Submitter : **Miss. Juliana Reed** **Date: 06/29/2006**

Organization : **Hospira Worldwide, Inc.**

Category : **Device Industry**

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

see attachment

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

see attachment

Education and Outreach

Education and Outreach

see attachment

Gap-filling

Gap-filling

See attachment

CMS-1270-P-805-Attach-1.DOC

Hospira

Hon. Mark B. McClellan, M.D., PhD.
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

June 29, 2006 Delivered Electronically

File Code CMS-1270-P: Comments Related to Proposed Rulemaking re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006).

Dear Dr. McClellan:

Hospira Worldwide, Inc. (Hospira) is pleased to provide this comment letter to the CMS-1270, "Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (Proposed Rule).

Hospira is a global specialty medication delivery company dedicated to Advancing Wellness™ by developing, manufacturing and marketing products that improve the productivity, safety and efficacy of patient care. Created from the core global hospital products business of Abbott Laboratories in April 2004, Hospira has a 70-year history of service to the hospital industry and is building its future from a strong foundation as one of the largest manufacturers of hospital products in the United States. Hospira has established long-standing customer relationships that span the "continuum of care" (hospitals, alternate site facilities, home healthcare providers and long-term care facilities). Hospira has a leading position in the manufacture and supply of a broad range of hospital products including:

- Specialty injectables
- Medication delivery systems (including electronic infusion pumps)
- Infusion therapy solutions/supplies
- Critical care devices

Hospira thanks CMS for the opportunity to comment on the CMS-1270-Proposed Rulemaking re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006). As a manufacturer

of medical technologies, and in particular, infusion devices and their related drugs, Hospira is deeply concerned in regards to several components as outlined in CMS-1270 Proposed Rulemaking. Our comments will focus on the reasons why CMS should EXCLUDE infusion pumps and their related drugs from the CMS DMEPOS Competitive Bidding Program as outlined in CMS-1270-P and on the areas of gap filling that appear to set precedence for CMS to limit beneficiary access to new technologies in the future.

To ensure beneficiary safety, positive health outcomes, access to new technologies and potential reduction in overall costs to the Medicare program, Hospira recommends to CMS the following:

Recommendation #1: CMS should EXCLUDE the product category "Infusion Pumps and drugs" from the competitive bidding program.

Recommendation #2: CMS should require that the "composite bid" and the 'single payment amount for the individual items" within each product category reflect ALL the costs associated with safe administration of a piece of DMEPOS in a beneficiary's home.

Recommendation #3: CMS should REMOVE all references to the technology assessment as part of gap filling from the Final Rule and that a separate proposed rule, with specific procedural requirements, be published for comment.

Specifically, our comments will support these recommendations as we address the areas of:

- **Criteria of Item Selection**
- **Determining Single Payment Amounts for Individual Items –(proposed 414.416)**
- **Education and Outreach**
- **Gap Filling**

I. Criteria for Item Selection:

Our comments in this area will outline two conclusions: 1) why the product category or policy group, "Infusion Pumps & Related Drugs" should be EXCLUDED from the CMS DMEPOS Competitive Bidding Program, and 2) why CMS should exercise its authority to subdivide product categories by HCPCS code for bidding purposes.

Hospira

<u>Recommendation #1</u>): Infusion Pumps & Related Drugs should be EXCLUDED from DMEPOS Competitive Bidding:

A) Competitive bidding of such a broad group of medical devices that deliver critical therapies to Medicare beneficiaries could reduce beneficiary access to medically necessary products and adversely impact the quality of care.

The broad spectrum of infusion technologies and drugs represented in this category represent very different beneficiary medical needs, lengths of treatment time and have no medical relationship to each other, other than the mode of delivery for the medication is infusion. For example, within the American Medical Association's HCPCS 2006 handbook, the infusion pumps listed under "Infusion Supplies" range from "Mechanical reusable pumps (E0780)", to "Ambulatory infusion pumps, single or multiple channels, electric or battery operated (E0781)" to "External ambulatory infusion pump, insulin (E0784), "Infusion pump, implantable, nonprogrammable (E0782) and finally "Infusion pump system, implantable, programmable (E0783)". These infusion devices vary in: the critical drug therapies they administer to Medicare beneficiaries, the infusion technology required within the different devices to deliver each medication safely, the length of time these treatments are required and the site of care where Medicare beneficiaries obtain these infusion devices. The therapies administered by the infusion technologies outlined in this category range from the critical acute care medical infusions such as the administration of Dobutamine for a cardiac patient, to the administration of narcotic painkillers to control the pain of cancer or to the chronic infusion of insulin through a small implanted infusion device. Each of these critical therapies has its own unique clinical requirements creating a significant variance in the way the therapies need to be administered. The only similarity in the product category is in the description of the devices is the word "infusion". The methods for the infusion of the different drugs vary greatly; the supplies necessary for the safe operation of the devices vary from device to device, from manufacturer to manufacturer and from drug to drug.

In addition, where the beneficiary obtains each device varies. For example, Medicare beneficiaries receive their implantable pumps (E0783) surgically in the hospital while on the other hand, another beneficiary may receive their ambulatory infusion pump (E0781) in their home from a home infusion company. Each type of these infusion devices is obtained from very different clinically specialized suppliers with their own unique requirements and regulations, patient education requirements, and monitoring. For clinical reasons, such as the surgical requirement to implant an implantable pump into a beneficiary, an implantable pump would not be an infusion device that could be safely supplied to a beneficiary in their home by a home infusion pump supplier, the provision

of these pumps should be part of the hospital surgical procedure. Vice versa, requiring a beneficiary to obtain their home infusion pump and related drugs from the hospital versus the home infusion supplier is neither medically necessary nor cost-effective alternative.

Each of the individual devices varies from manufacturer to manufacturer and the supplies used to operate the pumps, such as the intravenous solution sets, are not swappable with differing pumps. Different medical drug therapies require different intravenous lines. Chemotherapy drug intravenous sets are manufactured from different materials than general-purpose intravenous sets, yet both intravenous sets would be categorized as "supplies" under a competitive bid of the product category or policy group. A competitive bid of such a broad policy group that would fail to recognize the unique clinical parameters of each of the products contained within the group or category could result in unqualified suppliers providing beneficiaries with infusion devices, drugs and their related supplies in an unsafe manner. Therefore, Hospira recommends in recognition of the variability and unique clinical requirements associated with various types of infusion therapies and devices, Infusion Pumps & Related Drugs should be excluded from the CMS competitive bidding program.

Hospira notes that CMS has already recognized this variability by choosing to exclude Infusion Devices for Parenteral Nutrition from competitive bidding. We recommend that CMS expand this exclusion to all other infusion pumps and related drugs.

B) Infusion Pumps & Related Drugs were not part of either the Polk County, Florida or the San Antonio, Texas DMEPOS Competitive Bidding Demonstration Projects.

Throughout the proposed rules, CMS refers to initially choosing product categories and/or policy groups that a) create savings for the Medicare program and b) were part of the initial demonstration projects. As outlined above, the technologies and therapies contained under the overly broad category of Infusion Pumps & Related Drugs are not compatible with competitive bidding. Furthermore, the fact that CMS has no demonstration project experience with this category supports the need to exclude Infusion Pumps & Related Drugs from competitive bidding projects. As a result, we believe it would be most prudent for CMS not to attempt to add new product categories early in the life of a competitive bidding program. A delay for these devices would give the Agency time to assess what fine tuning is needed in the competitive bidding methodology and related policies (for example, with respect to physician authorization,

beneficiary travel and transition issues) before deciding whether the program is ready to be expanded to include additional DMEPOS products.

C) Infusion Pumps & Related Drugs as part of a DMEPOS competitive bidding program may demonstrate limited savings the Medicare program.

CMS proposes to use HCPCS codes individually or grouped together in "Product Categories" as the basis for competitive bidding. Because there are significant inconsistencies in the specificity of existing codes included in the product groups listed in the Proposed Rule, we are concerned that use of poorly defined HCPCS codes in competitive bidding could reduce beneficiary access to medically necessary products and adversely impact the quality of care.

An inappropriate lack of code specificity exists when products with a limited set of basic features and benefits are assigned to the same code with related products that have advanced features. This is true of the Infusion Pump & Related Drugs Policy Group as outlined above and even within the E0781 Ambulatory Infusion Pump HCPCS Code.

For example, as a leading manufacturer of infusion pumps, Hospira manufacturers a wide range of pump technologies varying from multi-therapy infusion pumps with medication safety software most commonly used in hospitals and the intensive care setting, to patient controlled analgesia infusion pumps that have specific mechanisms to administer narcotics in a safe, controlled manner, to smaller portable ambulatory multi-therapy pumps that can deliver a range of drugs in the home. In each of these devices, there are different technological features that provide different therapeutic benefits and/or support the special needs of each beneficiary. All these technologies can safely administer drugs to patients, but due to the lack of specificity within the HCPCS coding system each device currently would qualify for reimbursement under the same HCPCS code: E0781. Because of the additional provider costs associated with advanced features when required for beneficiaries, the advanced products would exceed the price range for general-purpose devices. Current fee schedules do not allow for separate payment for the advanced products. Given the proposed bid methodology, there is a real risk that suppliers may choose to provide only the less-advanced, less-costly products classified in the code in order to win the bid and be selected as a contracted supplier. If this occurs, we are concerned that there could be such significant reductions in payments that the advanced products, even though medically necessary, would no longer be available to Medicare beneficiaries. Competitive bidding should not restrict or reduce beneficiary and/or clinician access to the most appropriate, medically necessary products. We believe that that the bid process must ensure Medicare

beneficiaries receive the critical therapies they require in the safest manner with the medically correct device. To achieve this objective, CMS should work with manufacturers to evaluate the wide range of technologies available within the Infusion Pump & Related Drugs Product Category and each individual applicable HCPCS code.

CMS has the authority to establish separate subcategories for items within a given category if there is differential clinical benefit and or value for specific items within the category. Therefore, Hospira recommends that before any of the infusion device codes listed above are included in any stage of competitive bidding, CMS should exercise its authority to subdivide the product category Infusion Pumps & Related Drugs and establish a separate cost for each subdivided category. For example, the National Home Infusion Association has found that Infusion drugs, supplies and pumps comprise a very small part of the Part B expenditures. In it's analysis, the National Home Infusion Association (NHIA) found that when divided into subcategories, and the subcategories outlined below are excluded, the remaining allowed charges for home infusion therapy products totals $87.4 million, 14th on the list of product categories ranked by level of allowed charges. (NHIA, 2006)

Subcategories of Infusion Devices & Related Drugs: (NHIA, 2006)

a. **Insulin pumps and supplies** ($10,275,629)
b. **IVIG** (only $29,515 in 2003, but increasing thereafter)
c. **Limited distribution products** ($30,747,401 in 2003, but along with IVIG, the fastest growing product areas in this category)
d. **Inotropic Therapies** used to treat patients with Classes III and IV congestive heart failure – milrinone and dobutamine ($26,156,345)

As can be seen from this information, no single product used in home infusion drug therapy falls within the list of high volume items found in Table 3 in the preamble to the proposed rule per the NHIA analysis. (NHIA, 2006)

Therefore, Hospira recommends that CMS exclude Infusion Pumps & Related Drugs from the DMEPOS Competitive Bidding Program for the following reasons:

A) Competitive bidding of such a broad group of medical devices that deliver critical therapies in different ways to Medicare beneficiaries could reduce beneficiary access to the medically necessary products and adversely impact the overall quality of care.

B) Infusion Pumps & Related Drugs were not part of either the Polk County or Texas DMEPOS Competitive Bidding Demonstration Projects. As such, CMS has no experience in bidding this technology.

C) Infusion Pumps & Related Drugs as part of a DMEPOS competitive bidding program may demonstrate limited savings to the Medicare program.

Hospira recommends that CMS consider product categories other than Infusion Devices & Related Drugs for the initial round of DMEPOS Competitive Bidding. In later competitive bidding cycles, Hospira recommends that CMS start gradually with these devices by only bidding one Infusion Device subcategory and a gradual phase-in of subcategories of infusion devices to allow CMS and suppliers to gain experience and learn about applications in this area.

