Avenue Medical

1277 S. Governors Ave
Dover, DE 19904
302-674-0907 • 800-541-8119
Fax 302-674-1421
sales@avemed.com

REHAB EQUIPMENT ASSISTIVE TECHNOLOGY ORTHOPEDIC BRACING MASTECTOMY

April 26, 2006

Department of Health and Human Services
CMS
Comments on Competitive Bidding

Marosa Surgical Industries dba Avenue Medical
Adam Samuel, CRTS, President
1277 S. Governors Ave.
Dover, DE 19904

302-674-0907
Fax 302-674-1421
adam@avemed.com

Background

I own a small DME with annual sales under 2 million dollars. Medicare billings represent about 30% of our total business. We are in process to receive accreditation in fall 2006 by ACHC. Approximately 75% of our total sales are rehab with the remainder being standard DME, no oxygen or enteral feeding.

I read through the entire proposed rule and have comments on the following areas:

E. Criteria for item selection.

I would encourage your committee to separate the wheelchair product group into manual chairs, PWC and POVs. I would not bundle these products with other products such as hospital beds/ accessories. Wheelchairs require a fitting like an orthosis. Beds do not require this level of service. I would also require, in the accreditation standard that the suppliers have accreditation for "rehab technology supplier". Both JACHO and ACHC offer this specific credentialing. I would also require that the supplier has a CRTS designation. This credential requires at least 4-5 years experience in wheelchair fittings, three independent letters of recommendation, passing RESNA exam for ATS, and maintaining 15 hours of continuing education annually. I would further require that PWC and POV require a PT or OT assessment and in-home "field assessment" to ensure that the client can operate the equipment safely in the home and that it fits in the home. This would eliminate the problem of companies that "advertise mobility" on television. An independent clinician would sign-off, in addition to the face to face visit of the physician. I think bundling these items would encourage poor fittings and reduce beneficiary compliance.

Wheelchairs/POVs represent a huge dollar amount for Medicare and your agency has been diligent in processing fraud. However I think if specific criteria were put into place there would be fewer problems with fraud.

F. Submission of Bids Under the Competitive Bidding Program.
I think that suppliers need to be within 50-100 miles of the CBA. If they are not then service and follow-up with Medicare beneficiaries will be an issue. There is significantly more follow-up and service needed for wheelchair, PWC and POVs than any other piece of equipment on your list. There should be enough accredited suppliers in a CBA to make the program cost effective.

I can see this working for enteral supplies, diabetic supplies, etc. not equipment.

3. Product categories for Bidding purposes.
Again I would make wheelchairs separate from other product categories with the above mentioned stipulations.

4. Bidding Requirements section d. capped rental.
Lump sum purchase option should be mandatory for any piece of equipment that requires "life time" use. The supplier then can maintain and bill separately for servicing the equipment. I agree that "purchase" bids should be submitted for these items.

G. Conditions for Awarding Contracts
4. Evaluation of Bid
The development of Item weight, composite bid and pivotal bid seems extremely difficult. I would think that for each item the supplier wants to bid on they would simply look at retail cost and discount the item. Evaluation, set-up and delivery time should be considered. Your methodology would be appropriate for enteral feeding, diabetic supplies, incontinence supplies etc. Single items could not be bundle priced such as a bed or a wheelchair.

I would still use the concept of median range based on the number of bids in the CBA. All suppliers have MSRP available to use for equipment. So the starting point would the same for each contracted supplier. Some suppliers may discount 20% some 30% some more.

Supplier	Item	Discount	Saving	Avg Cost
A	1000	0.2	200	800
B	1000	0.3	300	700
C	1000	0.3	300	700
D	1000	0.2	200	800
E	1000	0.5	500	500
F	1000	0.35	350	650
G	1000	0.4	400	600
H	1000	0.2	200	800
I	1000	0.4	400	600
J	1000	0.2	200	800
				695

Each supplier would submit their discounted bid. The supplier who is +/- 10% would win the bid. So supplier B,C,F,G and I would win the bid at the lump sum of $695. This addresses aggressive suppliers who will gouge and not aggressive enough suppliers who will discount too little. This still saves Medicare a significant amount of money and keeps the "playing field" even.
Small suppliers will not form networks with distinct legal identities. This would not happen.

H. Determining Single Payment Amounts for individual items

2. Rebate program- **Don't do it.** Even though it would not be permitted to advertise that suppliers are offering rebates, it would be done. Also suppliers could offer false rebates and write it off as advertising expense. Suppliers who offer bids below the average price should not be awarded the bid. Rebates would encourage suppliers to provide inferior goods and services. They would receive more referrals and ultimately the beneficiaries would suffer.

If the program is managed by the CBIC's correctly and fairly, Medicare could show savings between 20-30% which is higher than the test results from Polk County or San Antonio.

Thank you for your consideration of my comments. I can be reached for questions, Monday through Friday 9am to 5pm.

Adam Samuel, CRTS
President
Marosa Surgical Industries

MIDWEST MEDICAL SERVICE, INC.
Medical Equipment & Supplies for Home Use
615 6th St. SE, Watertown, South Dakota 57201-4956
Phone: (605) 882-4210 Fax: (605) 882-4211
1-800-657-8098

2

May, 2006

MAY 1 1 2006

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

RE: Comment of CMS-1270-P Proposed Rule

ELIMINATION OF SUPPLIERS

We are a small DME company (one store) in the Midwest. After reading the complete document I'm sure that the authors have not been to a DME supplier like ours and actually seen what we do everyday. We are part of the 90% (page 148 of the document) you will eliminate. We are not a big national company that has set up shops all over the US, with nothing in them, but the standards posted and the back room full of oxygen supplies. On a daily bases if you stop at these shops, no one is there, and it is impossible to return any equipment or speak to a person about problems with equipment, or extra education of the equipment. Yes, they qualify as a supplier because they have a building, with a sign, posted hours, standards posted, but where is the service to beneficiaries, which is what CMS is saying this is all about, when no one is at the site and phone calls go to an answering machine. However, our company sees every type of patient, every day, including ostomy, diabetic, wheelchair, wound care, along with hip kits, reachers, bed pans, etc. So, who will service all of these beneficiaries with these products, and still stay in business. National companies only have respiratory in mind and will leave the small stuff to the small companies. In the trial counties has

there been a site visit to the winning bidder's locations to check all this out before we move on to the next competitive bidding step.

ACCREDITATION

We are not accredited, but for our 25 years of service we have always complied with the standards, and slowly worked on heading toward this step. We think accreditation is a good move, making everyone accountable. Our concern is who will do the accreditation that knows our industry. The big accreditation organizations, which we have investigated, are hospital orientated, and they have a whole different agenda, and offerings to their mix (ex. home health nursing). We need an agency that will understand driving 90 miles to see a patient, address the limited staff, the limited office space, and income.

BIDDING PROCESS

The bidding process is complicated for a small DME company. Why does it have to be such a mystery and confusing? We do not have one person in this company (8 people) that isn't working every minute of every day. Who would have 70 hours to do a bid and how do we justify the cost of $2200, when we can't understand the complicated bidding process to see if there is even a chance against all the large nationals, that have planted themselves everywhere.

You want quality at the lowest price, and believe me, quality will suffer. We know the cost of taking care of patients. It has been our passion for years, and we can only hope that someone will step up and look at the "big picture" of who the winners really are in this game.

Peggy Silliman

Peggy Silliman, Owner
Midwest Medical Service
Watertown, South Dakota

3

MAY 15 2006

Sarah L. Gales
AdLib Center for Independent Living
215 North Street
Pittsfield, MA 01201

May 5, 2006

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

To whom it may concern,

I am writing to express my concern regarding the proposed low vision aid exclusion. I work as a Peer Counselor/Advocate at an independent living Center and I am also legally blind.

I am certain that this proposed exclusion will have a negative effect on the lives of visually impaired MediCare recipients. I am especially worried about the independence of elderly individuals and their inability to receive necessary equipment under the proposed rule. There are few resources to assist blind and low vision citizens in obtaining items such as glasses, magnifying implements, CCTVs and other such tools. These products are essential for people with visual impairments to function in their daily lives. They are a necessary part of achieving independence, not a luxury item.

I urge you to re-consider this proposed rule which would prevent blind and visually impaired MediCare recipients from receiving assistance with the purchase of low vision aids. I ask you to put yourself in the shoes of said individuals, to see through their eyes, and to support them as they strive to lead productive lives. I know the importance of low vision equipment first hand, as I have used many such products throughout my life. I strongly suggest that you listen to the stories of people like myself, and let them serve as a guide in the decision making process.

Thank you for your time and consideration.

Sincerely,
Sarah L. Gales

4

MAY 17 2006

REEVES•SAIN

May 10, 2006

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

To Whom It May Concern:

As per your request, I am sending you a written comment regarding the CMS initiative to implement a nationwide competitive bidding for DME. (File code CMS–1270-P).

I own a moderate size medical equipment/respiratory/infusion company in middle Tennessee. My company provides critical, life sustaining products and supplies to thousands of patients. The new competitive bidding initiative will put my business and many others just like mine on the brink of bankruptcy. I am concerned about the patients that we serve and the staff that I have employed for many years.

Furthermore, what is more concerning is that my company is more than willing to match the winning competitive bid and to meet the quality standards as set forth by CMS's designated accrediting organizations. My company is simply being marginalized by the very government that we pay taxes to support.

What is the government going to be put out for bid next? **Maybe hospitals, or doctor's offices, or perhaps even nursing homes.** I believe that the United States government should be in the business of creating opportunities for small business not creating barriers to our financial and operational solvency. This is bad legislation that is simply not a reflection of the freedoms that our forefathers dreamed of for America. On behalf of my patients and my staff, I am requesting that further study be done on how to keep small businesses viable throughout this competitive bidding process

Best Regards,

W. Shane Reeves, Pharm.D.
Reeves-Sain
1837 Memorial Blvd
Murfreesboro, TN 37129
615-278-3146 (work)
615-278-2262(fax)
sreeves@reevessain.com

5/10/06 5 (3)

To whom it may concern

I am one of the peoples who use Low vision Aids. I can't get along without a magnifier. I have a book which I have written all the Telephone numbers and addresses which I use every day and a pen that I can see what I write. Please approve Low Vision Aids

Thank you

Bertie Kinnaird 836 W. Oakland
Bloomington, Il. 61701

MAY 17 2006

5-11-06 (6)

To whom it may Concern

I have borrowed a Walker from Life Center and Stacy came by with numerous items to help me. Unfortunately I can't read the newspaper it would be nice to have a television but they are so expensive

Sincerely.

Lois E Waters

982 N Maple St

Normal, IL 61761

Item # 2071000

Dear Leaders and Policy makers: (7) MAY 18 2006

Please give me a vote for medicare coverage for all Low Vision Aids or technologies. A vote (yes) and not overlook our needs. Have very little eyesight. am legally blind. Hope our needs will be considered. thank you

Glenn D. Murphy

602 Mercer Ave.

Bloomington, IL. 61701

Item # 2071000

(18)

MAY 17 2006

Section 414.15

It would be a tremendous help to anyone with low vision to have needed equipment covered as a benefit.

Thank you

Raymond Whittaker

Item # 2071000

(9)

MAY 2 2 2006

3802 Avenue B
Scottsbluff, NE 69361
308-635-1017

MES Team, Inc.

May 19, 2006

To Whom It May Concern

Please consider this as my official comments for the Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). As you know, the proposed rule would implement competitive bidding for certain covered items throughout the United States in accordance with sections 1847 (a) and (b) of the Social Security Act.

I believe the proposed rule is a mistake for the following reasons:

- Different areas of the United States are quite different in culture, geography, population, and demographics. The proposed rule assumes all areas are created equally and all Medicare beneficiaries obtain their DMEPOS items in the same manner. Obviously, a disabled bed ridden patient living on a farm in Western Nebraska nearly 80 miles away from a DMEPOS provider receives his oxygen (for example) differently than a relatively active patient living in the apartment above a DMEPOS provider in Los Angeles.

- The proposed rule establishes the requirement for a DMEPOS provider to obtain accreditation status. However, the standards required to become accredited have not been announced and vary greatly based upon accrediting bodies. The fees for accreditation also are quite high and affect the smallest provider the most negatively. Also, the number of active Medicare supplier numbers is too vast and the accrediting bodies ability to survey each one is too small for a realistic opportunity for those seeking accreditation.

- The cost to oversee another new program like this will have an administrative expense that is quite large. I don't believe a study has been done to determine what this expense will be. In the demonstration areas, a savings of about 20% is indicated but no mention is made of the expense required to realize that 20% savings. I believe a study is needed to determine how much savings are needed to realize the newly created expenses. For example, I can save the government billions of dollars if you allow me to spend a trillion dollars to do it. Study it first, determine the break even point for savings, and for those items that don't reach the break even point, then they should be eliminated from the competitive bidding program.

- You indicate that the government has uncovered numerous accounts of fraud and abuse. I agree that fraud and abuse is a huge concern. However, I take exception to the broad generalization that our industry is to blame. I believe those who oversee the Medicare funding are just as guilty for not following protocol, not finding the offenders earlier, and not policing the already adequate supplier standards. More rules don't make fraud and abuse disappear, only those in charge of making sure people are following the rules make fraud and abuse disappear.

- Transferring title of medical equipment that dispense a legend drug is a mistake. Oxygen concentrators are not like toasters. When a toaster stops turning your bread brown, you

know it isn't working. When an oxygen concentrator stops putting out pure oxygen, you have no way of knowing it. Only skilled technicians, with the appropriate diagnostic tools can determine the effectiveness of the machine which is a service not a commodity. How can a Medicare beneficiary be expected to maintain a highly technical machine? Since it dispenses a legend drug, how will Medicare ensure the legend drug isn't getting into the hands of those who don't need it? When the patient dies, families will be selling them at auctions, garage sales, flea markets, etc., how can our government endorse the legalized sale of a legend drug. I believe this is a conflict with policies drafted in the war on drugs through the FDA.

- This proposal does not identify what a rural or underserviced area is to qualify for exemption. Further, you can deny exemption based on a "catalog availability" concept which also has not been defined. I believe it is within our rights as providers to know what a rural area is, what an underserviced area is and what products qualify under the catalog provision.

- You make reference to the financial capacity requirements to ensure providers are able to adequately take care of the bid if received for the duration of the term. Yet, no mention of what exactly the financial standards are. However, it is safe to assume that small businesses will not meet the financial standards, nor will they be able to service an entire bid area. Therefore, I believe small businesses will be unfairly ruled out under this provision which would be a violation of **Small Business** Regulatory Enforcement Fairness **Act** of 1996.

My comments are designed to help ensure access to all Medicare beneficiaries in all areas of our country. Saving money is the desired outcome which will most definitely be realized if you can effectively eliminate the care provided to patients which is what I feel this proposal does. Health care is one of the primary initiatives when the Social Security Act was established, not cost. We have forgotten this simple portion of Medicare. Please ensure access to all by defining rural areas, allowing small businesses to participate, and not over regulating an already over regulated portion of the Medicare program.

Sincerely,

Derek Lovesee
CEO

(10)

MAY 2 2 2006

DACC

Diabetes Access to Care Coalition

May 19, 2006

Herb Kuhn,
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
Mail Stop C5-01-14
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Request for Comment Period Extension on Proposed Rule on Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues, Docket Number CMS-1270-P

Dear Mr. Kuhn:

The Diabetes Access to Care Coalition ("DACC") respectfully requests a 120-day extension of the comment period for the Centers for Medicare and Medicaid Services' ("CMS") Proposed Rule on Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues published on May 1, 2006 (*See* 71 Fed. Reg. 25654 (May 1, 2006)) (the "Proposed Rule"). The DACC includes the leading manufacturers of blood glucose monitoring systems in the United States. We are committed to working closely with CMS on this important program and we believe that additional time is required to permit stakeholders to develop the detailed, substantive responses to both overarching and specific issues raised in the Proposed Rule. We offer five (5) reasons for our request.

1. The Rule is Complex and Requires Careful Consideration by Stakeholders

The 50-page Federal Register notice outlines an entirely new program for CMS. In contrast to many proposed rules that simply outline amendments to existing regulations, this Proposed Rule creates a new, complex program from the ground up. Moreover, the topics addressed by the Proposed Rule include intricate rules for selecting products and geographic areas for inclusion, conducting the bidding process and selecting winners and losers. Those topics require very sophisticated economic, legal and clinical analyses. To pick but one example, the factors surrounding the task of selecting the winning bid is an area that economists have studied for years and requires a detailed analysis to ensure that both the program pays no more than it should and that beneficiaries have access to a sufficient supply.

In the past, CMS has extended its comment periods to allow for additional public comment on significant policy changes – most recently with respect to the inpatient psychiatric facilities prospective payment system (February 2006) and the HIPAA standards for claims attachments (December 2005). CMS has explained that it has granted extensions when due to the scope and complexity of the rule and the significant implications for the health care system, the extension is in the substantial public interest so that additional information and comments can be provided. To illustrate the complexity of the Proposed Rule, we understand that CMS has been working on it for more than two and a half years, since Congress enacted the Medicare Modernization Act of 2003 (P.L. 108-173).

We believe that additional time is required to enable large organizations and associations (particularly those that represent beneficiaries) to adequately educate and engage their constituencies and to aggregate the diverse comments of these stakeholders in a way that improves and strengthens the final rule.

2. The Proposed Rule Raises Regulatory Matters Beyond the Competitive Bidding Process

The Proposed Rule includes several topics beyond the competitive bidding rules that will require additional, separate analysis by stakeholders. Those topics include, but are not limited to, the gap filling measures to be used for establishing prices, and the rules for taking a price determined through competitive bidding and applying it to other geographic areas. Those additional topics add a considerable amount of work for stakeholders to respond to the Proposed Rule, and makes the 60-day period simply inadequate.

3. Experience with Medicare Part D Pharmaceutical Competitive Bidding Counsels in Favor of A Thorough Evaluation

In spite of CMS' and the stakeholder community's best efforts to finalize the Medicare Part D pharmaceutical competitive bidding program through the regulatory process, additional consideration was required to make certain that beneficiaries were not adversely impacted by the monumental policy changes inherent in competitive bidding. That experience suggests the agency should take the time required up front to ensure that competitive bidding of DMEPOS does not have a negative impact on persons with diabetes whose daily care depends on having interrupted access to blood glucose monitoring equipment systems and related supplies.

4. Commenting Will Require the Gathering and Analysis of Complex Data

Like others commenting, as a part of our review, we will need to collect and analyze data, and that process requires extra time. We are confident that the agency expects those offering comments to go beyond merely expressing opinions and making rhetorical arguments. The agency values comments that are supported with data.

For the Proposed Rule, to begin with we will need to study the data from the demonstration projects. The agency uses that data to underpin many of its conclusions, and we cannot comment on the appropriateness of those conclusions without examining the data on which the agency relies. Going beyond that, however, we will need to collect data on the nature of the markets that CMS may be converting to competitive bidding as well as on the bidding techniques that CMS is planning to employ. As we are sure CMS is aware, the economics literature is replete with studies on bidding systems. Collecting that data simply takes time.

5. Actions Need to Be Prudent And Measured Because Major Health Issues Are At Stake

DACC is dedicated to the needs of patients with diabetes across the nation. At least 20% of persons over the age of 65 have diabetes and that population is expected to grow. Beneficiaries with diabetes account for nearly one-third of overall Medicare program costs. These beneficiaries will continue to need access to the day-to-day blood glucose monitoring equipment systems and supplies required to maintain safe blood sugar levels and compliance with their physician recommended testing regimen. The care and self-monitoring that includes the use of meters, lancets, blood glucose test strips and other diabetic testing supplies improves health and saves lives each day. From a programmatic standpoint, this care and self-monitoring results in significant cost-savings to the Medicare program as beneficiaries are able to care for themselves at home and avoid the harmful effects of inadequate monitoring, such as renal failure, that can lead to expensive dialysis, trips to the emergency room and unnecessary hospitalizations. In fact, the AHRQ has found that appropriate primary care for persons with diabetes could reduce hospital admissions due to complications and save Medicare $1.3 billion annually.

We appreciate that Congress intended the competitive bidding program to provide additional cost-savings for the Medicare program – and we support that goal. We also believe that Congress did not intend for the competitive bidding process to create barriers to access to blood glucose monitoring systems or to threaten the care that is so critical in diabetes disease management.

Thus, our overarching concern regarding the Proposed Rule relates to access to quality care. Indeed, on first review we are concerned that the Proposed Rule may create the potential for geographic barriers to arise within an MSA. The short and long-term impact of any gaps in supply availability in local neighborhoods within MSAs could be devastating.

Other specific concerns that the DACC wants to study fall within the following key areas:

- The impact that forcing a particular method of delivery on a patient would have on the patient's access to face-to-face advice and the coordination of care by a pharmacist;

- The selection criteria for establishing items to be bid competitively, and in particular the need to consider the impact on access to quality products;
- The selection of the single payment amount being based on price and not other access related factors;
- The impact of the proposed rule on existing small providers who are engaged in providing care to many Medicare beneficiaries in local neighborhoods;
- The potential disruption that could be caused by radically changing the means of supplying one of the most significant items of DME;
- The finalization of the quality standards for DMEPOS suppliers;
- The legality of the rebate program and its impact on quality;
- Due process related to agency determinations of items and pricing;
- Phase-in for old/new suppliers;
- Capacity of contract suppliers to meet needs;
- Standards of beneficiary "customer" service – especially to vulnerable populations.

To allow a thoughtful and data-driven analysis of this important Proposed Rule, we respectfully ask CMS to extend the deadline for comments by an additional 120 days. We appreciate your consideration of this request. We look forward to working with you and other members of the Administration on implementation of the Proposed Rule. If you would like to discuss this issue further, please contact me at Epstein Becker & Green at 202-861-0900.

Very truly yours,

Bradley Merrill Thompson,
For the Diabetes Access to Care Coalition

cc. Proposed Rule Docket Number CMS-1270-P

CMS-1270-P (11)

MAY 17 2006

Medicare & Medicaid

Those of us whose vision loss make it necessary to be provided with low vision devices are anxious. We are anxious that our needs be considered in your thinking. Please reduce our dependency on others by approving Vision Loss devices as medical equipment along with other aids at Medicare/Medicaid

Faulena Sherman
1200 E College Ave #115
Normal IL 61761

(12)

May 17, 2006
PO Box 814
St. Joseph, IL 61873-0814

Centers for Medicare/Medicaid Services
Dept. of Health and Human Services
Attention: CMS-270-P
PO Box 8013
Baltimore, MD 21244-9013

To Whom It May Concern:

We have been waiting for the day when vision needs would be considered under the "medical equipment" rulings. We've seen wheelchairs get approved, crutches, and bathroom aids approved. We are now ready and anxious to see our Vision Loss devices approved! In the Section 414.15 Los Vision aid Exclusion you have proposed to "bar, without exception, Medicare coverage for any device such as CCTV system, magnifiers, and any other Low Vision Aids or Technologies". Macular degeneration is rampant among our seniors and to deny them access to equipment that can help them to live fuller lives is unacceptable.

At the age of 66, my Mother came to live with my husband and I thirteen years ago, at which time she was still able to drive. But we knew she could not continue to work to support herself. Her vision continued to decline so she no longer drives. We live in a bedroom community with limited resources. Luckily my sister in Colorado was able to help Mom with acquiring a CCTV through the Lions Club there in Collbran. The Lions Club here in Champaign County said they only help with glasses. We must start considering additional equipment for those on very limited incomes in acquiring equipment to help them navigate through the rest of their lives. They NEED to feel they can still handle what we take for granted our vision in reading our own mail, the daily paper, and yes even their birthday cards. It is important that we support this growing need in our senior population.

With Best Regards,

Donna L. Guzy

Donna L. Guzy

May 17, 2006
PO Box 814
St. Joseph, IL 61873-0814

Centers for Medicare/Medicaid Services
Dept. of Health and Human Services
Attention: CMS-270-P
PO Box 8013
Baltimore, MD 21244-8013

To Whom It May Concern:

At the age of 66, my Mother came to live with my husband and I thirteen years ago, at which time she was still able to drive. But we knew she could not continue to work to support herself. Her vision continued to decline so she no longer drives. We live in a bedroom community with limited resources. Luckily my sister in Colorado was able to help Mom with acquiring a CCTV through the Lions Club there in Collbran. The Lions Club here in Champaign County said they only help with glasses.

We have been waiting for the day when vision needs would be considered under the "medical equipment" rulings. We've seen wheelchairs get approved, crutches, and bathroom aids approved. We are now ready and anxious to see our Vision Loss devices approved! In the Section 414.15 Los Vision aid Exclusion you have proposed to "bar, without exception, Medicare coverage for any device such as CCTV system, magnifiers, and any other Low Vision Aids or Technologies". Macular degeneration is rampant among our seniors and to deny them access to equipment that can help them to live fuller lives is unacceptable.

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With Best Regards,

Donna L. Guzy

(13)

Centers for Medicare/Medicaid Services
Attention: CMS-270-P
RE: Low Vision Aid Exclusion

Dear Sirs,

MY NAME IS RUBEN YBARRA
I HAVE LOW VISION I WOULD LIKE
SEE OUR NATIONAL ELECTED
LEADERS TO APPROVE- MEDICARE
/MEDICADE UNDER THE MEDICAL
EQUIPMENT RULING TO INCLUED
LOW VISION DEVICES.

RUBEN YBARRA

349 E. MORRIS
BEMENT, IL
61813

217-678-8434.

Item # 2071000

5/12/06

(14)

Attention Just For Me
Redemption Center.

I use MANY visual aids
Magnifiers, Talking Clock,
Wrist Watch (talking) timer,
lg. no# telephone Kitchen
Clock, Cards & Probably
other vision devices that
I can't think of presently.
I am thankful for the
visual aids as I could not
AFFORD to pay — Pat Thompson

(15)

Centers for Medicare/Medicaid Services
Attention: CMS-270-P
RE: Low Vision Aid Exclusion

Dear Sirs,

May 25, 2006

My mother, who is now deceased, needed vision assisted devices because she suffered from macular degeneration. She lost most of her independence for quite sometime, because she could not afford to buy the needed assistance. I would drive two hours from my house to hers to read her mail, pay bills, balance her checkbook, etc. After visiting the low vision house in Champaign, IL, I purchased for her magnifiers, talking alarm clock, large faced watch, sunglasses. These items sure were an assistance to her. We were also able to get an OVAC machine, which helped her read her mail. Since eye disorders are a medical condition, I believe Medicare/Medicaid should cover glasses, CCTV systems, magnifiers with lights & anything needed that costs over a certain amount - get a deductible

Sincerely, Rebecca L. Sheridan

HOMECARE PHARMACY LLC

1006 WOODWARD AVENUE • BELOIT, WI 53511

Home Medical Equipment
Supplies & Convalescent Aids
PH. (608) 362-1234 • FAX (608) 362-2744

Joint Commission
on Accreditation of Healthcare Organizations

Rehabilitation Services
PH. (608) 362-1986 • FAX (608) 363-5547
1-800-579-6700 (WI & IL Only)

(16)

Tues.
5/16/06

Attn. CMS-1270-P

To whom it may concern,

I have been caring for Medicare patients about 20 years. Since the mid 90's reimbursement has been cut several times for home medical equipment. On Jan. 1, 1997 or 1998 our oxygen reimbursement was cut by 30% in one day. How fair was that?? Now more cuts have lapped & competative bidding threatens to eliminate thousands of small business providers. It bothers me that CMS officials don't seem to realize that HME is your best value in healthcare. Most of Medicare's HME providers are small businesses. We total over 60% of the medicare provider base. We all would rather give up more revenue than be eliminated from helping our customers due to competative bidding & its complicated and unfair bidding formula. Instead of dropping forty years of fine tuning for this radical competative bidding, just modify the existing formula so all willing providers are able to still serve our patients. Please act with integrity & I pray you will change your thinking. Sincerely Joe M. Navarro

(1M)

Centers for Medicare/Medicaid Services
Attention: CMS-270-P
RE: Low Vision Aid Exclusion

Dear Sirs,

I have low vision. I appreciate the sight I have - but it is A struggLE, There are aids available - but they are very costly. I ATTENDED A low VISION conference a few years ago. A physcian showED visual AIDS which could help in certain eye conditions. They were amazing DEVICES. Then, Someone from the audience would ask the cost - (an astronomical figure) The entire audience would groan. This went on for an hour. It was actually painful.

Making low vision AIDS available through Medicare WOULD open so many doors OF opportunity for those of us who just need a little enlarging and illuminating to fit in with the rest. Thanking you in advance. Don't let me down - Lee Petrie-Springer

(18)

Centers for Medicare/Medicaid Services
Attention: CMS-270-P
RE: Low Vision Aid Exclusion

Dear Sirs,

My name is Connie Williams I am 53 and have been legally Blind for 7 years - Diabetic Retinopathy I had to give up my career in Nursing - and the Right to drive. I had to go on Social Security at the age of 46 and went thru horrible depression. Forced to move in a dangerous housing AREA - alone Pace helped me with many options. I thought my life was over. Their staff lifted my spirits. My income is low - so it is still Difficult to afford my needs to improve my needs Due to vision loss Please consider our needs Thank You

Connie Williams (217) 337.5543

(19)

Written by - 5/17/06

K. Mc Lane
2077 N. Graceland Ave.
Decatur, IL 62526-4070

Centers for Medicare/Medicaid Services
Attention: CMS-270-P
RE: Low Vision Aid Exclusion

Kathryn M(c Lane)

Dear Sirs,

I am a 81yr old person with a vision impairment. Through these 81yrs I have learned to cope by the Grace of God. Modern technology has been a tremendous help as has research on eyes. The 2nd part Medicare does not help pay for the things we need. Our disabled community seems to be forgotten when it comes to financial Aides. It is not for myself I write, but for so very many who develope impairment as they age and those who will come after me who are blind or visual impaired. Thanks for your Concern

5/16/06

(20)

Centers for Medicare/Medicaid Services
Attention: CMS-270-P
RE: Low Vision Aid Exclusion

Dear Sirs,

I am writing this to address the need of low vision aids to be made available thru Medicare & Medicade. People who are blind, like my Mother, who has RP is robbed of the joy of reading, seeing friends and family, or watching movies or television. Low vision aids help bring her world back into "focus". Her progessive retinal deteriation is as much of a handicap as those who have limited mobility. Does CMS have no right to deny those with limited or no vision the equipment they need to regain their independance. Section 414.15 to exclude these much needed aids is being unfair and judgemental. Having low or no vision makes prisoners of those individuals afflicted by diseases like RP. I would also like to see Guide Dogs and their Veterinary Care added to the list of "technologies" made available to Medicare/Medicade patients including Veterinary Care for pets as needed. Keeping working to improve the quality of life to those who need help. Thanking You in Advance,

Lisa Hoosel - 94 Carroll - Mahomet, IL. 61853

Dear Sir: – CMS Proposal. (21)

I am elderly and visually handicapped. Please will you consider approving at this time "Low Vision Aid" for those on Medicare/Medicade. The need for such a service is very real to me and countless others like myself who are hard pressed to afford the devices availabe – and they will make a difference in daily challenges requiring better vision.

