

As the experience of DMEPOS providers demonstrates, these costs are recognized through increased administrative, oversight and program management expense, and often prevent patients from getting the most efficient and optimal health care available.

RECOMMENDATIONS: We recommend that CMS should stagger the bidding in MSAs in 2007 to allow for an orderly rollout of the program. This will actually allow CMS to identify problems that occur in the competitive bid areas and to work with providers and patients alike to help correct them before the problems become even more widespread.

The initial MSA's and products selected should be clearly and distinctly identified in the final rule. Unfortunately however, under the current proposed CMS timeline, it appears that small DMEPOS providers will not have enough time to create legitimate and functional networks, which will ultimately eliminate "small" DMEPOS providers that want to participate, regardless of their industry knowledge, experience, and/or specialized expertise.

CMS' process to determine the number of suppliers to meet projected demand in an MSA, along with its defined methodology to estimate supplier capacity, appears to heavily favor the large, high volume regional suppliers, rather than the smaller, independent DMEPOS providers.

CMS' assertion that the NPRM provides an "equal" opportunity for small suppliers to participate is questionable, and there appears to be no guarantee that any of the winning bidders might be a small business, or even a network of small business providers.

We would urge that CMS consider the significant and potential negative impact that the NPRM may/will ultimately have on small DME businesses and upon the actual, "true" competitiveness of the second and third rounds of the competitive bidding process.

CMS should at the very least consult with the Small Business Administration to better assess the impact the NPRM will have on small businesses as both tax-paying members and constituents of the communities that they serve.

CMS should further explain and clarify the specific methodology that will be used to determine whether an MSA is "competitive" during the 2008 - 2009 bid expansion process.

CMS Bid scoring still needs to be researched, and more clearly defined. Suppliers need to know exactly what factors are/will be utilized and what weights will be given to these factors, especially if/when providers are attempting to bid subsets of a major product category.

CMS should explain and clarify what specific measures will be used to decide which items are going to be bid, and how much an item's potential savings could be as a result of competitive bidding.

QUESTIONS: Annual Medicare DMEPOS allowed charges - Is there a specific volume/quantity, or simply a dollar threshold expenditure level that will trigger "competitive acquisition" for a particular product and/or product category? Alternatively, is there a specific threshold growth percentage in a product category that will determine whether it will be subject to competitive acquisition and/or will it vary by the overall dollar expenditures within the product category?

How will CMS determine the appropriate number of suppliers for a product category in each MSA? What specific supplier capacity thresholds will be used to determine this and how will those "capacity" thresholds be specifically determined?

How will potential "cost savings" through Competitive Acquisition be statistically determined and/or validated by actual data for the vast majority of products and categories that were not included in the two initial Demonstration Projects in FL and TX? What reports and/or types of data will be reviewed and considered when evaluating potential cost-savings? Who (either within or outside of CMS) will review the studies to determine their actual statistical validity and applicability for modeling potential future Medicare program savings?

Lack of Established Quality Standards and/or qualified "Accrediting Bodies"

The NPRM clearly states that providers must meet "quality standards," yet the proposed "final" version of the DMEPOS provider quality standards have not yet been released. It is, therefore, difficult at best, if not impossible, to fully articulate and provide clear comments on these proposed rules for competitive biding when these rules refer to quality standards that have not been fully defined and released.

Ultimately, in the interest of establishing and providing some type of a baseline "provider standard," only accredited providers should be eligible to submit and be awarded "winning bids". CMS should not proceed with competitive bidding until it is certain that this is possible. CMS needs to clearly identify and establish both the objective and subjective criteria that it will use to identify and deem the accrediting bodies now, before proceeding with trying to implement the actual competitive acquisition processes.

Accreditation is and should be required for any provider to service patients under the proposed rules, but again, no final specific accreditation standards and criteria and/or approved accrediting bodies have yet been clearly identified. The proposed rule appears to still allow non-accredited organizations to bid and be awarded a bid prior to being accredited.

It remains unknown if any of the accreditation bodies will even be interested and/or have the functional accrediting capacity to undertake the standards and criteria which are yet to be specifically defined and established by this proposed rule. Therefore, accreditation organizations, as well as the associated standards, should be in place prior to any further movement towards any competitive bid. Only providers that have attained accreditation should be allowed to bid or be awarded any bid. Patient safety and care dictates that providers should not be awarded a bid and be able to provide equipment and supplies without first demonstrating competency and proficiency in this area.

CMS should however, grandfather any/all providers that are already accredited by organizations that meet the new criteria that CMS identifies. However, CMS should then allow additional time for providers to analyze the quality standards in conjunction with the overall NPRM rule. The quality standards will ultimately affect the overall cost of servicing beneficiaries and are an integral part of the bid process. Therefore, CMS should consider further extending the NPRM comment period and any subsequent implementation plan(s), at least until those "definitive" quality standards are available and have completed the actual rule making process.

It is unrealistic to classify this process as a competitive bid when bidders are ultimately being encouraged, and essentially being forced to bid below a pre-determined price level. The result of this rule could result in bid awards that are established at unrealistic and unsustainable pricing levels. To maintain the integrity of the bidding process, CMS should have some way to objectively evaluate bids for statistical validity, sustainability and overall economic reasonableness. A mechanism for unreasonable bids needs to be incorporated in the final rule to weed out and eliminate purely "lowball" bids.

The prohibition on entities' ability to change ownership during specific periods of the bid award seems overly intrusive and an infringement on an entity's basic business rights.

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, 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.

REBATE COMMENTS/ISSUES:

The NPRM mentions a rebate option that contracted providers may choose to underbid and utilize based upon the idea of increasing patient volume...We believe that the potential use of "rebates" to beneficiaries in health care delivery is ultimately an unwise, and potentially fraud-encouraging concept that is without clear or reasonable legal precedent. The provision of rebates to beneficiaries is actually contradictory to other laws and regulations applicable to the Medicare program, including the Anti-Kickback Statute and the beneficiary inducement statute.

We therefore strongly encourage the elimination of this proposed "rebate" provision. Rebates could and would potentially encourage an increase in over utilization and could result in beneficiaries placing pressure on their healthcare providers to order unnecessary products and services. It is fairly certain that Congress did not intend competitive biding to include cash rebates to consumers with the potential of increasing unnecessary product utilization. We question as to whether this feature is consistent with the law.

RECOMMENDATION: The actual items that will be put up for bid should be identified now to solicit and allow further provider-based discussions and comments. 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.

The bid process needs to allow for economically realistic and sustainable bids, rather than simply encouraging "lower priced" bids. In the demonstration projects, some items were bid higher than the current Medicare allowable at that time. Mandating that all "winning" bids below the current Medicare level is ultimately short-sighted and unrealistic in that it effectively could negate reasonable and sustainable pricing levels which are based upon actual activity-based operational costs.

A statistically valid and accurate screening mechanism needs to be developed to completely remove and eliminate unreasonably low and ultimately unsustainable bids. The proposed rule appears to have a loophole where bidders can "low ball" their bid to grantee inclusion, yet not have to honor that "low ball" bid as their actual price paid. The use of statistical models to prevent this situation should be clearly established, defined and implemented prior to the actual biding process.