II. "Determining Single Payment Amounts for Individual Items" -- (proposed §414.416)

Under this section, Hospira encourages CMS to work with physicians, beneficiaries, manufacturers and suppliers to ensure that all of the necessary components for administering certain items considered DMEPOS are considered in "determining single payment amounts for individual items" as part of the bid and resulting payment amount. For example, to safely administer home infusion therapy in a beneficiary's home, the home infusion DMEPOS supplier must provide the following minimum items:

- Medically required infusion pump technology,
- Supplies medically necessary to safely administer the drug;
- The drug compounded and/or packaged in a fashion in which it can be safely administered to the beneficiary;
- The facilities to safely compound the infusion drug as required by FDA standards and state laws;
- The beneficiary education and training on the device and the therapy;
- 24-hour monitoring services necessary to safely supervise beneficiary care;
- The clinical services necessary to ensure that the technology is working properly in the beneficiary's home (An infusion pump cannot be checked for proper drug administration and safety by an unqualified or non-licensed professional, such as a delivery person. The supplier must provide licensed professionals, such as nurses to the beneficiary's home to ensure safety.);
- A program that meets accreditation standards per Medicare regulations;
- All necessary physician communication;
- All necessary documentation per state and federal regulations; and

- All necessary program functions to adhere to the yet released CMS Home Infusion Quality Standards.

In considering all the necessary components required for the safe administration of home infusion in a beneficiary's home, CMS should include the Temporary National Home Infusion codes used by the Blue Cross / Blue Shield Association and the Health Insurance Association to report drugs, services and supplies as published in the 2006 Healthcare Procedural Code System (HCPCS) manual. The "S" codes for home infusion serve as an excellent tool for suppliers for defining the clinical services component of home infusion. CMS should instruct suppliers to list the "S" codes as one of the components and necessary costs to included as part of the composite bid. Hospira envisions that as suppliers submit bids for DMEPOS, CMS will only consider bids that address all the necessary components required for safe administration of the equipment and the drug in the beneficiary's home. Hospira recommends that CMS consider the home infusion scenario outlined above as a model for other equipment bids and for how the single payment amount for an item must include all the necessary factors as outlined above.

III. Education and Outreach

In the 'Education and Outreach" section, CMS outlines some of the early education that the Competitive Bidding Implementation Contractors (CBICs) will provide to potential suppliers. We urge CMS to include specific educational requirements that address each of the components included in the composite bids that will create the single payment amount for each item. For example, Hospira is concerned that a supplier may not address all the clinically required components that make up the safe operation of a piece of durable medical equipment in a beneficiary's home. If a supplier does not include the costs for the equipment, the supplies, the beneficiary's education in the safe use of the equipment, the training of the supplier's staff, the transportation of the device, the monitoring of the beneficiary's safe utilization of the device, the maintenance of the device and the supplier's compliance with the yet to be released CMS Supplier Quality Standards, to name a few components, the successful bidder could greatly under bid the true cost to safely supply equipment to beneficiaries in their homes.

Hospira points CMS to the experiences of Medicare beneficiaries who were dual eligibles transitioned from their Medicaid drug benefit to the Medicare Part D drug benefit earlier this year. Many of these dual eligibles were safely receiving injectable drugs and infusion therapies in their homes under a Medicaid benefit that accounted for the costs of the supplies and other components necessary for the safe administration of

these drugs. When these dual eligibles were transitioned to the Medicare Part D program, many experienced difficulties with obtaining their drugs and supplies in the formats necessary to safely continue their therapies at home. Under Medicare Part D, the Prescription Drug Programs (PDPs) did not plan for the coverage of these drugs and their necessary supplies when these patients transitioned to Medicare Part D. Prior to the January 1, 2006 start date, Hospira contacted each of the 10 National PDPs to inquire on their preparations for the dual eligibles who required infusion drugs and supplies and each of the 10 Part D PDPs reported they were unaware of the dual eligible requirements for injectable and infusion drugs under the Medicare Part D program.

We urge CMS to work with physicians, patient advocacy groups, suppliers and manufacturers to outline all the components required to safely utilize DMEPOS in a beneficiary's home, and to require that education and outreach of this part of the bid be included for suppliers.

Recommendation #2: CMS should require that the "composite bid" and the single payment amount for the individual items within each product category reflect a composite bid that includes not only the cost of the DME item by HCPCS code and related supplies, but also the cost for all the other necessary components, such as the clinical services, beneficiary education and adherence to the yet unpublished quality standards for DMEPOS suppliers.

IV. Gap Filling

CMS proposes to amend its current gap filling methodology for establishing fee schedule amounts for certain items of new DMEPOS and for readjusting fee schedules for some items of DMEPOS which had been previously established using gap filling. The proposed new procedure would include a technology assessment based on a comparison of three areas: function, price and medical benefit. CMS contends that the Council on Technology and Innovation has endorsed this initiative in order to coordinate the activities of coverage, coding and payment and to coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

While we agree that it is important to coordinate communication of technology information among different sections of CMS and between CMS and its contractors, the administration and review of a comparative technology assessment is a comprehensive effort that raises many important procedural questions, such as:

- What would trigger such an assessment?
- Which of the three areas (function, price and medical benefit) of the assessment would be the first area of comparison?
- Which criteria would be used for assessment in each of the three areas (function, price and medical benefit)?
- Which entities within CMS would participate and at what level?
- What is the role of the FDA?
- When and how would outside contractors be used?
- When and how would outside stakeholder opinions be solicited?

Because of the complexity, comprehensive nature and serious implication for this type of initiative, CMS's use of the comparative technology assessment should be held to at least the same level of procedural predictability and transparency as the process for development of a National Coverage Determination, which has recently been defined in a guidance document published by the CMS Coverage and Analysis Group.

Moreover, this new initiative is not required as part of the implementation for competitive bidding and is not mandated by either the MMA or the DRA.

Recommendation #3: Hospira recommends that all references to the technology assessment as a part of gap filling should be removed from the Final Rule and that a separate proposed rule, with specific procedural requirements, be published for comment.

Summary:

In conclusion, as the manufacturer of Infusion Pumps & Related Drugs, Hospira recommends to CMS that this product category and policy group not be included in a DMEPOS Competitive Bidding Program. Overall the safety of the Medicare beneficiary may be compromised under such an approach. In addition, we recommend that CMS carefully consider all the necessary service components required to safely utilize piece of DMEPOS into a beneficiary's home and only consider bids that address all of these components. Finally, we strongly suggest CMS provide significant education and outreach to suppliers on the requirements of the competitive bid program to ensure beneficiary safety and seamless transition of Medicare beneficiaries without disruption of their medically necessary therapies.

As CMS considers adding Infusion Devices & Related Drugs to later rounds of competitive bidding, Hospira recommends that CMS start gradually with this broad category by only bidding one Infusion Device subcategory. A gradual phase-in of subcategories of Infusion Devices would allow CMS and suppliers to gain experience in this highly specialized area of devices without taking on all varieties of Infusion Devices at once.

Hospira Worldwide Inc. thanks CMS for the opportunity to comment on the CMS-1270, "Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (Proposed Rule). We applaud CMS in reaching out to manufacturers throughout the process, including the creation of the yet-to-be released Quality Standards for Infusion Suppliers and Total Parenteral Nutrition Suppliers. We invite CMS to contact us in the future for any additional information or feedback.

Respectfully submitted,

Juliana M. Reed
Director, Health Policy
Hospira Worldwide, Inc.
275 N. Field Drive
Bldg. H1, Dept. 36V
Lake Forest, IL. 60045
224-212-2333
juliana.reed@hospira.com

Submitter : Mary Beth Leep **Date:** 06/29/2006

Organization : Med-Ox Home Medical

Category : Other Health Care Provider

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

My main concern with this area is the quality of patient care. This seems to get lost in some of these types of decisions. Companies with proven "track records" of patient care and effeciency in cost should get considered before companies that have no such record. My fear is that new home care companies will "spring up" just to become a part of this bidding process and give low bids, without having the experience to understand the costs involved. Thank you for allowing me to be part of this forum.

Submitter : **Mr. Leo Blais** **Date: 06/29/2006**

Organization : **Pawtuxet Valley InfusionCare**

Category : **Pharmacist**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

See attachment

CMS-1270-P-807-Attach-1.DOC

PAWTUXET VALLEY INFUSIONCARE
A Division of
Pawtuxet Valley Prescription & Surgical Center, Inc.

June 28, 2006

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

File Code CMS-1270-P: Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan:

Pawtuxet Valley InfusionCare (PVIC), a division of Pawtuxet Valley Prescription and Surgical Center, Inc. (PVPSC) is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

PVPSC was founded in 1980 and is the only vertically integrated pharmaceutical care provider in the state of Rhode Island. For the past 26 years, we have been located at the same location in Coventry, RI. Our InfusionCare division was created in 1994 and offers a variety of hi-tech home infusion services, an extensive nursing staff and a state-of-the-art compounding laboratory. Our current census is at approximately 200 patients.

CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

We urge you to carefully consider and adopt the detailed recommendations being sent to you under separate cover by our national organization, the National Home Infusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for infusion and enteral therapies, but urge CMS to recognize that Medicare payments both within and outside the competitive bidding program need to be at a level sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. CMS should affirm this point in the final rule.

3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

4. The preamble to the proposed rule indicates that Medicare expenditures for DME infusion pumps and related drugs in 2003 were approximately $149 million. This number appears to include expenditures made for insulin and insulin pumps for patients with diabetes, which are not provided by infusion pharmacies and is largely a different market than infusion. It also includes drugs that have sole or limited national distribution arrangements with particular pharmacies, where there would appear to be little savings to be gained from the imposition of competitive bidding. In addition, it includes drugs that are administered to the "sickest of the sick" patients who are very compromised and which require extraordinary expertise for safe and effective provision. These drugs should never be subject to a competitive bidding regimen. The more accurate amount of Medicare expenditures for 2003 for DME infusion pumps and related drugs was approximately $87 million.

5. Similarly, enteral nutrition is not a good candidate for competitive bidding. The differing quality standards between the nursing home and home care settings

make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services. It creates serious policy and operational issues for nursing homes as well as for CMS. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

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

6. The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at (401) 821-5721.

Sincerely,

Leo R. Blais, R.Ph.
President/CEO
(401) 821-5721

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

Submitter : Mr. Eric Burback **Date:** 06/29/2006

Organization : St Als Rehabilitation Services (STARS)

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

My name is Eric Burback OTR/L CHT, I'm the lead Hand Therapist for our areas major trama hospitol. I'm an occupational therapist and a certified hand therapist specializing in upper extremity rehabilitation. I believe that if this ammendment is passed it will greatly limit the qualitity and specializtion myself and my peers put into our custom braces during patient care. Often braces change throughout a rehab course and making patients go elsewere for adjustments is not only unreasonable but could be impossible for some. This would also make recieving a prefab brace confusing and complicated to the point of possible frustration for many patients hindering their recovery process as I believe some may choose not to get the brace at all.
Please reconsider other options as I believe this could cause decreased patient outcomes nad overall patient disatifaction.
Thanks you for you time
Eric S Burback OTR/L CHT

Submitter : **Darryl Coplan** **Date: 06/29/2006**

Organization : **Keene Medical Products**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-809-Attach-1.DOC

CMS-1270-P-809-Attach-2.DOC

Date: June 29, 2006

To: Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013
http:/www.cmshhs.gov/erulemaking

From: Darryl Coplan, General Manager
Keene Medical Products, Inc.
PO Box 439 240 Meriden Road
Lebanon, NH 03766
603-448-5290
dcoplan@keenemedicalproducts.com

Re: **Comments regarding Competitive Bidding Rule CMS-1270-P**

To Whom It May Concern:

As a private family owned and operated home medical equipment company, we have several concerns regarding the proposed competitive bidding rule scheduled for 2007.

We have been in business since 1975 serving thousands of Medicare beneficiaries throughout the states of New Hampshire and Vermont. We have built a reputation based on the best possible customer service. Our territory is of a very rural nature and we feel that competitive bidding will force suppliers to cut costs resulting in diminished customer service. CMS is trying to take a very service intensive industry and turn it into a commodity business. Collectively our 9 branch locations are not considered a small business entity. Our individual branch locations cover a large service area and would not be protected by a small business provision.

MSA Comments

Some of our territory is part of a larger MSA area. We would have difficulty covering the entire MSA without the use of a supplier network. Not knowing the first round of chosen MSAs in a timely fashion is a disadvantage for suppliers. This delay leaves little time to form a supplier network.

We feel that even though some rural areas adjoin MSA boundaries, they should be excluded from NCB. Rural areas are difficult to service and beneficiary access could be a problem.

Mail Order Competitive Bidding

Please be more specific about the supplies you are considering for this project. We are also concerned that rural suppliers who offer mail order service will lose their ability to continue to service their local clients.

Smaller suppliers will not be able to compete with large national or regional mail order companies and may lose most of their customers.

Off the Shelf Orthotics

Although special adjustments are not always necessary by an orthotic appliance fitter, it is very difficult to assure a proper fit of a support without seeing the client and obtaining proper measurements. Other products such as breast prosthesis require personal contact to assure proper fit. These items should be excluded from NCB.