Please do not exclude section 414.5 on low vision aid.

Ruth L Short – 144 Eastview Dr. Normal, Il. 61761

Item # 2071000

(22)

Centers for Medicare/Medicaid Services
Attention: CMS-270-P
RE: Low Vision Aid Exclusion

Dear Sirs,

My brother is blind. He needs adaptive technology. Section 414.15 Low Vision Aid Exclusion is terrible. Wheelchairs, crutches, etc. are approved. CCTV, magnifiers, and low vision aids should be approved. Please consider these needs.

Thank you.

Sincerely,
Christina Locher
Urbana, IL.

(23)

Center for Medicare & Medicaid Services May 25, 2006
Department of Health & Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

I understand that no help is provided under current regulations for low vision people by assisting them to obtain magnifiers or CCTV type equipment. I have low vision and fortunately I have the resources to obtain software (cost $345) that magnifies the data from my computer. I also have a camera cost ($315) that magnifies printed material. This has made such a difference for me since I can now read my mail and other items as well as use my computer. The camera magnifier can plug into the video input on most TV sets. This has made such an improvement in my daily activities that I would hope you would make it possible for those who do not have adequate resources to obtain similar visual aids.

I would be willing to have you or a representative contact or visit me to better understand the tremendous benefit of such devices.

Respectfully,

Dale Lehman phone 309-828 8352
903 East Emerson Street
Bloomington, Illinois 61701

5-12-06

(24)

Centers for Medicare / Medicaid

I take exception to your proposed Low Vision aid Exclusion. As a 21 year veteran of the military the government keeps reducing benefits. I have macular degeneration which is worsening and need all the vision aids which should be continued. I shall be aware of your vote as to the above in Section 4.4.15.

The above is my viewpoint, and have had my spouse write this for me

Daniel W. Reploge
2025 E. Lincoln Apt 2212
Bloomington, IL 61701

(25)

Centers for Medicare/Medicaid Services
Attention: CMS-270-P
RE: Low Vision Aid Exclusion

Dear Sirs,

I am an 80 year old senior, I have been "legally blind" for 20 years. We need vision aids to remain and continue an independant life. Please vote NO on section 414.15 LOW

Thank you

Joan P. Hunt
104 W. Vermont Av
Urbana, Il. 61801

1/4/06

(26)

... Medicare Claim.

Please allow for reason

... covered by Medicare

Thank you —

Emma H. Parker

5025 E. Lincoln

Bloomington, Ill. 61701

Item # 2071000

Centers for Medicare/Medicaid Services
Attention: CMS-270-P
RE: Low Vision Aid Exclusion

27

Dear Sirs,

IN REGARDS TO SECTION 414.15 (LOW VISION AID EXCLUSION)

TO BAR AN AID SUCH AS THESE ~~BUT~~ AND ALLOW AIDS FOR MOBILITY SEEMS VERY UNFAIR TO ME. WITH THESE LOW VISION AIDS MANY PEOPLE ARE ABLE TO CONTINUE TO BE PRODUCTIVE MEMBERS OF SOCIETY AND PAY TAXES.

YES, THE NUMBER OF LOW VISION PEOPLE IN THIS COUNTRY IS GROWING RAPIDLY, LETS NOT FORGET THEIR NEEDS AND HELP WHERE WE CAN,

GLENN L. LONG C.O.T

Glenn Long.

CERTIFIED OPHTHALMIC TECHNICIAN

(ILLINOIS)

May 27, 2006

(28)

52 W Wilkinson Rd
Wilmore, MN 56392

Dear Medicare Personell,

I am coordinator of a Low Vision group many of us have macular degeneration, Retinitis Pygmentosa & other visual defects. We are opposing the passing of file Code-1270-P Low Vision aid exclusion as it affects the elderly & others with Low Vision problems. We need the items that Code-1270-P legislation will bar. Please do not allow this to pass.

Sincerely.
Agnes Sageman

CMS-1270-P (29)

P O Box 443
Salisbury, MD 21803-0443
February 3, 2006

Sen. Paul S. Sarbanes
United States Senate
309 Senate Hart Office Building
Washington, DC 20510-2002

Dear Senator Sarbanes:

You may be aware that the Center for Medicare and Medicaid Services (CMS) is taking steps to create a standardized system of diabetes care through competitive bidding. CMS is pushing to competitively bid blood glucose meters, test strips, and lancets as durable medical equipment (DME). This means that patients using CMS services would not have access to all the equipment that is available on the market, but instead to only a select few items. Plus, they may be forced to change their established routine if their current meter or product is not chosen in the competitive bidding process.

CMS claims that competitive bidding will (1) operationalize and determine appropriate prices for DMEs covered by Medicare Part B, (2) protect beneficiary access to quality DMEs, (3) reduce the amount Medicare pays for DMEs, and (4) reduce beneficiary out-of-pocket expenses. However my concern is that this system will limit patient choice, access and services.

Choice in diabetes care is critical. A patient forced to use a meter, which requires more blood for its test strips than the patient can produce, will be defeated. The medical result will be uncontrolled blood sugars with more medical problems to be treated.

The variety of options available now to diabetes patients is vital in helping them to manage their chronic disease. The continued freedom of choice in the treatment will also reduce health care costs by reducing the number of complications. Limiting choice would only weaken the system and thus damage the already fragile state of care especially for the elderly population and people on disability.

Since meters became available for glucose monitoring in the 1980s, I have been checking my own blood sugars. I now use the FreeStyle meter made by TheraSense because it requires only 0.33 micro liter of blood to satisfy its test strips. The other meters require 1 to 10 micro liters of blood. If I were forced by Medicare to use another meter, I would have to use many more strips to obtain a successful reading. In the past, when I used other meters, I would had to stick myself seven or eight times and used as many strips and lancets before I could get a glucose reading. Comfort and confidence are critical in chronic disease care.

2463715

Another disadvantage of the competitive system is that Medicare costs would rise in relation to the number of test strips used to get a single reading. If Medicare then limited the number of strips allowed because of this problem, the result would be increased payment for more long term nursing home care due to diabetic complications. Comfort and confidence are critical in chronic disease care.

Still another objection is that competitive bidding will impede the services and innovation within the diabetes manufacturing industry. Companies will not be able to afford to create new products, programs, and services as they have in the past. For instance, the educational materials and claim-processing services offered by many companies may be discontinued. Currently, neither patients nor Medicare are billed for these services.

The variety of options now available to diabetes patients is vital in helping them to manage their disease. The continued freedom of choice in their treatment will reduce health care costs by limiting the number of complications.

I totally disagree with CMS's competitive bidding system. I feel that glucose monitoring equipment should not be placed in the same category as bedpans and hospital beds. Please do not allow CMS to create a standardization system of diabetes care through competitive bidding.

Sincerely,

Sharon Palmer

Sharon Palmer

56 years with Type 1 Diabetes since October 8, 1949
Member of Former Eastern Shore Diabetes Council
Former Advocate for the American Diabetes Association
Top Individual Fundraiser America's Walk for Diabetes Eastern Shore 2001 & 2002

PAUL S. SARBANES
MARYLAND

309 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510
202-224-4524

#5842745

United States Senate

WASHINGTON, DC 20510-2002

February 21, 2006

MAR 10 2006

Mr. Mark McLellan
Administrator
Center for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

VOGEL

Dear Mr. McLellan:

Enclosed is a copy of correspondence I received from Ms. Sharon Palmer. The letter raises some concerns regarding CMS taking steps to create a standardized system of diabetes care that includes competitive bidding for medical equipment. I would certainly appreciate it if you would carefully review this matter and provide me with an appropriate response.

Your attention to this matter is greatly appreciated.

With best regards,

Sincerely,

Paul Sarbanes

Paul Sarbanes
United States Senator

PSS/slm
Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
150 S. Independence Mall West
Suite 216, The Public Ledger Building
Philadelphia, Pennsylvania 19106-3499

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Region III/Division of Medicare Operations

R3-18(19)
File Code: Cong

May 10, 2006

The Honorable Paul Sarbanes
United States Senate
309 Hart Senate Office Building
Washington, DC 20610

Dear Senator Sarbanes:

Thank you for your inquiry on behalf of Ms. Sharon Palmer of Salisbury, Maryland, who wrote to you concerning Medicare reimbursement for certain durable medical equipment used in the treatment of diabetes.

Ms. Palmer is commenting on a Proposed Rule published in the Federal Register on May 1, 2206. The rule is called "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues." The comment period for this rule ends on June 30, 2006.

Our office cannot answer respond to comments on a Proposed Rule. We will, however, forward Ms. Palmer's comments to those considering the comments for inclusion in the Final Rule, at the following address:

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-12270-P
P.O. Box 8013
Baltimore, MD 21244-8013

If you have questions concerning this, please do not hesitate to call Mark Vogel of my staff at 215-861-4323.

Sincerely,

/s/
Dennis J. Carroll
Associate Regional Administrator

(30)

Please make it possible for low vision people to stable to get low devices

Sincerely

Louise M. Luker

Item # 2071000

Milford Pharmacy & Wellness Center

931 Highway 28 • Suite 205 • Milford, Ohio 45150 • (513) 831-8211 • (800) 944-8211 • Fax (513) 831-2419

31-0
(30)

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

June 1, 2006

Re: CMS-1270-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments for consideration.

1) Competitive Bidding Areas- I strongly object to CMS's alternative proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers- this restricts beneficiaries' choice. This proposal would severely restrict such access to needed items and supplies and may compromise patient health outcomes.

2) Criteria for Item Selection- The competitive bidding program should NOT include common DMPOS supplies such as diabetic testing supplies and diabetic shoes. If CMS intends to centralize and consolidate the provision of DMEPOS items and supplies, the Agency should limit the competitive bidding program to those UNIQUE products that could be provided by a central supplier.

3)Opportunity for Participation by Small Suppliers- I urge CMS to take steps to ensure that small suppliers- which include the majority of pharmacy-based suppliers- 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 bid competitively in large metropolitan areas.
--After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier.
--CMS must take these steps to preserve convenient access to DMEPOS supplies and to maintain established provider/patient relationships.
--I currently provide DMEPOS services in my pharmacy that include; diabetic supplies, blood glucose strips, diabetic shoes and inserts. Without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients.

In conclusion, I urge CMS to revise the regulation to remove diabetic shoes and routine diabetic supplies from this bidding process.

Thank you for considering my view.

Sincerely,

Jeffrey D. Hill, R.Ph.
Milford Pharmacy & Wellness Center

To Department of Health + Human Services!

In regard to help for people with Low Vision — Please see that Medicare + Medicade provide or help provide care for those with Low Vision problems. I know people who are blind who could live a better life if they were given an opportunity. Please see that that happens. Thank you

Dorothy Swanson

(33)

BORDEN'S PHARMACY, INC.

415 W. Vienna St.
Clio, MI 48420
Phone: 810-686-4550, Fax 810-686-7077
Website: bordenspharmacy.com
Provider #: 5516390001

June 3, 2006

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

Dear Sirs:

The purpose of my letter is to comment on proposed changes concerning suppliers of DME, prosthetics, orthotics and supplies.

Point #1: Proposed Mail Order Program

This should be optional for patients, not mandatory. Mail order is not working for prescription medicine and it won't work for medical supplies either. Patients deserve a choice of healthcare providers, any other system would limit access. Patients need easy access to diabetic testing supplies, mail order would not be able to accomplish this.

Point #2: Competitive Bidding

This shouldn't' be implemented due to a number of factors. First, prices change on a regular basis, bids would have to be modified. Second, the amount paid by CMS for diabetic testing supplies is already super competitive, without us submitting bids. Markups are already tiny, we can't stay in business selling items below cost.

Point #3: Determining Single Payment Amounts

This system takes the median bid, which would set an artificially low payment rate. Many suppliers cannot survive on such rates. This amount would have to reviewed regularly to assure that payments would be adequate to cover costs. It would also have to be adjusted when manufacturers raise prices. All this would have to be done on a timely basis to assure adequate reimbursement.

Point # 4: Opportunity for Participation by Small Suppliers;

CMS must ensure that small suppliers (ie: Community Pharmacies) can participate in the process. Our patients should be allowed to continue to shop where they feel they get the best service and value for the healthcare dollars spent on their behalf. The community pharmacy is in a unique position to help their patients with all their healthcare needs, and we are accessible to our patients more than any other healthcare provider. It is imperative that the patient is allowed to continue in the professional relationships they have developed over the years.

Sincerely,

William Dudewicz, RPh.
President

(34)

MARK S. BLOCK, DPM, FACFS, CWS
Podiatrist & Foot Surgeon
Board Certified in Foot Surgery
Diplomate American Board of Podiatric Surgery
Board Certification in Wound Management
Fellow American College of Foot & Ankle Surgeons
Sports Medicine & Laser Podiatry

660 Glades Road, Suite 120 • Boca Raton, FL 33431
(561) 368-3232 • Fax (561) 368-3234

June 7, 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:

As a podiatric physician who has been in practice for more than 20 years, I am concerned with the recent proposal from the Centers for Medicare & Medicaid Services (CMS) that would require physicians to participate in the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I support excluding all physicians, including podiatric physicians, from the new program.

I currently am a DMEPOS supplier. I recognize the importance of being able to supply DMEPOS items to patients as part of the quality care I provide. A number of these patients are referred to me by other physicians with the understanding that their condition requires dispensing of an appropriate DME at the time of treatment. If I am no longer able to supply these items due to the competitive acquisition program, my patients will suffer. I use a wide range of DMEPOS items, including walking boots for foot fractures and ankle braces for acute ankle injuries. If, as a result of the new program, my patients will be required to obtain these items from another supplier away from my office, additional injury could result. In a number of cases, the inability to dispense the appropriate item at the time of treatment puts the patient at further risk with potential complications. These considerations were factored in to my decision to become a DMEPOS supplier. I would have a difficult time telling a patient that they need to travel across town to obtain an item that is both medically necessary and appropriate.

I respectfully request that you reconsider your proposal and exclude all physicians, including podiatric physicians, from the new competitive acquisition program for certain

DMEPOS. Instead, allow me as a qualified supplier to continue to directly supply items to Medicare beneficiaries.

Sincerely,

Mark S Block DPM
Insurance Chairman FPMA/CAC Representative
First Vice-President FPMA (Florida Podiatric Medical Association)

35

Katrina Di Pasqua, DPM
Family FootCare Specialist
2017 Jefferson St
Napa, CA 94559

June 5, 2006

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

Dear Dr. McClellan:

I am writing in opposition to the proposed rule, *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*. In its current form, this rule would include physicians in a competitive acquisition program for certain DMEPOS items. I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid.

As a podiatric physician, I supply DMEPOS items to Medicare beneficiaries. I believe that the proposed rule, if implemented, would significantly impact my ability to continue to provide medically necessary care of the highest quality to my patients. I urge the Centers for Medicare & Medicaid Services (CMS) to exclude all physicians, including podiatric physicians, from the competitive acquisition program and to instead allow physicians to continue to supply DMEPOS items as part of the normal course of providing patient care.

A competitive acquisition program that requires physicians to bid to supply items to patients will result in the elimination of some physician suppliers from the program. If physicians can no longer supply DMEPOS items, patients will suffer.

Consider a patient who presents with the chief complaint of foot pain following an injury. I diagnose the patient with a foot fracture and determine that a walking boot is necessary to treat the fracture. 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 could result, which could result in other additional injuries.

As another example, consider a patient who sustains an acute ankle injury. As the treating physician, I determine that an ankle brace and crutches are appropriate in treating the patient. If I am not a DMEPOS supplier in the new competitive acquisition program and those items are among those subject to bidding, 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.

There are many other examples that could be provided to demonstrate how including physicians in the competitive acquisition program can be detrimental to patient care. Again, I urge CMS to exclude all physicians, including podiatric physicians, from this program and to continue to allow physicians to supply DMEPOS items used in the treatment of Medicare beneficiaries.

Sincerely,

K Di Pasqua DPM

Katrina Di Pasqua, DPM

(36)

SUPLIDORES DE EQUIPO MÉDICO ASOCIADOS, INC.

May 25, 2006

AA Homecare
625 Slaters Lane
Suite 200
Alexandria, Virginia 22314-1171

By Hand or Courier:
7500 Security Boulevard,
Baltimore, MD 21244-1850

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

Re: Competitive Bidding Areas (Comments)
Federal Register Vol. 71, No. 83 – Monday, May 1, 2006 – Proposed Rules

Dear Distinguished Members of the PAOC and CMS Evaluators,

In my capacity as President of SEMA (Suplidores de Equipo Médico Asociados, Inc.), a Puerto Rico DMEPOS association that for the past 13 years has been representing and providing orientation to DME suppliers in Puerto Rico, it has been brought to my attention by our internal committee in charge of studying the impact of the Competitive Bidding Program on the island, local DME members, patient advocates and practitioners in Puerto Rico's health care system, their concerns regarding the methodology proposed by CMS and the possibility of Puerto Rico being selected for the initial phase of the Competitive Bidding Program in 2007.

Under section 302 of the Medicare Modernization Act of 2003, the law requires Medicare to replace the current durable medical equipment payment methodology for certain items with a competitive acquisition process to improve the effectiveness of its methodology for setting DME payment amounts. According to CMS this new bidding process will harness marketplace

P.O. Box 8746, Ponce, P.R. 00732
Tel. 787-259-4646, Fax. 787-843-0014
Email: semapr@aim.com

dynamics and will create incentives for suppliers to provide quality items and services in an efficient manner and at reasonable costs.

According to section 1847(a)(1)(B) of the Social Security Act, CMS has the authority to phase-in Competitive Bidding Programs so that the bidding under the program occurs in 10 of the largest metropolitan statistical areas (MSA's) in 2007. Within their proposal CMS presents a methodology for selecting the initial Competitive Bidding areas for 2007 by selecting 10 areas from a pool of the top 50 MSA's using Census Bureau population data and excludes the top three major metropolitan areas that included New York, Los Angeles and Chicago. They propose to eliminate the 25 MSA's that had the fewest DMEPOS allowed charges for items furnished in 2004 and scored the remaining 25 MSA's on combined rankings based on DMEPOS allowed charges per fee-for-service beneficiaries and ratio of providers to beneficiaries using DMEPOS in 2004. Based on this ranking formula, Puerto Rico may possibly be selected as one of the ten areas for the initial phase of the Competitive Bidding Program in 2007.

We vehemently oppose the inclusion of Puerto Rico in this 2007 initial phase program and we present the following rationale as to why Puerto Rico should not be included in this initial phase.

The primary objective of the Competitive Bidding Program is to reduce the amount Medicare pays for DMEPOS and bring the reimbursement amount more in line with that of a competitive market. With the implementation of the Medicare Advantage (MA) program in Puerto Rico, this objective has been achieved. According to information provided by the CMS Director of Puerto Rico, Ms. Delia Lasanta, more than 50% of the beneficiaries in Puerto Rico are presently enrolled in an MA program as of May 9, 2006. Currently in Puerto Rico there are eleven Medicare Advantage Organizations providing services to beneficiaries across the island. Geographically, Puerto Rico is a relatively small island, ranging 100 miles east to west and 35 miles north to south, and is composed of 78 municipalities of which the vast majority are rural areas. Two of these municipalities may be considered slight metropolitan areas. The major city and capital, San Juan, is considered the largest metropolitan area in Puerto Rico, however large sections of this city are still rural in nature and does not fully encompass the conceived idea of a major metropolitan city such as Houston, Detroit or Boston, which are cities fully recognized as metropolitan in nature. Therefore, upon considering the total amount of MA Organizations that cover Puerto Rico, the small size of the island, the aggressive marketing and reach-in programs used by these MA Organizations, and the steady increment of enrollment by beneficiaries, it is strongly believed that by 2007 the number of MA enrollees could come close to cover all beneficiaries on the island.

When evaluating Puerto Rico's marketplace one must consider that currently Puerto Rico does not possess any local DMEPOS manufacturers, which forces local suppliers to order supplies from companies in the United States, causing an increase of costs. Only companies that

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Email: semapr@aim.com

can order in large, bulk quantities would have the ability to endure the Puerto Rico market and be competitive within the Competitive Bidding Program. The result would be an economic catastrophe for many small DME supply companies and would eventually lead to possible healthcare anti-trust violations. This outcome has proven to be probable, between 1999 and 2001 a Medicare pilot program was initiated in Polk County, Florida and after only two rounds of bidding, one national company emerged as dominant in the Medicare oxygen market. This is extremely worrisome for the constituents of Puerto Rico healthcare systems having the majority of DME suppliers forced out of the market due to their small business volume, which consists mostly of beneficiaries located in difficult to reach rural areas; therefore the Competitive Bidding Program would inadvertently impact the beneficiaries access to DME supplies that previously were available in their region. This eventual result would defeat one of the main objectives of the program, which consists in the protection of beneficiary access to quality DME supplies. Although CMS through the Competitive Bidding Program contends that standards can protect quality, the government's ability to develop and enforce standards in Puerto Rico has proven to be very poor specifically when enforcing standards against MA Organizations regarding marketing tactics. Relying on government defined and enforced standards are no substitute for the ability for beneficiaries to choose among various suppliers.

In addition, long-standing relationships between beneficiaries and familiar suppliers will be interrupted causing disruption in service and dissatisfaction for patients. Given Puerto Rico's location in the heart of the Caribbean Sea the island is impacted yearly by hurricanes and tropical storms that makes it impossible for distant suppliers to provide the service needed because of sudden flooding in many of the small, rural roads in the vast regions of the island, these common events impacts the beneficiaries access to DME supplies, such as oxygen tanks that are needed on a regular basis. In summary, the result of the implementation of the Competitive Bidding Program would be that small, community-based suppliers would be displaced by larger chain suppliers that can take advantage of economies of scale, but which may not be in the interests of beneficiaries. The Competitive Bidding Program will make it impossible for the beneficiary that decides to continue with Traditional Medicare to do so, because although in essence the beneficiary would be entitled to continue under the label of "Traditional Medicare", they would not have the actual benefits of selecting from an array of suppliers since only one or two suppliers would be available to provide services. It is this freedom of selection that is currently provided by Traditional Medicare that must be vigilantly safeguarded.

Another relevant aspect to consider is that the Allowed Charges used to consider Puerto Rico in the implementation of this initial phase corresponds to the 2004 fee schedule. During 2003 to 2004 CMS allowed charges to Puerto Rico which were higher than in the States due to the recognition of the added costs involved in importing DME supplies, such as local importation taxes, shipment/transportation expenses and freight-insurance charges, but in 2005 this fee-schedule was reduced by CMS and presently the DME suppliers now have to absorb these previous added costs, therefore the use of Allowed Charges of 2004 does not reflect the current

P.O. Box 8746, Ponce, P.R. 00732
Tel. 787-259-4646, Fax. 787-843-0014
Email: semapr@aim.com

reality of Allowed Charges in Puerto Rico, which the PAOC is using to select the MSA's that are to be included in the initial phase of the program in 2007.

Another important factor that needs to be addressed is the language barrier that currently exists between Puerto Rico and the United States, given that the majority of the islanders are native Spanish speakers. The implementation of this program will be at a high cost for many suppliers and will cause a decrease in supplier access to beneficiaries, resulting in a less competitive market.

Since Puerto Rico is composed of almost 100% Hispanic communities, there is a high predisposition to certain health conditions, such as Diabetes and Heart Diseases, which have a direct impact in the Allowed Charges made to Medicare. Based on studies performed by the Department of Health of Puerto Rico, statistics showed that 18 out of every 100 women 65 years of age or older were diagnosed with chronic heart conditions and 22 out of every 100 men 65 years of age or older were also diagnosed with chronic heart conditions. Regarding diabetes, statistics demonstrated that 20 out of every 100 women 65 years of age or older were diagnosed with diabetes and 22 out of every 100 men 65 years of age or older were also diagnosed with diabetes. This data demonstrates a steady increment in the diagnosis of these chronic conditions on the island, therefore it is important that when analyzing the Allowed Charges one has to consider the reality that many beneficiaries in Puerto Rico possess these serious and chronic illnesses. In fact, the supply costs in Puerto Rico are currently competitive and even though the Allowed Charges numbers are high, one cannot conclude that the high Allowed Charges is a result of suppliers not being competitive.

Another CMS objective for the implementation of the Competitive Bidding Program is to limit the burden on beneficiaries by reducing their out-of-pocket expenses, it is SEMA's belief that MA Organizations have already achieved this goal by providing their enrollees with no out-of-pocket expenses or low out-of-pocket expenses.

Based on the rational presented in this letter it is SEMA's understanding that the objective of the Competitive Bidding Program will not be achievable in Puerto Rico and will cause a contrary effect for the implementation will result in attaining the opposite results originally intended. In fact Medicare will incur a larger economic expense to achieve an objective that is already taking place because of the MA Organizations actions and the changes resulting from the Medicare Reform of 2003. It is SEMA's position and request that the Competitive Bidding Program in Puerto Rico not be implemented in 2007 or in 2009, because the current system already provides a way to harness marketplace dynamics that creates incentives for suppliers to provide quality items and services in an efficient manner and at a reasonable cost.

For these reasons, we present these rationales to our distinguished members of the PAOC and CMS Evaluators that have the difficult task of recommending to CMS the methodology to select

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the regions that will be included in the 2007 initial phase. We strongly recommend that the PAOC and CMS Evaluators consider the rationale previously presented when deciding whether to include Puerto Rico in the initial phase or in the program all together.

Sincerely,

Ramon Bonilla
President - SEMA

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(37-1)

June 5, 2006

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

Dear Dr. McClellan:

I am writing in opposition to the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

As a podiatric physician, I supply DMEPOS items to Medicare beneficiaries. I believe that the proposed rule, if implemented, would significantly impact my ability to continue to provide medically necessary care of the highest quality to my patients. I urge the Centers for Medicare & Medicaid Services (CMS) to exclude all physicians, including podiatric physicians, from the competitive acquisition program and to instead allow physicians to continue to supply DMEPOS items as part of the normal course of providing patient care.

A competitive acquisition program that requires physicians to bid to supply items to patients will result in the elimination of some physician suppliers from the program. If physicians can no longer supply DMEPOS items, patients will suffer.

Consider a patient who presents with the chief complaint of foot pain following an injury. I diagnose the patient with a foot fracture and determine that a walking boot is necessary to treat the fracture. 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 could result, which could result in other additional injuries.

As another example, consider a patient who sustains an acute ankle injury. As the treating physician, I determine that an ankle brace and crutches are appropriate in treating the patient. If I am not a DMEPOS supplier in the new competitive acquisition program and those items are among those subject to bidding, 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.

There are many other examples that could be provided to demonstrate how including

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severe, with greater recovery time and increased risks for complications.

There are many other examples that could be provided to demonstrate how including physicians in the competitive acquisition program can be detrimental to patient care. Again, I urge CMS to exclude all physicians, including podiatric physicians, from this program and to continue to allow physicians to supply DMEPOS items used in the treatment of Medicare beneficiaries.

Sincerely,

Adam J. Teichman, DPM, AACFAS

38

FOOT & ANKLE PODIATRY ASSOCIATES, P.C.

ADRIANA M. PACE, D.P.M.
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June 5, 2006

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

Dear Dr. McClellan:

As a well trained surgical podiatric physician who has been in practice for 7 years, I am concerned with the recent proposal from the Centers for Medicare & Medicaid Services (CMS) that would require physicians to participate in the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I support excluding all physicians, including podiatric physicians, from the new program.

I currently am a DMEPOS supplier. I am against my patients having to go elsewhere to obtain their DME for clinical problems that I have diagnosed and am capable of treating. As a surgically trained DPM, I find it essential to provide my patients with DME, as I understand what surgery has been performed. I have experienced many problems thus far with some private insurance carriers who tried to institute the same concept. When I send a patient to a particular location, rarely do they get what I prescribe, although it says it clearly on a prescription. When I provide DME, they get exactly what I want and what I know will benefit my patient. Ultimately they are happy and I can always adjust or accommodate them as needed. If I am no longer able to supply these items due to the competitive acquisition program, my patients will suffer. I provide a variety of DMEPOS items, including custom ankle foot orthoses for severe deformity both before and after surgery, Cam walkers for fractures, diabetic shoes and custom inserts, night splints, orthotics, and ankle braces for acute foot and ankle injuries. If, as a result of the new program, my patients will be required to obtain these items from another supplier away from my office, additional injury could result. Often the patient will delay in obtaining the DME that is extremely important to their care and healing process. If they go elsewhere for their DMEPOS items, another supplier will often have no idea about the

FOOT & ANKLE PODIATRY ASSOCIATES, P.C.

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Surgery or what the item is supposed to achieve for the clinical problem. I cannot imagine telling any Medicare beneficiary that I am capable but unable to supply an item and that he or she must travel somewhere else to obtain an item that is both medically necessary and appropriate. I practice in a region where the elderly do not travel far and they often need someone else to transport them, which could result in a further delay in obtaining a medically necessary item.

Please reconsider your proposal and exclude all physicians, including podiatric physicians, from the new competitive acquisition program for certain DMEPOS. Instead, allow me as a qualified supplier to continue to directly supply items to Medicare beneficiaries.