The determination of supplier's potential service capacity also needs to be better defined. It is still somewhat unclear exactly how CMS will determine a supplier's potential capacity. The proposed rule appears to discriminate and favor the large, regional providers, while the small and medium providers will effectively be shut out of the bidding process as it is currently proposed.

The process for the establishment of networks needs better definition. It is unclear as to the required corporate structure, the responsibilities of the network providers to the network administrator, the patient and CMS. The accreditation requirements for potential established or new provider networks are also still very unclear.

The two initial Competitive Acquisition demonstration projects in TX and FL ultimately neglected to look at the overall impact and costs that NCB will place on other areas of the healthcare continuum.

What economic provider relief is being considered for other areas of the healthcare continuum that will ultimately be exposed to increased costs and administrative burdens posed by NCB? Since none of these impacts were apparently evaluated or studied during the demonstration projects, there is certainly additional potentially negative care and cost implications that will likely be the result of the implementation of widespread NCB.

The NPRM in effect will result in an unfunded federal mandate for other associated members of the healthcare continuum as they seek to move and transition patients to the most clinically appropriate and cost-effective setting of care. To rapidly facilitate acute-care inpatient and/or outpatient facility discharges, the implementation of an NCB mandate has the potential to disadvantage patients within physicians networks, hospitals, integrated healthcare delivery systems, home health, hospice, outpatient and long term care settings who will simply have to employ detrimental cost-shifting.

This concludes our comments. We value our partnership with CMS in our common mission to provide quality health care services and products for Medicare beneficiaries.

Sincerely,

James Howard, Manager IRB Medical Equipment, LLC

June 30, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1270-P
P.O. Box 8013
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Re: Centers for Medicare & Medicaid Services (CMS)
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This concludes our comments. We value our partnership with CMS in our common mission to provide quality health care services and products for Medicare beneficiaries.

Sincerely,

James Howard, Manager IRB Medical Equipment, LLC

Submitter : **Dr. joseph caporusso** **Date: 06/30/2006**

Organization : **APMA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 30, 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 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 weightbearing 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,

Joseph M. Caporusso, DPM
Board of Trustees
American Podiatric Medical Association

Submitter : **Mr. Dennis Herrick** **Date: 06/30/2006**

Organization : **Beaumont Hospitals**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1270-P-1157-Attach-1.DOC

#1157

Beaumont ®

William Beaumont Hospitals, Corporate Administration
Dennis R. Herrick, Senior Vice President and Chief Financial Officer

June 30, 2006

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

Re: Centers for Medicare & Medicaid Services (CMS)
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

Dear Colleagues:

On behalf of the Beaumont Hospitals, I am writing to provide comments on the proposed rule for competitive bidding for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) under the Medicare program. We have serious concerns with this approach as it could seriously disadvantage non-profit community hospitals that provide a full range of healthcare services to Medicare beneficiaries while benefiting for-profit durable medical equipment companies that provide only limited services to Medicare beneficiaries.

The following is information about our Royal Oak hospital and our integrated health system, which I hope will give you an understanding of our perspective.

In 2004, Beaumont, Royal Oak had the highest number of admissions--57, 970--of any single hospital in the country. It also had the second highest number of surgeries--63,627. And, according to CMS data, it had the second highest number of Medicare admissions of any hospital in the country--24,853. Therefore, we have a significant population of our patients who are candidates for DMEPOS when they are discharged from the hospital. Last year, our home medical equipment program serviced over 24,000 new patients, and had over 4,000 recurring "rental equipment" patients on service, in addition to several thousand more repetitive supply (diabetic, ostomy, wound care, and urological) reorder-patients on an annual basis.

Beaumont's focus has always been on the patient and providing the most appropriate, cost-effective health care possible. We are consistently listed on the *U.S. News & World Report's* "America's Best Hospitals" and on *Solucient's* "Top 100 Hospitals" lists. In order to achieve efficiencies, Beaumont provides a continuum of health care services, including skilled nursing homes, home infusion, home health care, and a durable medical equipment (DME) company. And, because our integrated health system shares the same patient-focused mission, Beaumont acts differently than a for-profit durable medical equipment company that does not have the same financial incentives in providing services. Let me give you some real-life examples to illustrate this point.

A Beaumont patient was ready to be discharged on a Friday but needed a special bariatric, heavy duty bed as well as a specialized low air loss mattress for the treatment of existing pressure sores, which had to be provided by the DME company that had been "exclusively" contracted with the patient's private health insurer. Unfortunately, that single, exclusive provider DME company did not have the correct bed or mattress system available needed to facilitate a safe and effective hospital discharge. Instead, it informed our Care Management Department that it could only deliver it to the patient's home by the following Tuesday, which would have resulted in an unnecessary four-day increase in the patient's length of stay. We looked at the patient's needs and the potential increase in hospital costs if the patient was not discharged. Beaumont's own DME company delivered the appropriate bed and mattress so she could be discharged on Friday, and then replaced our bed with the other DME company's bed the following Tuesday. Did we incur costs for which we were not reimbursed for our DME services? Yes. Did that reduce overall health care costs in the system by discharging the patient from an acute care setting to her home? Yes. Did her DME company have any financial incentive to provide the bed more quickly? No.

Two years ago, there was a major electrical outage in southeast Michigan and in the entire Midwest portion of the United States, where hundreds of thousands of homes lost power for over 48 hours. During that time, the two largest, for-profit DME companies in the country actually advertised on the radio that they would not be able to deliver oxygen to their customers during the blackout. Instead, they advised their customers to go to their nearest hospital emergency room. Did this result in higher health care costs to the Medicare program? You bet. Beaumont's DME company, along with most of the other hospital-based DMEPOS providers, and even many of the smaller, independent DMEPOS providers, continued providing services to not only all of our patients, but to numerous other patients whose DME companies were not responding to calls during the blackout – patients for whom we were not paid.

These two examples illustrate why Beaumont is very concerned over any competitive bidding process for DME, oxygen, or other supplies. For-profit health care businesses have a totally different motivation and mission than do nonprofit, hospital-based DME organizations. Beaumont is committed to the patient and overall cost-effectiveness of health care services. While a competitive bidding program may save some dollars on DME equipment or supplies, we question whether there will be overall savings in the Medicare program or whether there will only be cost-shifting that will occur.

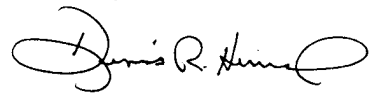
Beaumont is also concerned that with competitive bidding, one patient could end up having to receive differently awarded supplies or equipment from two or even three different DME companies in the area. This could be confusing, if not overwhelming, for that patient and will certainly increase the administrative/delivery costs in total for that one patient, as opposed to having one provider supplying all of the services that patient may need.

For these reasons, we encourage CMS to include in the definition of a contract provider "an entity that is owned and operated by a hospital system."

You will be receiving numerous letters with specific recommendations from hospital-based and community-based DME providers. While I hope you will consider their detailed recommendations, I also hope you will reconsider whether competitive bidding is in the best interests of Medicare beneficiaries.

Thank you for the opportunity to comment.