Determining Single Payment Amounts

CMS has routinely cut reimbursement for certain items such as oxygen, hospital beds, wheelchairs, etc. The HME industry has had no recent CPI increases and is currently faced with a CPI freeze. What data do you have that proves the current fee structure is fair and adequately covers supplies costs for conducting business?

There are no provisions for providing reimbursement for delivery, pick up or other service costs. If suppliers are truly measuring costs and calculated services outweigh the current fee structure, there isn't a methodology to reflect this in the bid structure.

Rebates

The proposed rebate program seems to go against customer enticement programs currently controlled by CMS. There are very strict rules on what suppliers can and cannot do to solicit Medicare beneficiaries. The rebate program will provide an unfair advantage for low bid suppliers if they are able to market this program through the assistance of a CMS directory. How much time and effort will be required to have CMS monitor the integrity of this program?

Opportunity for Participation for Small Providers

As mentioned earlier, collectively our branch locations do not fall under the small business definition. Is there an opportunity to categorize small providers based on their annualized Medicare business volume? Each of our locations does have a separate supplier number.

Accreditation for Suppliers

This section is somewhat unclear as to the time line for accreditation vs. competitive bidding implementation. Defining who the accreditation entities are and a copy of the final home care standards should be provided prior to NCB implementation. Providers will require a significant amount of time to comply with becoming accredited or undergo survey with new standards.

Provider Acquisition

CMS should not have the authority to interfere with a provider acquisition based on MSA supplier capacity. Financial data and the ability to meet quality standards should be the qualifying conditions to approve an acquisition.

Gap Filling

The gap filling pricing methodology seems outdated and somewhat confusing. Suppliers could stand to lose a reasonable profit margin if gap filling is inaccurate. It would seem logical to utilize a fair market cost and provide an adequate mark up on products in a certain HCPC category. Additional HCPCs should be considered for products with additional features and benefits that don't quite fit into the standard HCPC category.

Implementation

It does not appear that CMS has all the answers at this time and we would like to see a delay on NCB implementation until the entire program is finalized. We anticipate Medicare beneficiaries and small providers will be the big losers once NCB is implemented. CMS has not clearly indicated what the actual implementation and administrative costs will be. Nor has there been any information published as to the savings, if any, that will be realized compared to the cost of running the program.

In conclusion, HME expenditures make up a small component of the overall Medicare health care budget. The NCB restricts free enterprise and does not consider the impact on what will happen to the future of home health care.

Sincerely,

Darryl Coplan
General Manager

Accredited by CHAP

Submitter : Dr. Bruce Cunningham **Date:** 06/29/2006

Organization : American Society of Plastic Surgeons

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Mr. Jeffrey Garrett **Date:** 06/29/2006

Organization : St. Augustine Health and Rehab Center

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-811-Attach-1.RTF

June 29, 2006

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

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at St. Augustine Health and Rehabilitation Center. We are located in St. Augustine FL, licensed for 120 beds and have approximately 150 employees. We are a skilled nursing facility that meets the rehabilitation and long-term needs of our community.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At St. Augustine Health and Rehabilitation Center we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,

Jeffrey W. Garrett, NHA
Administrator

Submitter : Mrs. Kimberly Lynn **Date:** 06/29/2006

Organization : Carolina Apothecary

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

see attachment in word

CMS-1270-P-812-Attach-1.DOC

CAROLINA APOTHECARY

"Your Complete Home Health Care and Prescription Center"

www.carolinaapothecary.com

726 South Scales Street
P.O. Box 29
Reidsville, NC 27323-0029
(336) 342-0071 (HME)
(336) 349-8221 (RX)

Toll Free (800) 633-1447
Fax (336) 394-1110

238 West Kings Highway
Eden, NC 27288
(336) 623-3030 (HME)
Fax (336) 623-3031

June 29, 2006

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

Dear Sirs:

This letter is in response to the requested Competitive Bidding Comments due by June 30th. As a DMEPOS provider for over 25 years, this causes us great concern regarding the effects on patient care. Medicare Part D has already put our elderly patients in distress because it is hard for them to understand their new insurance benefits and carriers. Competitive bidding would limit selection of product and possibly put multiple providers in a patient's home. This would be confusing to the referral source/physician as well as the patient/caregiver.

Another concern is accreditation standards. CMS should not proceed with competitive bidding until the standards have been established. Quality standards are an integral part of the bidding process.

Since New York, Chicago, and California have been exempted from the top 10 MSAs in 2007 this shows that implementation is going to be a difficult transition for large cities as well as small. CMS should not implement competitive bidding until they know how they are going to determine the bids. It seems we are rushing this process before we have all the needed information for implementation.

Sincerely,

Charles Britt, President/Owner
Kim Lynn, DME/POS Operations Mgr

Submitter : **Date: 06/29/2006**

Organization : **New England Medical Equipment Dealers Association**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Date: 06/29/2006**

Organization : **New England Medical Equipment Dealers Association**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-814-Attach-1.PDF

Via Electronic Transmission

June 29, 2006

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

Re: Comments on Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

To Whom It May Concern:

The New England Medical Equipment Dealers Association (NEMED) appreciates the opportunity to submit comments relative to the proposed rule for competitive acquisition for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). NEMED is the regional association that represents the home medical equipment industry in New England, comprised of the States of Maine, New Hampshire, Vermont, Massachusetts, Rhode Island and Connecticut. Our membership consists of 141 providers in over 200 locations who deliver home medical equipment including respiratory, custom rehab/assistive technology and home infusion therapy products and services to approximately 85% of the Medicare beneficiaries in New England.

NEMED is also a member of the American Association for Homecare (AAHomecare). As such, we fully endorse the opinions of AAHomecare and support their comments and concerns on this proposed rule.

TIMELINE CONCERNS

Since the competitive acquisition model of delivering durable medical equipment to Medicare beneficiaries is vastly different from the current model, NEMED recommends that CMS proceed with caution as it implements this program. 2007 is fast-approaching and providers are still waiting for the quality standards to be announced. Additionally, the proposed rule does not name the product categories or the 10 MSAs where implementation will begin. This lack of detail in the proposed rule makes it extremely difficult, if not impossible, for providers to submit comprehensive comments. NEMED recommends that CMS publish an interim final rule for additional input from the industry.

509 Kempton Street • New Bedford, MA 02740-3835 • (508) 993-0700 • Fax: (508) 993-0797
E-mail: Karyn@nemed.org • Website: www.nemed.org

Patient care should not be compromised. Since it is unknown what negative consequences may arise in a competitive acquisition area, NEMED also recommends that when competitive acquisition begins in the 10 MSAs, CMS should stagger the roll out of the program in order to identify and correct any problems before they become widespread.

ACCREDITATION CONCERNS

It is our understanding that CMS received more than 5600 comments relative to the proposed quality standards in November 2005 for which a final rule has yet to be published. CMS should publish the criteria it will use for accrediting agencies as soon as possible in order for these agencies to submit their applications. There are many small providers who want to begin the accreditation process and have been hesitant because they do not know which agencies will be approved by CMS. The quality standards should be in place and enough time allowed for providers to become accredited *prior* to submission of bids as it is not known whether or not a backlog will develop as providers apply for accreditation. Additionally, there are costs involved with accreditation and these costs will need to be taken into consideration when submitting comments on this rule.

NEMED recommends that CMS *grandfather* all providers who are currently accredited.

The NPRM states that CMS will allow a grace period during which unaccredited providers can participate in the bidding process. NEMED recommends that the grace period be eliminated and *only* accredited providers be allowed to submit a bid and enough time should be allowed for all providers to complete the accreditation process *prior* to submitting a bid. As mentioned above, there are costs involved with accreditation that need to be taken into account when submitting a bid.

Competitive acquisition should not move forward until the quality standards are in place in order to ensure that Medicare beneficiaries in these areas receive quality care. Quality healthcare for Medicare beneficiaries should not be jeopardized in order to meet a deadline.

NAME BRANDS

The proposed rule states that a physician/treating practitioner may prescribe a particular brand of an item or a particular mode of delivery for an item, if they determine that this would avoid an adverse medical outcome for the Medicare beneficiary. NEMED recommends that this proposal be removed for the following reasons:

- Physicians are not always informed about the features and benefits of new technology. The supplier is better equipped to make a recommendation.
- The contracted supplier may not carry the brand being requested but may carry a comparable brand.
- Since competitive acquisition is based on price, a contract supplier may only be able to offer a limited number of products. Since name brands are usually most expensive, it is possible that they will not be available to Medicare beneficiaries in a competitive acquisition area.

REBATES

NEMED recommends that the proposal to allow rebates be removed from the final rule. We believe that this constitutes an inducement and as such is illegal.

PRODUCT SELECTION

When selecting the items that will be put out for bid, CMS should take into consideration the unintended consequences that may be imposed on the beneficiary. CMS should ensure that beneficiaries will not have to deal with multiple suppliers and should not include items that require customization (i.e. custom wheelchairs) or a high level of clinical follow up.

AWARDING CONTRACTS

CMS should publish the 10 MSAs where competitive acquisition will begin in an interim final rule and schedule a meeting with the PAOC once the MSAs have been identified.

CMS should publish the list of items that will be included in the initial competitive acquisition area in the interim final rule as well as schedule a meeting with the PAOC before it announces the final product selections.

NEMED is concerned that CMS will receive *low ball* bids either by design or because the supplier does not know his true costs. CMS should establish a process that would determine whether or not a bid is reasonable. Additionally, bids that are above the current fee schedule should not be automatically disqualified. When setting the allowed amounts, CMS should evaluate savings in the overall category and not by specific item.

CMS should make sure that the number of winning bidders *exceeds* the capacity needed. Since other payors, like Medicaid, purchase items that Medicare does not, CMS needs to make sure that there are enough providers in a competitive acquisition area to ensure that these payors will have appropriate product coverage. Additionally, it should be noted that in the aftermath of Hurricanes Katrina and Rita, it was the small independent supplier that came to the rescue to deliver emergency services, not the larger, national companies. Awarding more small providers a contract would help ensure coverage in the event of a natural disaster.

The proposed rule requires that a bidding company service the entire MSA. This may be unrealistic for small companies and CMS should remove this proposal.

CONTRACT TERMS

NEMED recommends that CMS remove the proposal that winning suppliers must repair patient-owned equipment. The current reimbursement rates are inadequate and it would be impossible for a supplier to factor these costs into their bids. CMS should also eliminate the proposal that only winning bidders may repair patient-owned equipment.

Regarding products that beneficiaries *outside* the bidding area can receive, CMS should remove the proposal that restricts what they can receive. It is unrealistic to think that beneficiaries *within* a competitive acquisition area will be able to receive the same products and services as those outside the area. In order for suppliers to lower prices, they will have to lower the cost of products and/or services. Suppliers should be able to use formularies in a competitive acquisition area showing the products that would be available to these beneficiaries. If a beneficiary does not live in a competitive acquisition area, they should not be required to receive a reduced level of service or inferior equipment/supplies.

When a winning supplier takes on a beneficiary with an existing capped rental piece of equipment, a new capped rental period should begin. It would be impossible for a provider to calculate the cost of taking Medicare beneficiaries who are currently being serviced by another provider.

FINANCIAL REPORTING

CMS needs to clearly define the financial documentation that will be necessary in order to submit a bid. It needs to take into account that small companies will not be able to produce the same level of information as a large company (i.e. audited financials).

SMALL PROVIDER PARTICIPATION

Since 86% of NEMED's membership is comprised of small businesses as defined by the Small Business Administration (annual revenue of$6M and under), we are very concerned about the ability for small companies to be able to win a bid. While we appreciate the proposal in the rule that would allow small providers to form a network, we do not consider the proposal to be viable based on the complexity of establishing a network and the timeline in which providers would need to establish one. NEMED recommends that at least 50 percent of the winning bidders be comprised of small businesses.

In conclusion, NEMED would like to emphasize the need to delay the implementation date of competitive bidding until all of the industry's concerns have been met. We believe that an interim final rule should be published for additional industry comment and that a PAOC meeting should be scheduled as well. The negative impact to Medicare beneficiaries is too important to rush forward with an unproven, experimental model to deliver durable medical equipment and services.

We thank you for the opportunity to comment on the proposed rule. If you need additional clarification or information, please contact me at 508-993-0700.