Sincerely,

Glenn D. Weinfeld, DPM, AACFAS

East Cobb Foot & Ankle Care

DR. MARK LIGHT

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(39-0)
(21)

June 8, 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 in opposition to the proposed rule, *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*. In its current form, this rule would include physicians in a competitive acquisition program for certain DMEPOS items. I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid.

I am concerned that if physicians, including podiatric physicians, are not excluded from the new program, patient care will suffer. I provide certain DMEPOS items to my patients as part of the normal course of quality care. If I am no longer able to supply those items as a result of not being selected as a DMEPOS supplier under the new program, my patients will suffer.

I want to ensure that my patients receive appropriate care for their particular problem(s). Being able to dispense a medically necessary DMEPOS item when I am the one treating the patient just makes sense and is better medicine. I want to make sure the product fits the patient and functions as it should. I want the patient to receive exactly what they need without someone else making that decision for me. Patients should be able to get from me the full range of care they require for a particular problem, yet with this proposal that may no longer occur.

I do not believe that the Centers for Medicare & Medicaid Services (CMS) considers it to be in the best interest of patient care to impede a physician's ability to provide medically necessary and quality care to Medicare beneficiaries. Again, I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid. Instead, continue to allow physicians to supply

appropriate DMEPOS items used in the care of patients without being forced to competitively bid for that privilege.

Sincerely,

Mark Light, DPM FACFAS

(40)

STAMFORD PODIATRY GROUP, P.C.

24 THIRD STREET STAMFORD, CT 06905-5195
TELEPHONE: 203 323 1171 FACSIMILE: 203 323 4649

MICHAEL L. SABIA, JR., D.P.M., AACFAS
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FRANCISCO LAGO, D.P.M., AACFAS
RUI DEMELO, D.P.M., AACFAS

June 8, 2006

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

Dear Dr. McClellan:

We request that the Centers for Medicare & Medicaid Services (CMS) exclude all physicians, including podiatric physicians, from the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). We believe that the proposal, if finalized in its current form, could interfere with our ability to provide medically necessary and quality care to Medicare beneficiaries and could actually harm our patients.

We are podiatric physicians who are associated with a practice that has been located in Stamford. CT since 1946. We routinely treat Medicare beneficiaries and, as a current DMEPOS supplier, we are able to provide our patients with the wide range of care they require. If the new program results in our elimination as a supplier, we may no longer be able to supply medically necessary items, such as walking boots used for fractures or other structural instabilities, or ankle braces used for acute ankle injuries. We realize that CMS is still determining which items will be subject to competitive bidding but we believe that if <u>any</u> item is medically necessary in caring for a patient, a physician should be able to supply it.

We respectfully request that CMS modify its proposal to exclude all physicians, including podiatric physicians, from the competitive acquisition program. Instead, please allow physicians DMEPOS suppliers to continue to provide appropriate and medically necessary items that are used for patient care.

Sincerely,

Michael L. Sabia, Jr., DPM

Marissa Girolamo, DPM

Rui DeMelo, DPM

Francisco Lago, DPM

41-D
(3)

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cunninghamdrugs@xcenter.net

June 6, 2006

Dear: Department of CMS

Thank you for the opportunity to comment on the proposed regulation to implement a compettitve bidding program for the DMEPOS. I offer the following comments for consideration as CMS develops the final regulation.

I STRONGLY OBJECT TO CMS ALTERNATIVE PROPOSAL THAT WOULD REQUIRE BENEFICIARIES TO OBTAIN REPLACEMENT SUPPLIES OF CERTAIN ITEMS THROUGH DESIGNATED PROVIDERS- THIS RESTRICTS BENEFICIARIES CHOICE. This proposal would severely restrict beneficiaries access to needed items and supplies and compromise patient health outcomes.

The competitive bidding program should not include common DMEPOS supplies such as diabetic testing supplies.

Sincerely,

Russell Essary

PHARM D

42-0
(2)

June 5, 2006

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

Dear Dr. McClellan:

I am writing in opposition to the proposed rule, *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*. In its current form, this rule would include physicians in a competitive acquisition program for certain DMEPOS items. I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid.

I am concerned that if physicians, including podiatric physicians, are not excluded from the new program, patient care will suffer. I provide DMEPOS items to my patients as part of the normal course of quality care. If I am no longer able to supply those items as a result of not being selected as a DMEPOS supplier under the new program, my patients will suffer.

I would like you to consider yourself or a relative seeking the care of a physician as I give a real life example. A patient comes to my office with a broken bone in their foot. It is critical that they stay non-weight bearing as part of the treatment. By putting any weight on the foot coming to my office they may have already done more damage. Can you imagine me having to tell the patient that I can not dispense them a pair of crutches and a fracture walker? And, they will have to incur more pain and possible further, and some cases, irreversible damage going across town to a supplier instead of getting it right on the spot?

Consider the case of a DMEPOS item able to give a patient immediate relief and protection from injury that I can longer dispense to them. They would need to go across town to get it, and then return to my office to find it to be an ill-fitting or incorrect item. They would need to back to the supplier and get a new or different item that is hopefully correct. Suppose the item dispensed is one of poor quality that I would never dispense to a patient. Do I tell the patient this information? Would I then be liable for their subsequent inability to progress to healing? How do I look a patient in the eye with this information?

As it is now, if a patient receives an ill-fitting devise or a devise that has broken, I fix the problem immediately. With this proposed rule, this patient will be making multiple formerly unnecessary trips, all the while not receiving the immediate care they need and would have formerly received.

I want to ensure that my patients receive appropriate care for their particular problem(s). Being able to dispense a medically necessary DMEPOS item when I am the one treating the patient just makes sense and is better medicine. I want to make sure the product fits the patient and functions as it should. I want the patient to receive exactly what they need without someone else making that decision for me. Patients should be able to get from me the full range of care they require for a particular problem, yet with this proposal that may no longer occur.

I think you would be interested to know that my office spends numerous and continuous hours researching and using DMEPOS items before we select the best quality devise for a patient, all at our expense. We physicians want this liability and responsibility in order to provide our patients the best care.

I do not believe that the Centers for Medicare & Medicaid Services (CMS) considers it to be in the best interest of patient care to impede a physician's ability to provide medically necessary and quality care to Medicare beneficiaries. Again, I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid. Instead, continue to allow physicians to supply appropriate DMEPOS items used in the care of patients without being forced to competitively bid for that privilege.

Sincerely,

Jonathan Purdy, DPM
Foot Specialists of Acadiana, APMC
2309 E. Main St. Suite 501
New Iberia, LA 70560

(43)

June 6, 2006

Center 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

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments for consideration as CMS develops the final regulation.

I strongly object to CMS' alternative proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers – this restricts beneficiaries' choice. This proposal would severely restrict beneficaries' access to needed items and supplies and may compromise patient health outcomes.

The competitive bidding program should not include common DMEPOS supplies such as diabetic testing supplies. If CMS intends to centralize and consolidate the provision of DMEPOS items and supplies, the Agency should limit the competitive bidding program to those unique products that could be provided be a central supplier.

I urge CMS to take steps to ensure that small suppliers – which include the majority of pharmacy-based suppliers - can participate in the competitive bidding program. Small supplies should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to be competitive in large metropolitan areas.
After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier.
CMS must take these steps to preserves beneficaries' convenient access to DMEPOS supplies and to maintain established provider/patient relationships.

Thank you for considering my view.

Sincerely,

Frank H Sumi, President

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Ankle & Foot CARE CENTERS
Podiatric Physicians and Surgeons

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Dr. John E. Barrett
Dr. Craig Beaudis
Dr. Gregory A. Blasko
Dr. Christian Carbonell
Dr. John Chiaro, Jr.
Dr. Robert Debiec
Dr. Lawrence A. DiDomenico
Dr. Kenneth J. Emch
Dr. Joseph J. Francisco, Jr.
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Dr. Eric Masternick
Dr. David Podolsky
Dr. Mark S. Smesko

44-0
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June 5, 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) exclude all physicians, including podiatric physicians, from the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I believe that the proposal, if finalized in its current form, could interfere with my ability to provide medically necessary and quality care to Medicare beneficiaries and could actually harm my patients.

I am a podiatric physician who has been in practice for 10+ years. I routinely treat Medicare beneficiaries and, as a current DMEPOS supplier, I am able to provide my patients with the wide range of care they require. If the new program results in my elimination as a supplier, I may no longer be able to supply medically necessary items, such as walking boots used for fractures or other structural instabilities, or ankle braces used for acute ankle injuries. I realize that CMS is still determining which items will be subject to competitive bidding but I believe that if an item is medically necessary in caring for a patient, a physician should be able to supply it.

I respectfully request that CMS modify its proposal and exclude all physicians, including podiatric physicians, from the competitive acquisition program. Instead, allow physician DMEPOS suppliers to continue to provide appropriate and medically necessary items that are used for patient care.

Sincerely,

Gregory A. Blasko, DPM, FACFAS
Fellow American College of Foot and Ankle Surgeons
Diplomat, American Board of Podiatric Surgery

Ankle & Foot CARE CENTERS
Podiatric Physicians and Surgeons

Dr. Michelle C. Anania
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Dr. Robert Debiec
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Dr. Eric Masternick
Dr. David Podolsky
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45-D
(12)

June 5, 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:

As a podiatric physician who has been in practice for more than 20 years, I am concerned with the recent proposal from the Centers for Medicare & Medicaid Services (CMS) that would require physicians to participate in the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I support excluding all physicians, including podiatric physicians, from the new program.

I currently am a DMEPOS supplier. I recognize the importance of being able to supply DMEPOS items to patients as part of the quality care I provide. If I am no longer able to supply these items due to the competitive acquisition program, my patients will suffer. I use a wide range of DMEPOS items, including walking boots for foot fractures and ankle braces for acute ankle injuries. If, as a result of the new program, my patients will be required to obtain these items from another supplier away from my office, additional injury could result. I cannot imagine telling a Medicare beneficiary that I am unable to supply an ankle brace to treat an ankle injury and he or she must travel across town to obtain an item that is both medically necessary and appropriate.

Please reconsider your proposal and exclude all physicians, including podiatric physicians, from the new competitive acquisition program for certain DMEPOS. Instead, allow me as a qualified supplier to continue to directly supply items to Medicare beneficiaries.

Sincerely,

E. David Podolsky DPM

E. David Podolsky, DPM, FACFAS
Fellow American College of Foot and Ankle Surgeons
Diplomat, American Board of Podiatric Surgery

(46)

June 7, 2006

Lighthouse Foot & Ankle Center
Colette D'Altilio, DPM

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

Dear Dr. McClellan,

I am writing in opposition to the proposed rule, *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*. In its current form, this rule would include physicians in a competitive acquisition program for certain DMEPOS items. I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid.

I am a practicing podiatric provider in Lighthouse Point, FL, where as you may know the patient population is of retirement age and are often non-surgical candidates. The DMEPOS products provided to the elderly in a timely fashion is imperative to their care and healing processes. Certain DMEPOS items are supplied to my patients as part of the normal course of quality care. As a supplier of pneumatic boots, ankle braces and wound care products such as polymem, the elderly especially benefit form immediate and appropriate delivery of these products. I am concerned that if I am no longer able to supply those items as a result of not being selected as a DMEPOS supplier under the new program, my patients will not receive the timely care they could have received resulting in a slower healing process, longer duration and increase in pain and a reduction in ability to perform activities of daily living.

Being able to dispense a medically necessary DMEPOS item when I am the one treating the patient just makes sense and is better medicine. I want to make sure the product fits the patient and functions as it should. I want the patient to receive exactly what they need without someone else making that decision for me. Patients should be able to get from me the full range of care they require for a particular problem, yet with this proposal that may no longer occur.

I do not believe that the Centers for Medicare & Medicaid Services (CMS) considers it to be in the best interest of patient care to impede a physician's ability to provide medically necessary and quality care to Medicare beneficiaries. Again, I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid. Instead, continue to allow physicians to supply appropriate DMEPOS items used in the care of patients without being forced to competitively bid for that privilege.

Sincerely,
Colette D'Altilio, DPM Colette D'Altilio

2034 E. SAMPLE ROAD LIGHTHOUSE POINT, FL 33064
PHONE: 954-933-9033 FAX: 954934-0060

HM

CME IV
DIVISION OF
COOLEY MEDICAL
1152 RIVERSIDE DRIVE
PRESTONSBURG, KY 41653

June 7, 2006

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

RE: CMS-1270-P

Gentlemen:

I offer the following comments for consideration as CMS develops the final regulations implementing a competitive bidding program for DMEPOS.

COMPETITIVE BIDDING AREAS
I strongly object to CMS' alternative proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers. This proposal severely restricts beneficiaries choice to access needed items and supplies and may compromise patient health outcomes.

CRITERIA FOR ITEM SELECTION
The competitive bidding program should NOT include common DEMPOS supplies such as diabetic testing supplies, ostomy supplies or nebulizer medications. If CMS intends to centralize and consolidate the provision of DMEPOS items and supplies, the Agency should limit the competitive bidding program to those unique products that could be provided by a central supplier.

OPPORUNITY FOR PARTICIPATION BY SMALL SUPPLIERS
I urge CMS to take steps to ensure that small 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 or impossible for small suppliers to be competitive in large metropolitan areas.

After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should be allowed to join the competitive bidding program as a contracted supplier.

CMS must take these steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established provider/patient relationships.

I currently provide the following types of DMEPOS in my practice diabetic testing supplies, ostomy supplies and nebulizer medications.

Thank you for consideration my view.

Sincerely,

Harold W. Cooley, R. Ph.
606-886-0333
hwcooley@cooleymedical.com

FOOT AND ANKLE CENTER
OF
NORTH CAROLINA

DR. PHILLIP E. WARD
PODIATRIST · FOOT SURGEON
FOOT ORTHOPEDIST

BOARD CERTIFIED
ABPS
ABPOPPM

FELLOW
ACFAS
ACFAOM

48

June 7, 2006

Mark B. McClellen, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellen:

I am writing in opposition to the proposed rule, *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*. In its current form, this rule would include physicians in a competitive acquisition program for certain DMEPOS items. I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid.

As a podiatric physician who has been in practice for more than 16 years, I am concerned that if physicians, including podiatric physicians, are not excluded from the new program, patient care will suffer. I provide certain DMEPOS items to my patients as part of the normal course of quality care. If I am no longer able to supply those items, my patients will suffer due to complications related to this mandated delay of appropriate care.

A competitive acquisition program that requires physicians to bid to supply items to patients will result in the elimination of some physician suppliers from the program. If physicians can no longer supply DMEPOS items, patients will suffer.

Consider a patient who presents with the chief complaint of foot pain following an injury. I diagnose the patient with a foot fracture and determine that a walking boot is necessary to treat the fracture. 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 could result, which could result in other additional injuries.

North Carolina Foot & Ankle Society

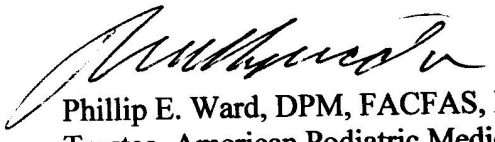
PHONE (910) 295-9262
3 REGIONAL CIRCLE, SUITE B, PINEHURST, NC 28374
FACNC@earthlink.net
FAX (910) 295-1131

As another example, consider a patient who sustains an acute ankle injury. As the treating physician, I determine that an ankle brace and crutches are appropriate in treating the patient. If I am not a DMEPOS supplier in the new competitive acquisition program and those items are among those subject to bidding, 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.

I want to ensure that my patients receive appropriate care for their particular problem(s). Being able to dispense a medically necessary DMEPOS item when I am the one treating the patient just makes sense and is better medicine and in the long run more cost effective. I want to make sure the product fits the patient and functions as it should. I want the patient to receive exactly what they need without someone else making that decision for me. Patients should be able to get from me the full range of care they require for a particular problem, yet with this proposal that will no longer occur.

I respectfully request that the Centers for Medicare & Medicaid Services (CMS) exclude all physicians, including podiatric physicians, from the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I believe that the proposal, if finalized in its current form, would interfere with my ability to provide medically necessary and quality care to Medicare beneficiaries and could actually harm my patients.

Sincerely;



Phillip E. Ward, DPM, FACFAS, FACFAOM
Trustee, American Podiatric Medical Association
Past-President, North Carolina Foot and Ankle Society

Baltimore Podiatry Group
Drs. Scheffler & Lipton, P.A.

EAST DRIVE SHOPPING CENTER
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ARBUTUS, MD 21227
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THE GARWYN MEDICAL CENTER
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BALTIMORE, MD 21216
(410) 624-3338

ROSSVILLE CENTER
7850 ROSSVILLE BLVD., SUITE 210
BALTIMORE, MD 21236
(410) 882-2225

90 PAINTERS MILL ROAD, SUITE 236
OWINGS MILLS, MD 21117
(410) 247-5333

(49)

June 7, 2006

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

Dear Dr. McClellan:

I am writing in strong opposition to the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

I currently supply DMEPOS items to my patients who are on Medicare. The proposed changes would severely affect my ability to treat these patients.

I treat many patients with diabetes. I am considered an expert in the field. I am a past President, Health Care & Education, Mid-Atlantic Region, American Diabetes Association (ADA) and I am the author of the book "*101 Tips On Foot Care For People With Diabetes, 2nd Edition*", recently published by the ADA.

Permit me to use a hypothetical patient with diabetes as an example. Mrs. Jones, a 69-year-old obese female with diabetes, diabetic neuropathy and peripheral vascular disease (not an uncommon scenario) presents to my office in Arbutus (10 minutes from your location at CMS by the way) on a Saturday morning. Yes, I have had Saturday AM hours for 33 years. Her son, who came in from out of town to drive her to the office, since she cannot drive due to her diabetic retinopathy, accompanies her. Mrs. Jones foot is swollen and, despite the neuropathy, painful. X-rays show a fracture. Under the current system I would immediately, and appropriately, treat the problem and provide Mrs. Jones with an Air Cast type walking brace. Under the proposed new system the patient would have to leave my office, risk additional injury to the unprotected foot and even hazard progression to a Charcot deformity. If the new "supplier" is not available on the weekend she may have to wait until someone could again transport her the following week. THIS IS NOT GOOD MEDICINE! We learn "First do no harm." This proposal runs counter to that concept.

There are many such examples that I could give. Patients with ankle sprains requiring splints where walking on the injury could create further damage are seen regularly. How can asking them to limp out to go elsewhere for a supply, while risking additional injury, when I could immediately make them comfortable, be justified? Again, THIS IS NOT GOOD MEDICINE!

I urge the Centers for Medicare & Medicaid Services (CMS) to exclude all physicians, including podiatric physicians, from the competitive acquisition program and to permit us to continue to supply DMEPOS items as part of the normal course of providing GOOD MEDICAL CARE to Medicare beneficiaries. If physicians can no longer supply DMEPOS items, patients will suffer.

Sincerely,

Neil M. Scheffler, DPM, FACFAS

The University of Texas
Health Science Center at San Antonio
Mail Code 7774
7703 Floyd Curl Drive
San Antonio, Texas 78229-3900

Orthopaedic Residency Office
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(210) 567-6326 • *Fax* (210) 567-6295

Division of Orthopaedic Traumatology
(210) 567-5154 • *Fax* (210) 567-3113

Division of Podiatric Medicine and Surgery
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General Orthopaedics
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Deputy Chairman and
Residency Program Director
Paul S. Chang, DO
Chief, VA Service
Duane E. Griffin, MPAS, PA-C
James A. Jelen, MPAS, PA-C
David E. Zinsmeister, MMS, PA-C

Hand and Plastic Surgery
Fred G. Corley, MD
Douglas T. Cromack, MD

Pediatric Orthopaedics
Robert M. Campbell, Jr., MD
President's Council/Dielmann Chair in
Pediatric Orthopaedic Surgery
Kent A. Reinker, MD
Kaye E. Wilkins, MD
Theresa Castillo, PA-C

Shoulder Surgery
Charles A. Rockwood, Jr., MD
Chairman Emeritus
Michael A. Wirth, MD
Charles A. Rockwood, Jr. MD Chair
Anil K. Dutta, MD

Sports Medicine
Andrew L. Whaley, MD

Spine Surgery & Scoliosis
Albert E. Sanders, MD
John S. Toohey, MD

Total Joint Arthroplasty
Lorence W. Trick, MD

Orthopaedic Trauma and
Posttraumatic Reconstruction
Animesh Agarwal, MD
Chief, Division of
Orthopaedic Traumatology
Christina Ng, PA-C

Orthopaedic Research
David D. Dean, PhD
Victor L. Sylvia, PhD

Wound Care
William. H. Matthews, MD

Podiatric Medicine and Surgery
Lawrence B. Harkless, DPM
Chief, Division of Podiatry
Louis T. Bogy Professor
Karen Brooks, DPM
Javier La Fontaine, DPM
Rosemay Michel, DPM
Thomas Zgonis, DPM
Gary Meyn, CHE
Project Coordinator

Residency Education
Theresa Hill
Orthopaedic Residency
Program Administrator
Sue Casteel
Podiatric Residency
Program Administrator

Toni Hensley, MA, MBA
Department Administrator

50

June 8, 2006

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

Dear Dr. McClellan:

I am writing in opposition to the proposed rule, *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*. In its current form, this rule would include physicians in a competitive acquisition program for certain DMEPOS items.

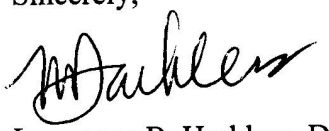
I am concerned that if physicians, including podiatric physicians, are not excluded from the new program, patient care will suffer. I provide certain DMEPOS items to my patients as part of the normal course of quality care. If I am no longer able to supply those items, my patients will suffer.

Occasionally, a Medicare patients comes into my office with a foot fracture. A plaster or fiberglass cast may be heavy or awkward for the patient, especially in cases where mobility is already limited. I may choose to instead place that patient in some type of walking boot. When treating fractures, it is essential that I am able to provide the medically necessary DMEPOS item at the time I diagnose the injury. If I am not selected as a supplier in the new program, I will not have the option of using the walking boot. Since it could be considered medical malpractice to diagnose a patient with a fracture and then send them elsewhere for immobilization, I may be forced to apply a fiberglass or plaster cast. If I am not a supplier, I will not be able to provide crutches, a cane or a walker if those items

are among the ones subject to competitive bidding. Imagine the difficulty a frail, 79 year old woman might have in trying to ambulate with a plaster cast but without a walker. The patient could risk falling, which could result in a hip fracture or worse.

I do not believe that the Centers for Medicare & Medicaid Services (CMS) considers it to be in the best interest of patient care to impede a physician's ability to provide medically necessary and quality care to Medicare beneficiaries. I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid. Physicians should be able to continue to supply appropriate DMEPOS items used in the care of patients.

Sincerely,



Lawrence B. Harkless, D.P.M.
Professor, Department of Orthopaedics
and Louis T. Bogy Professor of
Podiatric Medicine and Surgery

LBH:mg

(51)

June 6, 2006

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

Re: CMS-1270-P

Dear Sir or Madam:

Thank you for allowing me to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. Please consider my comments.

I **strongly** object to CMS' alternative proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers—this restricts beneficiaries' choice. We are in a small community with an elderly population and it is hard for older individuals to drive. They detest mail order and many are unable to do required paperwork for mail order. This proposal would severely restrict beneficiaries' access to needed items and supplies and **would** compromise patient health outcomes.

Please consider including 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 competitive in large metropolitan areas. After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier. CMS **must** take these steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established provider/patient relationships.

I currently provide diabetic testing supplies, diabetic shoes, inhalation therapy, wheelchairs, and walkers. Without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients. Please have consideration for the older population as well as small independent pharmacies like ours.

Thank you for considering my comments.

Sincerely,

Karen Bright, D.Ph.
Karen Bright
Apple Discount Drugs
512 Clinch Ave.
Clinton, TN 37716

Ph. 865-457-0300
Fax 865-457-1383

52

CMS-1270-P-49

Submitter: Madison J. Ledford R.PH.

Organization: Ledford's Rx Express Pharmacy

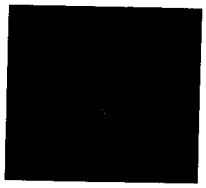
Category: Home Health Facility

Regulatory Impact Analysis

The proposal suggesting one supplier for DME is unfair to all small independent businesses. We are only allowing larger retails to corner the market with no understanding of customer service or the personal touch that the consumer needs when these services are rendered. The retail businesses are only concerned with the dollar and could care less about giving the patient the care that they need. I know because I have worked retail for over 10 years and know how the big chains work. I am much more appreciated where I am now than where I was. People need that extra touch when it comes to healthcare services.

I strongly urge you to reconsider this proposal due to the fact that our patients need the extra care and information that only a business that cares can give them. Not a business that profits on giving the least amount of service and products just to make the numbers look better to corporate.

Thank you,
Madison Ledford R.Ph.
Owner of
Ledford's Rx Express Pharmacy
1201 A North Main Street
LaFayette, Ga. 30728
706 638-1281



VILLAGE PODIATRY GROUP, P.C.
Your Family's Foot and Ankle Doctor

Evan M. Brody, DPM, AACFAS
Austell/Marietta

Craig A. Camasta, DPM, FACFAS
Douglasville • Sandy Springs

Anthony M. Cutsuries, DPM, FACFAS
Duluth • Lawrenceville

Wayne J. Dubner, DPM, FACFAS
Piedmont • Sandy Springs

David N. Helfman, DPM, FACFAS
Greensboro • Smyrna

Mitchell P. Hilsen, DPM, FACFAS
Roswell

Mike C. Laur, DPM, FACFAS
Hiram

Michael C. McGlamry, DPM, FACFAS
Piedmont • Sandy Springs

Stephanie C. Merritt, DPM, AACFAS
Cumming

La'Genia Mitchell-Smith, DPM
Nursing Home Division

Jayson B. Phelps, DPM
Duluth • Lawrenceville

Felicia D. Pierre, DPM, FACFAS
Stone Mountain

Jennifer S. Price, DPM, AACFAS
Douglasville • Smyrna

Mohammad A. Sharif, DPM, AACFAS
Atlanta/Midtown

Stuart M. Tuck, DPM, FACFAS
Decatur • Greensboro

Andrew D. Warner, DPM, FACFAS
Alpharetta

Steven A. Weiskopf, DPM, AACFAS
Woodstock

53-0
(9)

June 14, 2006

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

Dear Dr. McClellan:

I am writing in opposition to the proposed rule, *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*. In its current form, this rule would include physicians in a competitive acquisition program for certain DMEPOS items.

I am concerned that if physicians, including podiatric physicians, are not excluded from the new program, patient care will suffer. I provide certain DMEPOS items to my patients as part of the normal course of quality care. If I am no longer able to supply those items, my patients will suffer.

Occasionally, a Medicare patient comes into my office with a foot fracture. A plaster or fiberglass cast may be heavy or awkward for the patient, especially in cases where mobility is already limited. I may choose to instead place that patient in some type of walking boot. When treating fractures, it is essential that I am able to provide the medically necessary DMEPOS item at the time I diagnose the injury. If I am not selected as a supplier in the new program, I will not have the option of using the walking boot. Since it could be considered medical malpractice to diagnose a patient with a fracture and then send them elsewhere for immobilization, I may be forced to apply a fiberglass or plaster cast. If I am not a supplier, I will not be able to provide crutches, a cane or a walker if those items are among the ones subject to competitive bidding. Imagine the difficulty a frail, 79 year old woman might have in trying to ambulate with a plaster cast but without a walker. The patient could risk falling, which could result in a hip fracture or worse.

I do not believe that the Centers for Medicare & Medicaid Services (CMS) considers it to be in the best interest of patient care to impede a physician's ability to provide medically necessary and quality care to Medicare

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www.villagepodiatrygroup.com

beneficiaries. I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid. Physicians should be able to continue to supply appropriate DMEPOS items used in the care of patients.

Sincerely,

Felicia D. Pierre (ap)

Felicia D. Pierre, DPM, FACFAS
Village Podiatry Group, P.C.

/d

54

THE CLEVELAND CLINIC FOUNDATION

Department of Pharmacy Hb3

June 13, 2006

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

Re: CMS-1270-P

Dear CMS,

As you are undoubtedly aware, pharmacists serve as a crucial link between patients and their physicians when dealing with dangerous yet life-saving medications (reference the Medicare Part D drug benefit rollout earlier this year). Much of the same can be said of pharmacists when working with patients to ensure their durable medical equipment (DMEPOS) needs are met.

I applaud CMS's efforts to update and revise current policies on how DMEPOS is paid for in the U.S.; however, I have some concerns. I don't feel it's in the patient's best interest to restrict their freedom of choice when selecting where to purchase supplies. The competitive bidding process may put smaller suppliers such as the Cleveland Clinic Pharmacies at an unfair disadvantage when trying to compete with large supply houses. This will drive some pharmacies out of the DMEPOS business entirely. Lastly, requiring patients to use mail-order service over that of their preferred drugstore is a mistake. Many of our patients are referred to us because we can offer one-on-one consultation (to address questions and concerns, make sure the DMEPOS fits properly, etc.) and mail-order service does not lend itself to do this properly.

9500 Euclid Avenue, Cleveland, OH 44195

Pharmacists are counted as one of the most accessible and ethical professionals in society today and millions of patients access their pharmacist on a weekly or monthly basis for both their prescription and DMEPOS needs. Please consider these comments in light of CMS-1270-P and make the necessary changes to protect patients and pharmacies across the U.S. which will ensure DMEPOS remains accessible and affordable to the public at large. Thank you.

Kind regards,

Michael P. Wascovich, M.B.A., RPh,
Director, Ambulatory Pharmacy Services
Cleveland Clinic
9500 Euclid Ave – JJ10
Cleveland, OH 44195
(P) 216/445-2357 (F) 216/445-0025
wascovm@ccf.org

55

June 15, 2006

James B. Ashby
3624 Timbrook Court
Lexington, KY 40517

Re: CMS-1270-P

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

To Whom It May Concern:

Medicare pays $73.86 for a box of 100 One Touch Ultra test strips. These same strips costs pharmacies $79.32 resulting in a loss of $5.46 each time we supply these test strips to our patients, your beneficiaries. Many pharmacies have chosen to provide this service, at their own expense, because they are fundamentally interested in the health of the patient.