Sincerely,



Dennis R. Herrick

KJM/sk

3601 West 13 Mile Road Royal Oak, Michigan 48073-6769
(248) 551-0677

Submitter : Dr. MAX TODD HYATT **Date:** 06/30/2006

Organization : THE TRIAD FOOT CENTER

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 30, 2006

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

Dear Mr. McClellan:

I am writing to urge the Centers for Medicare & Medicaid Services (CMS) to revise 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).

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 judgement 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, 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)(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 negative impacted.

Sincerely,

Max Todd Hyatt, DPM
The Triad Foot Center, PA

Submitter : **Ms. Barbara Garlock** **Date: 06/30/2006**

Organization : **Wyrick Robbins**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-1159-Attach-1.DOC

CMS-1270-P-1159-Attach-2.DOC

#1159

BARBARA B. GARLOCK
bgarlock@wyrick.com

June 30, 2006

Via Electronic Submission

The Honorable Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human services
Attention: CMS-1270–P
PO Box 8013
Baltimore, MD 21244-1850

Re: [CMS-1270–P] Comments to Proposed Rules for Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS), 71 Fed. Reg. 25654 (May 1, 2006)

Dear Dr. McClellan,

The comments that follow are submitted on behalf of our client, a durable medical equipment (DME) supplier, regarding the above-referenced proposed rules.

Our Client

The supplier we represent is a DMEPOS supplier in three states in the southeast, with approximately $1.3 million per year in sales. It is accredited by ACHC, and specializes in orthopedic orthoses, OTS as well as custom, and provides certain DME, such as CPMs. Not a retail operation selling directly to the public, our client has contracts with hospitals, surgery centers and clinics to provide the specific type of products the physician requires for proper care and treatment of their patients. Representing numerous manufacturing lines ensures that physicians can readily obtain the best product for the care and treatment of their patients. Our client also provides support to physicians and facilities -- and their patients -- in rural as well as metropolitan areas. Services to Medicare beneficiaries constitutes 14% of our client's total volume, and some facility/clinic accounts have a Medicare patient mix as high as 27%.

General Comments

We understand that these proposed rules are a result of provisions in section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and recognize that these rules are authorized by that Act.

General Comment: This program affords a substantial competitive advantage to large suppliers and product manufacturers that have their own internal distribution networks. By doing so, this program will cut out the small or specialty supplier. Competitive bidding will funnel most of the small supplier business to large national chains, eliminating small businesses from the local landscape. Small business is an integral component of every community and should be promoted, not undermined (or destroyed) by government regulation.

By eliminating the small or specialty supplier, the Medicare patient will not always get the best product to meet his or her needs. Moreover, if the number of approved suppliers in a specific MSA is limited, and those suppliers are also product manufacturers, then the variety of similar products available for a physician to dispense will be limited. Patients and physicians will have a dramatically reduced choice of suppliers and DME products. This artificial limitation of available products not only may translate to patient harm, but could affect physician malpractice liability if the physician elects not to prescribe a product outside the approved list.

General Comment: We note that the monopolistic effects of the underlying legislation have not been wholly overlooked by Congress and should be borne in mind by CMS as the public comments are considered: H.R. 3559, the Hobson-Tanner Bill, now pending in Congress and with more than 100 co-sponsors, if enacted would rectify some of the inequities and anti-competitive effects of both the MMA and this proposed rule. The Bill provides protections for beneficiaries and suppliers that remedy many of the flaws in the competitive acquisition provisions of MMA. CMS should take official notice that this Bill explicitly acknowledges the inherent anti-competitive effects of this program.

Recommendation: CMS should carefully consider the provisions of H.R. 3559, which seeks to amend the MMA to add protections for beneficiaries and providers. Among other provisions, the bill would:

- Protect patients by requiring that "competitive bidding" not begin until quality standards are in place;
- Exempt smaller, rural areas (Metropolitan Statistical Areas with populations under 500,000);
- Allow all qualified providers to participate at the selected award price;
- Restore the rights of participating providers to administrative and judicial review;

• Exempt items and services unless savings of at least 10 percent can be demonstrated.

General Comment: Competitive bidding will curtail the innovation in DME products, which will translate in practical terms to lower quality of life for patients. As reimbursement is forced down, manufacturers will have no economic incentive to continue to develop innovative products and enhancements. DME innovators do not have the research and development support that pharmaceutical companies enjoy to develop beneficial new products, and reduced reimbursement and barriers to entry or exclusion from the market will create powerful disincentives toward innovation.

General Comment: In our view, there is no place for so-called "competitive bidding" in health care. Scholars and industry commentators have long observed that health care inherently is not subject to the normal forces of market competition, in part because the industry is driven by

patient needs which vary across individuals and over time, and require the inviolable duty to provide quality products and responsive service to protect patient health and well-being. It is for this reason that health care is so highly regulated, and appropriately so; market forces do not readily lend themselves to the competing demands of health care delivery. We assert that the bidding process will keep prices artificially low and erode choice, quality and service, ultimately to the detriment of patients.

General Comment: The bidding process is flawed because it ignores market forces forcing suppliers to take a loss in order to win a demonstration bid. Anecdotal evidence not presented in the proposed rule but reported elsewhere in the literature indicates that many of the suppliers in the Polk County demonstration project did not understand the bidding process and bid extremely low on certain items —considering them loss leaders—in the hope of winning bids on other equipment. Those low bids led to severe drops in revenue which imperil the very existence of their businesses.

General Comment: The proposed competitive bidding program will create a government-sanctioned monopoly in a limited number of suppliers. It also will serve as an effective bar to the entry of new suppliers and innovative equipment into the marketplace. Any program -- even if its name suggests that it *promotes* competition -- which has the effect of *limiting* competition, is not good for health care, for patients, or for taxpayers. Certainly Medicare dollars need to be saved, but this is not the way to do it.

Section I.G. Program Advisory and Oversight Committee

Comment: The CMS Program Advisory and Oversight Committee on competitive bidding (PAOC) wields great power within the DMEPOS industry. Affected persons

have not had an opportunity to review or respond to PAOC assertions or recommendations.

Recommendation: The POAC should be subject to the Federal Advisory Committee Act (FACA), which requires public access to meetings and proceedings.

Section II.B. Implementation Contractor

Comment: We are concerned about the identity and business relationships of "appropriate entities" that the CMS Secretary will contract with to implement the competitive bidding program. In our view, much of this proposed rule appears to create potentially monopolistic power in certain selected entities, rather than allow free market competition. We recommend that competitive bidding implementation contractors (CBICs) and any entities to which they are structurally or contractually affiliated with through partnerships, subsidiaries, or direct or indirect contractual arrangements be absolutely prohibited from participating in bidding.

Section II.C. Payment Basis
Section II.H. Determining Single Payment Amounts for Individual Items

Comment: It appears that information from unqualified bidders may be used in calculating the "single payment amount" (the winning bid amount). This means that a business which is incapable of meeting the financial and quality standards to be a supplier under the competitive

acquisition program nonetheless can submit a "lowball bid" that will fundamentally taint the calculation of the final amount.

Recommendation: Lowball bids submitted by contractors who are not selected should not be included in determining the single payment amount.

Section II.D. Competitive Bidding Areas

Comment: The timetable for the program roll-out, set to begin in the Fall of 2006, does not provide an adequate opportunity for CMS to meaningfully review the comments to the proposed rule.