Respectfully submitted,

Karyn Estrella

Karyn Estrella
Executive Director

Submitter : Mr. Charles Kelly **Date:** 06/29/2006

Organization : Mr. Charles Kelly

Category : Pharmacist

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

Competitive bidding is a contradiction. It creates a noncompetitive practice that is predatory to all competitors. You fail to realize that every DME company your initiatives eliminate, eliminates jobs, and adversely affects the economy of the communities that they serve. When considering this global change in your policies have you considered the imact to the medicare recipient. With no competition, will the provider consider the patient's needs, or will that provider be managing dollars and trimming costs where ever possible. (I have seen this practice with mail order diabetes, and respiratory supplies.)

It certainly would make more sense to have fair and equitable fee schedules, where providers could choose participation or not. I don't understand a policy established by a democracy that eliminates Freedom of Choice. Medicare's impact in this market is overwhelming, and medicare can effectively eliminate many providers, and jobs.

I don't understand the desire to slam the door on businesses that are serving the public, and creating jobs while supporting our economy. It would seem to me that you would want to encourage the growth of small to medium businesses in our society, not make them extinct.

Charles Kelly

Submitter : **Ms. Deborah Markey** **Date: 06/29/2006**

Organization : **Daytona Beach Health & Rehab Center**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Dr. Allan Hetelson** **Date: 06/29/2006**

Organization : **Foot & Ankle Center, Inc**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

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

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

In my practice, I use a variety of DMEPOS items. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries.

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

Sincerely,
Allan Hetelson, DPM

Submitter : Malinda Peeples **Date:** 06/29/2006

Organization : Amer Assoc Of Diabetes Educators

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-818-Attach-1.PDF

CMS-1270-P-818-Attach-2.PDF

AMERICAN ASSOCIATION OF DIABETES EDUCATORS

June 29, 2006

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
Room 445-6
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Administrator McClellan:

On behalf of the American Association of Diabetes Educators, I am pleased to submit these comments in response to the May 1, 2006 issuance of a proposed rule for the Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) as noticed in 71 Fed. Reg. 25654 by the Centers for Medicare and Medicaid Services (CMS).

The American Association of Diabetes Educators (AADE) is a multi-disciplinary professional membership organization dedicated to advancing the practice of diabetes self-management training and care as integral components of health care for persons with diabetes, and lifestyle management for prevention of diabetes. AADE currently has 105 local chapters and 17 specialty practice groups, and represents more than 11,000 members, including nurses, dietitians, pharmacists, physicians, social workers, exercise physiologists and other members of the diabetes teaching team.

As an organization dedicated to improving the health of people with diabetes, AADE applauds the Centers for Medicare and Medicaid Services for its efforts to foster improved delivery of products for certain beneficiaries who have diabetes. But, AADE believes that all diabetes patients must have access to quality, clinically appropriate products that are used to manage their condition so they can achieve an optimal state of health and well-being. Any changes being considered by Medicare, Medicaid, or any other government entity must not in any way diminish the quality of products available for doctors to prescribe to their patients.

Each year more than 1.5 million adults are diagnosed with diabetes, and nearly 21% of the population over age 60 has the disease. According to a report released on March 1, 2005 by the Agency for Healthcare Research and Quality (AHRQ), the agency found that "Medicare could save $1.3 billion annually and Medicaid $386 million a year by reducing hospital admissions for diabetes complications. Up to $2.5 billion—roughly two thirds of the total—might have been averted with appropriate primary care for individuals with complications."

Consistent self-monitoring of blood glucose levels by patients is central to the effective care and management of diabetes and to avoiding serious and costly complications. Patients with diabetes are in control of their own care regimen, in which they rely on self-monitoring of blood glucose systems to maintain control of their glucose levels.

Devastating and costly diabetes complications due to lack of appropriate glucose control may include: kidney failure, heart attack, stroke, diabetic retinopathy and other vision problems, neuropathy, and amputation. Regimented self-testing is a critical component to tight glucose management. While it is difficult for any patient to effectively manage a chronic condition, even more challenges exist when older Americans are faced with the daily struggles of proper glucose control often managed by multiple therapies (oral agents, insulin, behavior modification including diet and exercise) and possibly the added burden of treating co-morbidities. If Medicare beneficiary access or continued access to the most appropriate glucose-monitoring device is disrupted, patient compliance with their treatment regimen may be jeopardized and health outcomes could be adversely impacted.

CMS must make sure that all Medicare beneficiaries with diabetes get the care and treatment necessary to meet their medical needs and have access to suitable products to manage their condition. As CMS considers making changes that may significantly impact the quality of Self Monitoring Blood Glucose (SMBG) equipment available to beneficiaries with diabetes, AADE urges CMS Medicare to consider:

Patients **must have access to quality, clinically appropriate medical products** that their doctors determine are most appropriate to manage their diabetes. Coverage must ensure access to products such that the medical needs of beneficiaries are adequately addressed. SMBG systems have significant differences, beneficiaries have different needs and physical abilities, and *one size SMBG does not fit all beneficiaries' requirements.* **CMS must assure beneficiaries have reasonable access to a sufficient range of products within a HCPCS code to ensure individual requirements are met.**

Medicare must **promote patients' ability to self-manage their care using SMBG equipment** and take no actions that would discourage patient self-management. In order to properly protect beneficiaries in the event of emergency situations, beneficiaries must be able to access, at all times, the components of blood glucose monitoring systems including, but not necessarily limited to, a meter, testing strips, testing lancets, and a lancet-delivery

device. **CMS must recognize that blood glucose meters and test strips are an integrated system; if subjected to competitive bidding, these products must be included in the same product category.**

The Medicare system **must allow for the introduction of technological innovations** so as to ensure beneficiary access to new products that demonstrate clinical improvements. Variation and fluctuation in patient condition may require product, testing frequency and other adjustments in blood glucose monitoring in order to continue to meet the current needs of the individual. Manufacturers of BGMS continue to provide innovative products designed to better meet the needs of patients with diabetes. **Unimpeded access to the most appropriate products, including the latest innovations, is very important to a successful diabetes treatment program.**

Thank you for consideration of our comments.

Respectfully submitted,

Malinda Peeples

Malinda Peeples, RN, MS, CDE
President
American Association of Diabetes Educators

Submitter : **Date: 06/29/2006**

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Talk about knocking out smaller business, a bidding war will sure do that. How are we supposed to compete. Some people, especially the elderly, need that extra TLC that a small company provides. Let's think humanistic for a change instead of monetary. I also feel that all businesses should have to prove that they meet all the quality standards before they are allowed to participate in the bidding process to make sure it is a valid process. Let's be fair.

Submitter : Dr. Edward Epstein **Date:** 06/29/2006

Organization : APMA

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 28, 06

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

Dear Dr. McClellan:

I am writing to urge the Centers for Medicare & Medicaid Services (CMS) to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) from 1861(r)(1) to 1861(r). I practice in a Rural small city in Northwest Pennsylvania and many of my patients travel more than 30 miles to my office for care.

As a podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. These individuals are my patients and they rely on me to use my best medical judgment and clinical skills in treating them. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to my patients only and the right to execute a physician authorization. I feel that your interpretation that Physician only applies to MD and DO suppliers goes against the definition that includes Podiatrists in the category of Physician and is discriminatory toward Podiatry as a profession of independent practitioners with extensive training and scope.

In my practice, I use a variety of DMEPOS items. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries. The only other DPMOS suppliers in my area are one that travels from a city in another state to my town only once each week and does not supply the DEPMOS items that I prescribe, substituting other items for them that have over the last 32 years of dealing with this company not been acceptable. The physical therapy department at Bradford Regional Medical Center also has limited ability to supply DPMOS items, but not all that I utilize on my patients. I am not a heavy prescriber of DPMOS items, but when I must prescribe them, it is usually because they are needed immediately. Not including Podiatrists in the definition of Physician will place my patients not only at a disadvantage in receiving first class care, but will placed them in danger.

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

Very truly yours,

Edward P. Epstein, D.P.M.
84 Boylston Street
Bradford, PA 16701
814-362-4104

Submitter : Dr. James Thomas **Date:** 06/29/2006

Organization : American College of Foot

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-821-Attach-1.DOC

American College of
Foot and Ankle Surgeons

8725 West Higgins Road, Suite 555
Chicago, IL 60631-2724 USA
Tel: 773.693.9300
Fax: 773.693.9304

info@acfas.org
www.acfas.org
www.FootPhysicians.com

June 29, 2006

VIA ELECTRONIC SUBMISSION

Mark B. McClellan, MD, PhD
CMS Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

RE: CMS-1270-P
Comments on Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues, Proposed Rule (71 Fed. Reg. 25654, May 1, 2006).

Dear Dr. McClellan:

The American College of Foot and Ankle Surgeons (ACFAS) appreciates the opportunity to offer comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). The ACFAS is a professional society of over 6,000 foot and ankle surgeons and all Fellows of the College are certified by the American Board of Podiatric Surgery, the surgical board for foot and ankle surgery recognized by the Joint Committee on the Recognition of Specialty Boards. Foot and ankle surgeons currently are members of the medical staff in 85% to 90% of U.S. hospitals and are afforded a full range of medical and surgical privileges.

Competitive Bidding Process

The College is 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). Foot and ankle surgeons regularly supply DMEPOS items to Medicare beneficiaries as part of good patient care and preventative treatment. The proposed rule, if implemented, would significantly impact foot and ankle surgeons' ability to continue to provide medically necessary care of the highest quality to its patients. The College urges 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 high quality 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 complaining of foot pain following an injury. The patient is diagnosed with a foot fracture and it is determined that a walking boot is necessary to treat the fracture. If a physician can 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. The treating physician determines that an ankle brace and crutches are appropriate in treating the patient. If that physician is 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, **we 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.** The College does not believe that 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.

In addition, CMS proposes to implement a physician authorization mechanism that allows a physician or treating practitioner to specify that a particular DMEPOS item is necessary to avoid an adverse medical outcome, but few details are provided on this provision. The specific requirements of this provision will significantly impact the new competitive bidding program, especially for medically complex patients. **We urge CMS to develop a streamlined and expeditious process that facilitates the role of physicians as the key decision-makers for each patient.** We also urge CMS to clarify "adverse medical outcome" in a manner that recognizes the harm of delays that cause untimely discharge for patients. Further, CMS should provide for expedited appeals to ensure disputes are settled quickly in order to facilitate timely DMEPOS access upon discharge from a hospital. The failure of this provision would cause unnecessary delays for the patient and could exacerbate back-ups in the hospital that can needlessly postpone the admission of new patients requiring acute care.

Definition of Physician

Although podiatric physicians will be eligible to participate in the competitive bidding program, it is not clear that CMS will use the Social Security Act Section 1861(r) definition of physician, which includes podiatric physicians, in defining individuals who may bid to supply DMEPOS to only their patients. Instead, it appears CMS will define physician as only MDs or DOs. As a result, foot and ankle surgeons will be expected to bid to supply DMEPOS items to an entire metropolitan statistical area (MSA). Since all other DMEPOS suppliers also will be required to bid to supply items to an entire MSA, foot and ankle surgeons will compete with large, traditional DMEPOS suppliers for the right to supply items to Medicare beneficiaries. At the same time, physicians meeting the CMS definition (MD/DO) will be allowed to competitively bid to supply DMEPOS items to only their patients. This physician definition selected by CMS will negatively impact all podiatric physicians and potentially impede their ability to provide medically necessary DMEPOS items to Medicare beneficiaries.

Additionally, physicians will be able to execute a physician authorization, which means that in the case that a physician determines that a patient needs a particular brand of DMEPOS item, that brand can be specified, though no additional payment will be made for brand items. CMS also will recognize such authorizations from certain treating practitioners, including physician assistants, nurse practitioners, and clinical nurse specialists, and the Medicare agency acknowledged that these individuals also order DMEPOS items that are paid for by Medicare. **We urge CMS to use the more Section 1861(r) definition of physician, which includes podiatric physicians, in the provision that allows physicians to bid to supply DMEPOS items to only their patients. The 1861(r) physician definition is essential so that podiatric physicians may bid to supply DMEPOS items to only their patients and so that they may execute physician authorizations.**

Quality Standards and Accreditation

Finally, many hospital-based DMEPOS have certification from an external entity such as JCAHO, the Community Health Accreditation Program, and the Accreditation Commission for Health Care, Inc. **Hospitals and other health care providers with certified DME programs should not be required to acquire new certification until the current certification expires.** By allowing this grace period, CMS would avoid imposing a redundant cost on DMEPOS providers. However, since the final quality standards are not yet published, it is impossible to comment at this time.

The College appreciates the opportunity to submit comments on CMS' plans to implement competitive bidding for selected DMEPOS. Please address any questions about our comments and recommendations to Julie K. Letwat, JD, MPH, Director of Health Policy, Practice Advocacy and Research, at (773) 693-9300.