Now, in the interest of saving money, CMS is implementing a bidding program. We see this as an opportunity to *RAISE* the price of test strips since there is no incentive to further cut a price that is already well below our purchase price. CMS will be gathering information and using this information to calculate a 'ceiling' price for DMEPOS and it may be surprised to find that some items will be higher than current reimbursement rates.

This new bidding process comes at a time when pharmacies are suffering lower reimbursement rates generally due to the Medicare Part D program. As an additional insult, pharmacies are being forced to wait months to gain reimbursement for prescription drugs through the Part D program. Now CMS is interested in further cutting pharmacy reimbursement and our ability to provide the best possible care for patients.

It is my opinion that the bidding program is fundamentally flawed in that, if further cuts are forthcoming many pharmacies will choose not to participate. This will decrease the access to care to the very patients that need it most - further driving patients to a mail-order supplier. It may be that this is the very driving force behind the bidding program.

Thank You,

James B. Ashby

DHPPC

FYI - Reg Staff

#1 59313

56

June 5, 2006

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

JUN 15 2006
7:57 A.M.

Dear Dr. McClellan:

I am writing in opposition to the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I have been practicing since 1990 and supplying DME for a number of years.

I believe that the proposed rule, if implemented, would significantly impact my ability to continue to provide medically necessary care of the highest quality to my patients. I urge the Centers for Medicare & Medicaid Services (CMS) to exclude all physicians, including podiatric physicians, from the competitive acquisition program and to instead allow physicians to continue to supply DMEPOS items as part of the normal course of providing patient care. This allows the patient the convenience as well as the hands on expertise of a medical provider.

A competitive acquisition program that requires physicians to bid to supply items to patients will result in the elimination of some physician suppliers from the program. If physicians can no longer supply DMEPOS items, patients will suffer.

The patient would be put at greater risk if physicians can no longer supply the items. In the case of podiatrists, this would lead to increased morbidity and even mortality. Our diabetic patients would see increased ulcerations, amputations and other complications resulting in tremendous costs to the medicare program.

There are many other examples that could be provided to demonstrate how including physicians in the competitive acquisition program can be detrimental to patient care. Again, I urge CMS to exclude all physicians, including podiatric physicians, from this program and to continue to allow physicians to supply DMEPOS items used in the treatment of Medicare beneficiaries.

Sincerely,

Lonnie Resnick DPM

LONNIE RESNICK DPM
83 EAST AVE. SUITE 313
NORWALK, CT 06851
(203) 853-6570

LONG
83 EAST AVE. CONN
NORWALK, CT 06851
(203) 853-6570

SOUTHERN CT 064

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Mark B. McClellan MD, PHD
Administrator
Centers For Medicare • Medicaid Services
Dept. of Health • Human Services
Attn: CMS-1270-P
[redacted], MD
21244-8013

COLUMBIA
Foot & Ankle Associates, P.A.
Ross E. Taubman, D.P.M.
Stephen D. Palmer, D.P.M.

5005 Signal Bell Lane, Suite 204 ✦ Clarksville, MD 21029 ✦ 443-535-8770 ✦ Fax 443-535-8775
2086 Generals Highway, Suite 101 ✦ Annapolis, MD 21401 ✦ 410-266-7575 ✦ Fax 410-266-7703
www.columbiafootandankle.com

57

June 8, 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 in opposition to the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

As a podiatric physician, I am also a supplier of DMEPOS items to Medicare beneficiaries. The proposed rule, if implemented, would significantly impact my ability to continue to provide medically necessary care of the highest quality to my patients. I urge the Centers for Medicare & Medicaid Services (CMS) to exclude all physicians, including podiatric physicians, from the competitive acquisition program and to instead allow physicians to continue to supply DMEPOS items as part of the normal course of providing patient care.

A competitive acquisition program that requires physicians to bid to supply items to patients will result in the elimination of nearly all physician suppliers from the program. The ability of small physician practices to competitively bid with major supply companies is illogical and will cause harm to patients. In addition, since physician suppliers account for only 3.1% of the dollars spent on DME items, the potential savings that may be realized by requiring physician suppliers to competitively bid is miniscule.

Consider an actual patient of mine as an example. A 73-year-old female was seen in my office with multiple metatarsal fractures from a fall in her home. The nature of mid-shaft fractures is that they are inherently unstable and are prone to dislocate. It was determined because of the nature of the injury and the edema; the patient required a pneumatic walking boot. If I were no longer able to function as a supplier, the patient would have been forced to travel to another location to obtain this item. Dislocation, requiring

surgical reduction is a distinct possibility. In my opinion, this is below the standard of care for this patient.

I could easily provide numerous other examples demonstrating the harm to Medicare beneficiaries that could result from implementation of this rule. I urge CMS to exclude all physicians, including podiatric physicians, from this program and to continue to allow them to supply DMEPOS items used in the treatment of Medicare beneficiaries.

Sincerely,

Ross E. Taubman, DPM

Advanced Foot Care, LLP

**Ira Kraus, DPM* **Palmer Branch, DPM,* *Aaron Solomon, DPM* *Clair Bello III, DPM*
**Diplomate, American Board of Podiatric Surgery*

June 14,2006

58

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

Dear Dr McClellan,

I am a podiatric physician who has been in practice for 17+ years. I routinely treat Medicare beneficiaries and, as a current DMEPOS supplier, I am able to provide my patients with the wide range of care they require. If the new program results in my elimination as a supplier, I may no longer be able to supply medically necessary items, such as walking boots used for fractures or other structural instabilities, or ankle braces used for acute ankle injuries. . I recognize the importance of being able to supply DMEPOS items to patients as part of the quality care I provide. If I am no longer able to supply these items due to the competitive acquisition program, my patients will suffer. If my patients have to obtain these items from another supplier as a result of the new program, additional injury could result. I cannot imagine telling a Medicare beneficiary that I am unable to supply an ankle brace to treat an ankle injury and he or she must travel across town to obtain an item that is both medically necessary and appropriate.

Consider a patient who presents with the chief complaint of foot pain following an injury. I diagnose the patient with a foot fracture and determine that a walking boot is necessary to treat the fracture. 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 could result, which could result in other additional injuries.

I want to ensure that my patients receive appropriate care for their particular problem(s). Being able to dispense a medically necessary DMEPOS item when I am the one treating the patient just makes sense and is better medicine. I want to make sure the product fits the patient and functions as it should. I want the patient to receive exactly what they need without someone else making that decision for me. Patients should be able to get from me the full range of care they require for a particular problem, yet with this proposal that may no longer occur.

I do not believe that the Centers for Medicare & Medicaid Services (CMS) considers it to be in the best interest of patient care to impede a physician's ability to provide medically necessary and quality care to Medicare beneficiaries. I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid. Instead, continue to allow physicians to supply appropriate DMEPOS items used in the care of patients without being forced to competitively bid for that privilege.

Thanking you in advance for you time and consideration.

Professionally,

Ira H Kraus, DPM, FACFAS
APMA Board of Trustees

Acadia Foot & Ankle, P.A.
Comprehensive Medical and Surgical Treatment of the Foot & Ankle

59

F. Douglas Reynolds, D.P.M.*
Adam W. Darcy, D.P.M.

June 5, 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 concerned with the recent proposal from the Centers for Medicare & Medicaid Services (CMS) that would require physicians to participate in the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I support excluding all physicians, including podiatric physicians, from the new program.

Our office is currently a DMEPOS supplier. I recognize the importance of being able to supply DMEPOS items to patients as part of the quality care I provide. If I am no longer able to supply these items due to the competitive acquisition program, my patients will suffer. I use a wide range of DMEPOS items, including walking boots for foot fractures and ankle braces for acute ankle injuries. If, as a result of the new program, my patients will be required to obtain these items from another supplier away from my office, additional injury could result. I cannot imagine telling a Medicare beneficiary that I am unable to supply an ankle brace to treat an ankle injury and he or she must travel across town to obtain an item that is both medically necessary and appropriate.

Please reconsider your proposal and exclude all physicians, including podiatric physicians, from the new competitive acquisition program for certain DMEPOS. Instead, allow me as a qualified supplier to continue to directly supply items to Medicare beneficiaries.

Sincerely,

Adam W. Darcy, DPM, AACFAS
Acadia Foot and Ankle, P.A.
33 Penn Plaza, Suite A
Bangor, ME 04401

CROFTON • PODIATRY
DR. BRAD TOLL, DIPLOMATE, AMER. BD. OF PODIATRIC SURGERY

2411 Crofton Lane, Suite 25 • Crofton, Maryland 21114
(410) 721-4505 • Fax (410) 721-2394

(60)

June 7, 2006

Mark B. McClellan, M.D., 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 in opposition to the proposed rule, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues. In its current form, this rule would include physicians in a competitive acquisition program for certain DMEPOS items. I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid.

It has been my experience that when we have to send patients out for durable medical equipment that they frequently do not receive those supplies which I deem are most appropriate for their care. Further, the timeliness with which these supplies are available is frequently a problem.

In our office, we have always made a great effort to keep in stock those items that are needed for proper patient care, and to have them available when the supplies are needed. In particular, the molding for diabetic shoe inserts is not a process which I am comfortable sending the patients out for.

I do not believe that the Centers for Medicare & Medicaid Services (CMS) considers it to be in the best interest of patient care to impede a physician's ability to provide medically necessary and quality care to Medicare beneficiaries.

Again, I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid. Instead, continue to allow physicians to supply appropriate DMEPOS items used in the care of patients without being forced to competitively bid for that privilege.

Sincerely,

Brad A. Toll, D.P.M.

BAT/vk

(61)

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June 9, 2006

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

Re: CMS-1270-P

Dear Sir or Madam:
Thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPO's. I offer the following comments for consideration as CMS develops the final regulation.

Competitive Bidding Areas

- I strongly object to CMS' alternative proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers—this restricts beneficiaries' choice. This is especially true in our case as we are located across the street from a hospital and three medical clinics. We carry many items that are urgently needed, but not available elsewhere in the community. This proposal would severly restrict beneficiaries' access to needed items and supplies and may compromise patient health outcomes.

Criteria for Item Selection

- The competitive bidding program should NOT include common DMEPOS supplies such as diabetic testing supplies, orthotic supplies, nebulizers and inhaled drug, oxygen, wound care products. As a pharmacy and medical supply company located in a rural community, our customers rely on one trip into town to get all of their medical attention. Some of them live so far out, that they can not wait until "delivery day" for items.

Opportunity for Participation by Small Suppliers

- I urge CMS to take steps to ensure that small suppliers—which include the majority of pharmacy-based suppliers—can participate in the competitive bidding program. Small suppliers should be allowed to designate a smaller service area in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to be competitive in large metropolitan areas.

- After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowd to join the competitive bidding program as a contracted supplier.
- CMS must take these steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established provider/patient relationships.
- I currently provide the following types of DMEPOS in my practice: Medication through part D, oxygen and related equipment, walkers, canes, hospital beds and accessories, wheelchairs, urinary supplies, incontinence supplies, ostomy, seat lift chairs and electric scooters, wound care products, braces, commodes and supplies often needed but not covered by Medicare such as bathroom equipment. How do I tell the gentleman standing at my counter wheezing that he will have to go home and wait several hours or days until a centralized company can provide his nebulizer? or the patient discharged from the ER that they will have to drive hours to another city to be fit with crutches or braces? Without these revisions to the final regulation I will be unable to continue to provide these valuable services to my patients.

In conclusion, I urge CMS to revise the regulation to:

1. Restrict competitive bidding to items that are not needed urgently
2. Not include supplies such as diabetic supplies, urinary, ostomy
3. Ensure that the process allows small pharmacy/medical equipment companies be part of the bidding process by not insisting on large service areas
4. Assure any small supplier that is willing to accept the payment be able to supply products, equipment and supplies to their Medicare clients.

Thank you for considering my view.

Sincerely,

Ronnie Eaton

Ronnie Eaton
Pharm-A-Save Monroe
17788 147th ST SE
Monroe, WA 98272

PH: 360-794-4641
e-mail Ronniee@verizon.net

Cooley Medical

62

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www.cooleymedical.com

June 12, 2006

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

Re: CMS-1270-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments for consideration as CMS develops the final regulations.

I urge CMS to keep in mind that some of the contracting provisions in the MMA have the effect of restricting competition, reducing access to homecare, and hurting small homecare providers. The regulations should be written so as to protect patient access to homecare and allow qualified small providers to participate in the bidding program. CMS should:

- Require that competitive bidding not be implemented until quality standards are in place. Only accredited providers should be eligible to submit bids. CMS needs to identify the criteria it will use to evaluate the accrediting bodies now, and grandfather all providers accredited by organizations that meet the criteria CMS identifies;

- Exempt smaller, rural (populations under 500,000) Metropolitan Statistical Areas (MSAs);

- Allow all qualified providers that are small businesses and that submitted a bid below the current allowable to participate at the selected award price. Specifically, after a single payment amount for each item of DMEPOS is established, any supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier;

- Not disqualify bids above the current fee schedule amount for an item. This artificially limits bidding and does not reflect pricing that is rational and sustainable in a truly competitive market;

- Exempt items and services unless savings of at least 10 percent can be demonstrated, compared to the fee schedule in effect January 1, 2006;

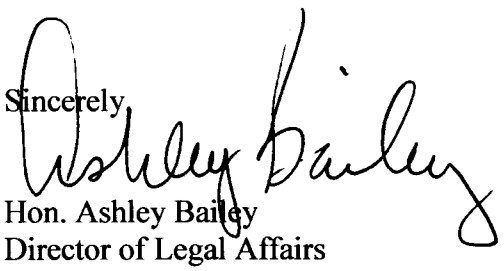
- Protect beneficiary access to care by conducting a comparability analysis for areas that are not competitively bid to ensure the rate is appropriate to costs and does not reduce access to care.

Cooley Medical is a provider of DMEPOS in mostly rural areas of Appalachia. We have built a reputation of going above and beyond to service the needs of our patients in isolated and impoverished areas. Exclusion of local companies such as ours will restrict the market to national chain suppliers better capable of controlling costs, but only at the expense of quality service to our patients.

In conclusion, I urge CMS to preserve beneficiaries' convenient access to DMEPOS and their freedom of choice of a healthcare provider. Without these assurances within the final regulations, we will be unable to continue providing these valuable services to our patients.

Thank you for considering my view.

Sincerely,



Hon. Ashley Bailey
Director of Legal Affairs
Cooley Medical Equipment

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5901 Lincoln Drive Edina MN 55436

63

June 15, 2006

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

Re: UnitedHealthcare comments submission regarding:
Federal Register / Vol. 71, No. 83 / May 1, 2006 / Proposed Rules / pages 25654-25704,
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

Dear Sir or Madame:

Following your invitation UnitedHealthcare submits the attached comments on the referenced **Federal Register** publication regarding the proposed Competitive Acquisition program for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies.

The opportunity to participate in this forum is appreciated.

Sincerely,

Michael Ile, Vice President Network Management
UnitedHealthcare
5901 Lincoln Drive, MN012-S204
Edina, MN 55436
(952) 992-7384
Fax: (952) 992-4320

Enclosure: One original and two copies

CC: Robert Holman, Director, Pricing Schedule Management
Steve Affield

Comment 1 [BACKGROUND] Class III Device Updates DME for 2007 and 2008

UnitedHealthcare comments

Listed Class III devices have either one sole or a small number of manufacturers. In spite of limited opportunities for manufacturer level competition, Class III device competitive bidding at the distributor level is feasible. Setting the Medicare single payment amount based on distributor level competitive bidding is recommended.

Comment 2 [PAYMENT BASIS] Authority to Adjust Payments in Other Areas

UnitedHealthcare comments

Fee schedule amounts should be adjusted in the short term on not lower than a regional level and not on a local basis. A national DMEPOS fee schedule should be the eventual goal, analogous to the process by which Average Sale Prices for drugs are set nationally.

The DMEPOS market follows commodity pricing dynamics. There is no labor component to justify differential pricing in different localities as is the case for the physician fee schedule. It may have been assumed in the past that prices in one urban area should be different than other areas because manufacturers and distributors operate in different regional or local markets. Evolving DMEPOS industry business practices under which national markets have developed render obsolete the assumptions upon which local DMEPOS pricing is based.

Current state level DME pricing is an historical vestige. Evidence of this point is that commercial third party payers have for several years nationalized DMEPOS pricing.

A national DMEPOS fee schedule would be an important advance toward a market in which all suppliers have an opportunity to compete nationally across local markets. The proposed Competitive Acquisition Program is an opportunity to foster national DMEPOS pricing.

Comment 3: [PAYMENT BASIS] Payment Amounts to Grandfathered Suppliers

UnitedHealthcare comments

Grandfathering provisions may be appropriate for the oxygen product category because a large portion of patients receiving oxygen are terminally ill and changing suppliers may be clinically disruptive for them. However, no similar rationale substantiates extending grandfathering provisions to other DMEPOS product categories. Overextension of grandfathering would have the practical effect of making the competitive bidding program apply to new patients only, which would in turn undermine the program's intent to harness marketplace dynamics in the introduction of new procedures and technology.

Comment 4 [PAYMENT BASIS] Payment Adjustment to Account for Inflation

UnitedHealthcare comments

DMEPOS items should not be subject to automatic annual CPI-U pricing updates which would not be governed by the actual market value of the products. Instead, DMEPOS pricing should be locked in for the three year competitive bidding contact period. CMS should contractually reserve the right to reopen pricing for specific product categories to allow contractual flexibility to respond when necessary to changing market conditions.

Comment 5 [COMPETITIVE BIDDING AREAS] Proposed nationwide or regional competitive bidding program for mail order suppliers effective on or after January 2010.

UnitedHealthcare comments

Mail order is a proven and successful DMEPOS supply delivery method. The new mail order delivery program should be regional and would be even more efficiently administered at a national level. Development of the Medicare DMEPOS mail order delivery program should be assigned a high priority and implemented before 2010.

Comment 6 [SUBMISSION OF BIDS UNDER THE COMPETITIVE BIDDING PROGRAM] Proposal to base used and rental item rates on the single payment amount for new items, using the same percentages of the new DMEPOS item as under current procedures (e.g., used price is 75% of new price).

UnitedHealthcare comments

Carrying forward into the post Medicare Modernization Act competitive bidding era the historic practice of basing used and rental pricing on a fixed percentage of the new price would perpetuate out-of-date pricing methods. Rather than continuing the historic fixed percentage arrangement, used and rental item prices should be competitively bid along with new items.

Comment 7 [Gap-filling] Establishing Payment Amounts for New DMEPOS Items

UnitedHealthcare comments

The proposed rule represents important progress toward rational DMEPOS pricing. Pricing methodologies presented appear to meet five key criteria:

1. **Understandable**: The methodology is clear and readily understood by persons with health care industry knowledge.
2. **Transparent:** Rate setting validity is backed up in the public domain with detailed pricing calculations.
3. **Reasonable:** Rates neither over-compensate nor under-compensate.
4. **Credible:** Rate setting is based on accepted health care industry standards.
5. **Timely:** Rates are based on current pricing levels.

Emerald Coast Podiatry and Wound Care Center

64

Dr. Robert D. Siwicki, D.P.M., P.A.
Board Certified in
Podiatric Medicine
Podiatric Surgery
Wound Care

Dr. Cosimo A. Ricciardi, D.P.M.
Board Eligible in
Podiatric Medicine
Podiatric Surgery
Podiatric Orthopedics

June 15, 2006

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

Dear Dr. McClellan,

I am a podiatrist that has been practicing for almost 30 years. As a current DMEPOS supplier, I treat Medicare patients with a wide range of problems that may need cam walkers for fractures, ankle braces for ankle injuries, night splints for heel pain, and the list can keep going on and on. I feel that it is important for the physician to properly fit for the care of these individuals. The patients, over the years, have expressed how nice it is that they do not have to travel across town and do not have to make any other appointments or do not have to delay in getting the treatment they need especially when it is regarding a fracture or other serious injuries.

I respectfully request that CMS modify its proposal and exclude all physicians including podiatric physicians from competitive acquisition program. Instead, allow physician DMEPOS suppliers to continue to provide appropriate and medically necessary items that are used for patient care. If CMS does go through with this proposed plan, I foresee it will only cost more money for additional medical expenses because of poor patient care and the cost will only complicate the medical system beyond what it already is.

Sincerely,

ROBERT D. SIWICKI, D.P.M.

Fort Walton Beach Office
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Crestview, FL 32536
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ecpodiatry@aol.com

65-0
(40)

June 15, 2006

Dynamedics, Inc.
PMB Suite 267
90 Avenida Rio Hondo
Bayamon P.R. 00961

Center for Medicare and Medicaid Servicies
Department of Health and Human Services
Attention: CMS1270P
P.O. Box 8013
Baltimore, MD 21244-8013

Comment on Competitive Biding (Puerto Rico)

Geographically, Puerto Rico is a relatively small island, ranging 100 miles east to west, and 35 miles north to south, and is composed of 78 municipalities of which the vast majority are rural areas. Two of these municipalities may be considered slightly metropolitan areas. The major city and capital san Juan, is considered the largest metropolitan area in Puerto Rico however large sections of this city is still rural in nature and does not fully encompass the conceived idea of a major metropolitan city such as Houston, Detroit or Boston, which are cities fully recognized as metropolitan in nature.

Therefore, upon considering the total amount of MA Organizations that cover Puerto Rico, the small size of the island, the aggressive marketing and reach-in programs used by these MA Organizations, and the steady increment of enrollment by beneficiaries, it is strongly believed that by 2007 the number of MA enrollees could come close to cover all beneficiaries on the island.

Thank you for the attention to this matter.

Sincerely,

Wanda Rivera

Wanda Rivera
Dynamedics, Inc.

Kauffman-Gamber Physical Therapy

804 New Holland Avenue, Lancaster, Pennsylvania 17602
(717) 396-7766 Fax (717) 295-7233
www.kauffmangamber.com

Satellite Offices

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Leola, PA 17540
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234B Manor Avenue
Millersville, PA 17551
(717) 871-8727

June 16, 2006

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

Dear Dr. McClellan:

I am writing concerning the "proposed rule for competitive acquisition of certain DMEPOS". Although competitive acquisition sounds attractive, it has been my experience over the past 34 years that this has been a failure. Actually, it contradicts the free market and competitive system that is now in place. That is, once a single or several providers are selected as being the "most competitive", they become the least competitive and the most expensive. This is indeed the experience that I live in on a daily basis with other commercial insurance companies. Often I am able to fabricate, modify, or purchase an inexpensive brace or splint for a patient. Unfortunately, my patients are often required by their insurance companies to go to a single provider at which time the cost is 2-6 times greater.

When considering this proposal, please listen to providers in the field.

Sincerely,

Timothy L. Kauffman, Ph.D., P.T.

TLK/lks

67

APTA American Physical Therapy Association

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services

June 15, 2006

My name is Judy Hershberg, PT, DPT,MS. and I am a Private Practice Physical Therapist from Boston, Massachusetts. I own The Boston Center for Physical Therapy and Sports Medicine which is an outpatient physical therapy clinic located in the Boston Athletic Club. We treat patients with musculoskeletal dysfunction, including sports injuries. We frequently provide orthotics for our patients as an integral part of patient care and would like to continue doing so, as it is critical to the care of our patients. We also perform regular adjustments on these orthotics to insure the proper fit. It is rare for an orthotic to fit perfectly after the initial fabrication. This is part of our practice and an area we were trained in by education.

Frequently, without the ability to fabricate and adjust these orthotics, time is wasted on either getting an appointment with a certified orthotist or worse, waiting for the DMEPOS to be sent in the mail. This time loss slows down the rehabilitation of the patient. This delay is costly for the patient and costly in terms of health care dollars. I urge CMS to revise the proposed regulations and establish a process that will enable physical therapists to continue to furnish orthotics, a task we are well trained to perform.

I also urge CMS to revise the regulations, to recognize the need for physical therapists to be able to specify brands to prevent adverse medical outcomes. The physical therapist in collaboration with the physician addresses the individual needs of the patients with the final result being properly fitted orthotics. This facilitates recovery and improves the gait pattern, stability of the patient during ambulation, and diminishes a painful unstable gait pattern. This would eliminate an adverse medical outcome.

Thank you for consideration of my comments and thank you for your help with this important issue.

Sincerely,

Judy Hershberg, PT, DPT, MS.
Director/Owner
The Boston Center for Physical Therapy and Sports Medicine
653 Summer Street
Boston, MA 02210

68

Yost Pharmacy, Inc.
120 West Main Street
Mason, Ohio 45040
Telephone 513-398-5010 Facsimile 513-459-7013

June 13, 2006

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

Re: CMS-1270-P

Yost Pharmacy is a pharmacy that also provides DMEPOS supplies to eligible Medicare recipients. The facility would be considered a small supplier by your standards. I appreciate the opportunity to comment on the proposed regulation as I see it.

Consolidating the distribution of many everyday used items such as diabetic testing supplies would add a layer of restrictions that hampers the beneficiaries' access to the supplies they need. This would negatively impact the patients' health. Routinely purchased items should be exempt from the bidding process.

I would strongly suggest to you that the small suppliers such as Yost Pharmacy provide a positive impact on the patient health by providing access to frequently needed items and also giving the needed consultation and education for proper use. CMS should provide an avenue for participation of these suppliers.

My suggestion would be that after the completion of the bidding process that CMS establish a payment amount for each item of DMEPOS and that any willing provider be allowed to join in the bidding at the determined amounts.

Yost Pharmacy in providing a variety of DMEPOS items such as, diabetic supplies, ostomy and urinary supplies, braces and supports, ambulation aids, wheelchairs and lift chairs, we offer a convenient, cost effective service with positive health outcomes.

Thank you again for this opportunity and urge you to take this into consideration in revising the regulation.

Sincerely,

Richard Yost

F·L·A
ORTHOPEDICS
INC.

69

June 14, 2006

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

Re: Comments on Competitive Acquisition for DMEPOS

To Whom It May Concern:

FLA Orthopedics, Inc. is a leading manufacturer and marketer of orthopedic bracing and support devices including off-the-shelf orthotics. Our products are dispensed by thousands of home medical equipment retail stores, independent pharmacies, DME suppliers and physicians across the United States. We are submitting our comments to the proposed rule published in the May 1, 2006 *Federal Register.*

We are concerned that the proposed rule will have unexpected negative impacts on patient care, accessibility of products, and the financial condition of many providers. The proposed rule deviates in many substantial respects from the methods used in the San Antonio, Texas and Polk County, Florida trials. No one can predict the impact of this proposed rule with any degree of confidence. For the roll out in the first 10 MSA's, we suggest that the number of product categories implemented in each MSA be limited so that the effectiveness of the rules that are implemented and the beneficiary impact of these rules can be evaluated and optimized before a full roll-out is initiated.

One significant possible consequence of the proposed rule is that many small DME's will close their doors. Small DME's provide a valuable service to patients and are often located in areas that provide easy patient access and improved patient compliance. Many of these small dealers provide products and services that larger service providers will not provide. CMS should provide an exemption for small dealers as long as they become accredited and agree to meet the pricing set by CMS. Failure to make these exceptions is likely to destroy the very fabric of how home health care is delivered in the United States.

We thank you for the opportunity to comment on the proposed rule.

Sincerely,

Rex A. Niles
President and CEO

Website: flaorthopedics.com • E-mail: marketing@flaorthopedics.com

2881 CORPORATE WAY · MIRAMAR, FLORIDA 33025 · TEL: 954-704-4484 · FAX: 954-431-8781 · 800-327-4110

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June 14, 2006

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

To Whom It May Concern:

I have been involved in the medical supply industry for over 20 years. Some of the new mandates are disconcerting to me.

If CMS creates a national or regional mail service program, beneficiaries must have the option to continue to obtain their medical supplies on a local basis. Local pharmacists, especially in rural area's often act as the first place beneficiaries ask questions about their medical supplies (especially during the evening or weekend when the physician is not available). Additionally, CMS should prohibit supplier's from automatically filling orders, especially for diabetic supplies. These requests need to come directly from the patient. This will reduce the fraud and abuse.

Competitive bidding should not include diabetic testing supplies as well as other common medical supplies. These items have been traditionally purchased in pharmacies before the Medicare program started in the 1960's.

CMS should do more to ensure small suppliers can participate in the competitive bidding process. I urge CMS to take these steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established provider/patient relationships.

Sincerely,

David Warshofsky
Sales Manager

Coral Reef-My Pharmacy	Allen's-My Pharmacy	Royal Palm-My Pharmacy
15043 S Dixie Highway	4000 SW 57 Ave	806 North Krome Ave
Miami, FL 33176	Miami, FL 33155	Homestead, FL 33030
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M1

June 15, 2006

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

To Whom It May Concern:

The CMS Center ***must*** consider that every pharmacy represents a point of distribution to the American public. In the event of a national emergency, distribution will be the most important issue.

Having said all of the above, all other items (price) become secondary. Leave your billing system as is, set a fair price and the merchant will participate or not. In rural America, the pharmacy is the only health care retailer left.

Sincerely,

Joe D. Reynolds

Joe D. Reynolds
Pharmacist

72

June 15, 2006

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

Re: CMS- 1270- P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments for consideration as CMS develops the final regulation.

Competitive Bidding Areas

I strongly object to CMS' alternative proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers—this restricts beneficiaries' choice. This proposal would severely restrict beneficiaries' access to needed items and supplies and may compromise patient health outcomes.

Criteria for Item Selection

The competitive bidding program should not include common DMEPOS supplies such as diabetic testing supplies. If CMS intends to centralize and consolidate the provision of DMEPOS items and supplies, the Agency should limit the competitive bidding program to those unique products that could be provided be a central supplier.

Opportunity for Participation by Small Suppliers

I urge CMS to take steps to ensure that small suppliers- which include the majority of pharmacy- based suppliers- can participate in the competitive bidding program. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to be competitive in large metropolitan areas.

After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier.