Recommendation: Implementation should be delayed indefinitely to permit thoughtful review, and as necessary, revision of the proposed rule and additional opportunity for public comment.

Comment: Under the MMA, the Secretary can use competitive acquisition bid rates in one MSA to set the reimbursement for another MSA. Before doing so the Secretary should conduct a comparability analysis of the two MSAs to help prevent any applications of bid rates outside of an MSA that are inappropriate.

Recommendation: Beneficiary access to care should be protected by requiring CMS to conduct a comparability analysis for areas that are not competitively bid to ensure the rate is appropriate to costs and does not reduce access to care.

Section II.D. Competitive Bidding Areas
Section II.E. Criteria for Item Selection

Comment: A number of our client's product groups are expected to be affected by the competitive bidding rules: lower limb orthoses; upper limb orthoses; spinal orthoses; walkers; commodes; and continuous passive motion exercise devices. Without a specific list of included HCPCS Codes, however, we cannot project exactly which products will be affected, and therefore we find it challenging to offer specific comments that will assist CMS in evaluating the proposed rules. For this reason, after the initial roll-out of the competitive bidding program, DME suppliers and other affected persons should be offered additional opportunity to submit public comments before the implementation of the next phase of the program.

Recommendation: After the initial roll-out of the competitive bidding program (now projected to occur in 2007), we will have a better sense than we do now of what products are included and how the program will affect suppliers; therefore, CMS should issue new proposed or interim final rules and provide an additional opportunity for affected persons to submit public comments before the implementation of the next phase of the program (now projected to occur in 2009).

Section II.D. Competitive Bidding Areas

Comment: The failure to identify the geographic regions where competitive acquisition programs become effective in 2007 leaves prospective suppliers without adequate information to submit bids. By waiting until the final rule is published, it will be impossible for providers to begin gathering the necessary data to submit realistic bids. This is especially problematic because, once the single payment amount is established, winning suppliers will have to live with that amount for years. While this payment purportedly will be adjusted each year for inflation, Congress has a practice of freezing Medicare payment rates.

Section II.E. Criteria for Item Selection

Comment: By failing to identify the specific products that will be included in the competitive acquisition program, CMS prevents suppliers from accurately evaluating all of the costs associated with procuring, delivering, and servicing those products. In our view, this is a transparent attempt to elicit unsustainable lowball bids.

Recommendation: A list of the products subject to competitive acquisition should be published at least 12 months in advance of the date that bids are due.

Section II.E. Criteria for Item Selection
Section II.F. Submission of Bids Under the Competitive Bidding Program

Comment: Continuous passive motion exercise devices (CPMs) are not listed in Table 3 ("2003 High Volume Items [HCPCS Codes]"), 71 Fed. Reg. 25670, or in Table 10 ("Allowed Charges: Top Eligible DME Policy Groups"), 71 Fed. Reg. 25691, but are specifically mentioned as affected by this proposed rule on 71 Fed. Reg. 25673 under item 4(b).

In addition, we note that the list of possibly-affected DMEPOS does not include canes or crutches, which presumably are frequently-purchased items.

Section II.F. Submission of Bids
Section V. Effect on Suppliers

Comment: The argument that bundling and product specialization will allow suppliers "to realize economies of scope" and "furnish a bundle of items at a lower cost" is bogus, 71 Fed. Reg. 25673, as is the assertion that "the increase in the supplier's volume could offset the decrease in revenue per item." 71 Fed. Reg. 25694.

Suppliers may be able make up for some of the reduced reimbursements by furnishing a bundle of items at a lower cost than it can produce each item individually. This only makes sense if a bundle of products goes to the same patient. Otherwise, the administrative/overhead costs of supplying products, supporting patients, filing claims and billing patients are not reduced. In addition, the cost of manufacturing a bundle of products would not be reduced as each item in the bundle still has to be manufactured individually.

Similarly, the assertion that small suppliers might be able to offset some of the lower reimbursements through product specialization is questionable. For a company like our client, the administrative and overhead costs associated with supplying, for example, only Upper Body Orthoses, are no different than supplying both Upper and Lower Body

Orthoses. Consequently, if a small provider who currently offers a wide range of products decides to specialize in one

product category, that provider would have to see a significant increase in volume in the product specialization area to offset the loss of income in the expanded areas. Finally, it is doubtful that

a small, specialized provider would be selected as one of only a few approved providers in an MSA when the larger providers could supply a wider range of products and services. Thus innovation and specialization are not promoted by this proposed rule.

Section II.F. Submission of Bids

Comment: There is no provision for allowing approved suppliers to add new products to their offering mix during the contractual period, thereby limiting provider growth only to products within the contracted product categories. Bids initially will be solicited and approved each year for the first two years and then move to a three-year schedule. This will prevent an approved provider from expanding its product line until the bid renewal stage. While the proposed rules do have a provision for new product development, they do not address enhancements to existing products that an approved provider may want to offer.

For example, if our client were an approved provider of Upper and Lower Body Orthoses and wanted to move into Spinal Orthoses, as a practical matter it could not do so until the contract was next up for renewal.

Comment: Bids are submitted for items grouped into product categories consisting of items that are used together to treat a medical condition, though separate bids for each item are required, for example, hospital beds and necessary accessories. Medicare patients will be able to receive all of their related products from one supplier by using this method. Bids must include all costs related to furnishing an item, including all services directly related to the furnishing of the item. CMS apparently believes that this approach is more favorable for small suppliers because they can choose to specialize in only one product category. This means, however, that small suppliers will have to retool their business lines, abandon other product lines, and likely be unable to compete with larger contracting suppliers. This is not an advantage.

Section II.G. Conditions for Awarding Contracts

Comment: The proposed rule references quality standards and accreditation, but these standards have yet to be published in final form. In addition, suppliers need sufficient time to become accredited, once accreditation organizations have received "deemed status" from CMS. By publishing the proposed rule on competitive acquisition before the

quality standards have been published, CMS has acted prematurely, to the substantial detriment of those in the industry striving to comply with CMS requirements.

Comment: The proposed rules concerning market demand detail how the number of suppliers per area will be selected and how markets will be expanded. It appears that these projections are based off of two years of *previous* claims data and the number of new beneficiaries that entered the program on a monthly basis over the *previous* two years. This approach means that there probably will not be sufficient providers in the system when "Baby Boomers" start retiring. It is surprising that CMS is not taking a proactive approach and projecting how many beneficiaries are likely to enter the program each month over the *future* three years (since the contracts are on a three-year basis).

As is widely known, the Baby Boomers just started turning 60. In five years, the first of the Boomers will become eligible for Medicare. If CMS bases its selection of providers (the number of providers per area) on 2009 and 2010 data and gets hit with the Boomers turning 65 in 2011 and 2012, wouldn't we be a little short of providers?

Comment: CMS will want to estimate supplier capacity to meet the projected demand. CMS will ask suppliers to say how many units they are willing and capable of supplying at the bid price in the competitive bidding area and will require evidence of financial resources to support potential market expansion. As discussed above, without full information, this will be difficult to project, and a supplier risks either overstating or understating the amount. In addition, the examination of financial resources for market expansion likely creates a bias against small suppliers.