Sincerely,

James Thomas

James L. Thomas, DPM, FACFAS
President

Submitter : **Dr. Rudolf Cisco** **Date: 06/29/2006**

Organization : **North Georgia Foot and Ankle Specialists, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

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

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

In my practice, I use a variety of DMEPOS items. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries. In many instances, elderly and disabled patients with limited family and financial support and often severely restricted available modes of transportation and assistance could possibly be forced to wait long or extended periods of time before receiving treatment and DMEPOS items immediately necessary and vital to their recovery and well-being. This lapse in treatment would obviously increase recovery time and the effectiveness of the preferred plan of action for prompt attention and healing.

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

As a podiatric physician, I feel not only a professional but a moral obligation to provide my patients with prompt attention and effective treatment to the best of my ability and resources.
I feel the above rule revision and proposal is both warranted and necessary in the best interest of the patient.

Sincerely,

Rudolf W. Cisco, DPM
1224 Sherwood Park Dr., NE
Gainesville, GA 30501
Email: drcisco@bellsouth.net
(770) 287-0606

Submitter : Mr. Jeffrey Fannon **Date:** 06/29/2006

Organization : Oklahoma Respiratory Care, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

The current procedure for the implementation of competitive aquisation has no protections for small business. When implemented, the organization awarded the contract will have no incentive to provide superior service to Medicare beneficiaries, as there will be nearly no competitors to be superior to. Competitive acquisition will most surely have a negative effect on the quality of service provided to Medicare beneficiaries, and will likely end the businesses of numerous small DME companies nation wide.

Submitter : **Dr. Gary Stones** **Date: 06/29/2006**

Organization : **APMA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 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 in private practice 22 years, treating medicare patients, specializing in diabetic footcare and limb salvage.
The new rule would have a serious impact on my patient care protocol and have an adverse affect on treatment and outcomes.

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

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

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

If I see a patient who I diagnose with a fracture of the mid-foot, I may decide that it is medically necessary and appropriate to use a walking boot to treat my patient. I want to make sure the patient is not putting weight on the injured extremity and I need to make sure the walking boot fits properly for that patient. If I am not a supplier in the new program, I will not be able to do that and my patients will suffer.

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

Sincerely,

Gary F. Stones, DPM

Submitter : Ms. Liz Moran **Date:** 06/29/2006

Organization : Medical Equipment Suppliers Assoc. (MESA)

Category : Device Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-825-Attach-1.DOC

CMS-1270-P-825-Attach-2.DOC

Comments on the Notice of Proposed Rulemaking (NPRM) on Competitive Acquisition

Timing Concerns

Supplier Standards and Deficit Reduction Act Implementation
Because of the impact that the implementation of the Deficit Reduction Act of 2005 will have on competitive bidding, the information in the NPRM is inadequate to serve as a basis for public comments. Before implementing competitive bidding, we recommend that CMS issue an interim final rule to allow additional stakeholder comments.

Because the NPRM raises more questions than it answers, does not identify the markets, or the products, and the final quality standards have not been published, we advise that CMS also allow adequate time to schedule a meeting of the Program Advisory Oversight Committee (PAOC) after it publishes an interim final rule. This will allow CMS to have industry input one more time before publishing a final rule and implementing the program.

Opportunity to Comment on the Supplier Standards
All interested parties must have an opportunity to comment on the quality standards before they are finalized. Our understanding is that CMS received comments from more than 5600 organizations and individuals on the draft supplier standards, and it is anticipated that the final standards will differ significantly from the draft. If so, under principles of administrative law, CMS has an obligation to give stakeholders another comment period.

Moreover, an additional comment period is essential because CMS has chosen to by-pass the procedural protections of the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget that would otherwise be part of the rule-making process applicable to the quality standards.

It is extremely important that final supplier standards apply to every supplier desiring to submit a bid. Allowing an additional comment period is unlikely to have a substantial impact on the overall implementation time-line. Competitive bidding is a radical departure from traditional Medicare and this program is still largely experimental; consequently, we think that CMS should consent to reasonable delays and not rush to implement the quality standards or any other aspect of competitive bidding.

Overall Implementation Time-line
It is crucial that CMS establish an implementation time-line that identifies all steps leading up to competitive bidding. Given the number of steps that must be commenced and completed, however, we ask that CMS adopt a realistic time-line and not rush through the process. Some of the remaining steps include:

- Publication of the supplier standards
- Selection of the accrediting bodies
- Publication of interim final and final regulations
- Publication of the initial 10 MSAs and product categories
- Publication of the RFB
- Evaluation of bids and selection of contract suppliers
- Education of beneficiaries and referral sources
- Implementation within each MSAs

Payment Basis

Inflation Update
CMS says that providers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U, but providers have no promise that Congress will not override the update through subsequent legislation in any given year. CMS must make certain that the inflation update to the competitive bid prices will not be subject to subsequent freezes in the CPI-U. If CMS cannot provide this guarantee, then the only appropriate course of action is to instruct bidders to include an inflation adjustment in their bids.

Grandfathering Medicare Advantage
The NPRM does not address the impact of competitive bidding on Medicare Advantage patients who leave their plan to re-enter traditional Medicare. These patients may have a provider who is part of the MA plan network, but that may not be a contract supplier. What rules will apply to this patient population under competitive bidding? Will these patients have the opportunity to continue to use their existing supplier when they re-enter the traditional Medicare program? We recommend that patients moving from an MA plan to traditional Medicare be given the option of remaining with their existing providers under the grandfathering provisions proposed in the NPRM.

Beneficiary Switch to Contract Suppliers

The NPRM says that a beneficiary can decide to use a contract supplier at any time. Contract suppliers will be required to furnish capped rental or oxygen equipment to beneficiaries in the competitive bidding area regardless of the rental months remaining on the equipment. CMS states that suppliers must factor these additional costs into their bids. Suppliers will be unable to include these additional costs into their bids because it is not possible to predict whether beneficiaries may decide to switch to a grandfathered supplier and how many rental months remain on a piece of equipment. Moreover, CMS also states that suppliers may not submit bids higher than the current fee schedule amount for an item. This artificial ceiling on the bids further complicates bidding under this scenario. We appreciate CMS desire to preserve the beneficiary's freedom to change suppliers even under a competitive bidding program; we do, however, strongly recommend that CMS initiate a new period of continuous use if a beneficiary decides to switch from a grandfathered supplier to a contract supplier.

Application of DRA to Oxygen Patients

The NPRM is very vague on how CMS intends to apply the DRA provisions on oxygen to grandfathered suppliers and beneficiaries. Will the grandfathered relationship terminate at the conclusion of 36 months? As noted above, the implementation of the DRA forced ownership provisions on oxygen and capped rental equipment has important ramifications for competitive bidding. Stakeholders cannot provide meaningful comments on many issues in the NPRM without understanding how CMS will administer the DRA requirements. It is vital that CMS publish an interim final rule before it publishes the final rule on competitive bidding.

Authority to Adjust Payment in Other Areas

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

Limitation on Beneficiary Liability

Our understanding is that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. Under current Medicare rules, a supplier may furnish the beneficiary with an ABN notifying him that Medicare will not pay for an item. Other portions of the NPRM specifically state that ABNs will be permitted under a competitive bidding program, and the MMA requires that CMS continue to allow suppliers to use ABNs. CMS must clarify what it means when it states that a beneficiary will have no financial liability to a non-contract supplier for competitively bid items furnished by that supplier.

Competitive Bidding Areas

Staggered Implementation

The NPRM is silent on whether CMS will commence competitive bidding in 10 MSAs at the same time, or stagger the initial implementation of competitive bidding in 2007. We recommend that CMS phase-in the first 10 MSAs; we also *strongly recommend* that select only one MSA per state when implementing the first 10. This will allow CMS to identify and correct problems as competitive bidding commences before the problems become widespread; selecting only one MSA per state will also minimize negative impacts on beneficiaries in each state – especially those states with higher beneficiary populations – until problems can be solved.

Nationwide or Regional Mail Order Competitive Bidding Program

We are uncertain as to why CMS proposes a separate competitive bidding program for mail order suppliers in 2010. Mail order suppliers are not excluded from participating in competitive bidding during 2007 and 2009; a separate program for them in 2010 is completely unnecessary. In addition, there is no definition for a mail order supplier under Medicare program rules. Many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes.

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

Though mail order is an appropriate and cost effective vehicle for delivery of some replacement supplies such as test strips and lancets, it may not meet the needs of all beneficiaries who require such supplies. Mail order is subject to the ability to get the supplies to the beneficiary by commercial carrier. Whether or not a beneficiary receiving such supplies lives in a competitive bidding MSA, they should have the option of being able to obtain these supplies locally. The Medicare program must allow multiple distribution channels to meet beneficiary needs.

Finally, we note that this proposal represents another example of CMS' lack of success in providing the necessary level of detail for notice and comment rule-making. We recommend that CMS publish an interim final rule to solicit additional public comment before implementing any type of competitive bidding program.

Establishing the Competitive Bidding Area

CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established ***in*** an MSA. CMS must identify the MSAs in which it will commence competitive bidding in 2007 in an interim final rule.

Criteria for Item Selection

Items Included in Competitive Bidding

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

Potential for Savings

CMS has an obligation to explain and clarify what specific measures will be used to decide an items potential savings as a result of competitive bidding. CMS must address the following:

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

Additional Criteria for Item Selection

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

We strongly recommend that CMS publish the items it intends to include in the initial competitive bidding program in an interim final rule to solicit additional public comment after it announces the product selections.

Brand-Specific Requirements

The NPRM proposes to allow physicians and practitioners to prescribe a specific brand or type of equipment. According to CMS, this type of provision would preserve beneficiary access to equipment. Although contract suppliers will not be required to carry all brands/models of equipment included in competitive bidding, if a physician orders a brand/model the supplier

does not carry, the supplier must choose whether to fill the order, refer the beneficiary to another supplier, or ask the physician to change the order. Medicare will not pay for another item if the supplier failed to provide the brand name item the doctor ordered.

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

Coding Issues and Item Selection

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

Product Categories for Bidding Purposes

General Issues

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

Requirements to Bid on all Products in a Category

Suppliers may choose to bid on one, some, or all of the product categories, but if a provider bids on a category, that provider must bid on each item included in the category. We advise that CMS define products categories narrowly to ensure that they are consistent and representative of the products that a supplier might actually furnish. Including a broad category for wheelchairs or power wheelchairs is likely to be very problematic. Suppliers who do not specialize in rehab may not carry power wheelchairs under certain codes. Similarly, suppliers who do specialize in providing equipment to patients with complex needs may not carry all of the power wheelchairs designated by that product category.

- Power wheelchair codes are in the process of being revised. A high probability exists for compromise of patient care due to the breadth of the category combined with the complexity of needs for the high-end rehab patient. Complex Rehab wheelchairs are predominantly custom-configured, and they utilize a minimal amount of standard in-stock components. Due to the high probability of inappropriate equipment being provided to the complex Rehab patient in the first level of review as well as subsequent provision of appropriate equipment, it is highly probable that a categorical bidding process will be more costly in the long run for complex Rehab and Assistive Technology.
- Manual wheelchairs HCPCS codes will be subjected to a similar recoding process beginning in 2007. Because of its greater breadth as a category, manual wheelchairs will probably cost more to bid categorically for similar reasons. Complex Rehab Technology patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the proposal in the NPRM, a provider who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. In many cases complex Rehab manual wheelchairs require multiple components from multiple manufacturers to achieve appropriate fit and function for the individual.
- Those providers who are awarded a winning bid in a category for Wheelchairs could end up not being a winning bidder for the associated seating. In effect, many patients may need to deal with two or more providers for a single rehab wheelchair. This situation could lead to access issues in areas of the country where a winning provider is not equipped to provide the complexity of multiple seating and positioning services required in that area.

- Current HCPCS codes are too broad, encompassing items that represent vastly different technologies. CMS should develop narrow product categories so that providers may submit proposals for more standard bases with general purpose seating and positioning products compared to high end complex rehab technology services. It is dangerous to the end user for non-qualified providers to be submitting bids for services that they do not provide.

Conditions for Awarding Contracts

Quality Standards and Accreditation

The NPRM says that CMS will allow a grace period during which unaccredited providers can participate in the bidding process. Unaccredited providers who are winning bidders may complete accreditation during the unspecified grace period. Winning bidders who do not become accredited during the grace period will loose the contract supplier status. Because the overwhelming majority of DME suppliers are small businesses, it is likely that many will not be accredited at the time they are awarded contracts. As a result, bids from providers who are ultimately disqualified will be considered in the determination of the pivotal bid and single payment amount. By definition, *only* accredited suppliers should be eligible to bid. CMS should not proceed with competitive bidding until it is sure that all suppliers who may want to submit bids have had a fair and reasonable opportunity to get accredited.