CMS must take these steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established provider/ patient relationships.

I currently provide the following types of DMEPOS in my practice diabetic supplies, walkers, wheelchairs, canes, crutches, nebulizers, and nebulizer drugs and without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients.

In conclusion, I urge CMS to revise the regulation to implement a competitive bidding program for DMEPOS. I believe this program will hurt the majority of pharmacy- based suppliers from participating in the program. In my store I will be unable to continue providing these services to my patients. I strongly urge CMS to not do this program.

Thank you for considering my view.

Sincerely,

Ken Gaskins, RPh.
City Pharmacy of Zebulon, P.C.
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June 22, 2006

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

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 DMEPOS and Other Issues

Dear Colleagues:

The Michigan Home Health Association (MHHA) welcomes 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.

MHHA is the state trade association representing the home care industry in Michigan, including stand alone and hospital based providers of home medical equipment, certified home health care, private duty home care, hospice and pharmacy-infusion. The following comments reflect the collective experience of our providers and their assessment of the impact the above rule would have upon beneficiaries of the Medicare 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 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.

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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: MHHA recommends 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 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 better, 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?

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.

<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 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 network providers to the network administrator, the patient and CMS. The accreditation requirements for established or new provider networks are also 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. 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,

Mary Ann Rayrat	Harvey Zuckerberg	Michael Bartz	Jim Shurlow
President	Executive Director	Board Member	Board Member

74

June 19, 2006

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

Dear CMS,

I am writing this letter to voice my grave concerns regarding the competitive bidding proposal (42 CFR Parts 411, 414, and 424).

As a nursing home owner/operator, I am extremely concerned that the new proposal will put safety of patients in my facilities as well as others at great risk. Suppliers of enteral nutrition products and services to nursing home patients are **highly specialized**. The potential for a facility to lose their choice of a preferred supplier or to have the ability to provide the products on their own puts patient's health and safety at risk.

Patients that reside in nursing facilities are more clinically complex with multiple ailments than patients cared for at home. They have established care plans which could be interrupted as a result of competitive bidding. Patient access to quality products and services, like disease-specific enteral nutrition therapy, could be compromised resulting in serious complications and overall increased costs of care. Current specialty providers are more than "box movers". They also offer insight and education that nursing facilities rely upon. I do not believe companies that need to keep their costs down in order to "win the bid" are going to be able to afford the proper staff let alone become "experts" in a specialty.

If I'm not mistaken, in a test completed in Polk County Florida's skilled nursing homes, it was ruled in a final report that enteral nutrition "is not as well suited for competitive bidding" as other products tested. With this information in hand, I strongly urge competitive bidding in nursing homes be carved out of the proposal.

Sincerely,

Avery Eisenreich

Omni Asset Management, LLC.
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75

June 21, 2006

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

Re: Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") and other issues (42 CFR Part 411, 414, and 424).

To Whom It May Concern:

On behalf of Nutritional Support Services, as Vice President of Reimbursement, I am writing to comment on the Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") and other issues (42 CFR Part 411, 414, and 424).

We strongly believe that Skilled Nursing Facilities (SNFs) should be excluded from the Competitive Acquisition Program. There are very strong practical issues from a nursing and facility perspective that must be considered. As a nurse, I can only imagine the confusion that the competitive acquisition rules will cause and how this confusion will disrupt care and services for nursing home residents.

1. The rules do not address the monitoring of multiple beneficiaries as occurs in a nursing facility; furthermore the rules are incompatible with plan of care requirements imposed on nursing homes:
    a. First and foremost, home patients have individual caretakers that monitor and communicate with suppliers, thus protecting the privacy of **one** patient and monitoring the quality of the service and equipment for **one** patient. This is a fairly easy process.
    b. SNFs, in comparison, have limited personnel to communicate for **many** patients in the facilities and must monitor the quality of supplies and privacy of **multiple** patients. The place of service the supplies are delivered makes a significant difference in the ease of monitoring the supplier.

2. Most SNFs have **one** supplier that furnishes enteral, urological, tracheostomy, ostomy, and, sometimes, surgical dressings. Nurses, bookkeepers, purchasing staff, and administration communicate with this one supplier about multiple patients. Competitive Acquisition might result in multiple suppliers furnishing limited supplies to multiple patients. This would increase the likelihood of **HIPPA violations** due to the unintended release of protected information to the wrong supplier. Monitoring multiple suppliers furnishing to multiple patients is an unnecessary burden on the nursing staff and the SNF as a whole.

3. SNFs may experience increased liability as new suppliers may furnish unfamiliar products (different manufacturers) using unfamiliar personnel that may, or may not train on all three shifts in the SNFs. Training multiple caregivers on multiple shifts may present a new challenge for suppliers that have only provided home care.

4. Currently SNFs dealing with one supplier receive all supplies in one delivery on a periodic basis that is convenient for the SNFs. With the introduction of several suppliers and different delivery schedules, SNFs will be required to spend more time monitoring the suppliers' activities in their facilities and the availability of various products from multiple vendors.

5. Many nursing home chains have subsidiaries that supply all the DMEPOS services to all the facilities in the chain. This helps large organizations to internally control quality and cost. Large volume purchasing, and internal auditing of the subsidiary achieves this. If this system is disrupted, it may increase cost on the "private pay" and Medicaid patients, in situations where patients do not qualify for Medicare Part B benefits (medical necessity or lack of Part B benefits) because of the decreased purchasing volume.

6. I can only imagine the confusion caused by the necessity to fax new orders for supplies to multiple suppliers for multiple patients. This would be similar to faxing prescriptions to multiple pharmacies, depending on the drug ordered.

7. Patients in SNFs have a higher acuity than patients at home. Suppliers must have a wide variety of disease-specific enteral products available on short notice, and must be able to communicate knowledgeably with the professionals writing the care plans.

8. Competitive bidding has not been successfully tested in SNFs. Enteral products were dropped after the first round of the Polk County demonstration in order to concentrate on non-institutional settings. <u>In the final report it was concluded that enteral nutrition "is not as well-suited for competitive bidding" as other products tested.</u>

9. Quality Standards for DMEPOS Suppliers have not been published. These standards may conflict with the SNFs' Conditions of Participation and Accreditation Standards. Until these standards and conditions are compared, DMEPOS Suppliers and SNFs will be unable to evaluate the potential impact and/or conflicts that may arise.

Will you please consider excluding institutional settings from the competitive bidding process? We think it will be mutually beneficial to CMS and to SNFs to limit the Places of Service to those that can be evaluated on a level playing field.

Thank you for allowing me to voice my concerns about the Place of Service issue. I hope we will avoid unintended consequences for institutional workers and patients.

Sincerely,

Jane Hardman, RN, BSN

Jane Hardman, RN, BSN
Vice President of Reimbursement

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(39)

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Vega Baja, PR 00694-7004

June 15, 2006

Center for Medicare & Medicaid Services
Attention: CMS-1270P
Mail Stop C4-23-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Sirs:

Since Puerto Rico is composed of almost 100% Hispanic communities, there is a high predisposition to certain health conditions, such as Diabetes and Heart diseases, which have a direct impact in the Allowed Charges made to Medicare. Based on studies performed by the Department of Health in Puerto Rico, statistics showed that 18 of every 100 women 65 years of age and older are diagnosed with chronic heart conditions and 22 out of every 100 men 65 years of age or older were also diagnosed with chronic heart conditions. Regarding diabetes, statistics demonstrated that 20 out of every 100 women 65 years of age or older were diagnosed with diabetes and 22 out of every men 65 years of age or older were also diagnosed with diabetes. The data demonstrates a steady increment in the diagnosis on these chronic conditions on the island, therefore it is important that when analyzing the Allowed Charges one has to consider the reality that many beneficiaries in Puerto Rico posses these serious and chronic illness. In fact, the supply costs in Puerto Rico are currently competitive and even though the Allowed Charges number are high, one cannot conclude that the high Allowed Charges is a result of suppliers not being competitive.

Yours truly,

William Hernandez – President
R & C Medical Supply, Inc.

/med

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(8)

June 19, 2006

Provider 4642470001
Dorado Medical Supply, Inc.
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Center for Medicare & Medicaid Services
Attention: CMS-1270P
Mail Stop C4-23-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear CMS,

The last June 12, I received a notification that Puerto Rico had been selected between first 10 Metropolitan Statistic Area for Competitive Bidding at 2007 year. We understand the primary objective of the Competitive Bidding is to reduce the amount Medicare pays for DMEPOS and bring the reimbursement amount more in the line with that for a competitive market. With the implementation of Medicare Advantage (MA) program in Puerto Rico, this objective has been achieved. According to information provide by the CMS director of Puerto Rico, Ms. Delia Lasanta, more than 50% beneficiaries in Puerto Rico are presently enrolled in an MA program as May 9, 2006. Currently in Puerto Rico there are eleven Medicare Advantage Organizations providing services to beneficiaries across the island.

The result of the implementation of the Competitive Bidding Program would be that small, community-based suppliers would be displaced by large chain suppliers that can take advantage of economies of scale, but which may not be in the interest of beneficiaries.

Please reconsider this decision.

Sincerely,

Manuel Salas Rivera
President of Dorado Medical Supply, Inc.

DORADO MEDICAL SUPPLY, INC. # 130,427 PUERTO RICO

78

Submitter : **Dr. James Giebfried** **Date: 06/20/2006**

Organization : **Dr. James Giebfried**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

June 20, 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

RE: Proposed Rule for Competitive Acquisition of Certain DMEPOS CMS-1540-P2

Dear Dr. McClellan:

As a physical therapist of 34 years I have worked in a vast array of rehabilitation setting- acute care, head trauma, long term care and chronic geriatric care, inpatient pediatric rehabilitation, adult inpatient adult rehabilitation, chest physical therapy, wellness/prevention programming, research, teaching and community health center practice. I worked with the New York University Orthotic and Prosthetic school faculty and helped with testing new designs and development of new devices. Health care is about a team approach of best practices by sharing our skill, knowledge, research and education for the client s best interest.

As a provider I am often providing and writing for insurance authorization for medically necessary rehabilitation equipment, orthotics and prosthetics. I treat the individual who will use the device and know what is needed through my individual evaluation of the client, education, my advanced training, my experience and my on going continuing education. Fabricating hand splints, modifying foot orthotics, adjusting metal bracing and prosthetics, wheelchair modifications and teaching the client how to use these devices in their activities of daily living is a daily licensed responsibility that I have in Massachusetts. These immediate minimal self adjustments of medical equipment and orthotics are important to the client s safety and function. As the client gains range of motion it is important for me to immediately adjust tension of screws or bend plastic components. Working at an inner city community health center the clients are low income having no insurance, require interpreter services which we provide and have difficulty traveling in a timely manner around the city to see other vendors.

I treat all age groups and their equipment needs require using many different vendors who can supply the correct equipment to construct the necessary modifications to medical equipment. Not doing so would pose an adverse medical outcome which could possibly injure the client and leaving me liable.

I urge you to revise or reject the Proposed Rule for Competitive Acquisition of Certain DMEPOS.

Thank you for consideration of this rule change.

Sincerely,

James Giebfried, PT, DPT, EDT, MA, CPH, MBA

M9

June 22, 2006

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

To Whom It May Concern:

The ROHO Group is pleased to have this opportunity to submit comments with regard to the *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Proposed Rule* (the Proposed Rule). 71 *Fed. Reg.* 25654 (May 1, 2006). The ROHO Group is a leading manufacturer of medical seating and positioning products, support surfaces and related specialty medical products designed to address the needs of individuals with skin integrity and positioning issues. Our seat cushion line is recognized as the standard of care that all other products are compared to for protecting the skin and providing the proper environment for the body to heal itself in the event of a wound.

We would first like to commend CMS for its effort in developing the Proposed Rule. Clearly, the tasks associated with competitive acquisition are numerous and complex. The detail included in the Proposed Rule reflects CMS' understanding of this complexity. At the same time, while the document provides a methodology for numerous facets, many additional details will be necessary to implement the first round of competitive bidding. If the current schedule is to be achieved, then the first round of competitive bidding must be accomplished prior to the end of 2007, approximately 18 months from now. During this time period, the number of tasks to be to be done appears to be overwhelming. The following is a partial list of tasks that we believe are essential to starting the program off fairly and well:

- Finalize quality standards specific to product categories.
- Finalize and announce the selection of accrediting organizations.
- Finalize and announce the initial 10 competitive bid areas (CBAs).
- Finalize and announce the competitive bidding implementation contractors (CBICs) to administer the bids.
- Finalize and announce the product categories to be bid in each CBA.

All of these must be completed before the bidding process can even begin. Further, during this period, providers interested in bidding will have to adapt their policies and procedures to comply with the applicable quality standards and pursue accreditation. In addition, none of the above

reflects the additional time required for accrediting organizations or bid administrators to organize themselves for their roles.

Our serious concern, therefore, is that this process is being driven by an unrealistic due date. We strongly encourage CMS to develop a realistic timetable for implementation and make the appropriate requests to Congress and the Administration to allow for such an implementation schedule.

In reviewing the Proposed Rule in detail we have identified numerous areas of concern. The remainder of these comments will focus on these specific areas.

I. Criteria for Item Selection

With regards to item selection we have concerns that can be divided into three categories:

A. The Combining of Items / Codes from Different Medical Policy Groups into Competitive Bidding Product Categories.

We have very serious concerns regarding the suggestion that product / HCPCS codes from multiple medical policies (Local Coverage Determinations, LCDs) could be combined together in a single competitive bidding product category. *Id.* at 25670. Our concerns are based on the following:

1. Combining medical policies together diminishes the exclusion authority right and responsibility. Section 1847(a)(3)(B) of the Medicare Modernization Act grants CMS the authority to exempt items for which the application of competitive bidding is not likely to result in significant savings. In addition, it is certainly the intent of the Act that no items be included in competitive bidding that would result in diminished quality of care or a reduction in access to products by beneficiaries. Allowing for products / HCPCS codes from multiple medical policies to be combined into a single competitive bidding product category constrains this authority. Further, this authority must be considered as a check against the bidding of inappropriate products / HCPCS codes. Each medical policy should be assessed individually to determine whether or not it is appropriate for bidding. Combining medical policies / LCDs together into a competitive bidding product category virtually eliminates any rightful argument that a specific medical policy should not be bid. Under this proposed policy, there would be no opportunity to distinguish between those medical policies that offer no cost savings in bidding them, or that will negatively impact patient care and access. As an example, CMS could justify the bidding of any medical policy by combining it with oxygen. Indeed, the only way to effectively determine whether bidding on a particular medical policy / LCD would result in savings would be to *not* combine multiple medical policies together in competitive bidding product groups.

2. Medical policies / LCDs categorize more than just HCPCS codes and products; clinical conditions must be considered. The proposal to combine products from multiple medical policies together into a single competitive bidding product category undercuts

the purpose for which these medical policies were originally established. In addition to categorizing products and HCPCS Codes, medical policies were created to categorize medical conditions and coverage. For example, if we look at competitive bidding from the standpoint of managing specific conditions, it would be unreasonable to consider combining a wound care patient group together with a patient group requiring ambulation. Although it may seem appropriate to combine the medical policy associated with "wheelchair seating" with those medical policies associated with "wheelchairs" to form a competitive bidding product category, this would be inappropriate.

This is inappropriate because numerous codes within the wheelchair seating medical policy actually tie to individuals with skin integrity issues. Although DME regional carriers (DMERCs) have stated that seat cushions must be associated as an accessory to a piece of DME (in this case a wheelchair) in order for such items to be covered, ultimately, in order to insure quality and access in a competitive bidding environment we must insure that the best providers have the opportunity to bid for wheelchair seating. Many providers structure their business around addressing specific disease states and conditions. It should not be assumed that providers with a wound care expertise and focus are also wheelchair providers, nor can the reverse be assumed. In reality, some of the best wound care seat cushion providers do not include wheelchairs in their product offering. There are numerous other examples where a simplistic approach would result in combining medical policies together inappropriately, such as support surfaces with hospital beds, CPAP's with volume ventilators, negative pressure wound therapy with support surfaces, surgical dressings with a variety of other policies, etc. Only by bidding each medical policy separately can we insure that providers who specialize in addressing the needs of individuals with specific disease states / conditions are given the opportunity to participate in the competitive bidding program.

3. Bidding each medical policy separately provides the greatest protection to quality and access while maximizing competition and savings in the bidding process. Ultimately, the goal of competitive acquisition must be to reasonably reduce system and beneficiary costs while maintaining or enhancing quality and access. While it is quite common for providers to include the necessary product and service options relative to a specific Medical Policy / LCDs, any arbitrary combination of HCPCS codes from multiple medical policies together into one competitive bidding product category will reduce the number of providers capable of bidding for specific goods and services. Those providers that carry the broadest product offering will benefit to the detriment of the specialty providers. Encouraging such an outcome is contrary to the goal of competitive acquisition. Fewer bidders will result in less competition and less potential savings. Further, the providers that are most adept at providing quality goods and services for a specific medical policy will be prohibited from bidding due to medical policies being combined.

4. Combining HCPCS codes from multiple medical policies together into one competitive bidding product category provides little additional benefit in the first round of bidding, while dramatically increasing the complexity and the risks. As described previously, there are numerous reasons why combining HCPCS codes from multiple

medical policies together for purposes of competitive bidding would be inappropriate and detrimental. In addition, we believe that it is imperative to keep the competitive bidding product categories for the first round of bidding as homogenous as possible. CMS' logic to exclude the three largest MSAs in the United States from the first round of competitive bidding also seems to justify the bidding of narrow, more clearly defined product categories in the first round as well. Ultimately, the first round of bidding will be a learning process for all involved. As such, keeping the number of variables to a minimum is essential.

Further, according to the Proposed Rule, it is CMS' intention to bid approximately 10 product categories during the first round of bidding in 2007 with the highest expenditure product categories being the primary focus areas. *Id.* at 25691. It must be assumed that any combination of medical policies together into a competitive bidding product category could be the result of associating a high dollar, DMEPOS medical policy with other medical policies that have considerably lower expenditures. Under such a situation, the potential additional savings would not necessarily warrant the additional complexity and risk, especially in the first round. For example, according to CMS' BESS Carrier Data Files, the total allowed charges for all seat cushions in 2003 was $55,565,820. In 2004, after the implementation of the new wheelchair seating policy, and the gap filling of the new codes, the total expenditure for seat cushions dropped to less than $40,000,000. During the same period, according to Table 4 of the Proposed Rule, the total allowed charges for wheelchairs / POVs in 2003 was $1,926,210,675. *Id.* at 25671. Seat cushion expenditures represent less than 3% of the expenditures associated with wheelchairs. Increasing the complexity and risk in the first round of bidding by combining medical policies together is certainly inappropriate if the "potential" return pertains to such a small percentage.

B. Identifying Specific Product Groups and HCPCS Codes within a Product Group that Should be Included in a Competitive bid.

CMS has stated in the Proposed Rule that their primary focus will be on those product groups with the largest allowed charges. While this is understandable, it seems that "potential savings" is the only factor that CMS has proposed to consider in the Proposed Rule. *Id.* at 25670. Instead, CMS should propose a clear, logical methodology to identify appropriate product categories and HCPCS codes to include in competitive bidding, as it proposed with regard to selecting MSAs. While the methodology should allow for the identification of product categories and HCPCS codes that can provide the desired savings, it should also consider beneficiary care and access.

1. Selecting the appropriate medical policies / product categories for competitive bidding. In evaluating medical policies for potential competitive bidding we would suggest that following factors be considered:

- Total allowed charges.

- Number of suppliers furnishing products for the specific medical policy within an MSA. This is important in order to insure that there is adequate access to the specific products within the CBA.
- Level of service associated with the products included in the medical policy. At the very least, this is necessary to be specified in the bid requirements to insure that said services are provided.
- Complexity of the product selection decision tree beyond that represented by the specific HCPCS codes and descriptors. For example, HCPCS code "E0255 – Hospital Bed, variable height, HI-LO, with any type side rails, with mattress" is very descriptive and provides a visual image of the associated products. The actual variation between specific products assigned to this code would be quite small. However, HCPCS codes "K0734 – Skin protection wheelchair seat cushion, adjustable, width less than 22 inches, any depth", or "E2605 – Positioning wheelchair cushion, width less than 22 inches, any depth", do not provide a visual image and include a multitude of additional decisions to be made by the beneficiary and their caregivers relative to size, materials, configurations, specific technologies, etc.
- Therapeutic nature of the products included in the medical policy. For example, a report published by AHQR in April of 2006 indicates that there has been a 63% increase in hospitalizations associated with wounds between 1993 and 2003. Further, it suggests that the average cost to treat these patients is $37,800.00. Clearly, we must consider the risk of costs being shifted to other portions of the system if quality and / or access are reduced for specific product groups as a result of competitive bidding.

To this end, we have included a suggested scoring methodology in **Appendix A.**

2. Selecting appropriate HCPCS codes within a medical policy for competitive acquisition. In the Proposed Rule CMS states that "bids could be a subset of items from a 'policy group'..." *Id.* at 25670. We support this, and the underlying logic that not all HCPCS codes are necessarily appropriate for competitive bidding. However, again, a clear methodology is necessary to appropriately evaluate each code, once MSA-specific medical policies are identified for competitive bidding. We would suggest that a similar logic to that we have described above should be considered to evaluate specific codes, the potential for savings and any issues related to complexity and access. To this end, we have included an additional scoring methodology in **Appendix B.** In **Appendix C** we have provided details regarding the wheelchair seating policy necessary to score this policy and the corresponding seat cushion HCPCS codes.

II. Monitoring and Complaint Services for the Competitive Bidding Program

In this section of the Proposed Rule, CMS proposes that "[s]ome examples of problems that we would consider to be serious include...contract suppliers furnishing items of inferior quality than those they bid to furnish." *Id.* at 25684. While we certainly agree that this would be a serious problem, we would point out that suppliers will be bidding HCPCS codes, and not unique manufacturer, make, or model items. If the code is too vague or includes multiple

technologies, there is no way to provide such monitoring or address such complaints. As such, this policy would be ineffective unless the HCPCS codes that are competitively bid include the necessary level of detail and specificity.

III. Terms of Contract

With regards to item selection our comments pertain to subsections:

- 3. Repairs and Replacement of Patient Owned Items…
- 4. Furnishing Items to Beneficiaries Whose Permanent Residence is within the CBA

A. "3. Repairs and Replacements of Patient Owned Items Subject to Competitive Bidding":

We would strongly encourage CMS to exclude any repair parts, accessories or replacements from consideration for competitive bidding. Within the proposed rule it suggests that "repair or replacement of patient-owned items subject to a competitive bidding program must be furnished by a contract supplier". While we understand the intent of this provision we would suggest that this will not always be feasible. It cannot assume that winning providers will have access to every manufacturer, make and model item that may fall under competitive bidding. In fact, as described previously, in some cases the manufacturer may be the sole distributor. Repair parts and accessories are not necessarily interchangeable and may void a manufacturer's warranty. In addition, replacement may relate to a warranty claim or require the same product to insure continuity of care.

B. "4. Furnishing Items to Beneficiaries Whose Permanent Residence is Within the CBA":

The proposal that a provider must offer a beneficiary the choice to rent or purchase items classified as inexpensive / routinely purchased is not feasible and should not be included in the final rule. The proposed rule contains the following statement:

> *"… in order to ensure beneficiary access to the competitively bid items in the inexpensive or routinely purchased DME payment category… the contract supplier must agree to give the beneficiary or his or her caregiver the choice of either renting or purchasing the item and must furnish the item on a rental or purchase basis as directed by the beneficiary or the beneficiary's caregiver."*

By the very nature of such products a provider cannot afford to routinely offer them on a rental basis. If such a requirement is included in the final rule the result will be that Medicare beneficiaries will lose access to such items unless they are willing to pay for them privately. Please consider the following:

1. Normally, such items are going to have an allowable of less than $500.00 as a new purchase. Once the cost of product is taken out the provider is probably left with some gross profit amount under $250.00. The cost of billing, cash application, lag on cash etc.

will certainly exceed $10.00 per claim filed. In the thirteen months of a capped rental there will be at least twenty-six claims filed (primary and secondary) resulting in a cost to the provider of over $260.00. Ultimately, in such a situation the provider is guaranteed to lose money.

2. Now that capped rental rules have been changed requiring that title be transferred at the end of thirteen months there is no opportunity for the provider to produce a profit over multiple rental periods.

3, In many cases, inexpensive and routinely purchased items are specified for "single patient use only" by the manufacturer. Even if the provider could rent such an item profitably, which they cannot, there is no opportunity for them to use the same product for multiple beneficiaries. In addition, what happens in the event that the beneficiary expires after only a few months of rental? The provider is left with a financial loss and an unusable product.

IV. Physician Authorization / Treating Practitioner

We would like to express our full support for the provisions outlined in this section. Physicians and other treating practitioners must have the opportunity to specify the appropriate product for their patients. This provision provides protection from any provider having only the "cheapest" products within their offering without consideration for efficacy and individual needs.

V. Conclusion

Thank you for the opportunity to submit these comments on the Proposed Rule. We look forward to working with CMS as it continues its efforts to implement a competitive bidding program for DMEPOS. Please do not hesitate to contact us should you have any questions about this information or need any further information.

Sincerely,

J. David McCausland
Senior Vice President of Planning and Government Affairs
The ROHO Group
100 N. Florida Avenue
Belleville, Il 62221
Office: 618-277-9173, ext. 2014
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davem@therohogroup.com

APPENDIX A

Question	Points
1. What was the total annual expenditure by Medicare Part B for this medical policy in 2005? (If < $50M = 0 pts, < $100M = 5 pts, $100 to 250M = 10 pts, $250 to 500M = 15 pts, > $500M = 20 pts)	
2. What is the ratio of suppliers furnishing products from the medical policy to the number of beneficiaries requiring such products within the defined MSA? (If X then 20 pts, Y then 10 pts, Z then 0 pts.)	
3. Do the products associated with the medical policy commonly require unique, "individualized" set-up and / or adjustment? (Never = 20, moderate = 10, considerable = 0)	
4. For products within the medical policy, are there additional decisions required beyond what is defined by the HCPCS codes themselves? For example, shape, size, materials, and physical configuration? (None = 20, moderate = 10, considerable = 0)	
5. Are the products defined by the medical policy intended to address a specific condition via prevention or treatment? (no = 20, yes = 0)	
Total Score (out of 100 possible):	

Using such a methodology on a medical policy basis within in an identified MSA (CBA) would certainly provide the greatest likelihood for achieving savings while protecting care and access. Question one would address potential savings. Question two would address access. Questions three and four would address the needs for skilled delivery / quality service. Question five would consider the potential impact to the Medicare system as a whole as it considers the potential for additional medical complications and expenses that could result from poor product and service performance.

APPENDIX B

Question	Points
What was the total annual expenditure by Medicare Part B for this HCPCS code in 2005? (If < $##M = 0 pts, < $##M = 5 pts, $xx to yyM = 10 pts, $yy to zzM = 15 pts, > $zzM = 20 pts)	
Do the products associated with the HCPCS code commonly require unique, "individualized" set-up and / or adjustment? (Never = 20, moderate = 10, considerable = 0)	
Are there additional decisions required beyond what is defined by the HCPCS codes itself in selecting the product for the individual? For example, shape, size, materials, and physical configuration? (None = 20, moderate = 10, considerable = 0)	
Would replacement of the specific manufacturer, make and model product the beneficiary is currently using with another product assigned to the same code have a potentially detrimental impact on the individual's health? Does the code include multiple technologies? (Yes = 0, no = 10)	
Is the HCPCS code associated with sale or rental items? If it is a sale, is it a reoccurring sale or an individual sale during the course of a year? (Rental = 20, Reoccurring sale = 10, single sale = 0)	
Are the products defined by the HCPCS code intended to address a specific condition via prevention or treatment? (no = 10, yes = 0)	
Total Score (out of 100 possible):	

Once again, using such a methodology on a medical policy basis within an identified MSA (CBA) would certainly provide the greatest likelihood for achieving savings while protecting care and access.

APPENDIX C

To illustrate these points, we can once again utilize the LCD for Wheelchair Seating. Please consider the following:

- The LCD for Wheelchair Seating went into effect in 2004 and was the first LCD to require that products be code verified by the SADMERC before the product could be billed under the new HCPCS codes established.

- The seat cushion codes included in this policy fall into six specific groups based on the intended use of the cushion and an additional code for "custom". As of this date, *Figure 1* provides a breakdown of the specific groups with the number of unique manufacturer, make and model products that have been code verified to each.