Comment: The MMA allows the Secretary to contract with only as many providers as the Secretary deems necessary to meet the demand of an area. Any provider not awarded a contract would be prohibited from participating in Medicare for up to three years. Small businesses not awarded a contract should be entitled to continue to provide DME in Medicare at the competitive acquisition bid rate.

Recommendation: Allow all qualified suppliers that are small businesses and that submitted a bid below the current allowable to participate at the selected award price.

Section II.H. Determining Single Payment Amounts for Individual Items

Comment: The proposed rule introduces the concept of "consumer rebates." Although the rebate is described as "voluntary," the language of the proposed rule indicates that if a rebate is offered in one instance, it must be offered in all cases and becomes "a binding contractual obligation ... during the term of the contract with CMS." Requiring a low-bid contracting supplier to offer rebates has no legitimate basis, including in the authorizing sections of the MMA, and indeed runs counter to decades of health law that prohibits suppliers from offering inducements to beneficiaries as potentially violative of the fraud and abuse laws. By failing to identify the specific products that will be

included in the competitive acquisition program, suppliers cannot accurately evaluate all of the costs associated with procuring, delivering, and servicing those products to arrive at an appropriate price. Because the bids will be submitted without full information, including the as-yet-to-be-determined "single payment amount," requiring the supplier to offer a consumer rebate for a bid below the single payment amount will be punitive. In addition, if the contracting supplier inappropriately offered too low a bid as compared to others in the same market due to a lack of full information, mandating a rebate could threaten the viability of continued participation as a supplier.

Recommendation: Abandon the concept of consumer rebates.

Section II.L. Opportunity for Networks

Comment: The supplier network concept will increase costs, legal liabilities, and financial exposure for small suppliers. Small suppliers typically have higher operating expenses as they are not the actual manufacturers and do not have volume negotiating clout with their manufacturers.

The proposed rule provides that to compete, small suppliers can band together to submit a "group or network" bid on the products. Not only does this sound like government sanctioned price-fixing, but there are severe limitations to the workability of this proposal. In particular, the small supplier network has to be a formalized, legal (contractual) arrangement with one entity designated as the primary entity. If one party to the network "goes down," the entire network will be affected – and possibly terminated -- by Medicare.

The proposed rule does not address the substantial expenses associated with affiliating with other accredited small suppliers. There also will be increased costs to the small supplier to formalize the contractual arrangement and a huge legal and financial liability to the small supplier if one of the network parties is a "bad apple," or competitors participating in the network do not provide full information or provide faulty information.

Those small suppliers whose competitors elect not to include them in a network likely will soon go out of business.

It is especially problematic that a small supplier can be part of only *one* network group. Equally troublesome is the proposed rule that a small supplier may not submit an independent bid for one product group and also bid as part of a network for another product group. For example, a small supplier could not bid independently for Upper Body Orthoses and as part of a network for Spinal Orthoses. Therefore the small supplier most likely will have to find and negotiate a contract with more than one other partner to ensure all items in all of the product groups are covered. *Each* of those partners would have to meet Medicare's financial requirements and be accredited, likely a substantial expense – and possibly prohibitively expensive to the smaller suppliers. This is not a

practical solution for small suppliers -- and probably why no one in the two pilot programs in Florida and Texas participated this way.

Comment: Each network must form a single legal entity that acts as the bidder. Each member of the network must meet all accreditation and quality standards. The network members' share of the market for a product category cannot exceed 20% of the Medicare market within a competitive bidding area. How are members to determine this share? If it fluctuates, must the network close down?

Section II.J. Administrative or Judicial Review

Comment: The non-availability of administrative review violates not only the Administrative Procedures Act, but also individual and corporate rights to due process and to redress grievances.

Recommendation: Appeal rights should be restored; these rights exist elsewhere in the Medicare program.

Section II.O. Physician Authorization/Treating Practitioner

Comment: Section 1847(a)(5)(A) of the MMA allows a physician to prescribe a specific brand of product or mode of delivery if the physician determines that use of that item "would avoid an adverse medical outcome." Even so, the proposed rule indicates that contract suppliers would have the option of (a) providing the product, (b) finding another contract provider who can

provide it, or (c) consulting with the physician to find a "suitable alternative product." This will lead to delays, possible patient harm, and attempts to unduly influence physician judgment regarding appropriate DME items for patients.

Comment: Manufacturers will look to reduce their production costs by using cheaper materials, or cut corners in manufacturing processes. Large suppliers will look to improve their profit margins by switching to lower end products.

Comment: The Medicare patient will end up with cheap products or "alternative substitutes" that may not provide the degree of support needed, which could ultimately lead to increased costs to Medicare for repeat patient treatments.

Section V.C. Implementation Costs
Section V.D. Program Savings

Comment: There is no evidence that competitive bidding lowers governmental expenditures. The government's own test cases are inconclusive as very modest rate differentials were offset by incremental administrative costs.

It only makes sense that administrative costs will increase substantially, quite likely offsetting any cost savings. The only administrative costs listed in the proposed rules are the initial fixed costs for contractor startup, system changes, and bid evaluations for 2006, which are stated as $1 million. It strains credulity to imagine that all of the costs to administer a new competitive bidding program across this country would not exceed the current costs to review claim filing information and publish fee schedules. Although some of the tasks will be delegated to CBICs, that also will lead to substantial costs to the program, and ultimately to taxpayers. By overstating projected savings and understating costs, CMS violates not only the Administrative Procedures Act but also the various the federal statutes and Executive Orders requiring accurate reporting of overall impact to make it possible to determine whether other regulatory approaches would accomplish the objective more efficiently. (*See* 71 Fed. Reg. 25690.)

Recommendation: The numbers offered are not clear, and not credible. At minimum, CMS should publish the actual savings for the pilot programs reported at 71 Fed. Reg. 25692, the beneficiary savings reported at 71 Fed. Reg. 25693, and the estimated net cost savings to Medicare (that is, payouts less administrative costs). A new Notice of Proposed Rulemaking should be issued, with additional opportunities to comment, with more realistic figures.

Section V.D. Program Savings

Comment: Under the MMA, the Secretary can only competitively acquire an item if the Secretary believes that doing so would result in significant savings to Medicare. It is important for the Secretary to show that the savings from competitive acquisition justify constructing a bureaucracy to implement the program.

Recommendation: To justify this program, the Secretary should select as items for competitive acquisition only those shown to result in savings to the Medicare program of at least 10 percent.

Section V.F.2. Effect on (Small) Suppliers

Comment: Highly customized items will be excluded from the competitive acquisition program. This will have an adverse impact on patients, as well as specialty suppliers who cannot be contract suppliers for these items.

Comment: The cost to small suppliers is vastly understated. Suppliers who submit bids will incur the cost of bidding, as well as joining a network, and ensuring that all of its members are accredited. The proposed arrangement also will require members of the network to monitor the market share of the network to ensure that it does not exceed 20%. Even if this information were readily available, the proposed rules provide no protection from the antitrust laws from sharing price and other competitive information among members of the network.

Thank you for the opportunity to submit comments. We look forward to reading your responses, and encourage a wholesale rethinking of this program.