In addition, the evaluation of the suppliers' financial stability must take place before the bid prices are arrayed and the pivotal bid is selected. Bids from disqualified providers should not be considered in selecting the winning bid point or setting the payment amount. CMS should consider the following evidence of suppliers' financial stability:

- D & B report
- Insurance Certificates
- Trade References
- Income / Balance Sheets
- Letters of Credit

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

Market and Supplier Capacity

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

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

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

Assurance of Savings

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the

competition is not truly competitive based on market prices. Instead, CMS should adopt the methodology used in the demonstrations. CMS should look for savings in the overall product category even though a single payment amount for a specific item may be higher than its current fee schedule amount.

Determining the Single Payment Amount

CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the winning suppliers. This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects. We believe Congress did not have this methodology in mind when it authorized competitive bidding under the MMA.

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

Rebate Program

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

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

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

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

Bulletin at 1.

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

rental equipment. Second, the supplier could not advertise the fact that it offers a rebate.

Once an inducement is in the public domain, its harmful effects cannot be contained, even with the safeguards CMS intends to implement. The fact that a provider does not actively promote an inducement does not change the illegal nature of the activity or the disruptive repercussions it has on competition and quality of care. The OIG would be unlikely to approve of a rebate program like the one CMS proposes even if the supplier did not advertise the rebate:

The inducement element of the offense is met by any offer of valuable ... goods and services as part of a marketing or promotional activity, regardless of whether the marketing or promotional activity is active or passive. For example, even if a provider does not directly advertise or promote the availability of a benefit to beneficiaries, there may be indirect marketing or promotional efforts or informal channels of information dissemination, such as word of mouth promotion by practitioners or patient support groups.

Bulletin at 5 (Emphasis supplied).

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

Terms of Contract

Repair or Replacement of Equipment

CMS will compel contract suppliers to accept all beneficiaries within the competitive bidding area. CMS will also demand that contract suppliers repair or replace beneficiary owned equipment under the competitive bidding program. As we mentioned above, we propose that CMS allow a new period of continuous use to begin when a beneficiary switches to a contract supplier. This preserves the beneficiary's choice and protects the contract supplier who may have to furnish equipment to the beneficiary without adequate compensation for the item or the service it requires. The repair of patient owned equipment should be treated as a separately bid item on the RFB. In other words, CMS should solicit bids for the repair of patient owned equipment. We assume that replacement equipment will be provided and paid for in an amount equal to the single payment amount for the items or the contract suppliers bid, depending on the payment methodology CMS adopts in the final rule.

Termination of Contract

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

Judicial and Administrative Remedies

CMS must include a procedure for debriefing suppliers who did not win a bid and an opportunity for a review to determine at a minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

Change of Ownership

It is reasonable for CMS to review a change of ownership to determine whether the buyer meets the quality standards and whether a buyer has, in the past before granting the new company contract supplier status. However, CMS cannot unreasonably withhold its approval of a change of ownership and should not deny winning-supplier status to a new owner on the basis that its capacity is not necessary within the competitive bidding area. CMS should approve a change of ownership if the new entity will meet all applicable quality standards and confirm to other requirements of competitive bidding. CMS approval should not be withheld based on a determination that the supplier's capacity was not necessary.

Participation of Small Suppliers

CMS has taken a very narrow view of its obligation to ensure that small suppliers are adequately represented among contract suppliers. CMS proposal for allowing networks does not consider the practical hurdles involved in creating new entity. Under the timelines that CMS has announced, it will be difficult to establish networks that can meet the eligibility requirements for submitting bids. Consequently, this may not be a viable option for most suppliers. CMS has also stated that the market share for supplier networks cannot exceed 20%. CMS should expand this to allow greater participation by small suppliers. CMS should also consider small supplier set asides in at least some MSAs.

Submitter : Susan Christie **Date:** 06/29/2006

Organization : Bryn Mawr Rehab Hospital

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

Competitive Acquistion: I work with many beneficiaries who use custom power and manual wheelchairs. I believe that the competitive acquisition program outlined will limit their access to the services and equipment that they need, by limiting supplier choice and access to qualified DME companies who offer quick service for repairs. I suggest that the following NOT be sufject to the bidding process: seat cushions which offer skin protection and positioning, wheelchair backs, custom fabricated seating systems, manual wheelchairs which have adjustable configurations, and power wheelchairs which has programmable controls and wheelchair seating frames.

I suggest that the process be implemented with one DME item in each DMERC, to establish a process in 2007, and expanded based on what it learned by doing that.

I suggest that the "rebate" to beneficiaries be removed, as it appears unethical to me, as an inducement.

I believe that implementation of the rules as written will limit access by bendeficiaries, and put many small proviers out of business.

Submitter : **Karla Rivas** **Date: 06/29/2006**

Organization : **Governor's Council on Blindness and Visual Impairm**

Category : **Other Government**

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

June 28, 2006

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

The Arizona Governor s Council on Blindness and Visual Impairment object to CMS s proposed rule concerning Medicare s intent to exclude coverage of low vision aids for our nations visually impaired. To include low vision aids under the category of routine eyeglasses is based on a lack of knowledge. Low vision aids are needed to help unhealthy eyes see. Regular eye glasses help healthy eyes see. The two are not the same.

According to a 2004 National Eye Institute press release, the number of Americans with major eye disease is increasing and vision loss is becoming a major health problem. Low vision aids are one mode of treatment available that will allow people who are visually impaired to live safely and independently.

Medicare has just begun a 5-year Low Vision Demonstration Project. A decision to limit the coverage of low vision aids is premature and should only be considered after the Demonstration project has ended. The Low Vision Demonstration Project will show both the efficacy of low vision aids and that Medicare should begin coverage of this needed treatment modality and increase coverage of low vision rehabilitation.

Karla K. Rivas, MSW, CRC
GCBVI Staff
1789 W. Jefferson
Phoenix, AZ 85007
Phone: (602) 542-3946
Fax: (602) 542-3778
E-mail: krivas@azdes.gov

Submitter : Mr. WILLIAM FREDERICKS **Date:** 06/29/2006

Organization : ALLCARE MEDICAL SUPPLY

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1270-P-828-Attach-1.TXT

All*CARE* Medical Supply

30 Grafton St, Millbury, MA 01527

Tel: 508-865-4857

Fax: 508-865-6370

Thursday, June 29, 2006
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Comments on Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

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

Re: Comments on Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

TIMELINE CONCERNS

Since the competitive acquisition model of delivering durable medical equipment to Medicare beneficiaries is vastly different from the current model. 2007 is fast-approaching and providers are still waiting for the quality standards to be announced. Additionally, the proposed rule does not name the product categories or the 10 MSAs where implementation will begin. This lack of detail in the proposed rule makes it extremely difficult, if not impossible, for providers to submit comprehensive comments.

Patient care should not be compromised. Since it is unknown what negative consequences may arise in a competitive acquisition area, CMS should stagger the roll out of the program in order to identify and correct any problems before they become widespread.

ACCREDITATION CONCERNS

It is our understanding that CMS received more than 5600 comments relative to the proposed quality standards in November 2005 for which a final rule has yet to be published. CMS should publish the criteria it will use for accrediting agencies as soon as possible in order for these agencies to submit their applications. There are many small providers who want to begin the accreditation process and have been hesitant because they do not know which agencies will be approved by CMS. The quality standards should be in place and enough time allowed for providers to become accredited *prior* to submission of bids as it is not known whether or not a backlog will develop as providers apply for accreditation.
We just became accredited May 24th 2006 at considerable expense, not to mention time and effort. I would hope a small company like mine who has worked hard to receive accreditation, be grandfathered in.

NAME BRANDS

The proposed rule states that a physician/treating practitioner may prescribe a particular brand of an item or a particular mode of delivery for an item, if they determine that this would avoid an adverse medical outcome for the Medicare beneficiary. I believe that this proposal be removed for the following reasons:

- Physicians are not always informed about the features and benefits of new technology. For example, when people say Cleenex, they need facial tissue, not the brand Cleenex. The supplier is better equipped to make a recommendation.
- The contracted supplier may not carry the brand or have an account with a vendor being requested but may carry a comparable, if not better brand .
- Since competitive acquisition is based on price, a contract supplier may only be able to offer a limited number of products. Since name brands are usually most expensive, it is possible that they will not be available to Medicare beneficiaries in a competitive acquisition area.

REBATES

The proposal to allow rebates should be removed from the final rule. We believe that this constitutes an inducement and as such is illegal.

PRODUCT SELECTION

When selecting the items that will be put out for bid, CMS should take into consideration the unintended consequences that may be imposed on the beneficiary. CMS should ensure that beneficiaries will not have to deal with multiple suppliers and should not include items that require customization (i.e. custom wheelchairs) or a high level of clinical follow up from the bid process.

AWARDING CONTRACTS

CMS should publish the 10 MSAs where competitive acquisition will begin in an interim final rule and schedule a meeting with the PAOC once the MSAs have been identified.

CMS should publish the list of items that will be included in the initial competitive acquisition area in the interim final rule as well as schedule a meeting with the PAOC before it announces the final product selections.

As a small business, I'm concerned that CMS will receive *low ball* bids either by design or because the supplier does not know his true costs. CMS should establish a process that would determine whether or not a bid is reasonable. Additionally, bids that are above the current fee schedule should not be automatically disqualified. When setting the allowed amounts, CMS should evaluate savings in the overall category and not by specific item.

CMS should make sure that the number of winning bidders *exceeds* the capacity needed. Since other payors, like Medicaid, purchase items that Medicare does not, CMS needs to make sure that there are enough providers in a competitive acquisition area to ensure that these payors will have appropriate product coverage. Additionally, it should be noted that in the aftermath of Hurricanes Katrina and Rita, it was the small independent supplier that came to the rescue to deliver emergency services, not the larger, national companies. Awarding more small providers a contract would help ensure coverage in the event of a natural disaster.

The proposed rule requires that a bidding company service the entire MSA. This may be unrealistic for small companies and CMS should remove this proposal.

CONTRACT TERMS

I believe that CMS remove the proposal that winning suppliers must repair patient-owned equipment. The current reimbursement rates are inadequate and it would be impossible for a supplier to factor these costs into their bids. CMS should also eliminate the proposal that only winning bidders may repair patient-owned equipment.

Regarding products that beneficiaries *outside* the bidding area can receive, CMS should remove the proposal that restricts what they can receive. It is unrealistic to think that beneficiaries *within* a competitive acquisition area will be able to receive the same products and services as those outside the area. In order for suppliers to lower prices, they will have to lower the cost of products and/or services. Suppliers should be able to use formularies in a competitive acquisition area showing the products that would be available to these beneficiaries. If a beneficiary does not live in a competitive acquisition area, they should not be required to receive a reduced level of service or inferior equipment/supplies.

When a winning supplier takes on a beneficiary with an existing capped rental piece of equipment, a new capped rental period should begin. It would be impossible for a provider to calculate the cost of taking Medicare beneficiaries who are currently being serviced by another provider.

FINANCIAL REPORTING

CMS needs to clearly define the financial documentation that will be necessary in order to submit a bid. It needs to take into account that small companies will not be able to produce the same level of information as a large company (i.e. audited financials).

SMALL PROVIDER PARTICIPATION

As a small business as defined by the Small Business Administration (annual revenue of$6M and under), we are very concerned about the ability for small companies like mine to be able to win a bid. While we appreciate the proposal in the rule that would allow small providers to form a network, we do not consider the proposal to be viable based on the complexity of establishing a network and the timeline in which providers would need to establish one. A large percentage of winning bidders be comprised of small businesses.

In conclusion, I feel the need to emphasize having a delay the implementation date of competitive bidding until all of the industry's concerns have been met. There are too many variable still up in the air. I believe that an interim final rule should be published for additional industry comment and that a PAOC meeting should be scheduled as well. The negative impact to Medicare beneficiaries is too important to rush forward with an unproven, experimental model to deliver durable medical equipment and services.

Thank you for the opportunity to comment on the proposed rule.

Sincerely,

Bill Fredericks
Owner

Submitter : **Mrs. Robin Powers** **Date: 06/29/2006**

Organization : **Friendship Home Medical Equipment, Inc.**

Category : **Other Health Care Professional**

Issue Areas/Comments

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

I see a clear Rx for fraud activities with the issue of offering rebates. Companies may not advertise but people especially in smaller communities talk and word gets out. This is clearly against everything the OIG has preached. Rebates should not be allowed. One set price should be set and let that be the end of it.