Figure 1

Seat Cushion Code Categories / Codes	Number of Unique Product That Have Been Code Verified
General Use Wheelchair Seat Cushion (E2601 & E2602)	89
Non-adjustable Skin Protection Wheelchair Seat Cushion (E2603 & E2604)	91
Positioning Wheelchair Seat Cushion (E2605 & E2606)	10
Non-adjustable Skin Protection and Positioning Wheelchair Seat Cushion (E2607 & E2608)	94
Adjustable Skin Protection Wheelchair Seat Cushion (K0108, K0734 & K0735 as of 7/1/06)	35
Adjustable Skin Protection and Positioning Wheelchair Seat Cushion (K0108, K0736 & K0737 as of 7/1/06)	48

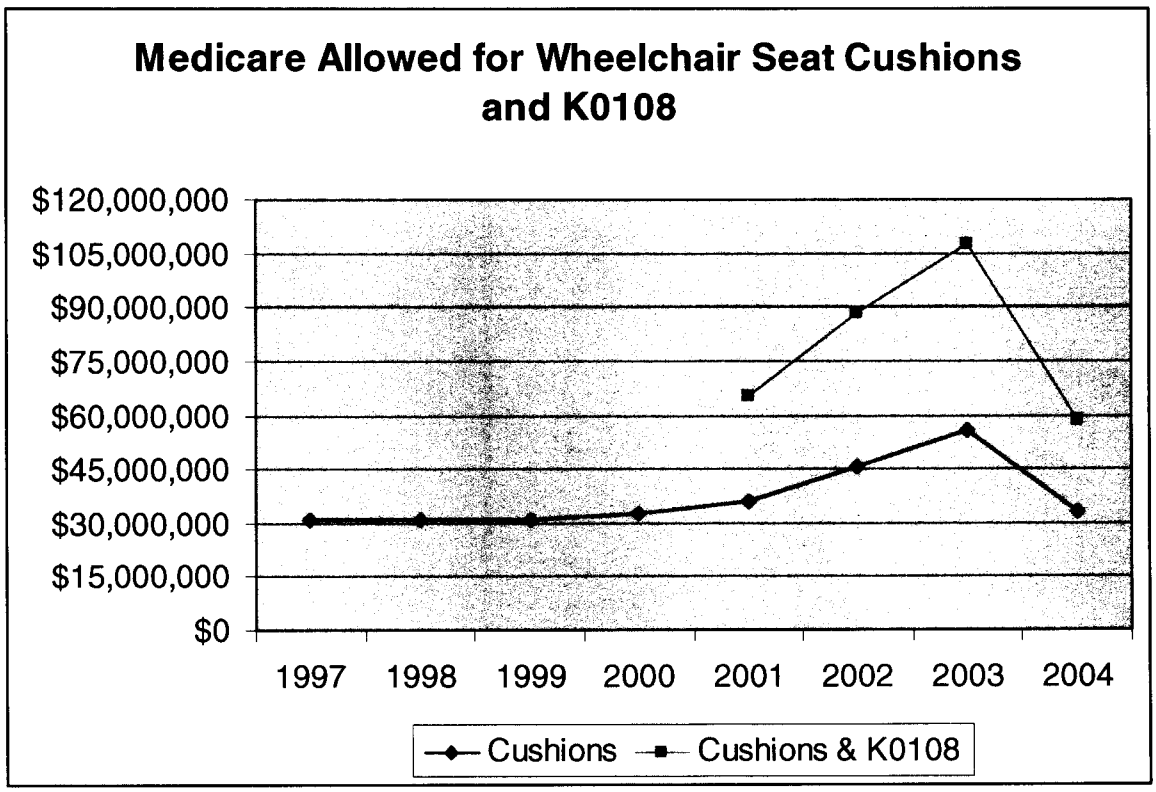
- Attachment 1 illustrates the coverage criteria decision tree that must be considered in determining whether a beneficiary qualifies for a cushion and, if so, which type. Please take note of "Inset A" which illustrates all of the additional factors that still must be answered in selecting the appropriate product for the individual once the cushion HCPCS code they qualify for is identified.

- *Figures 2 and 3* provide a historical look at Medicare Part B allowed charges for seat cushions since 1997. We have included "Total Cushion Allowed Charges" and "Total Cushion and K0108 Allowed Charges" due to the fact that adjustable seat cushions may have been billed under K0108 for October through December 2004. Prior to 2004 the amount of cushions that would have been billed under K0108 would have been nominal to non-existent.

Figure 2

Description	Allowed Charges	Allowed Services (Units)	Payment Amounts By Medicare	Average Allowed Per Service
Medicare Part B Expenditures for Wheelchair Cushions - 1997	$31,135,837	144040	$24,570,981	$216.16
Medicare Part B Expenditures for Wheelchair Cushions - 1998	$30,917,945	139527	$24,493,580	$221.59
Medicare Part B Expenditures for Wheelchair Cushions - 1999	$30,773,834	140949	$24,387,020	$218.33
Medicare Part B Expenditures for Wheelchair Cushions - 2000	$32,657,150	147598	$25,902,098	$221.26
Medicare Part B Expenditures for Wheelchair Cushions - 2001	$36,217,853	160297	$28,745,549	$225.94
Medicare Part B Expenditures for Wheelchair Cushions - 2002	$45,769,396	195187	$36,380,573	$234.49
Medicare Part B Expenditures for Wheelchair Cushions - 2003	$55,565,820	221506	$44,203,641	$250.85
Medicare Part B Expenditures for Wheelchair Cushions - 2004	$33,126,252	156576	$26,296,939	$211.57
Medicare Part B Expenditures for Wheelchair Cushions & K0108 - 2001	$65,327,327	270996	$51,778,881	$241.06
Medicare Part B Expenditures for Wheelchair Cushions & K0108 - 2002	$88,297,865	336075	$70,076,659	$262.73
Medicare Part B Expenditures for Wheelchair Cushions & K0108 - 2003	$107,722,792	382479	$85,522,494	$281.64
Medicare Part B Expenditures for Wheelchair Cushions & K0108 - 2004	$58,839,775	295382	$46,637,234	$199.20

Figure 3



Using this information the wheelchair seating medical policy and the specific cushion codes included in that policy could easily be scored. The results would certainly suggest the following:

- Neither the wheelchair seating medical policy nor the seating HCPCS codes should be included in competitive bidding; or, at the very least, not in the first round. There is very little potential for savings, service and individual selection

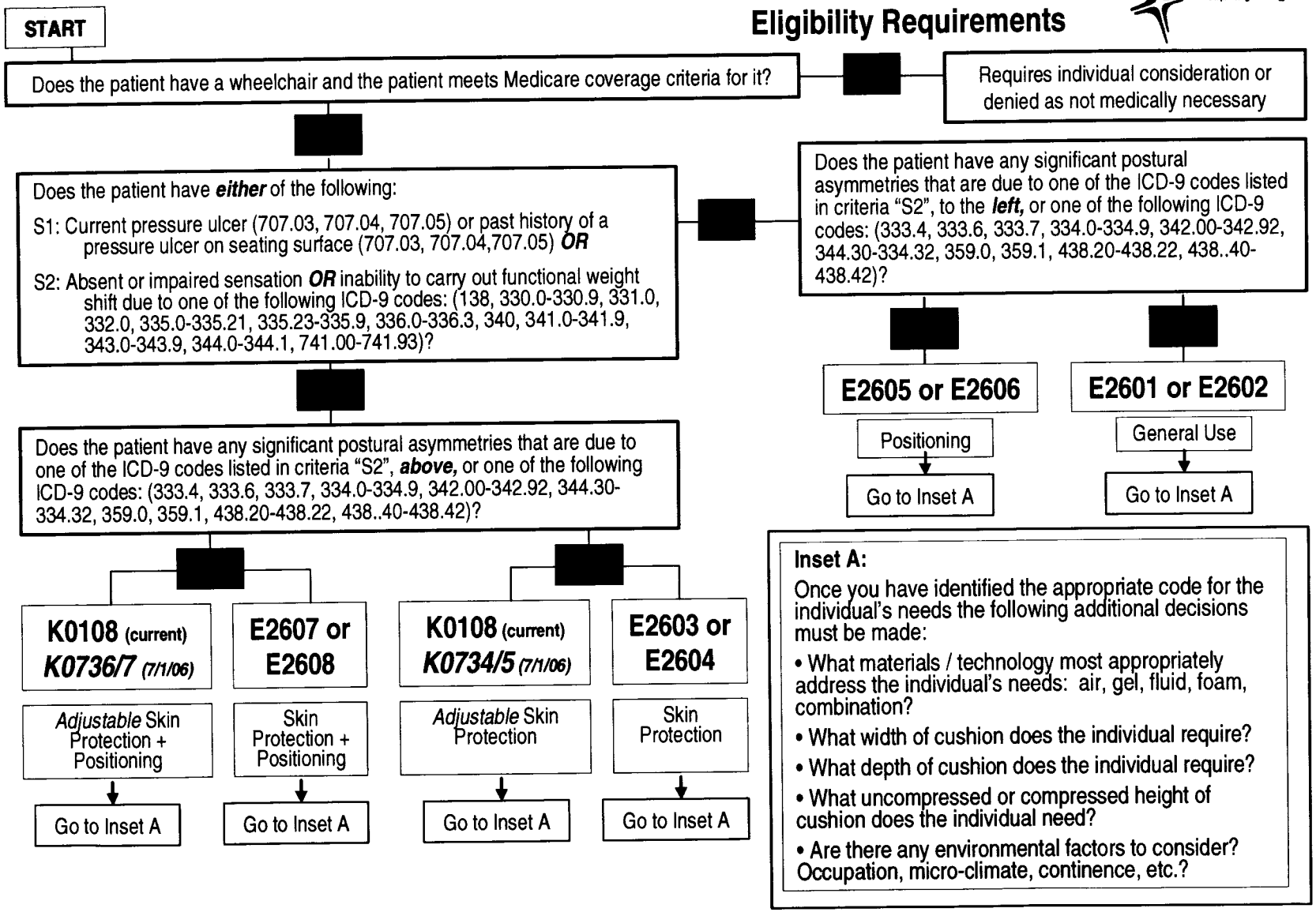
and adjustment are essential, and access / quality may be negatively impacted if they were bid.

- It is essential for a HCPCS code to provide enough specificity in order to bid it. If CMS were to bid "E0260 – Hospital bed, semi-electric (head and foot adjustment), with any type side rails, with mattress" the provider has enough information to know what product they must offer, what it will cost and what they need to bid. If CMS were to bid "E2607 – Skin protection and positioning wheelchair cushion, non-adjustable" a provider would not have adequate information to bid. As illustrated in *Figure 1*, there are currently 94 different product assigned to this code comprised of varying technologies, sizes and materials. Bidding such a code would place the provider in a very exposed position and would encourage the bidding of the cheapest technology and materials rather than the most effect, durable and appropriate. This point is reinforced by "Section II.N. – Monitoring and Complaint Services for the Competitive Bidding Program" in the proposed rule. In this section it states that "Some examples of problems that we would consider to be serious include: ...contract suppliers furnishing items of inferior quality than those they bid to furnish." While we certainly agree that this would be a serious problem we would point out that suppliers will be bidding HCPCS codes, not unique manufacturer, make and model items. If the code is too vague or includes multiple technologies there is no way to provide such monitoring or address such complaints.

- The implementation of new medical policies for specific product categories may actually exceed the savings goals intended by competitive bidding. If you look at the expenditure trends in *Figures 2 and 3* it is easy to see the impact that a new medical policy has had on wheelchair seating allowables and utilization. Total expenditures and utilization for such products dropped by more than 25% in 2004 as compared to 2003. Further, CMS is proposing to cut the allowables for wheelchair seat cushion by even more in July of 2006 by reapplying the admittedly flawed, gap-fill method to the list of products that have been code verified.

Attachment 1

Medicare Part B Standard Wheelchair Cushion HCPCS Coding Eligibility Requirements



VNAA Visiting Nurse Associations of America®

the voice of home healthcare

80

June 22, 2006

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

Dear Dr. McClellan:

I am writing on behalf of the Visiting Nurse Associations of America (VNAA) to offer comments on "Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and other issues, CMS-1270-P). The VNAA represents over 400 non-profit home health agencies across the United States.

The VNAA is concerned that CMS has interpreted its Congressional mandate to competitively bid certain items furnished by "suppliers" to encompass DME furnished by providers, specifically home health agencies. Home health agencies furnish incidental items of DME to their home health patients under an entirely different statutory and regulatory authority than that of suppliers. The rationale for allowing home health agencies to furnish DME in this was to facilitate the ready availability of DME to homebound patients under a Medicare home health plan of care. Because those VNAs that furnish DME to their patients do so in small volume for the benefit of their patients, it is not practical or cost-effective for them to participate in competitive bidding either as individuals or collectively. Thus CMS's overly broad interpretation has the effect of Section 302 PL 108-173 has the practical effect of repealing the longstanding authority of home health agencies to furnish DME under their Medicare provider (vs. supplier) status. This is something that Congress could have, but did not do, in the Medicare Modernization Act. Moreover, both the preamble and proposed regulatory text define supplier as: "...an entity with a valid Medicare supplier number...." Since home health agencies furnish DME without a valid supplier number, the rule would exclude them from coming under competitive bidding even under its own definitions of terms. We would urge CMS to clarify the final rule to apply competitive bidding only to suppliers, as it defines them, and not to providers furnishing DME as home health providers that do not participate in Medicare as suppliers to the general community.

VNAA's other concern is that CMS has not established a sufficient avenue to allow smaller DMEPOS suppliers to effectively participate in competitive bidding. Those

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99 Summer Street, Suite 1700
Boston, MA 02110
617-737-3200
1-888-866-8773
617-737-1144 (fax)
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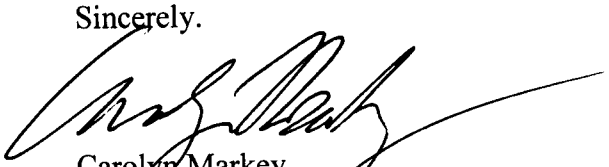
Washington Government Affairs Office
8403 Colesville Road, Suite 1550
Silver Spring, MD 20910
240-485-1858
240-485-1818 (fax)
www.vnaa.org

VNAs that offer DMEPOS to the general community though separate supplier status are small, non-profit, community providers. They entered the field of DME to provide a community-service where there was a need not being effectively met by others suppliers. As nonprofits, their business model is not compatible with forming bidding alliances with for-profit suppliers.

VNAs are not able to see a way under the proposed rule that they can participate in competitive bidding, yet the statute mandates that CMS make this feasible. VNAs suppliers are too small relative to large national or regional corporations to be successful bidders and forming a bidding coalition with for-profit suppliers will take a great deal of time and effort, if it is possible at all. At a minimum, more time needs to be allowed between the time bidding areas are announced and bids must be submitted to allow smaller entities to try to form a bidding group. CMS could also facilitate this process by allowing suppliers that have not been able to bid successfully a one-time opportunity to furnish bid items at the average bid price. This would allow time for wholesale prices to adjust and time for possible bidding coalitions to gel. CMS should also consider a small supplier set aside, requiring that some segment of the market is reserved to small entities. While this departs from the demonstration model, the alternative of CMS ceding entire area markets, and perhaps the entire national Medicare market for key DMEPOS items to a few, firms must certainly be viewed as untenable. The creation of a DMEPOS oligopoly would ultimately undermine any future progress made in competitive bidding.

Thanks you for considering these comments. You may direct any questions you may have to Bob Wardwell at our Washington office, 240-485-1855

Sincerely.



Carolyn Markey
President and CEO

81

June 22,2006

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

Re: Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DEMPOS") and other issues (42 CFR Part 411, 414, and 424).

To Who It May Concern.

On behalf of Institutional Pharmacy as Billing/Reimbursement officer, I am writing to comment on the Competitive Acquisition program for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies 9"DMEPOS") and other issues (42CFR Part 411, 414, and 424).

1. The rules do not address the multiple beneficiaries as in a nursing facility; the rules are incompatible with plan of care requirements in a nursing facility.

    a. Home patients have individual caretakers that monitors and communicates with the suppliers, having only one patient this is an easy process.
    b. SNFs have limited personnel to care for many patients and must communicate with the supplier. The place of service that the supplies are delivered makes a difference in monitoring the supplier.

2. SNFs usually have one supplier that furnishes enteral, urological, tracheostomy, ostomy, and sometimes dressings. All staff including nurses, bookkeepers, purchasing staff and administration communicates with the one supplier. This increases the likelihood of HIPPA violations due to release of protected information to the wrong supplier. Monitoring multiple suppliers is an unnecessary burden of nursing staff.

3. Currently SNFs dealing with one supplier receive all supplies in one delivery on a current basis that is convenient for the SNFs. If several suppliers were delivering more time would be spend monitoring the deliveries.

4. Another issue with competitive bidding is having to many suppliers, is the faxing of orders. This would be similar to faxing a prescription to multiple pharmacies.

5. Patients in a SNFs do not receive the same products. Suppliers must have various products and be available on short notice.

6. Competitive bidding has not been successfully tested in SNFs. Enteral products were dropped the first round in Polk County demonstration in order to concentrate on non-institutional settings. In a final report is was concluded that enternal nutrition "is not well-suited for competitive bidding" as other products.

Please consider excluding institutional settings from the competitive biding process?

Thank you for allowing me to voice my concerns about the Place of Service issue.

Sincerely,

Jamie Ivey
Billing/Reimbursement Officer

82

June 22, 2006

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

To Whom It May Concern:

The Support Surface Standards Initiative (S3I) is please to have this opportunity to submit comments regarding the proposed rule for *"Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)"*, 42 CFR Parts 411, 414, and 424. S3I is a coalition formed between leading wound care clinical associations, researchers, academia, clinicians and industry to develop, and see implemented, a set of standardized terms and definitions for support surfaces and a set of standardized tests to evaluate the efficacy, durability and lifespan of the various support surfaces on the market now, and in the future. Further, we are currently pursuing having our work serve as the basis for a new International Standards Organization (ISO) work item.

Our efforts began in January of 2002 as an initiative of the National Pressure Ulcer Advisory Panel (NPUAP) and the effort continues. The timeline speaks to the complexity of the issues requiring resolution necessary to implement a model to guide clinicians, industry, regulators, payers and, most importantly, the beneficiaries in product selection. This experience leads us to the conclusion that full support surfaces cannot be effectively bid under the current HCPCS codes and medical policy and would request that they be excluded from competitive bidding until such time as a new coding structure and a new medical policy is implemented.

The complexity associated with our efforts makes us acutely aware of the issues that CMS has faced in developing this proposed rule. To that end, we would like to commend CMS for the Herculean effort it has put forth. Clearly, the tasks associated with competitive acquisition are numerous and complex. The detail included in the proposed rule reflects CMS' understanding of this complexity and the interrelationship between the various facets. At the same time, while the document provides a methodology for the various facets, there remains a multitude of methodologies and tasks to be accomplished. A serious concern on our part is that the amount to be done cannot be effectively accomplished in the time remaining before the first round of bidding is to commence. For a historic example we need look no further than the recently implemented Medicare Part D program. While Medicare Part D does provide benefits, we doubt that anyone can deny that the time frame in which it was implement has caused numerous,

substantial problems, has increase implementation costs and reduced the program's benefits. We would strongly request that the lessons learned from the Medicare Part D implementation be applied to the implementation of competitive bidding and that steps be taken to insure that competitive bidding is implemented correctly, not quickly.

In reviewing the proposed rule in detail we have identified specific areas relative to our work which we wish to comment on. Our specific recommendations are preceded by numbers.

Criteria for Item Selection

Combining Medical Policies together in competitive bidding product categories:

1. We recommend that products / HCPCS codes from multiple medical policies **NOT** be combined together into one competitive bidding product category. Further, we are concerned that the proposed rule does not provide a sufficient method to evaluate whether specific medical policies and / or HCPCS codes should be included in a competitive bid. Our recommendation and concerns are based on the following:

- The Medicare Modernization Act grants CMS the authority to exempt items for which the application of competitive bidding is not likely to result in significant savings. However, the proposal to combine multiple medical policies together in competitive bidding product categories seems contradictory. How could the products included in any medical policy argue that there is no cost savings in bidding them if that medical policy is combined with another medical policy that does meet all of the appropriate requirements to be bid? Combining medical policies together diminishes the exclusion authority right, and responsibility.

- Medical policies are created as much to categorize medical conditions and coverage as they are to categorize products and codes. For example, if we look at competitive bidding from the standpoint of managing specific conditions, it would be unreasonable to consider combining a wound care patient group together with a patient group requiring a hospital bed or a wheelchair. On the surface it may seem appropriate to combine the medical policy for "wheelchair seating" with "wheelchairs" and "support surfaces" with "hospital beds" in forming competitive bidding product category. Yet, if we look at the coverage criteria / clinical indicators contained in these medical policies the stark contrast between them becomes evident.

- In order to insure quality and access in a competitive bidding environment we must insure that the best providers have the opportunity to bid. Many providers structure their business around addressing specific disease states and conditions. It cannot be assumed that providers with a wound care expertise and focus are also wheelchair or hospital bed providers, nor can the reverse be assumed.

- The goal of competitive acquisition must be to reasonably reduce system and beneficiary costs while maintaining or enhancing quality and access. Any combination of HCPCS codes from multiple medical policies together into one competitive bidding product category will

reduce the number of providers capable of bidding for specific goods and services. Those providers that carry the broadest product offering will benefit to the detriment of the specialty providers. Ultimately, the very providers most adept at providing quality goods and services for a specific medical policy may be prohibited from bidding due to medical policies being combined that extend beyond their expertise and product offering.

- It is essential that the competitive bidding product categories included in the first round of bidding be as homogenous as possible? Ultimately, the first round of bidding will be a learning process for all involved. As such, keeping the number of variables to a minimum is essential. Combining products from multiple medical policies increases complexity and should not be included in the first round.

Identifying which specific product groups and HCPCS codes within a product group that should be included in a competitive bid:

2. A methodology must be developed to identify appropriate product categories and HCPCS codes to include in competitive bidding that considers potential savings, beneficiary care and access. CMS has stated in the proposed rule that their primary focus will be on those product groups among the largest in terms of allowed charges. While this is understandable, it seems that "potential savings" is the only factor being considered. CMS has developed a clear, logical methodology to identify which MSAs to include in competitive bidding and a similar methodology is necessary to identify appropriate product categories and HCPCS codes.

- What level of service is required; what is the intended use and what are the overall system costs associated with the product group and treatment of the disease state?
  In evaluating medical policies for potential competitive bidding we would suggest that the level of service required and the intended use / goal of the products provided be considered. Clearly we must define expectations for service in the bid proposal so that this can be included in the bids, and subsequently in any quality audits. Further, if the medical policy is associated with the prevention or treatment of a specific disease state, for example wound care, we must consider whether any potential savings to Medicare B could be offset or exceeds by additional expenditures in other portions of the system if quality and access are diminished.

    - A recently published AHQR study indicated that wound care incidence in acute care facilities is on the rise and that it costs in excess of $37,000 on average to treat wound care patients in the hospital setting.

    - In 2003 Medicare's costs associated with wound care patients in institutions exceeded $118 billion. During that same year Medicare's costs associated with wound care patients in home care was $10.5 billion.

  Clearly, it is much more cost effective to treat these individuals at home. However, if access to medical equipment and supplies needed to care for such patients in the home is reduced or the quality of such items is diminished by cost reductions, then the occurrence of wound and number of hospital admissions will only go up.

- Does the HCPCS code clearly define a homogenous group of products?
  A critical factor that must be considered at the code level is whether the code defines a specific enough group of product in order to be effectively bid. For example, "E0277, Powered Pressure Reducing Mattress Replacement", is listed among the HCPCS codes having the highest Medicare Part B expenditures. However, this code currently contains a wide variety of technologies including air flotation, alternating pressure, low air loss, rotational therapy, etc. In addition, the minimum requirements for products to be billed under this code were written in the mid 1990's and are in desperate need for revision. Any bidding of this code right now would only result in denying access to the most effective products currently available. Once again, access and quality will suffer and any cost reductions by Medicare B will be overshadowed by increased costs in other wound care components and care settings.

Continued use of a specific product already demonstrating effectiveness (continuity of care):

3. We believe that a methodology must be developed and included in the final rule that allows the supplier caring for a beneficiary's needs in an institutional setting to continue servicing that beneficiary's needs in a home care setting, provided they are willing to accept the bid rate. A point not considered in the proposed rule relates to continuity of care and in insuring that a specific product has already demonstrated effectiveness with a specific beneficiary in an institutional setting (hospital / long term care).

- If a specific product is providing a benefit in the institutional setting we need to insure that its use is continued, as long as medical necessity justifies it, when the beneficiary goes home. For example, many wound care treatment plans will be initiated in an institutional setting, including support surfaces, therapies and dressings. If a specific wound care program has been initiated, and the patient is progressing under this care plan, it should be continued when they are discharged to the home care setting. This factor, however, is not considered directly in the proposed rule. Granted, the proposed rule does allow for physician / medical practitioner authorization of a specific product but we believe that this situation should be specifically illustrated and specified in the proposed rule.

- In addition, what happens if none of the winning providers have access to the required manufacturer make and model product in the home care setting? Once again, using wound care as an example, there are several situations where the manufacturer serves as the provider for specific support surfaces and wound care therapies. It is quite possible that these technologies will be effectively utilized in the institutional setting. Yet, the only way to insure beneficiaries continued access when they are discharged is to allow grandfathering for the technology in a fashion similar to that which is proposed for non-winning providers with existing patients.

Submission of Bids Under Competitive Bidding Program

Product categories for bidding purposes (proposed 414.412) regarding the requirement to submit a separate bid for all items that are specified in a product category:

4. We strongly recommend that the any decision made regarding to bidding requirements be decided on a category-by-category / bid-by-bid basis. If multiple HCPCS codes within a product category have the same clinical coverage criteria then the bidding requirement should be that a provider must bid at least one HCPCS code for each coverage criteria. We clearly understand the logic behind the draft proposal; however, in some cases the exact same coverage criteria may exist for multiple HCPCS codes within a medical policy. For example, the Group 1 Support Surface Medical Policy contains twelve HCPCS codes but the beneficiary coverage criteria are the same for each code. The Group II Support Surface Policy contains four HCPCS that have the same coverage criteria. It is very doubtful that any provider would carry products in their offering that encompassed all these codes. Rather, they have selected specific codes / technologies that they feel are most appropriate for their organization and in meeting the needs of their customers

Terms of Contracts

Repairs and Replacements of Patient Owned Items Subject to Competitive Bidding:

5. We would strongly encourage CMS to exclude any repair parts, accessories or replacements from consideration for competitive bidding. Within the proposed rule it suggests that "repair or replacement of patient-owned items subject to a competitive bidding program must be furnished by a contract supplier". While we understand the intent of this provision we would suggest that this will not always be feasible. We cannot assume that winning providers will have access to every manufacturer, make and model item that may fall under competitive bidding. In some cases the manufacturer may be the sole distributor and unwilling to sell repair or replacement part to other providers. Repair parts and accessories are not necessarily interchangeable. Unauthorized repairs and / or repair parts and may void a manufacturer's warranty. In addition, replacement may relate to a warranty claim or require the same product to insure continuity of care.

Furnishing Items to Beneficiaries Whose Permanent Residence is Within the CBA

"... in order to ensure beneficiary access to the competitively bid items in the inexpensive or routinely purchased DME payment category... the contract supplier must agree to give the beneficiary or his or her caregiver the choice of either renting or purchasing the item and must furnish the item on a rental or purchase basis as directed by the beneficiary or the beneficiary's caregiver."

6. The proposal that a contract supplier must agree to give the beneficiary... the choice to rent inexpensive or routinely purchased items is not feasible and must not be included in the final rule. The very nature of such products prohibits a provider from offering them on a rental basis. Consider the following:

- Normally, such items are going to have an allowable of less than $500.00 as a new purchase. Once the cost of product is taken out the provider is probably left with a gross profit amount under $250.00. The cost of billing, cash application, lag on cash etc. will certainly exceed $10.00 per claim filed. In the thirteen months of a capped rental there will be at least twenty-six claims filed (primary and secondary) resulting in a cost to the provider of over $260.00. In such a situation the provider is guaranteed to lose money.

- The cost for Medicare contracted carriers to administer the claims processing and payment for such items makes handling them as a rental cost prohibitive for similar reasons to those described for the provider, above.

- Now that capped rental rules have been changed requiring that title be transferred at the end of thirteen months there is no opportunity for the provider to produce a profit over multiple rental periods.

- In many cases, inexpensive and routinely purchased items are specified for "single patient use only" by the manufacturer. Even if the provider could rent such an item profitably, which they cannot, there is no opportunity for them to use the same product for multiple beneficiaries. In addition, what happens in the event that the beneficiary expires after only a few months of rental? The provider is left with a financial loss an unusable product.

Ultimately, requiring that a rental option be offered for inexpensive and routinely purchased items will result Medicare beneficiaries being denied access to such products unless they are willing to pay for the product privately.

Physician Authorization / Treating Practitioner

7. Physicians and other treating practitioners must have the opportunity to prescribe specific products for their patients. We would like to express our full support for the provisions outlined in this section. This provision provides protection from any provider having only the "cheapest" products within their offering without consideration for efficacy on individual needs.

- Physicians and practitioners order products based on experience and desired patient outcomes.

- Since physicians and practitioners will soon be accountable for patient outcomes as "Pay for Performance" becomes the standard, the practitioner must have the authority to order specific products to ensure an optimal clinical and financial outcome for their patients.

- Continuity of care from the institution to the home is critical as often the care plan is implemented and evaluated while in the institutional setting. The practitioner must have the option to continue the plan of care using the same interventions implemented and evaluated during the institutional stay. Often the beneficiary and care giver are familiar with the products, develop a comfort and reliability level by having experienced the product first hand during the course of their institutional stay.

Thank you very much for this opportunity to provide comments on the proposed rule for competitive acquisition of DMEPOS. In closing we would like to stress two final points:

- Competitive bidding of DMEPOS will result in a complete paradigm shift in the delivery and reimbursement of DMEPOS. It must be done very carefully or it will surely have a negative impact on quality of care and beneficiary access. We are very concerned that this program is being driven by an unreasonable date. The number of tasks for CMS, their contractors, accrediting organizations and providers to do before bidding should occur is almost overwhelming. This proposed rule will mandate many of these tasks, as will the quality standards and neither are in final form. We would strongly suggest that CMS provide this information to the Congress and Administration and request that the implementation timetable be revised to insure that competitive bidding is implemented correctly, not quickly.

- As described previously, S3I has been working on developing domestic standards for support surfaces for several years. We strongly believe that this category of products cannot be effectively bid under the current HCPCS codes and medical policy and would request that they be excluded from competitive bidding until such time as a new coding structure and a new medical policy is implemented. Recently, CMS implemented 64 new codes for power wheelchairs largely in order to insure that products were coded homogenously. This is needed for full support surfaces as well. We believe that our group (S3I) is well suited to assist with this process and we wish to express our desire to assist in any way that we can. Clearly, no other group in the United States represents a broader range of stakeholders and no group has spent more time focusing on the unique features and benefits of these products.

Once again, thank you for this opportunity to comment. Please do not hesitate to contact us if you have any questions or if S3I can be of any assistance.

Sincerely,

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83

June 23, 2006

The Honorable Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1270-P – DMEPOS Competitive Acquisition

Dear Dr. McClellan:

On behalf of Medtronic MiniMed, I am pleased to submit comments in response to the proposed rule published on May 1, 2006 regarding the new Medicare competitive acquisition program for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and certain miscellaneous issues. Medtronic is the world's leading medical technology company and Medtronic MiniMed is the market leader in diabetes technology such as external insulin pumps and continuous glucose monitoring.