Sincerely,

WYRICK ROBBINS YATES & PONTON, LLP

Barbara Garlock

#1159.

BARBARA B. GARLOCK
bgarlock@wyrick.com

June 30, 2006

Via Electronic Submission

The Honorable Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human services
Attention: CMS-1270–P
PO Box 8013
Baltimore, MD 21244-1850

Re: [CMS-1270–P] Comments to Proposed Rules for Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS), 71 Fed. Reg. 25654 (May 1, 2006)

Dear Dr. McClellan,

The comments that follow are submitted on behalf of our client, a durable medical equipment (DME) supplier, regarding the above-referenced proposed rules.

Our Client

The supplier we represent is a DMEPOS supplier in three states in the southeast, with approximately $1.3 million per year in sales. It is accredited by ACHC, and specializes in orthopedic orthoses, OTS as well as custom, and provides certain DME, such as CPMs. Not a retail operation selling directly to the public, our client has contracts with hospitals, surgery centers and clinics to provide the specific type of products the physician requires for proper care and treatment of their patients. Representing numerous manufacturing lines ensures that physicians can readily obtain the best product for the care and treatment of their patients. Our client also provides support to physicians and facilities -- and their patients -- in rural as well as metropolitan areas. Services to Medicare beneficiaries constitutes 14% of our client's total volume, and some facility/clinic accounts have a Medicare patient mix as high as 27%.

General Comments

We understand that these proposed rules are a result of provisions in section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and recognize that these rules are authorized by that Act.

General Comment: This program affords a substantial competitive advantage to large suppliers and product manufacturers that have their own internal distribution networks. By doing so, this program will cut out the small or specialty supplier. Competitive bidding will funnel most of the small supplier business to large national chains, eliminating small businesses from the local landscape. Small business is an integral component of every community and should be promoted, not undermined (or destroyed) by government regulation.

By eliminating the small or specialty supplier, the Medicare patient will not always get the best product to meet his or her needs. Moreover, if the number of approved suppliers in a specific MSA is limited, and those suppliers are also product manufacturers, then the variety of similar products available for a physician to dispense will be limited. Patients and physicians will have a dramatically reduced choice of suppliers and DME products. This artificial limitation of available products not only may translate to patient harm, but could affect physician malpractice liability if the physician elects not to prescribe a product outside the approved list.

General Comment: We note that the monopolistic effects of the underlying legislation have not been wholly overlooked by Congress and should be borne in mind by CMS as the public comments are considered: H.R. 3559, the Hobson-Tanner Bill, now pending in Congress and with more than 100 co-sponsors, if enacted would rectify some of the inequities and anti-competitive effects of both the MMA and this proposed rule. The Bill provides protections for beneficiaries and suppliers that remedy many of the flaws in the competitive acquisition provisions of MMA. CMS should take official notice that this Bill explicitly acknowledges the inherent anti-competitive effects of this program.

Recommendation: CMS should carefully consider the provisions of H.R. 3559, which seeks to amend the MMA to add protections for beneficiaries and providers. Among other provisions, the bill would:

- Protect patients by requiring that "competitive bidding" not begin until quality standards are in place;
- Exempt smaller, rural areas (Metropolitan Statistical Areas with populations under 500,000);
- Allow all qualified providers to participate at the selected award price;
- Restore the rights of participating providers to administrative and judicial review;

• Exempt items and services unless savings of at least 10 percent can be demonstrated.

General Comment: Competitive bidding will curtail the innovation in DME products, which will translate in practical terms to lower quality of life for patients. As reimbursement is forced down, manufacturers will have no economic incentive to continue to develop innovative products and enhancements. DME innovators do not have the research and development support that pharmaceutical companies enjoy to develop beneficial new products, and reduced reimbursement and barriers to entry or exclusion from the market will create powerful disincentives toward innovation.

General Comment: In our view, there is no place for so-called "competitive bidding" in health care. Scholars and industry commentators have long observed that health care inherently is not subject to the normal forces of market competition, in part because the industry is driven by

patient needs which vary across individuals and over time, and require the inviolable duty to provide quality products and responsive service to protect patient health and well-being. It is for this reason that health care is so highly regulated, and appropriately so; market forces do not readily lend themselves to the competing demands of health care delivery. We assert that the bidding process will keep prices artificially low and erode choice, quality and service, ultimately to the detriment of patients.

General Comment: The bidding process is flawed because it ignores market forces forcing suppliers to take a loss in order to win a demonstration bid. Anecdotal evidence not presented in the proposed rule but reported elsewhere in the literature indicates that many of the suppliers in the Polk County demonstration project did not understand the bidding process and bid extremely low on certain items —considering them loss leaders—in the hope of winning bids on other equipment. Those low bids led to severe drops in revenue which imperil the very existence of their businesses.

General Comment: The proposed competitive bidding program will create a government-sanctioned monopoly in a limited number of suppliers. It also will serve as an effective bar to the entry of new suppliers and innovative equipment into the marketplace. Any program -- even if its name suggests that it *promotes* competition -- which has the effect of *limiting* competition, is not good for health care, for patients, or for taxpayers. Certainly Medicare dollars need to be saved, but this is not the way to do it.

Section I.G. Program Advisory and Oversight Committee

Comment: The CMS Program Advisory and Oversight Committee on competitive bidding (PAOC) wields great power within the DMEPOS industry. Affected persons

have not had an opportunity to review or respond to PAOC assertions or recommendations.

Recommendation: The POAC should be subject to the Federal Advisory Committee Act (FACA), which requires public access to meetings and proceedings.

Section II.B. Implementation Contractor

Comment: We are concerned about the identity and business relationships of "appropriate entities" that the CMS Secretary will contract with to implement the competitive bidding program. In our view, much of this proposed rule appears to create potentially monopolistic power in certain selected entities, rather than allow free market competition. We recommend that competitive bidding implementation contractors (CBICs) and any entities to which they are structurally or contractually affiliated with through partnerships, subsidiaries, or direct or indirect contractual arrangements be absolutely prohibited from participating in bidding.

Section II.C. Payment Basis
Section II.H. Determining Single Payment Amounts for Individual Items

Comment: It appears that information from unqualified bidders may be used in calculating the "single payment amount" (the winning bid amount). This means that a business which is incapable of meeting the financial and quality standards to be a supplier under the competitive

acquisition program nonetheless can submit a "lowball bid" that will fundamentally taint the calculation of the final amount.

Recommendation: Lowball bids submitted by contractors who are not selected should not be included in determining the single payment amount.

Section II.D. Competitive Bidding Areas

Comment: The timetable for the program roll-out, set to begin in the Fall of 2006, does not provide an adequate opportunity for CMS to meaningfully review the comments to the proposed rule.

Recommendation: Implementation should be delayed indefinitely to permit thoughtful review, and as necessary, revision of the proposed rule and additional opportunity for public comment.

Comment: Under the MMA, the Secretary can use competitive acquisition bid rates in one MSA to set the reimbursement for another MSA. Before doing so the Secretary should conduct a comparability analysis of the two MSAs to help prevent any applications of bid rates outside of an MSA that are inappropriate.