GENERAL

GENERAL

I think there will be problems with patients who were grandfathered and then want to switch to another company or move to another state. There is no way the person getting the bid could plan for someone who has already had equipment from another provider say for 34 months and then they come to you and you get paid 2 months and it's theirs. I think definitions of a new capped rental period should be set. I generally think that there are many issues that still need to be addressed before going ahead with this. All the rules should be CLEAR at least 12 months before bids open. There should be ample opportunity for anyone who wants to submit bids to do so. You should look at staggering the areas in and not do them all at once. This would give you time to work out the problems before beginning the next area.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

There should be a method to ensure small suppliers are not forced out. Some of the small suppliers are your best source of DME as some national companies only want to do high dollar items. The bid process should be CLEARLY spelled out so that it does not take an attorney to submit this bid. Some suppliers will clearly not be eligible to meet the financial asspect yet you will still consider their bid when they can bid as low as they want to make it hard on other providers

Submitter : **Dr. Ross Taubman** **Date: 06/29/2006**

Organization : **Columbia Foot and Ankle Associates, DPM**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Ross E. Taubman, DPM
Columbia Foot and Ankle Associates, PA
5005 Signal Bell Lane, Suite 204
Clarksville, Maryland 21029

June 29, 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:

On June 21, 2006, I had the privilege to meet at the Baltimore Headquarters of CMS with several of my colleagues to discuss the DMEPOS competitive bidding issue. The CMS staff present at the meeting was Mr. Wilson, Ms Flaherty, Ms. Blackford, and Ms. Kuespert. First and foremost, we discussed the role that podiatric physicians in patient care and the office dispensing of DME. In fact, podiatric physicians dispense DMEPOS items in the exactly same manner as allopathic and osteopathic physicians. The DME items that podiatric physicians dispense are within the scope of our state practice acts and are an integral part of our practice. It was discussed with CMS staff that, as currently proposed, podiatric physicians will no longer be able to dispense DME directly to their patients. The proposed rule only allows allopathic and osteopathic physicians to dispense DME directly for patient use. Not only is that proposal discriminatory, it is poor patient care and may contribute to podiatric physicians practicing below the standard of care, especially in an acute care situation. For example, if treat a patient with an unstable calcaneal fracture, and as part of my treatment it is determined that the patient requires a fracture boot, it would be inappropriate for me to allow that patient to leave my office to obtain a walking boot. Not only would the stability of the fracture be potentially compromised, I have no way of insuring the appropriate fit of the device. There is absolutely no way that a medical supply house technician would have the expertise of a duly licensed and trained physician, including a podiatric physician. As part of the proposed rule, CMS will allow ONLY MD and DO suppliers to competitively bid to supply DMEPOS only to their patients and will also permit them to execute a physician authorization. As a podiatric physician in the Medicare program, I should have those same rights. I use DMEPOS items as an integral part of patient care and believe that CMS should use the 1861(r) definition of physician in finalizing its regulations.

It should be noted that Podiatric physicians dispense a very small array of items, purchased in small quantities from medical supply houses in order to serve our patients. Podiatric physicians, like allopathic and osteopathic physicians, would not be able to bid for an entire Metropolitan Service Area (MAS). There is no logistical manner in which a podiatric physician practice could dispense DMEPOS to the general public in an orderly fashion. We are not a retail business! We do not supply items to individuals who are not our patients. Requiring me to do so would create harm to Medicare beneficiaries.

As a current DME supplier with a valid supplier number I am required to adhere to the quality standards for DME. I gladly comply with those requirements. Additionally, I am subject to the Stark requirements, as well as all other regulatory requirements that apply to MD and DO suppliers.

Finally, in regards to the accreditation portion of the proposed rule, I believe that physicians are already credentialed by state licensing boards, including the requirement for continuing medical education. In fact, these credentialing requirements are more extensive than any additional credentialing requirements imposed by this rule. Therefore, I believe that if a physician supplier complies with the quality standards, then they should be exempt from additional credentialing requirements.

Thank you for allowing me to submit these comments. I trust that the rule will be changed as noted above for the good of the beneficiary.

CMS-1270-P-830-Attach-1.DOC

Submitter : Mr. Wesley David **Date:** 06/29/2006

Organization : Heal Mart Pharmacy/Health Mart Medical Co.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-831-Attach-1.DOC

HEALTH MART PHARMACY
HEALTH MART MEDICAL CO.

200 Main
Gueydan, La 70542
(337)536-9600

818 N Cushing
Kaplan, La 70548
(337)643-7952

500 Hwy 26
Lake Arthur, La 70549
(337)774-6622

1322 Elton Rd Ste. A
Jennings, La 70546
(337)616-9500

June 29, 2006

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

File Code CMS-1270-P: Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan:

Health Mart Pharmacy/Health Mart Medical Co. is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

We currently have four locations that provide Retail Pharmacy services, IV infusion services and Durable Medical Equipment Services. My locations are in Kaplan, Gueydan, Lake Arthur and Jennings, Louisiana, and I estimate our service area to encompass roughly two thousand square miles. I opened the Gueydan location in 1996, Kaplan in 2000, Lake Arthur in 2002 and Jennings in April 2006. The stores began selling DME many years ago and are just engaging in IV Infusion Services upon the opening of the Jennings location. Organization wide, I estimate our current client base to be over 10,000 customers at present. My stores play a vital role in the economy of each and every community in which we are located. I am also a huge financial supporter of these communities. My stores are Independent Pharmacies, not part of a large chain. My customers and patients patronize my stores because of the excellent personal service that they receive. It is our belief that most, if not all, of our current clients who would require IV Infusion or DME services, would prefer to receive these services from our pharmacy – not be forced to go to another pharmacy in which they are not familiar, nor is the pharmacy familiar with them. Please consider the following information as well.

CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

We urge you to carefully consider and adopt the detailed recommendations being sent to you under separate cover by our national organization, the National Home Infusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for infusion and enteral therapies, but urge CMS to recognize that Medicare payments both within and outside the competitive bidding program need to be at a level sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. CMS should affirm this point in the final rule.

3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

4. The preamble to the proposed rule indicates that Medicare expenditures for DME infusion pumps and related drugs in 2003 were approximately $149 million. This number appears to include expenditures made for insulin and insulin pumps for patients with diabetes, which are not provided by infusion pharmacies and is largely a different market than infusion. It also includes drugs that have sole or limited national distribution arrangements with particular pharmacies, where there would appear to be little savings to be gained from the imposition of competitive bidding. In addition, it includes drugs that are administered to the "sickest of the sick" patients who are very compromised and which require extraordinary expertise for safe and effective provision. These drugs should never be subject to a competitive bidding regimen. The more accurate amount of Medicare expenditures for 2003 for DME infusion pumps and related drugs was approximately $87 million.

5. Similarly, enteral nutrition is not a good candidate for competitive bidding. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services. It creates serious policy and operational issues for nursing homes as well as for CMS. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

   If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for DME patients. CMS should also modify the proposed payment structure for enteral pumps and, consistent with current law, ensure

that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

6. The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 1-337-523-1851.

Sincerely,

Wesley J. David, RPh., Doctor of Pharmacy
Owner/CEO
Health Mart Pharmacy
Health Mart Medical Co.
Email: healthmart@kaplantel.net

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

Submitter : Mr. William Muenchow **Date:** 06/29/2006

Organization : Laurel health Care Company

Category : Long-term Care

Issue Areas/Comments

Payment Basis

Payment Basis

Requirement to Obtain Competitively Bid Items From a Contract Supplier. Many Long Term Care guests travel South for the Winter months. This requirement will make the billing and procurement process for supplies very difficult. Also, what if our nursing home has a Standardized product formulary? Will we have to change our treatment protocols, because the items we were getting are no longer reimbursed or available from the Contract Supplier?

Submitter : Dr. David Levine **Date:** 06/29/2006

Organization : David J. Levine, D.P.M., C. Ped.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

www.Levinefeet.com

June 29, 2006

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

Dear Dr. McClellan:

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

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

In my practice, I use a variety of DMEPOS items from shoes to braces and removeable cast boots. An example follows: when a is diagnosed with a fracture(s) within the foot, immobilization is a critical part of treatment. 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. In addition, the hassle and follow through then become an issue. The key to good care is compliance. If patients are referred all ove town, the risk of complications increases.

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

Sincerely,

David J. Levine, D.P.M., C. Ped.
63 Thomas Johnson Drive O Suite C O Frederick, MD 21702 O Telephone 301-696-0818 O Fax 301-696-8872

Submitter : Dr. Steve Jensen **Date:** 06/29/2006

Organization : Foot Care of Sonora

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-834-Attach-1.TXT

June 22, 2006

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

Dear Dr. McClellan:

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

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

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

If I see a patient who I diagnose with a fracture of the mid-foot, I may decide that it is medically necessary and appropriate to use a walking boot to treat my patient. I want to make sure the patient is not putting weight on the injured extremity and I need to make sure the walking boot fits properly for that patient. If I am not a supplier in the new program, I will not be able to do that and my patients will suffer.

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

Sincerely,

Submitter : Mr. James Frederick **Date:** 06/29/2006

Organization : Mitchell Home Medical

Category : Other Practitioner

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

1. Without clear and concise standards of practice NPRM)in which to understand the federal governments expectations specific to patient care and the economic impact that will effect home care providers in meeting those patient service/care expection it is impossible to arive at a reasonable competitive bid. It also will lead to unrealistic bid by providers that do not have understand the regulatory cost impact the standards may pose. (e.g. JCAHO stds., DOT,FDA,24 hour on-call support, licensed practicioners, State licensure, etc.)

Submitter : **Dr. Christopher Ross** **Date: 06/29/2006**

Organization : **Dr. Christopher Ross**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Christopher D. Ross, DPM
198 Route 22, Ste #2
Pawling, NY 12564
(845) 855-1853

June 22, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-1270-P
Electronic Comments

Dear Dr. McClellan:

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

As a podiatric physician, I prescribe and supply DMEPOS items to my Medicare patients as an integral part of their foot care and they rely on me to use my best medical judgment and skills in treating them. In my practice, I use a variety of DMEPOS items including Cam walkers, Air casts, various AFO s, and Therapeutic shoes. Patients who present with acute injuries require immediate care and immobilization in some cases and it makes no sense to send them off to an unfamiliar supplier for a device that can easily be dispensed from my office.

Because I practice in a rural area, I have found many of my elderly Medicare patients deferring necessary care when I refer them to a 3rd party for certain appliances, shoes, etc. They find it difficult to arrange transportation and clearly prefer the option of having DMEPOS supplied by me when at all possible. My patients have had to travel up to 30 miles in years past for appliances and other items and clearly this makes no sense when the same item can be dispensed by me at the same cost to CMS.

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

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

Sincerely,

Christopher Ross, DPM

Submitter : **Mr. Frank Baratta** **Date: 06/29/2006**

Organization : **Atlantic Healthcare Products**

Category : **Other Health Care Provider**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

The Competitive Bidding process as it is currently proposed will have a negative effect on the beneficiaries access to quality Medical Equipment, as well as small businesses throughout the country. By forcing beneficiaries to use one low bid provider, the training on use of the equipment, maintenance, and overall customer service the beneficiaries will receive will fall by the waist side. This will open the beneficiaries up to more of a hazard by supplying them sub par equipment with little to no training, and no way to easily resolve the issue (ie: going to another supplier).

The most simple way to save CMS money, maintain the beneficiaries right to choose their supplier, and allow our small businesses to provide quality products and excellent service is to revise the current fee schedule to be in line with the current market.

If it is determined by CMS that competitive bidding is the only way to go (which it is not), we hope that you would keep in mind the struggles you will be putting on our aging seniors, their care givers, & the individuals that are coordinating their care. With competitive bidding, individuals will have to contact several different companies to set up several different deliveries to get multiple pieces of equipment. Today this can be accomplished by one phone call.

Also, by eliminating DME providers through competitive bidding this will have a detrimental effect on small business throughout the country thereby increasing business closing and decreasing the collection of payroll taxes.

Submitter : Mr. Byron Yarborough **Date:** 06/29/2006

Organization : Dura+Med, Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachement

CMS-1270-P-838-Attach-1.DOC

Comments on the Notice of Proposed Rulemaking (NPRM) on Competitive Acquisition

Timing Concerns

Supplier Standards and Deficit Reduction Act Implementation

Because of the impact that the implementation of the Deficit Reduction Act of 2005 will have on competitive bidding, the information in the NPRM is inadequate to serve as a basis for public comments. Before implementing competitive bidding, we recommend that CMS issue an interim final rule to allow additional stakeholder comments.