Our key comments and recommendations, discussed in more detail below, are as follows:

- Thus far CMS has not specified the product categories that will be subject to competitive bidding. We believe there is considerable justification to exclude insulin pumps and related accessories from competitive bidding, as summarized in the following section "Criteria for Item Selection". If CMS concludes otherwise, we urge the agency to at least begin by phasing in bidding for insulin pumps in a single competitive bidding area where the impact on quality and patient access can be carefully evaluated.

- We emphasize the need for CMS to address the complications that arise if a HCPCS code describing both Class II and Class III devices, such as the code for insulin pumps, is subjected to competitive bidding.

- We urge CMS to take specific steps to assure that DME manufacturers who are direct suppliers to patients, such as Medtronic, can serve or continue to serve as Medicare suppliers under the competitive bidding program.

- We recommend that fee schedule payments for Class III devices continue to be based on changes in CPI-U.

- We offer additional comments and recommendations on issues that would affect the entire spectrum of DMEPOS products, including the contents of Requests for Bids (RFBs), beneficiary transition policies, DMEPOS payment adjustments outside of competitive bidding areas, the single payment amount calculations, physician authorizations, and gap-filling.

I. Criteria for Item Selection

Excluding Insulin Pumps & Pump Accessories

In the proposed rule, CMS does not specify which DMEPOS products would be subjected to competitive bidding during the various rounds of bidding, but does provide fairly general language about the criteria CMS plans to use in selecting such products and creating product categories. CMS also notes that it would consider excluding items with low utilization and/or items with a low number of suppliers in a given area, and that its decisions about this would be based on area-specific utilization data.

We believe that when CMS conducts such an assessment, it will find that insulin pumps (HCPCS code E0784) and supplies related to such pumps (HCPCS codes A4221 (supplies for maintenance of drug infusion catheter) and K0552 (supplies for external infusion pump) should be excluded from the DMEPOS competitive bidding program entirely. We estimate that, at this time, only about 10,000 to 11,000 Medicare beneficiaries use insulin pumps nationwide. This means there would be relatively few beneficiaries in any given competitive bidding area using the product. For calendar year 2004, Medicare's own data indicate that there were 34,623 allowed services for HCPCS code E0784. Since this is a capped rental item, we believe this could be viewed as roughly equivalent to 2,885 beneficiaries on an annualized basis (i.e., 34,623 units ÷ 12 months).

We also note that draft product-specific quality standards for insulin pumps and other external infusion pumps (part of the phase 2 standards) have not yet been made available for comment. As we understand it, CMS does plan to provide the same opportunity for informal comment on draft phase 2 quality standards as it did for phase 1. The fact that these quality standards are less far along than those for phase 1 products provides another reason to exclude insulin pumps from competitive

bidding, at least during the first round. Also, as noted in more detail below, patients must receive considerable education, training and ongoing support in the proper use of insulin pumps and accessories, and we would want to assess how the draft quality standards for these products address this issue.

Phasing-In Competitive Bidding

The proposed rule notes that CMS "may elect to phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding." We note that insulin pumps were not included in the two Medicare competitive bidding demonstration projects. While we believe there is significant justification for excluding insulin pumps from competitive bidding altogether, if in fact CMS does choose to include them, we urge CMS to at least phase them in very carefully to minimize the risk of adverse consequences for Medicare beneficiaries with diabetes. In fact, given the very specialized nature of insulin pumps, the initial application of competitive bidding to these pumps should be restricted to no more than one competitive bidding area.

Class III Device Issues

There is a relatively technical issue that that could affect CMS decisions about item selection that warrants further discussion in the final rule. As CMS notes in passing in the proposed rule, Class III devices are excluded from the DMEPOS competitive bidding program. However, a potential difficulty arises if a HCPCS code subjected to competitive bidding includes both Class II and Class III devices. The HCPCS code for insulin pumps (E0784) is one such code, including older Class II technology and newer Class III technology.

The simplest solution would be to exclude such codes from competitive bidding and we would encourage CMS to take this approach. However, if CMS elects not to do this, it needs to explain how it will go about handling this issue, especially as part of any beneficiary and supplier education programs. We believe the HCPCS modifier, KF, would make it possible for DMERCs to distinguish between claims submitted for Class II and Class III devices for purposes of determining whether payment for the item should be based on competitive bidding (assuming the HCPCS code in question is subject to competitive bidding in a given area) or the relevant fee schedule amount.

Nevertheless, we fear that the task of educating beneficiaries and suppliers about the implications of competitive bidding would be made far more difficult if HCPCS codes containing both Class II and Class III devices are subjected to competitive bidding. In fact, beneficiaries might even erroneously conclude that they were being denied access to Class III devices as a result of the new competitive bidding program. For example, if HCPCS code E0784 were included in competitive bidding, how would

CMS propose to ensure that beneficiaries understand that they could continue to obtain Class III insulin pumps from any supplier, not just a contract supplier?

We will be looking for a detailed treatment of the generic issue of Class III devices in the final rule (for example, how HCPCS codes with Class III devices will be treated in RFBs, how beneficiary and supplier educational materials would address the issue, what steps would be taken to ensure that DMERCs would properly process claims for both Class II and Class III devices, etc.).

Technological Innovation at Risk

Finally, in terms of item selection, we offer one additional comment. While CMS obviously believes that the new DMEPOS competitive bidding program could increase quality while not impeding beneficiary access, competitive bidding could discourage DMEPOS manufacturer investment in research and development of path breaking new treatments. Insulin pumps, for example, are sophisticated, high-technology devices, and Medtronic's R&D efforts are currently focused on the evolution of insulin pumps into an artificial pancreas. We see a risk that Medicare's new DMEPOS competitive bidding program could end up reducing incentives for these kinds of product innovations.

II. Submission of Bids under the Competitive Bidding Program

DMEPOS Manufacturers as Suppliers

The proposed rule does not propose specific product categories but it does list the policy groups of diabetic equipment/supplies and infusion pumps, and assumes that interested bidders would be required to submit bids on all items included in a product category. However, in the case of DMEPOS products for which manufacturers now serve as suppliers, the requirement to bid on all HCPCS codes in a product category could be a major problem, especially if the product categories are very broad. In fact, this policy could even become a major barrier to beneficiary access and significantly disrupt the existing marketplace for some DMEPOS products.

Medtronic MiniMed now supplies patients with insulin pumps directly and serves the vast majority of insulin pump users in the United States. In addition, insulin pump therapy requires an intensive amount of direct training and education for patients on pump use. Once patients start pump therapy, ongoing 24/7 technical support is required. It is unclear to us how that patient education and ongoing support (much of it now provided by Medtronic MiniMed) would be handled if insulin pumps were subject to the competitive bidding requirements and manufacturers end up being shut

out from the bidding process because they were unable to bid on products they do not manufacture.

CMS could simply exclude from competitive bidding those DMEPOS products now commonly provided directly by manufacturers, perhaps on the grounds that these products are available from relatively few suppliers and would, therefore, not be good targets for producing Medicare savings.

In other cases, CMS could establish very narrow product categories for such products (possibly including only a single or a very closely related family of products, such as an item of DME and related supplies), although even this could be difficult to achieve if the same HCPCS code is used to describe accessories for a wide range of products (for example, a code describing both a key accessory for insulin pumps and accessories for other un-related external pumps, all produced by different manufacturers).

Alternatively, the agency could also adopt special rules for manufacturers wishing to bid, permitting them to bid only on the products they manufacture. Of course, if CMS chose this last option, it would also need to modify its proposed method for calculating composite bids and selecting contract suppliers.

In sum, we wish to highlight the fact that CMS could inadvertently end up precluding manufacturers from continuing to serve as suppliers in competitive bidding areas to the obvious detriment of the Medicare beneficiaries living in these locales.

III. Fee Schedule Updates for Class III Devices

The background section of the proposed rule is used to solicit comments on the appropriate Medicare fee schedule percentage change for Class III durable medical equipment for 2007 and 2008. CMS promises to consider these comments in conjunction with recommendations made in a March 2006 Government Accountability Office (GAO) report.

The GAO report asserts that Class III devices do not warrant a distinct annual payment update. However, the report does not include a rigorous assessment of payment adequacy, does not review the many factors contributing to manufacturer costs and changes in these costs over time, and does not recommend a specific percentage update. In addition, the report examines Class III devices in relation to only a very limited number of higher-technology Class II items that may not be reflective of Class II items more generally. The report even acknowledges that an earlier draft was criticized for failing to recommend a specific percentage update.

We believe that GAO's report falls markedly short of providing sufficient justification for concluding that the appropriate update for Class III devices for 2007 and 2008 would be zero, simply because the MMA specifies a zero update for Class II devices. In addition, stating that the update for both Class II and Class III devices should be "the same" or "uniform" is obviously not the same as specifying what that percentage update should appropriately be. In fact, the GAO report never once says that the appropriate update for Class III devices for 2007 and 2008 would be zero.

In view of all of this, we believe that the update for Class III devices should continue to be based on changes in CPI-U until a more thorough assessment of the issue can be completed. With energy and other prices increasing in the economy at large, it would be unreasonable to conclude that manufacturer costs for producing Class III devices are not also rising.

As noted above, we believe the HCPCS modifier, KF, would make it possible for DMERCs to distinguish between claims submitted for Class II and Class III devices for purposes of determining whether payment for the item should be based on competitive bidding (assuming the HCPCS code in question is subject to competitive bidding in a given area) or the relevant fee schedule amount. However, we fear that the task of educating beneficiaries and suppliers about the implications of competitive bidding would be made far more difficult if HCPCS codes containing both Class II and Class III devices are subjected to competitive bidding. In fact, beneficiaries might even erroneously conclude that they were being denied access to Class III devices as a result of the new competitive bidding program.

IV. Conditions for Awarding Contracts

Specifying Product Characteristics in RFBs

The proposed rule notes that individual products subject to competitive bidding will be identified by HCPCS codes and "will be further described in the RFB." However, no further details are provided about this. This "further description" could provide a means for assuring continued beneficiary access to a range of products now reported by a single HCPCS code. For example, the insulin pumps we manufacture are highly sophisticated and can communicate with certain glucose meters via radio frequency technology. If glucose meter choices are limited under the DMEPOS competitive bidding program because contract suppliers have chosen not to offer the brands of meters capable of interacting with our sophisticated insulin pumps, Medicare beneficiaries may find it more difficult to obtain the brand of meter that will assure full insulin pump functionality.

We recognize that the physician authorization process is being suggested as one means for addressing this kind of issue (and we comment more about that process below), but we also believe that the requests for bid could be used to specify that contract suppliers must be able to provide glucose meters that are compatible with the insulin pump being used by a Medicare beneficiary, rather than requiring such a beneficiary to obtain a physician authorization. We do not believe that Congress intended the DMEPOS competitive bidding program to become a barrier to beneficiary access to the products they need, and we therefore urge CMS to use its RFBs to help ensure continued beneficiary access to a reasonable range of products now described by a single HCPCS code (including both high and low functionality products) if that code is subjected to competitive bidding.

The RFBs could also be used to specify product-specific services that a supplier would need to assure but not necessarily provide themselves (for example, 24-7 toll-free patient assistance lines operated by many DMEPOS manufacturers). Medtronic MiniMed operates such assistance lines for the products it manufactures but CMS should not assume that all product manufacturers do so or that these services would continue to be available to Medicare beneficiaries under DMEPOS competitive bidding. The availability of patient support lines might be something CMS intends to address in the supplier quality standards but since we do not have access to the latest version of these standards, we cannot be sure this is the case. If not addressed in the quality standards, the issue should certainly be addressed in the RFBs, especially since there could otherwise be an increased risk of reductions in beneficiary services under the new competitive bidding program.

V. Payment Basis

Transition Issues

CMS proposes a grandfathering policy under which suppliers not chosen as contract suppliers (or suppliers losing their contract status in later rounds of bidding) could continue to furnish capped rental items under the existing rental agreement and continue to be paid the applicable fee schedule amount. We support this proposed policy but fear that it does not address all of the transition issues we consider important.

For example, we believe that Medicare beneficiaries now using non-rental items, such as a specific brand of glucose meter, should not be suddenly forced to switch to the brand of meter offered by one of the contract suppliers in a competitive bidding area, but should be allowed a "grace period" during which they could continue to obtain supplies compatible with the brand of meter they now use (and even a

replacement of the same brand of meter, if necessary). Such a "grace period" would give them time to work with their physician to develop an appropriate longer-term plan (for example, determining which meters are available from contract suppliers, which of these might be a reasonable substitute for the device they are now using, whether to insist on continuing access to the existing brand by executing a physician authorization, etc.).

Adjusting Payments Outside Competitive Bidding Areas

The proposed rule announces CMS' intent to use its statutory authority to adjust DMEPOS payments in areas not subject to competitive bidding based on its experience under competitive bidding. However, CMS notes that it has "not yet developed a detailed methodology" for using this authority, and invites comments on this issue. Since the authority in question does not take effect any earlier than January 1, 2009, our sole comment at this time is that CMS should continue to work on the issue and then publish a proposed methodology for public comment as part of future rule-making. In saying this, we presume that CMS will need to wait until there has been time to assess the impact of Round I and perhaps Round II of the new competitive bidding program (on Medicare expenditures, beneficiary access and quality) before deciding how best to proceed. In sum, we would strongly oppose any attempt to implement the special authority in question through manual instructions.

VI. Determining Single Payment Amounts for Individual Items

CMS is inclined to base the single payment amount for a HCPCS code at the median of the bids at or below the pivotal bid for the code. We strongly oppose this. First, it would be unreasonable to give each bid the same weight unless each bidder's promised capacity in terms of units of product were exactly the same. Second, the proposed methodology is a very significant departure from the methodology used under the two Medicare competitive bidding demonstration projects and would mean that many "winning" bidders would receive payment below their submitted bids. This could force some "winning" suppliers to significantly alter their plans for serving Medicare beneficiaries – for example, by substituting lower quality items for those they had planned to offer or reducing the level of beneficiary services. We urge CMS to set the single payment amount in a manner that will assure that all or nearly all "winning" bidders receive payment no lower than the amount of their bid.

VII. Physician Authorization/Treating Practitioner

CMS is proposing to implement a physician authorization mechanism under which a physician or treating practitioner would be able to indicate that a specific brand of DMEPOS is necessary to avoid an adverse medical outcome. We strongly support this provision. We urge CMS to keep the physician authorization process as simple as possible and not attempt to "second guess" physicians on the issue of adverse outcome, especially during the early rounds of the competitive bidding program. Instead, CMS should monitor the use of physician authorizations, determine the circumstances under which such authorizations are being sought, and assess the need for potential changes in the physician authorization process or other aspects of the competitive bidding program.

We hope that physician authorizations would rarely be required by Medicare beneficiaries. However, there remains uncertainty about the impact of competitive bidding, especially for DMEPOS products not included in the two Medicare competitive bidding demonstration projects. The physician authorization process provides a kind of "fail safe" mechanism should the competitive bidding program begin to negatively impact beneficiary access or quality. In saying this, however, we fully appreciate the fact that this "back end" protection should be viewed as a last resort, compared to such "front end" protections as supplier quality standards and CMS bid specifications.

VIII. Gap-Filling

Medtronic is extremely concerned about the proposed new functional technology assessment methodology for gap-filling. While CMS notes that this new methodology would involve a functional assessment, a price comparison analysis, and a medical benefit assessment, the discussion is rather general and no specific examples of how such an assessment would be done are provided. In our view, the concept remains a "black box," making it difficult for us to submit meaningful comments. We are especially troubled by the proposal to adjust existing payment amounts using this new methodology rather than applying it only prospectively.

We believe that CMS should drop the "gap filling" provisions from the final rule and return with a more developed proposal, including specific examples and providing for a reasonable amount of transparency. If CMS proceeds to finalize the new methodology (or a variant thereof), it should at least provide a more transparent process whereby the initial CMS assessment and proposed payment amount could be published or posted on the agency's website with an opportunity for public comment. Gap-filling obviously has significant implications for a wide range of stakeholders, including beneficiaries and manufacturers, and the process for arriving at a Medicare payment amount should be as transparent as possible.

Medtronic

MINIMED

We appreciate this opportunity to comment on the proposed rule and look forward to reading CMS' response to these comments in the final rule. In the interim, we would be happy to answer any questions CMS staff might have about our comments or try to provide any additional information that might be helpful in crafting the final rule.

Sincerely,

Claudia Graham

Claudia Graham, PhD
Vice President, Global Therapy Marketing

HARTZELL'S
HOME MEDICAL EQUIPMENT
A Division of Hartzell's Pharmacy, Inc.

84

Joint Commission
on Accreditation of Healthcare Organizations

June 16, 2006

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

To Whom It May Concern:

Thank you for the opportunity to comment on the proposed regulation to implement competitive bidding for DMEPOS. I offer the following comments for consideration as CMS develops the final regulation.

Opportunity for Participating by Small Suppliers
I urge CMS to take steps that ensure a small supplier, which includes a majority of pharmacy based supplies, can participate in the competitive bidding program. Small suppliers should be allowed to provide DMEPOS. Our country is composed of many small businesses that continue to work and strive to succeed. Our founding fathers, I am sure would not encourage the loss of small business. I urge you to consider allowing small businesses to participate in some way in competitive bidding.

The competitive bidding area should be reduced to allow for small independent companies the same opportunity to service individuals in their area as larger suppliers. It would be extremely difficult, if not impossible for a small supplier to compete with larger suppliers in the same metropolitan areas.

After CMS established the single payment amount for each item, any small supplier willing to accept that negotiated payment should be allowed to join the competitive program as a contracted supplier.

CMS must take these steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established provider patient relationships.

I currently provide the following types of DMEPOS in my practice: wheelchairs, walkers, commodes, ambulatory aids, bathroom aids, hospital beds and accessories, C paps, nebulizers, and home oxygen and without these revisions to the final regulation, I will be unable to continue providing these valuable services to Medicare beneficiaries.

Criteria for Item Selection
The competitive bidding program should not include common DMEPOS supplies such as diabetic testing supplies and ostomy supplies. Most people need assistance in learning about their condition and a "hands on" approach from knowledgeable people in this field provides these clients with this service and the necessary training to manage their condition. In reading your regulation it appears

that you want service and training. If CMS intends to centralize and consolidate the preliminary DMEPOS items and supplies the agency shall limit the competitive bidding program.

CMS has not specifically stated which products they will be looking at; however, they are seeking those products that have the highest cost and highest volume. As medical equipment supplier who provides patients with home oxygen therapy and other respiratory devices, our experience has shown us that these items require educated and/or trained individuals to initially instruct patients on the equipment and then require ongoing follow up care to ensure that the equipment is functioning properly. The beneficiaries also have a responsibility in the general care of the equipment and changing necessary supplies as needed. Has CMS taken into consideration that by placing a cap on oxygen equipment after 36 months it places a burden on the beneficiaries as well as the suppliers. If the equipment is not maintained properly after that 36 month cap, the cost to repair or replace could be more costly than the monthly rental.

Determining Single Payment Amounts
CMS has indicated that they will accept a median bid for a particular product. A smaller provider acquisition cost to purchase a product may be significantly higher than that of a larger (national) supplier and the median bid may fall short of that supplier's ability to accept the bid. We ask that you review the process to determine the single payment amount and ensure that the payment rate is adequate to cover a supplier's cost to acquire and provide the product.

CMS has indicated that the contract will be for a period of three years and that the payment will be reviewed and updated according to the consumer product index. This does not address situations in which the manufacturer or distributor raises the acquisition cost of the product or if the supplier needs to change wholesalers due to product availability. At this time, suppliers are still required to furnish the product and receive the same standard reimbursement regardless of manufacturer price increases or product availability. Suppliers will not be able to continue providing DMEPOS supplies in this situation. CMS must make provisions to increase the reimbursement during the year if the acquisition cost change.

Competitive Bidding Area
I strongly object to CMS alternative proposal that would require beneficiaries to obtain replacement supplies of certain item through designated providers; this restricts the beneficiaries' choice. This proposal would severely restrict beneficiaries' access to needed items and supplies and could compromise a patient health outcome. As a pharmacist, and medical equipment supplier of product and services, we have emergency requests and stat orders. Mail order is not the ideal way to treat here.

Sincerely,

Mr. Robert E. Hartzell, Jr. R. Ph., ND, CCN
President, Hartzell's Pharmacy Inc. & Home Health Care

Original

85

June 19, 2006

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

Re: CMS-1270-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments for consideration as CMS develops the final regulation.

Competitive Bidding Area
I strongly object to CMS' alternative proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers—this restricts beneficiaries' choice. This proposal would severely restrict beneficiaries' access to needed items and supplies and may compromise patient health outcomes.

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

Opportunity for Participation by Small Suppliers
I urge CMS to take steps to ensure that small suppliers-which include the majority of pharmacy-based suppliers-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 competitive in large metropolitan areas. After CMS establishers the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contract supplier. CMS must take these steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain establish provider/patient relationships. I currently provide the following types of DMEPOS in my practice (brochure enclosed) and without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients.

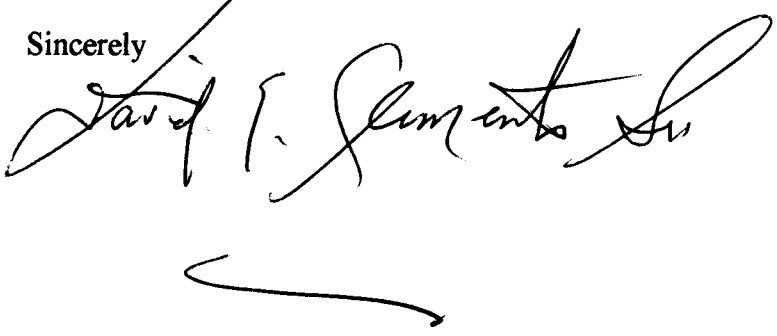
In conclusion, I urge CMS to revise the regulation to:

1) Continue to allow freedom of choice of provider.

2) Allow small providers same opportunity to participate (who have done so for years) at fee established thru bidding process.
3) Prohibit large suppliers from auto-shipping supplies due to the potential for waste and abuse. (Ex. Diabetic supplies). However, quick access to these supplies is necessary.
4) DMEPOS should take into consideration the cost to smaller suppliers—Example- some ostomy supplies are now reimbursed at or near cost on some items.
5) DMEPOS should build in price increase into their system to cover suppliers price increases from manufacturers.
6) Allowing rebates back to recipients will be an enforcement nightmare plus could lead to rampant fraud abuse, and false claims to recipients. Rebates to recipients would be difficult to impossible to verify by them.
7) Beneficiaries need convenient access to the benefit (suppliers) and should not be restricted in their choice it to maintain their current provider/patient relationships.
8) To restrict, limit and destroy the established networks of providers that have spent years to establish their business would be a disaster to them as well as all who depend on their convenient services.

Thanks for your time and allowing comments

Sincerely



86

DR. E. STEVEN DAMON
DIPLOMATE, AMERICAN BOARD OF PODIATRIC SUGERY

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FAX (860) 741-2482

6-20-06

Mark. B. McClellan, MD. PhD
Administractor
Centers for Medicare + Medicaide Services
Dept of Health + Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Dear Dr McClellan:

Please allow physicians, including podiatric physicians, to continue supplying durable medical equipment to medicare patients.

Many of my elderly patients are unable to travel to another location distant from my office to get the medical equipment they need. Other times, they are given the wrong equipment and have to make a second trip.

Therefore, please <u>oppose</u> the competitive acquisition program for durable medical equipment.

Sincerely,

C Steven Damon DPM

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6/15/06

87

Mark B. McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CMS: 1270-P
PO Box 8013
Baltimore, MD 21244-8013

Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS

Dear Doctor McClellan,

I am a Physical Therapist practicing primarily in outpatient orthopedics in Issaquah, WA as well as per diem practice in a local nursing facility with a large majority of Medicare patients. I am writing in concern to the recent proposed rule to implement a competitive bidding program for DMEPOS suppliers. This rule would significantly affect the physical therapists ability to supply our patients with off-the-shelf supplies and orthoses.

This rule would award those suppliers with the most cost savings to Medicare, not to the patient, and the rule does not take into account the quality, necessity and function of the supply. This rule would also restrict access to the specialized supplies which would only limit the patient's function and recovery. If CMS creates a rule to make it more difficult and complicated to obtain DMEPOS, then the patients are the ones who will suffer. The patients will not receive the appropriate equipment at the appropriate time, which can further hinder their therapy progression, therefore increasing Medicare costs.

I am opposed to the implementation of this rule for the above reasons and to avoid unnecessary cost, time and work for the patient.

Thank you for your time and hope that you will consider these points as well as the many other letters I am sure you have and will receive regarding this subject.

Sincerely,

Kendra Liere, PT

Kendra Liere, DPT

COMPREHENSIVE PODIATRY LLC
www.comprehensivepodiatry.com

Jennifer L. Goodman, D.P.M.
Foot and Ankle Specialist

88

June 21, 2006

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

Dear Dr. McClellan:

I am writing in opposition to the proposed rule, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues. This would include physicians in a competitive program to supply DMEPOS items that I do not believe physicians should be included in. By including physicians in this, it will end with not all current physicians who supply DME to continue doing so. This in turn will decrease the quality of care that the physicians who can no longer provide DME will be able to provide to their patients.

The inability to dispense a removable walking boot at the office is an example of the decreased quality of care. An example is an elderly Medicare woman who comes into my office who presents with foot fracture requiring immobilization. Due to the condition of her skin, vascular status, medical conditions, swelling, and fracture, she needs to be placed in a low removable boot walker to allow daily examination of her skin. If I am not selected as a supplier in the new program, I will not have the ability to dispense the walking boot to this patient in my office. It is medically necessary to provide the DMEPOS at the time of injury. It would be malpractice to allow the patient to leave my office and not know if she was properly immobilized. I also believe that the physician should be the supplier of the DMEPOS in this example so that he knows the patient was properly fit since she could develop skin ulcers if not properly fit. If the ulcers did form, the physician would be responsible for treating this complication of improper immobilization even though he had no control over the fitting of the walking boot. This puts both the patient and physician in unnecessary situations.

I do not think that the intent of this proposed rule is to impede the ability of physicians to provide medically necessary care and insure a high quality of care for their patients. I urge the Centers for Medicare and Medicaid Services to reconsider its original proposal and to exclude all physicians, including podiatric physicians from the requirement to competitively bid to be a DME supplier. All physicians should be able to continue to supply medically necessary DMEPOS items in their office.

Sincerely,

Jennifer L. Goodman

Jennifer L. Goodman, D.P.M.

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June 20, 2006

89

Sandie Vernier PT/Rehab Manager
Providence Valdez Medical Center
Valdez, AK 99686
(907) 834 - 1862

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

Dear Mr McClellan,

My name is Sandie Vernier a physical therapist for the past 11 years. I am the rehab manager and working clinician with patients here in an isolated region of Alaska. We are a small community and a small facility. But, we need to be able to provide the needed supplies to our patients as quickly and efficiently as possible. This rule could significantly impact the ability of our rehabilitation department to furnish items such as off the shelf orthotics, wheelchairs, ambulatory assistive devices, and numerous needed items to our patients.

When we evaluate a patient we include the assessment of the various braces or assistive device's that would be beneficial to the patient. I urge CMS to revise the proposed regulations and establish a process that will enable physical therapists to continue furnishing orthotics, adjustable assistive aids etc. that are critical to the immediate care of the patient. What should I tell the patient? Fly to Anchorage, take a taxi to the DME provider and pick up your brace, or don't walk or move the leg for perhaps up to two months when your brace might arrive?

I can't imagine the impact this rule would have to not be able to provide an elder with a walker after a slip on the ice and injuring a hip? Or for the week end warrior who stretched a ligament in his ankle and would benefit from the quick placement of a support to prevent further tearing or separation of the injured ligament? Do you prefer that medicare recipient lay in bed for two months before a DME provider can get the equipment shipped?

In our isolated facility we PT's often perform needed adjustments to the various splints, braces, ambulation aids etc. The surgeon is miles away

and we are the ones that he depends on to see that the patient has the correct brace setting, such as the extension stop or adjust to decrease flexion beyond a certain degree. As the patient rehabs, we consult with the Dr. and are able to provide the service adjustments without adding the travel expense and time expense of going great distances to town for every progression.

As the trained expert in rehabilitation for our patients we often collaborate with the physician and specify certain products that address the individual patient's needs. I once had a surgeon who only wrote prescriptions for a specific European brace as he did not know about the difficulty and the expense of trying to provide the patient with that brace, and once obtained it was not comfortable and the patient's mostly refused to wear them at all. I urge CMS to revise the regulations to allow physical therapist to do their job that they are trained to do. That is to know the various braces, be able to order, fit, make adjustments, which allow for the proper mobility of the injured body part

I truly hope that you will consider dismissing this proposal.

Thank you very much for your consideration into this matter of great importance.

Sincerely,

Sandie Vernier PT

OKLAHOMA PODIATRIC MEDICAL ASSOCIATION

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E-mail: execdir@okpma.org

Donald M. Barnum
Executive Director

90

June 25, 2006

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

Dear Dr. McClellan:

I am the Executive Director of the Oklahoma Podiatric Medical Association which represents eighty-eight doctors of podiatric medicine. I am writing to urge the Centers for Medicare Services (CMS) to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) from 1861(r) (1) to 1861 (r) (3).

Our doctors want to be able to supply DMEPOS items for their patients only and believe that if they are required to instead bid to supply the entire Metropolitan Statistical Area (MSA) their patients would be negatively impacted. I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.

Sincerely,

Donald M. Barnum

DONALD M. BARNUM
Executive Director

DMB/sf

91

The
Care Center
HOME MEDICAL EQUIPMENT

29 Arcadia Road
P.O. Box 129
Old Greenwich, Ct. 06870

06/25/06

Centers for Medicare and Medicaid Services
Comments on NRPM
CMS-1270-P

Gentlemen:

As the owner of The Care Center I urge you not to expand the competitive bidding project at this time. This concept is just too disorganized, untested and poorly thought out to be rolled out nationally let alone be expected to produce any savings for the Medicare program.