Recommendation: Beneficiary access to care should be protected by requiring CMS to conduct a comparability analysis for areas that are not competitively bid to ensure the rate is appropriate to costs and does not reduce access to care.

Section II.D. Competitive Bidding Areas
Section II.E. Criteria for Item Selection

Comment: A number of our client's product groups are expected to be affected by the competitive bidding rules: lower limb orthoses; upper limb orthoses; spinal orthoses; walkers; commodes; and continuous passive motion exercise devices. Without a specific list of included HCPCS Codes, however, we cannot project exactly which products will be affected, and therefore we find it challenging to offer specific comments that will assist CMS in evaluating the proposed rules. For this reason, after the initial roll-out of the competitive bidding program, DME suppliers and other affected persons should be offered additional opportunity to submit public comments before the implementation of the next phase of the program.

Recommendation: After the initial roll-out of the competitive bidding program (now projected to occur in 2007), we will have a better sense than we do now of what products are included and how the program will affect suppliers; therefore, CMS should issue new proposed or interim final rules and provide an additional opportunity for affected persons to submit public comments before the implementation of the next phase of the program (now projected to occur in 2009).

Section II.D. Competitive Bidding Areas

Comment: The failure to identify the geographic regions where competitive acquisition programs become effective in 2007 leaves prospective suppliers without adequate information to submit bids. By waiting until the final rule is published, it will be impossible for providers to begin gathering the necessary data to submit realistic bids. This is especially problematic because, once the single payment amount is established, winning suppliers will have to live with that amount for years. While this payment purportedly will be adjusted each year for inflation, Congress has a practice of freezing Medicare payment rates.

Section II.E. Criteria for Item Selection

Comment: By failing to identify the specific products that will be included in the competitive acquisition program, CMS prevents suppliers from accurately evaluating all of the costs associated with procuring, delivering, and servicing those products. In our view, this is a transparent attempt to elicit unsustainable lowball bids.

Recommendation: A list of the products subject to competitive acquisition should be published at least 12 months in advance of the date that bids are due.

Section II.E. Criteria for Item Selection
Section II.F. Submission of Bids Under the Competitive Bidding Program

Comment: Continuous passive motion exercise devices (CPMs) are not listed in Table 3 ("2003 High Volume Items [HCPCS Codes]"), 71 Fed. Reg. 25670, or in Table 10 ("Allowed Charges: Top Eligible DME Policy Groups"), 71 Fed. Reg. 25691, but are specifically mentioned as affected by this proposed rule on 71 Fed. Reg. 25673 under item 4(b).

In addition, we note that the list of possibly-affected DMEPOS does not include canes or crutches, which presumably are frequently-purchased items.

Section II.F. Submission of Bids
Section V. Effect on Suppliers

Comment: The argument that bundling and product specialization will allow suppliers "to realize economies of scope" and "furnish a bundle of items at a lower cost" is bogus, 71 Fed. Reg. 25673, as is the assertion that "the increase in the supplier's volume could offset the decrease in revenue per item." 71 Fed. Reg. 25694.

Suppliers may be able make up for some of the reduced reimbursements by furnishing a bundle of items at a lower cost than it can produce each item individually. This only makes sense if a bundle of products goes to the same patient. Otherwise, the administrative/overhead costs of supplying products, supporting patients, filing claims and billing patients are not reduced. In addition, the cost of manufacturing a bundle of products would not be reduced as each item in the bundle still has to be manufactured individually.

Similarly, the assertion that small suppliers might be able to offset some of the lower reimbursements through product specialization is questionable. For a company like our client, the administrative and overhead costs associated with supplying, for example, only Upper Body Orthoses, are no different than supplying both Upper and Lower Body

Orthoses. Consequently, if a small provider who currently offers a wide range of products decides to specialize in one

product category, that provider would have to see a significant increase in volume in the product specialization area to offset the loss of income in the expanded areas. Finally, it is doubtful that

a small, specialized provider would be selected as one of only a few approved providers in an MSA when the larger providers could supply a wider range of products and services. Thus innovation and specialization are not promoted by this proposed rule.

Section II.F. Submission of Bids

Comment: There is no provision for allowing approved suppliers to add new products to their offering mix during the contractual period, thereby limiting provider growth only to products within the contracted product categories. Bids initially will be solicited and approved each year for the first two years and then move to a three-year schedule. This will prevent an approved provider from expanding its product line until the bid renewal stage. While the proposed rules do have a provision for new product development, they do not address enhancements to existing products that an approved provider may want to offer.

For example, if our client were an approved provider of Upper and Lower Body Orthoses and wanted to move into Spinal Orthoses, as a practical matter it could not do so until the contract was next up for renewal.

Comment: Bids are submitted for items grouped into product categories consisting of items that are used together to treat a medical condition, though separate bids for each item are required, for example, hospital beds and necessary accessories. Medicare patients will be able to receive all of their related products from one supplier by using this method. Bids must include all costs related to furnishing an item, including all services directly related to the furnishing of the item. CMS apparently believes that this approach is more favorable for small suppliers because they can choose to specialize in only one product category. This means, however, that small suppliers will have to retool their business lines, abandon other product lines, and likely be unable to compete with larger contracting suppliers. This is not an advantage.

Section II.G. Conditions for Awarding Contracts

Comment: The proposed rule references quality standards and accreditation, but these standards have yet to be published in final form. In addition, suppliers need sufficient time to become accredited, once accreditation organizations have received "deemed status" from CMS. By publishing the proposed rule on competitive acquisition before the

quality standards have been published, CMS has acted prematurely, to the substantial detriment of those in the industry striving to comply with CMS requirements.

Comment: The proposed rules concerning market demand detail how the number of suppliers per area will be selected and how markets will be expanded. It appears that these projections are based off of two years of *previous* claims data and the number of new beneficiaries that entered the program on a monthly basis over the *previous* two years. This approach means that there probably will not be sufficient providers in the system when "Baby Boomers" start retiring. It is surprising that CMS is not taking a proactive approach and projecting how many beneficiaries are likely to enter the program each month over the *future* three years (since the contracts are on a three-year basis).

As is widely known, the Baby Boomers just started turning 60. In five years, the first of the Boomers will become eligible for Medicare. If CMS bases its selection of providers (the number of providers per area) on 2009 and 2010 data and gets hit with the Boomers turning 65 in 2011 and 2012, wouldn't we be a little short of providers?

Comment: CMS will want to estimate supplier capacity to meet the projected demand. CMS will ask suppliers to say how many units they are willing and capable of supplying at the bid price in the competitive bidding area and will require evidence of financial resources to support potential market expansion. As discussed above, without full information, this will be difficult to project, and a supplier risks either overstating or understating the amount. In addition, the examination of financial resources for market expansion likely creates a bias against small suppliers.

Comment: The MMA allows the Secretary to contract with only as many providers as the Secretary deems necessary to meet the demand of an area. Any provider not awarded a contract would be prohibited from participating in Medicare for up to three years. Small businesses not awarded a contract should be entitled to continue to provide DME in Medicare at the competitive acquisition bid rate.

Recommendation: Allow all qualified suppliers that are small businesses and that submitted a bid below the current allowable to participate at the selected award price.