First off, I think this entire idea is just plain stupid. What group of well-meaning but unrealistic bureaucrats dreamed this up? I mean, for crying out loud, this has got to be the most absurd attempt at trying to save a few bucks ever to come out of Washington. And, I'd be willing to bet that most of you reading this would be inclined to agree! So, lets get it right.

You want comments? How many millions has this "demonstration" cost you so far? Wouldn't it have been a whole lot easier to just lower reimbursement for durable medical equipment? Heck, you've been doing it for years. Why not just give it one big whack and watch the savings roll in. I know why. It's too easy. You need a "program" and a bureaucracy to administer it. Now it can look like our government at work.

I've heard it said that if the V.A. can get it at a lower price why can't Medicare? Never mind that a guy can grow old and die before he ever gets his wheelchair from the V.A. If we in our industry operated with the same callousness and inefficiencies demonstrated by the V.A. we'd all be out of business. No one would want to do business with us.

Oh, but you're going to roll out this dumb program anyway. What do you care what it costs in dollar terms. You certainly don't care what it will cost the hard working folks like me and my staff and others like me all over the country. There is a human cost to this. Has anyone considered that? You probably don't have a clue what this is doing to us right now let alone how this is going to impact us down the road if you keep on this course. Speaking of keeping on course: Of course, you can't just scrap this program having come to your senses and come up with a more fair and equitable way to save a dollar. God, someone might lose face. How do you go back and say, "Gee, we were wrong".

And how conveniently you've forgotten about the Medicare beneficiary. Who are you to decide where my mom and dad should get their home medical equipment? Or how long it should take for them to get what they need? It's so obvious that what you really want is far fewer suppliers serving an ever increasing Medicare eligible population. Hello? It's a sinister plan but we all know what you're up to! How could anyone possibly profess to be able to calculate market demand for our products and services and how many suppliers are needed to fill the need? Please! I mean, good God, this is socialized healthcare rationing!

But let's move on. You talk about *me*, in *my* business, having to meet *your* financial standards. Who are you kidding? You're the characters who paid how much money for medically unnecessary power wheelchairs in Texas. Look inward and clean your own house before you dare tell me how to manage mine. I know how to keep my finances in order, which is why I'm on solid footing after 15 years serving my community.

Let's look at accreditation for a moment. My company is accredited, has been for many years now but I think that the whole concept is totally overblown. We were a great organization before we were accredited. That's why we were able to meet someone else's standards. If you're a shoddy operator to begin with accreditation isn't going to change anything. What has accreditation done for The Care Center? It's given us the "*Good housekeeping*" seal of approval which, in itself, is great to have. It's also generated a mini bureaucracy and a lot of paperwork in a small business. Sure, I think it's a great idea to ensure that beneficiaries are dealing with a company that adheres to the highest standards. So, if you really want to "thin the ranks" of providers, just make accreditation a requirement to renew a supplier number.

While we're on the subject of small business...What's with you guys? You must really have it in for all the small business owners in this industry. Why don't you just come clean and make it public. You don't want small providers as Medicare suppliers. That sure as hell is the way it looks to us. Think about it. You're pitting us against the national suppliers. You expect us to manage the bid process but without the big guy's resources. Just how many lawyers and MBA's do you think I have on staff here? This whole process is skewed in favor of big corporations at the expense of small business. How un-American. You should all be ashamed.

It's all too obvious that you intend for many of us to go out of business. I would like to know how you propose to compensate me, when I don't make the bid cut, for the lost wages when I can no longer afford to stay in business because I can't supply my bread and butter products to Medicare beneficiaries. Further, what's your plan to reimburse me for the value of my business when I can't sell it because it no longer has any worth? At 50-something do you really expect me to go looking for a job after I've spent years building a high quality, reputable business to serve my community? And what of the people working for me? Come on, guys. Surely someone must have thought of this. Surely?

Ok. So if you folks can't find the guts to totally scrap this idiotic program in favor of something a little less destructive to the deserving souls we serve and the entire fabric of our industry, perhaps you will consider this. FIX IT! You know what's wrong. For crying out loud, you've been hearing it for how long? So, pay attention! Do something good! And thank you for listening.

Respectfully,

Frank DeLuca
President & Owner

ASHT
AMERICAN SOCIETY OF HAND THERAPISTS

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92

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 21233-8013

Re: Medicare Proposed Rule on Competitive Bidding System for Certain Durable Medical Equipment, including Prefabricated Orthoses (splints)

Dear Administrator McClellan:

Thank you for the opportunity to comment on the 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).

We represent the American Society of Hand Therapists (ASHT), an association of over 3000 occupational and physical therapists who specialize in the treatment of the upper extremity patient. As specialists in hand therapy (treating the hand, wrist, elbow, and shoulder) we have grave concerns regarding the initiation of a competitive bidding process for DMEPOS.

The overwhelming majority of therapists supplying orthotic devices to Part B of Medicare meet your definition of a small business. While our impact on Medicare payments is small, the impact that we have on the quality of life for the thousands of beneficiaries we treat is immeasurable. It is the hand therapist's goal to progress an injured and nonfunctional upper extremity patient to independent living. Orthoses, including the off-the-shelf orthoses proposed in the competitive bidding system, are a critical part of this therapeutic intervention.

As described in the proposed rule, our ability to select and supply the appropriate orthosis (as prescribed by a physician) will be severely affected by a competitive bidding system. In general, it is our position that competitive bidding fits poorly into an effective therapeutic intervention process. The lack of therapist involvement in the competitive bidding process in your demonstration projects supports our position that competitive bidding does not lend itself to cost efficient and effective therapy of the upper extremity patient.

In particular, we would like to comment on the following sections of the proposed rule as outlined in the Federal Register.

1. *Program Advisory and Oversight Committee*: We would like to take this opportunity to comment on the composition of the PAOC and to request better representation in the future for therapists in general, and hand therapists specifically. When the PAOC was established, occupational therapists and physical therapists were not represented on the committee. Although this may not have been the intention, it has had unfortunate consequences. It is our opinion that the predominately O&P representation on the committee, including 10 of the experts, has led to an overwhelmingly O&P perspective. It is our fear that this poor representation of therapists has led the committee to be silent on the important role that therapists play in the provision of orthoses to beneficiaries.

Occupational therapists and physical therapists would have provided valuable information on orthotics as it pertains to beneficiaries receiving orthoses in conjunction with their therapy services. OTs and PTs have a strong educational background, knowledge base, and clinical expertise in evaluating patients for orthoses and subsequently selecting or fabricating and fitting beneficiaries with the ideal orthosis based on their individual medical condition. Our role with orthotics goes back well before World War I, and thousands of OTs and PTs are sought out daily by physicians and surgeons to evaluate, determine, fit, and educate patients for specific orthoses. As therapists we are responsible for the beneficiary's care from the initiation of treatment to the final outcome. Orthoses serve as one vital component of this comprehensive rehabilitation process. Within the O&P scope, the orthosis is a device dispensed for a given purpose independent of the rehabilitation process. The importance of this unique difference needs to be clearly understood and represented as the committee finalizes this regulation.

It is very regrettable that a large volume producer of orthoses for Medicare beneficiaries has been represented only through open public comment. As a profession, the American Society of Hand Therapists respectfully requests the opportunity to actively participate as consultants to this committee, including input to CMS on the definition of off-the-shelf orthotics and how L codes would fit into this definition. We would provide valuable input as this committee continues its work towards reducing health care costs and maintaining the high quality of care to and for beneficiaries. Please provide us with this vitally important opportunity.

2. *Quality Standards for Suppliers of DMEPOS*: It is unfortunate that the quality standards are not available as we comment on the competitive bidding ruling. The uncertainty of these standards makes it difficult to comment on a competitive bidding system that requires its suppliers to comply with quality standards that are not currently available. While we applaud CMS's attempt to improve patient care through standards, we continue to assert that occupational therapists and physical therapists have already undergone rigorous standards to be qualified as a provider and that it is unnecessary to add another process for both CMS and therapists.

3. *Criteria for Item Selection*: We would like to comment on two issues re: this section. First, from a perspective of a health care professional providing orthoses, we feel that all upper extremity orthoses provided to an injured beneficiary should have the input of an occupational therapist, physical therapist, physician, or orthotist. In the delivery of an upper extremity orthosis, there is more to the thought process than just the mechanics of the device. In each case, the professional considers the disease/injury, precautions, ADL and functional needs, future orthotic needs, anticipated changes in condition, etc. A specific brand may be the only one that will appropriately meet the needs of a patient. Should this rule be enforced as written, suppliers will not be required to bid on all brands of a certain orthosis. As a result, it is not

guaranteed that a beneficiary will be able to find a specific orthosis in the local area, or that they will receive adequate instruction in their disease process and potential problems. This could potentially limit or delay their access to an important orthosis and information that can only be supplied by a professional. Hand therapists stock orthoses that are appropriate for their patients, allowing for immediate fitting and averting potential problems and/or injuries from inadequate or delayed orthosis delivery.

In addition, in the definition of off-the-shelf (OTS) Orthotics, you state that off-the-shelf items would be described as requiring "*adjustments that the beneficiary, caretaker for the beneficiary, or supplier of the devise can perform without the assistance of a certified orthotist (that is an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc or the Board for Orthotist/Prosthetist Certification). By contrast, we would consider any adjustments that can only be made by a certified orthotist to be adjustments that require an expertise in trimming, bending, molding, assembling, or customizing to fit the individual.*" The reference to certified orthotists, without simultaneously mentioning occupational therapists and physical therapists, infers that orthotists are the only suppliers that can provide custom orthotics. We strongly disagree with the wording of this passage. Occupational therapists and physical therapists have been providing a valuable service to Medicare beneficiaries in the fabrication of unique and custom orthoses. This passage is outside of the current Medicare statutes that allow therapists with DMEPOS supplier numbers to fabricate and bill for custom orthoses.

4. *Submission of Bids under the Competitive Bidding Program:* It is our opinion that providers, including occupational therapists, physical therapists, and physicians should be exempt from the competitive bidding process when supplying OTS orthoses in the course of therapeutic intervention. It is impossible to separate the supplier and provider components throughout the continuum of patient care. Occupational therapists and physical therapists give much consideration before selecting and dispensing an orthosis. Please realize when an "off-the-shelf" orthosis is dispensed to a patient by an occupational therapist or physical therapist, each of the following considerations is included in the selection and dispensing of the orthosis:

- Specific medical diagnosis or surgical procedure which determines the anatomical area that needs to be immobilized or mobilized.
- Determination of which type of orthosis would best serve the beneficiary, for example:
    i. Rigid vs. semi-rigid immobilization
    ii. Consideration of requirements for soft material due to fragile skin, open wounds, pins, or fixators.
    iii. Current stage of their medical condition including time frame of soft tissue structure healing, fractures, or stage of arthritic/joint condition.
    iv. Restrictions in range of motion, including limitations in a specific arc of motion.
    v. Specific limitations in opposite extremity requiring individual consideration for orthosis options.
- Customization of the prefabricated orthosis to meet the special medical need of the patient (e.g. adding thermoplastic materials in a customized fashion to support/stabilize specific anatomical structures)

- Comfort
    i. If the prefabricated orthosis does not have an exacting fit and is not comfortable, it will not be worn.
- Establishing interim therapy visits as appropriate to monitor the following:
    i. Benefits from orthosis (reduce-eliminate symptoms; influence range-of-motion, etc.)
    ii. Adjustments needed with edema changes, wound healing (where present)
    iii. Changes in the medical condition influencing the course of therapy
    iv. Transition to a different orthosis as the beneficiary progresses through their medical condition or surgery
- Providing specific patient education related to:
    i. Rationale for the orthosis – intended purpose
    ii. Wear schedule for the orthosis based on the individual medical condition or surgical procedure
    iii. Review of the comprehensive rehabilitation program in relationship to the wear schedule for the orthosis
    iv. Educating the beneficiary from a rehabilitation perspective on information essential to complement the orthosis for maximum benefit (e.g. instruction in proper body positioning and activities which exacerbate specific medical conditions such as carpal tunnel syndrome, wrist pain and tendonitis, lateral epicondylitis)
    v. Proper don/doff of the orthosis

- Problem-solving special needs of the patient
    i. Physical or cognitive limitations influencing the capacity to wear the orthosis
    ii. Limitations in function of the opposite extremity that may mandate alteration (e.g. special strapping) of the prefabricated orthosis
    iii. Cognitive limitations for following basic instruction that may result in the need for pictures of the orthosis, simple pictures on how to apply the orthosis, and/or colored straps or other visual clues to help them apply their orthosis
    iv. Visual limitations that may mandate special instruction and assistance with the design of the orthosis

As a Society and a profession, we genuinely believe that the supply of any orthosis through a competitive bidding program, which would normally be prescribed by a physician for an occupational therapist or physical therapist to dispense, would delay and fragment the care beneficiaries receive today. **This delay may put beneficiaries at risk for additional injuries.**

5. *Assurance of savings*: It is our position that minimal savings will be realized in the provision of upper extremity OTS orthotics. There is currently a very small margin of profit in the supply of these orthotics, and the opportunity to bid lower than the current reimbursement rate is minimal. As such, the benefits to CMS from competitive bidding of OTS upper extremity orthotics would be minimal. It should be noted that analysis of the demonstration projects supports our position that minimal savings to CMS will be reached by placing OTS upper extremity orthoses under the competitive bidding program.

6. *Opportunity for Participation by Small Suppliers:* Currently, the rule does not ensure that small suppliers will have an equal chance in the bidding process. The language, despite stating the importance of ensuring equality, fails to develop a plan to guarantee this protection. Therapists are at a huge disadvantage. They are not in the business of manufacturing and supplying high volumes of medical equipment. Individually, each therapist and/or therapy facility dispenses small volumes of medical supplies to their patients. It would be impossible for a therapist to compete with respect to pricing, volume warehousing, and the necessary business infrastructure for wide scale distribution within their medical model. The small amount of profit generated from these prefabricated orthoses serves, at best, as a very small source of revenue for most small practices. Small suppliers with a limited scope of orthotic goods and needs would be at a severe disadvantage in the competitive bidding system. It is our opinion that therapists in small businesses would find the cost and time needed to comply with the competitive bidding program prohibitive, and would not go through the process of bidding for this service. As such, Medicare will loose a very skilled profession in the delivery of OTS orthoses to the upper extremity beneficiary. We ask that items utilized in the treatment of the upper extremity patient (including but not limited to those OTS orthoses covering the shoulder, elbow, wrist, hand, and finger), be exempt from the competitive bidding program.

In conclusion, implementation of a competitive bidding system would significantly change and impede the standard of care for the provision of orthoses in the upper extremity beneficiary. We strongly feel that there should be a distinction between a therapist and/or physician providing an orthosis within a plan of care and a general durable medical equipment supplier in the treatment of these patients. A therapist providing a product to a patient within the doctor/therapist referral system should be exempt from the competitive bidding system.

Sincerely,

The American Society of Hand Therapists
L-Code Committee:

Chris Blake, OTR/L, CHT

Chris Blake, OTR/L, CHT

Nancy M. Cannon

Nancy Cannon, OTR, CHT

Ginger Clark, OTR, CHT

Ginger Clark, OTR, CHT

OTR, CHT

Jerry Coverdale, OTR, CHT

Elizabeth de Herder

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93

June 27, 2006

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

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

Dear Sir or Madam,

The Home Care Services Department of the University of Michigan Health System (UMHS) would like to thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for certain covered items of DMEPOS. We are writing to express our concern regarding the potential impact that a competitive bidding system would have on Medicare beneficiaries, providers, and the entire healthcare delivery system.

I am especially concerned with the impact that the National Competitive Bidding requirement would have on hospital-based DME providers that operate as part of a self-contained, fully integrated healthcare system and the negative impact NCB will have on other areas of the healthcare continuum.

This NCB option may simply cut PRICES on products, but will undoubtedly and dramatically reduce patient access, choice, and service, which will ultimately only increase overall Medicare beneficiary health care costs in other areas of the hospital system and health care continuum. Examples: Increased length of Stay in Inpatient/Acute settings, Increased patient re-admission frequency or severity, etc.

It needs to be recognized that any potential "product-cost" savings gained through National Competitive bidding for DMEPOS (Durable Medical Equipment Prosthetic Orthotic Supplies) including oxygen, wheelchairs, beds, respiratory equipment, wound care, diabetic supplies etc., will ultimately be off set by increased cost in the both the tertiary inpatient and outpatient care settings.

Our experience has been that competitively bid DMEPOS and/or other Home Care services do not result in TRUE overall health care cost savings, but merely result in hidden, but damaging "Cost-Shifts" within the health care continuum. Limited or "exclusive" provider panels that don't at least allow hospital entities to serve our own patient population often actually increase overall hospital costs, through increased administrative, oversight and program management costs, and often even prevent patients from getting the most efficient and optimal care available. These limited panel programs also frequently increase hospital re-admissions and lead to a higher proportion of less favorable or even negative clinical patient outcomes.

Our experience with competitively bid provider panels includes the following negative aspects.

- Will increase inpatient cost per case.
    - In an integrated health care delivery system we have very efficient information and ordering processes. Inherently, utilizing a provider that is

not part of the integrated healthcare delivery system will increase the efforts needed to provide the DMEPOS needs of these patients.

- Will increase inpatient length of stay.
    - It is inherent to the proposed rule that extra steps will be needed to obtain DMEPOS for patients that now receive their DMEPOS from a member of the integrated healthcare delivery model. Obviously an item can be delivered quicker and more efficiently when the source of the item is within that health system rather than an outside provider that is located across town or possibly across the State.
- Will require inpatient facilities to subsidize portions of the proposed rule.
    - The proposed rule discusses some potential items that will be provided via mail order. In Michigan we have experience with this type of limited provider panel. Patients can not wait for a mail order item to arrive and hospitals can not justify keeping a patient admitted while they wait for the delivery. The end result is the inpatient facility gives the patient non-reimbursed items to facilitate the timely discharge, in essence subsidizing this proposal.
- The proposed rule will make negative clinical outcomes more likely.
    - Again based on real life experiences with limited provider panels we have found that patients are more likely to be provided with DMEPOS items that do not meet their clinical needs when limited provider panels are not part of the integrated delivery system. Integrated systems are better able to meet patient's clinical needs as the result of the team approach. One of the more common negative outcomes we see involves wheelchairs. A rehab patient is specifically fitted with a wheelchair that meets their needs while an inpatient. In the limited provider panel model these patients frequently are not given the same wheelchair when they are discharged which commonly leads to serious complications.
- Will result in great difficulty in the development and implementation of clinical pathways.
    - In the integrated delivery model DMEPOS services are a part of the clinical pathway when appropriate. When patients must receive DMEPOS services from a limited provider panel outside the integrated delivery system the clinical pathway is difficult if not impossible to maintain inclusion of DMEPOS services in a limited provider panel situation would be difficult if not impossible.
- The demonstration projects conducted by CMS did not include any integrated healthcare delivery models.
    - The provision of DMEPOS services clearly has the potential of great impact on inpatient facilities, arguably impacting inpatient facilities more than any other group. Yet there is no evidence that CMS did any investigation on this impact.
- Will negatively impact the patient physician relationship.
    - Physicians that currently dispense certain items considered DMEPOS would not longer be able to provide this service to their patients. This problem is intensified when the DMEPOS item is actually a portion of the physician's treatment.

To remedy this situation I encourage CMS to remove health system/hospital based providers of HME from the competitive biding process, and allow these providers the ability to continue to provide HME services at the competitively bid prices.

FURTHER/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 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.

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 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 better, 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?

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 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. 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.

Sincerely,

James Shurlow
Director HME Services
University of Michigan Health System

JS/jess

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94

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June 27, 2006

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

Dear Dr. McClellan:

In my capacity as Board Chair of Trimark Physicians Group, 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)(3).

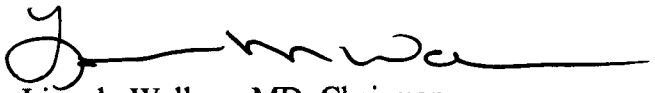
Trimark's Podiatric physicians prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. As our patients, these beneficiaries rely on our Podiatric physicians for best medical judgment and clinical skills in treating them. The Trimark Podiatrists are required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and are subject to the same Stark requirements that apply to MD and DO physician suppliers. It is our belief that 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 their patients only and the right to execute a physician authorization.

The Trimark Podiatrists use a variety of DMEPOS items in their Practice. As an example, when a patient presents complaining of foot pain and swelling following an injury, a diagnosis of multiple fractures of the metatarsals may be made and a subsequent determination that a walking boot is necessary for immobilization of the injured foot with associated edema. If our Podiatrists are no longer able to 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.

We urge CMS to modify the physician definition used in the proposed regulation from 1861(r) (1) to 1861(r) (3) before finalizing the regulations for the competitive acquisition program. It is our strong desire that our Podiatrists be able to continue to supply DMEPOS items for their patients, and believe that if they are required to

instead bid to supply the entire Metropolitan Statistical Area (MSA), their patients will be negatively impacted.

Sincerely,



Lincoln Wallace, MD, Chairman
Trimark Board of Directors

(95)

6/26/06

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

Dear Dr. McClellan,

I am writing in regards to the proposed rule of competitive bidding program for DMEPOS. I was shocked and dismayed that CMS used the definition of physician that excludes podiatric physicians. I have completed three years of surgical residency including an orthopedic foot and ankle fellowship at the University of Maryland and I have been in private practice for close to ten years. I have a number of MD and DO physicians which routinely send me patients for foot and ankle care including reconstructive surgery. Moreover we treat a myriad of conditions including charcot foot, fractures, tendon ruptures etc. I think it would be a disservice to our patients with pathology requiring an air cast, crutches etc to be sent out to another location to receive the items required. Furthermore it may put these patients at higher risk for worsening their problems i.e. fracture dislocation, charcot dislocation/breakdown and thus increasing the potential for complications.

I prescribe and supply DMEPOS items to Medicare beneficiaries as a regular part of patient care. I maintain a valid DMEPOS supplier number and adhere to the same supplier standards that apply to MD and DO physician suppliers. In addition I am subject to the same Stark requirements that apply to MDs and DOs. My use of DMEPOS items as an integral part of patient care is no different than that of my MD and DO colleagues.

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. I believe as a physician participating in the Medicare program I should have those same rights. I hope your office will reconsider the use of 1861(r)(1) to define physician and apply the broader definition which includes podiatric physician, 1861(r).

Respectfully Submitted,

Harold Gruber, DPM

Tri-State

Foot & Ankle Center
Medical and Surgical Care of the foot & ankle

Harold Gruber, DPM
Diplomat, American Board of Podiatric Surgery

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PHYSICIANS
Paul Dayton, D.P.M.
Brian Hamm, D.P.M.
Mark Hartman, D.P.M.

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(72)

June 26, 2006

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

Dear Dr. McClellan:

We are 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)(3).

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

In our practice, we use a variety of DMEPOS items. As an example, when a patient presents complaining of foot pain and swelling following an injury, we 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 we 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.

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

Sincerely,

Paul Dayton, DPM Brian Hamm, DPM Mark Hartman, DPM

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June 27, 2006

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

Reference:

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

Exclusion of Long Term Care facilities from the Competitive Bidding program: "Submission of Bids Under the Competitive Bidding Program" *(Proposed § 414.412)*

Thank you for the opportunity to provide written comments to the Centers for Medicare and Medicaid Services (CMS) regarding the exclusion of long term care facilities from the DMEPOS Competitive Bidding program.

First Point: Nursing Homes are not considered the same as someone's residence and should not be treated the same.

Comment:

42 U.S.C. 1395i-3 defines a skilled nursing facility as

an institution (or a distinct part of an institution) which—

(1) is primarily engaged in providing to residents—
(A) skilled nursing care and related services for residents who require medical or nursing care, or
(B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons, and is not primarily for the care and treatment of mental diseases;

According to CMS' Medicare Program Integrity Manual

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Phone: (703) 549-4432 • www.HIDA.org • Fax: (703) 549-6495

The following screening guides apply when the individual is in an SNF:

• *Where an institution is classified as a participating SNF, or where a SNF has a part classified as participating and a part classified as meeting the definition above, it cannot be considered the individual's home;*

• *If an institution has a part which is participating or a part which meets the definition, and a remaining part which does not meet the definition, identify the part in which the patient was physically located during the use period. The institution may be considered the individual's home only if he/she was in the part which does not meet the definition.*

If a DME rental start date coincides with the patient's discharge date from an institution not classified as a "home", DMERCs and DMERC PSCs pay for medically necessary DME.

Given the fact that CMS does not treat skilled nursing homes as a resident's home for the purposes of billing for DME, how can it claim that it is reasonable to treat skilled nursing homes as a resident's home for the purposes of this new competitive bidding program? This would be setting a legal precedent allowing skilled nursing homes or other providers to bill for DME products not eligible under previous law resulting in a significant expense.

Second Point: CMS Allowed LTC facilities to "opt out" of the demonstration.

Comment:

In San Antonio, the product category separately paid for and covered in nursing homes is non-customized orthotics. Claims for non-customized orthotics were processed under "modified" demonstration policies. Nursing homes were strongly encouraged to obtain demonstration items from Demonstration Suppliers.

According to the CMS website *"We realize that nursing homes often have contracts with suppliers to obtain DMEPOS items for all of its residents. It would be difficult for nursing homes to purchase non-customized orthotics from different suppliers for its Medicare and non-Medicare patients (i.e. if their contracted supplier is not a Demonstration Supplier, the nursing home will have to use a Demonstration Supplier to obtain non-customized orthotics for their Medicare patients)."*

CMS therefore allowed nursing homes to continue these relationships, regardless of the supplier's demonstration status. Payment to these suppliers was limited to the demonstration prices, and they must have met all demonstration requirements and standards.

Given this, it seems clear that CMS recognizes the difficulties in requiring LTC facilities to follow the same requirements as a home care setting. CMS should continue to treat LTC facilities as separate in nature; and excluding them from the program.

Given that we do not have any data from the pilot projects to show how much savings will be gained or how competitive bidding will effect the Medicare population, how can CMS state

that the competitive bidding program will give significant savings in skilled nursing facilities and/or that it won't adversely impact the Medicare population?

Third Point: The Quality Standards specifically apply to home health.

Comment:

According to the Quality Standards proposed regulation:

Section 1834(a)(20) of the Social Security Act added by section 302(a)(1) of the Medicare Modernization Act 2003 requires suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and other items and services to comply with quality standards. Medicare defines a supplier as a physician or an entity other than a provider that furnishes health care services under Medicare. ***For purposes of meeting the intent of this statute, suppliers of DMEPOS are defined as entities that furnish health care equipment and related services to beneficiaries under Medicare Part B. The Medicare Part B payment for DMEPOS is limited to items*** **and** ***supplies used in or delivered to the beneficiary's home.***

HIDA believes that the intent of section 302(a) (1) of the Medicare Modernization Act 2003 was to cover the services in a home health setting and not to include long term care facilities. As CMS knows long term care facilities work under a different payment structure and follow different quality standards than the home health community; these two environments are vastly different. Implementing a competitive bidding structure that would apply to both would not work effectively.

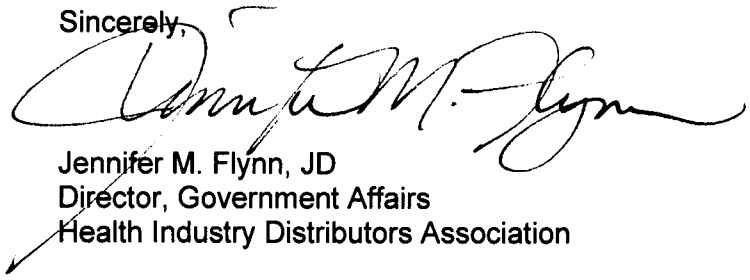
As we lay out in our first point, most skilled nursing facilities are not considered a patient's home. How can these quality standards, which specifically states that it applies to items and supplies delivered to the beneficiaries' home, be used to cover skilled nursing facility suppliers?

Given these concerns, HIDA asks that CMS amend the competitive bidding regulation, to exclude long term care facilities from this program.

HIDA is a nonprofit international trade association representing approximately 200 distributor companies. Our members account for roughly 80 percent of the medical products distributed through the healthcare supply chain. Competitive bidding will directly impact medical products distributors that supply to Medicare constituents in the long term care and home care markets.

Thank you for taking the time to review our concerns and consider our comments. Please contact me if I may be of assistance or provide any additional information.

Sincerely,



Jennifer M. Flynn, JD
Director, Government Affairs
Health Industry Distributors Association

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98

June 19, 2006

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

Dear Dr. McClellan,

I am writing in opposition to the proposed rule, *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues.* In its current form, this rule would include physicians in a competitive acquisition program for certain DMEPOS items. I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid.

I am a podiatric physician who has seen the type of shoe gear and inserts dispensed by non-physician suppliers. I must tell you that the product given to diabetic patients was sorely lacking (i.e. improper to their off-loading needs, not multidensity and simply no follow-up). This is only one area that would be negatively effected by the new rule. I'm sure you can see the problems that will occur.

I am concerned that if physicians, including podiatric physicians, are not excluded from the new program, patient care will suffer. I provide certain DMEPOS items to my patients as part of the normal course of quality care. If I am no longer able to supply those items as a result of not being selected as a DMEPOS supplier under the new program, my patients will suffer.

I want to ensure that my patients receive appropriate care for their particular problem(s). Being able to dispense a medically necessary DMEPOS item when I am the one treating the patient just makes sense and is better medicine. I want to make sure the product fits without someone else making that decision for me. Patients should be able to get from me the full range of care they require for a particular problem, yet with this proposal that may no longer occur.

I do not believe that the Centers for Medicare & Medicaid Services (CMS) considers it to be in the best interest of patient care to impede a physician's ability to provide medically necessary and quality care to Medicare beneficiaries. Again, I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid. Instead, continue to allow physicians to supply appropriate DMEPOS items used in the care of patients without being forced to competitively bid for that privilege.

Sincerely,

Kelley J. Woods D.P.M.

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