Section II.H. Determining Single Payment Amounts for Individual Items

Comment: The proposed rule introduces the concept of "consumer rebates." Although the rebate is described as "voluntary," the language of the proposed rule indicates that if a rebate is offered in one instance, it must be offered in all cases and becomes "a binding contractual obligation ... during the term of the contract with CMS." Requiring a low-bid contracting supplier to offer rebates has no legitimate basis, including in the authorizing sections of the MMA, and indeed runs counter to decades of health law that prohibits suppliers from offering inducements to beneficiaries as potentially violative of the fraud and abuse laws. By failing to identify the specific products that will be

included in the competitive acquisition program, suppliers cannot accurately evaluate all of the costs associated with procuring, delivering, and servicing those products to arrive at an appropriate price. Because the bids will be submitted without full information, including the as-yet-to-be-determined "single payment amount," requiring the supplier to offer a consumer rebate for a bid below the single payment amount will be punitive. In addition, if the contracting supplier inappropriately offered too low a bid as compared to others in the same market due to a lack of full information, mandating a rebate could threaten the viability of continued participation as a supplier.

Recommendation: Abandon the concept of consumer rebates.

Section II.L. Opportunity for Networks

Comment: The supplier network concept will increase costs, legal liabilities, and financial exposure for small suppliers. Small suppliers typically have higher operating expenses as they are not the actual manufacturers and do not have volume negotiating clout with their manufacturers.

The proposed rule provides that to compete, small suppliers can band together to submit a "group or network" bid on the products. Not only does this sound like government sanctioned price-fixing, but there are severe limitations to the workability of this proposal. In particular, the small supplier network has to be a formalized, legal (contractual) arrangement with one entity designated as the primary entity. If one party to the network "goes down," the entire network will be affected – and possibly terminated -- by Medicare.

The proposed rule does not address the substantial expenses associated with affiliating with other accredited small suppliers. There also will be increased costs to the small supplier to formalize the contractual arrangement and a huge legal and financial liability to the small supplier if one of the network parties is a "bad apple," or competitors participating in the network do not provide full information or provide faulty information.

Those small suppliers whose competitors elect not to include them in a network likely will soon go out of business.

It is especially problematic that a small supplier can be part of only *one* network group. Equally troublesome is the proposed rule that a small supplier may not submit an independent bid for one product group and also bid as part of a network for another product group. For example, a small supplier could not bid independently for Upper Body Orthoses and as part of a network for Spinal Orthoses. Therefore the small supplier most likely will have to find and negotiate a contract with more than one other partner to ensure all items in all of the product groups are covered. *Each* of those partners would have to meet Medicare's financial requirements and be accredited, likely a substantial expense – and possibly prohibitively expensive to the smaller suppliers. This is not a

practical solution for small suppliers -- and probably why no one in the two pilot programs in Florida and Texas participated this way.

Comment: Each network must form a single legal entity that acts as the bidder. Each member of the network must meet all accreditation and quality standards. The network members' share of the market for a product category cannot exceed 20% of the Medicare market within a competitive bidding area. How are members to determine this share? If it fluctuates, must the network close down?

Section II.J. Administrative or Judicial Review

Comment: The non-availability of administrative review violates not only the Administrative Procedures Act, but also individual and corporate rights to due process and to redress grievances.

Recommendation: Appeal rights should be restored; these rights exist elsewhere in the Medicare program.

Section II.O. Physician Authorization/Treating Practitioner

Comment: Section 1847(a)(5)(A) of the MMA allows a physician to prescribe a specific brand of product or mode of delivery if the physician determines that use of that item "would avoid an adverse medical outcome." Even so, the proposed rule indicates that contract suppliers would have the option of (a) providing the product, (b) finding another contract provider who can

provide it, or (c) consulting with the physician to find a "suitable alternative product." This will lead to delays, possible patient harm, and attempts to unduly influence physician judgment regarding appropriate DME items for patients.

Comment: Manufacturers will look to reduce their production costs by using cheaper materials, or cut corners in manufacturing processes. Large suppliers will look to improve their profit margins by switching to lower end products.

Comment: The Medicare patient will end up with cheap products or "alternative substitutes" that may not provide the degree of support needed, which could ultimately lead to increased costs to Medicare for repeat patient treatments.

Section V.C. Implementation Costs
Section V.D. Program Savings

Comment: There is no evidence that competitive bidding lowers governmental expenditures. The government's own test cases are inconclusive as very modest rate differentials were offset by incremental administrative costs.

It only makes sense that administrative costs will increase substantially, quite likely offsetting any cost savings. The only administrative costs listed in the proposed rules are the initial fixed costs for contractor startup, system changes, and bid evaluations for 2006, which are stated as $1 million. It strains credulity to imagine that all of the costs to administer a new competitive bidding program across this country would not exceed the current costs to review claim filing information and publish fee schedules. Although some of the tasks will be delegated to CBICs, that also will lead to substantial costs to the program, and ultimately to taxpayers. By overstating projected savings and understating costs, CMS violates not only the Administrative Procedures Act but also the various the federal statutes and Executive Orders requiring accurate reporting of overall impact to make it possible to determine whether other regulatory approaches would accomplish the objective more efficiently. (*See* 71 Fed. Reg. 25690.)

Recommendation: The numbers offered are not clear, and not credible. At minimum, CMS should publish the actual savings for the pilot programs reported at 71 Fed. Reg. 25692, the beneficiary savings reported at 71 Fed. Reg. 25693, and the estimated net cost savings to Medicare (that is, payouts less administrative costs). A new Notice of Proposed Rulemaking should be issued, with additional opportunities to comment, with more realistic figures.

Section V.D. Program Savings

Comment: Under the MMA, the Secretary can only competitively acquire an item if the Secretary believes that doing so would result in significant savings to Medicare. It is important for the Secretary to show that the savings from competitive acquisition justify constructing a bureaucracy to implement the program.

Recommendation: To justify this program, the Secretary should select as items for competitive acquisition only those shown to result in savings to the Medicare program of at least 10 percent.

Section V.F.2. Effect on (Small) Suppliers

Comment: Highly customized items will be excluded from the competitive acquisition program. This will have an adverse impact on patients, as well as specialty suppliers who cannot be contract suppliers for these items.

Comment: The cost to small suppliers is vastly understated. Suppliers who submit bids will incur the cost of bidding, as well as joining a network, and ensuring that all of its members are accredited. The proposed arrangement also will require members of the network to monitor the market share of the network to ensure that it does not exceed 20%. Even if this information were readily available, the proposed rules provide no protection from the antitrust laws from sharing price and other competitive information among members of the network.

Thank you for the opportunity to submit comments. We look forward to reading your responses, and encourage a wholesale rethinking of this program.

Sincerely,

WYRICK ROBBINS YATES & PONTON, LLP

Barbara Garlock

Submitter : **Ms. M Garrison** **Date: 06/30/2006**

Organization : **Self**

Category : **Individual**

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

Please do not deny coverage to the elderly who are already living in poverty and cannot afford to purchase life sustaining medication. They are the ones who can least afford to buy items to improve the quality of their life with the use of these aids. They are already denied coverage of hearing aides which I think is also a tradegy. Please remember, you are getting old too. The ditch you dig for them, may very well be the one that you fall in later.

Ms. Garrison