Because the NPRM raises more questions than it answers, does not identify the markets, or the products, and the final quality standards have not been published, we advise that CMS also allow adequate time to schedule a meeting of the Program Advisory Oversight Committee (PAOC) after it publishes an interim final rule. This will allow CMS to have industry input one more time before publishing a final rule and implementing the program.

Opportunity to Comment on the Supplier Standards

All interested parties must have an opportunity to comment on the quality standards before they are finalized. Our understanding is that CMS received comments from more than 5600 organizations and individuals on the draft supplier standards, and it is anticipated that the final standards will differ significantly from the draft. If so, under principles of administrative law, CMS has an obligation to give stakeholders another comment period.

Moreover, an additional comment period is essential because CMS has chosen to by-pass the procedural protections of the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget that would otherwise be part of the rule-making process applicable to the quality standards.

It is extremely important that final supplier standards apply to every supplier desiring to submit a bid. Allowing an additional comment period is unlikely to have a substantial impact on the overall implementation time-line. Competitive bidding is a radical departure from traditional Medicare and this program is still largely experimental; consequently, we think that CMS should consent to reasonable delays and not rush to implement the quality standards or any other aspect of competitive bidding.

Overall Implementation Time-line

It is crucial that CMS establish an implementation time-line that identifies all steps leading up to competitive bidding. Given the number of steps that must be commenced and completed, however, we ask that CMS adopt a realistic time-line and not rush through the process. Some of the remaining steps include:

- Publication of the supplier standards
- Selection of the accrediting bodies
- Publication of interim final and final regulations
- Publication of the initial 10 MSAs and product categories
- Publication of the RFB
- Evaluation of bids and selection of contract suppliers
- Education of beneficiaries and referral sources
- Implementation within each MSAs

Payment Basis

Inflation Update

CMS says that providers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U, but providers have no promise that Congress will not override the update through subsequent legislation in any given year. CMS must make certain that the inflation update to the competitive bid prices will not be subject to subsequent freezes in the CPI-U. If CMS cannot provide this guarantee, then the only appropriate course of action is to instruct bidders to include an inflation adjustment in their bids.

Grandfathering Medicare Advantage

The NPRM does not address the impact of competitive bidding on Medicare Advantage patients who leave their plan to re-enter traditional Medicare. These patients may have a provider who is part of the MA plan network, but that may not be a contract supplier. What rules will apply to this patient population under competitive bidding? Will these patients have the opportunity to continue to use their existing supplier when they re-enter the traditional Medicare program? We recommend that patients moving from an MA plan to traditional Medicare be given the option of remaining with their existing providers under the grandfathering provisions proposed in the NPRM.

Beneficiary Switch to Contract Suppliers

The NPRM says that a beneficiary can decide to use a contract supplier at any time. Contract suppliers will be required to furnish capped rental or oxygen equipment to beneficiaries in the competitive bidding area regardless of the rental months remaining on the equipment. CMS states that suppliers must factor these additional costs into their bids. Suppliers will be unable to include these additional costs into their bids because it is not possible to predict whether beneficiaries may decide to switch to a grandfathered supplier and how many rental months remain on a piece of equipment. Moreover, CMS also states that suppliers may not submit bids higher than the current fee schedule amount for an item. This artificial ceiling on the bids further complicates bidding under this scenario. We appreciate CMS desire to preserve the beneficiary's freedom to change suppliers even under a competitive bidding program; we do, however, strongly recommend that CMS initiate a new period of continuous use if a beneficiary decides to switch from a grandfathered supplier to a contract supplier.

Application of DRA to Oxygen Patients

The NPRM is very vague on how CMS intends to apply the DRA provisions on oxygen to grandfathered suppliers and beneficiaries. Will the grandfathered relationship terminate at the conclusion of 36 months? As noted above, the implementation of the DRA forced ownership provisions on oxygen and capped rental equipment has important ramifications for competitive bidding. Stakeholders cannot provide meaningful comments on many issues in the NPRM without understanding how CMS will administer the DRA requirements. It is vital that CMS publish an interim final rule before it publishes the final rule on competitive bidding.

Authority to Adjust Payment in Other Areas

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

Limitation on Beneficiary Liability

Our understanding is that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. Under current Medicare rules, a supplier may furnish the beneficiary with an ABN notifying him that Medicare will not pay for an item. Other portions of the NPRM specifically state that ABNs will be permitted under a competitive bidding program, and the MMA requires that CMS continue to allow suppliers to use ABNs. CMS must clarify what it means when it states that a beneficiary will have no financial liability to a non-contract supplier for competitively bid items furnished by that supplier.

Competitive Bidding Areas

Staggered Implementation

The NPRM is silent on whether CMS will commence competitive bidding in 10 MSAs at the same time, or stagger the initial implementation of competitive bidding in 2007. We recommend that CMS phase-in the first 10 MSAs; we also *strongly recommend* that select only one MSA per state when implementing the first 10. This will allow CMS to identify and correct problems as competitive bidding commences before the problems become widespread; selecting only one MSA per state will also minimize negative impacts on beneficiaries in each state – especially those states with higher beneficiary populations – until problems can be solved.

Nationwide or Regional Mail Order Competitive Bidding Program

We are uncertain as to why CMS proposes a separate competitive bidding program for mail order suppliers in 2010. Mail order suppliers are not excluded from participating in competitive bidding during 2007 and 2009; a separate program for them in 2010 is completely unnecessary. In addition, there is no definition for a mail order supplier under Medicare program rules. Many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes.

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

Though mail order is an appropriate and cost effective vehicle for delivery of some replacement supplies such as test strips and lancets, it may not meet the needs of all beneficiaries who require such supplies. Mail order is subject to the ability to get the supplies to the beneficiary by commercial carrier. Whether or not a beneficiary receiving such supplies lives in a competitive bidding MSA, they should have the option of being able to obtain these supplies locally. The Medicare program must allow multiple distribution channels to meet beneficiary needs.

Finally, we note that this proposal represents another example of CMS' lack of success in providing the necessary level of detail for notice and comment rule-making. We recommend that CMS publish an interim final rule to solicit additional public comment before implementing any type of competitive bidding program.

Establishing the Competitive Bidding Area

CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established ***in*** an MSA. CMS must identify the MSAs in which it will commence competitive bidding in 2007 in an interim final rule.

Criteria for Item Selection

Items Included in Competitive Bidding

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

Potential for Savings

CMS has an obligation to explain and clarify what specific measures will be used to decide an items potential savings as a result of competitive bidding. CMS must address the following:

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

Additional Criteria for Item Selection

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

We strongly recommend that CMS publish the items it intends to include in the initial competitive bidding program in an interim final rule to solicit additional public comment after it announces the product selections.

Brand-Specific Requirements

The NPRM proposes to allow physicians and practitioners to prescribe a specific brand or type of equipment. According to CMS, this type of provision would preserve beneficiary access to equipment. Although contract suppliers will not be required to carry all brands/models of equipment included in competitive bidding, if a physician orders a brand/model the supplier

does not carry, the supplier must choose whether to fill the order, refer the beneficiary to another supplier, or ask the physician to change the order. Medicare will not pay for another item if the supplier failed to provide the brand name item the doctor ordered.

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

Coding Issues and Item Selection

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

Product Categories for Bidding Purposes

General Issues

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

Requirements to Bid on all Products in a Category

Suppliers may choose to bid on one, some, or all of the product categories, but if a provider bids on a category, that provider must bid on each item included in the category. We advise that CMS define products categories narrowly to ensure that they are consistent and representative of the products that a supplier might actually furnish. Including a broad category for wheelchairs or power wheelchairs is likely to be very problematic. Suppliers who do not specialize in rehab may not carry power wheelchairs under certain codes. Similarly, suppliers who do specialize in providing equipment to patients with complex needs may not carry all of the power wheelchairs designated by that product category.

- Power wheelchair codes are in the process of being revised. A high probability exists for compromise of patient care due to the breadth of the category combined with the complexity of needs for the high-end rehab patient. Complex Rehab wheelchairs are predominantly custom-configured, and they utilize a minimal amount of standard in-stock components. Due to the high probability of inappropriate equipment being provided to the complex Rehab patient in the first level of review as well as subsequent provision of appropriate equipment, it is highly probable that a categorical bidding process will be more costly in the long run for complex Rehab and Assistive Technology.
- Manual wheelchairs HCPCS codes will be subjected to a similar recoding process beginning in 2007. Because of its greater breadth as a category, manual wheelchairs will probably cost more to bid categorically for similar reasons. Complex Rehab Technology patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the proposal in the NPRM, a provider who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. In many cases complex Rehab manual wheelchairs require multiple components from multiple manufacturers to achieve appropriate fit and function for the individual.
- Those providers who are awarded a winning bid in a category for Wheelchairs could end up not being a winning bidder for the associated seating. In effect, many patients may need to deal with two or more providers for a single rehab wheelchair. This situation could lead to access issues in areas of the country where a winning provider is not equipped to provide the complexity of multiple seating and positioning services required in that area.

- Current HCPCS codes are too broad, encompassing items that represent vastly different technologies. CMS should develop narrow product categories so that providers may submit proposals for more standard bases with general purpose seating and positioning products compared to high end complex rehab technology services. It is dangerous to the end user for non-qualified providers to be submitting bids for services that they do not provide.

Conditions for Awarding Contracts

Quality Standards and Accreditation

The NPRM says that CMS will allow a grace period during which unaccredited providers can participate in the bidding process. Unaccredited providers who are winning bidders may complete accreditation during the unspecified grace period. Winning bidders who do not become accredited during the grace period will loose the contract supplier status. ***Because the overwhelming majority of DME suppliers are small businesses***, it is likely that many will not be accredited at the time they are awarded contracts. As a result, bids from providers who are ultimately disqualified will be considered in the determination of the pivotal bid and single payment amount. By definition, *only* accredited suppliers should be eligible to bid. CMS should not proceed with competitive bidding until it is sure that all suppliers who may want to submit bids have had a fair and reasonable opportunity to get accredited.

In addition, the evaluation of the suppliers' financial stability must take place before the bid prices are arrayed and the pivotal bid is selected. Bids from disqualified providers should not be considered in selecting the winning bid point or setting the payment amount. CMS should consider the following evidence of suppliers' financial stability:

- D & B report
- Insurance Certificates
- Trade References
- Income / Balance Sheets
- Letters of Credit

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

Market and Supplier Capacity

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

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

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

Assurance of Savings

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the

competition is not truly competitive based on market prices. Instead, CMS should adopt the methodology used in the demonstrations. CMS should look for savings in the overall product category even though a single payment amount for a specific item may be higher than its current fee schedule amount.

Determining the Single Payment Amount

CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the winning suppliers. This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also **significantly different** than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects. **We believe Congress did not have this methodology in mind when it authorized competitive bidding under the MMA.**

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

Rebate Program

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

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

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

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

Bulletin at 1.

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

rental equipment. Second, the supplier could not advertise the fact that it offers a rebate.

Once an inducement is in the public domain, its harmful effects cannot be contained, even with the safeguards CMS intends to implement. The fact that a provider does not actively promote an inducement does not change the illegal nature of the activity or the disruptive repercussions it has on competition and quality of care. The OIG would be unlikely to approve of a rebate program like the one CMS proposes even if the supplier did not advertise the rebate:

The inducement element of the offense is met by any offer of valuable ... goods and services as part of a marketing or promotional activity, regardless of whether the marketing or promotional activity is active or passive. For example, even if a provider does not directly advertise or promote the availability of a benefit to beneficiaries, there may be indirect marketing or promotional efforts or informal channels of information dissemination, such as word of mouth promotion by practitioners or patient support groups.

Bulletin at 5 (Emphasis supplied).

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

Terms of Contract

Repair or Replacement of Equipment

CMS will compel contract suppliers to accept all beneficiaries within the competitive bidding area. CMS will also demand that contract suppliers repair or replace beneficiary owned equipment under the competitive bidding program. As we mentioned above, we propose that CMS allow a new period of continuous use to begin when a beneficiary switches to a contract supplier. This preserves the beneficiary's choice and protects the contract supplier who may have to furnish equipment to the beneficiary without adequate compensation for the item or the service it requires. The repair of patient owned equipment should be treated as a separately bid item on the RFB. In other words, CMS should solicit bids for the repair of patient owned equipment. We assume that replacement equipment will be provided and paid for in an amount equal to the single payment amount for the items or the contract suppliers bid, depending on the payment methodology CMS adopts in the final rule.

Termination of Contract

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

Judicial and Administrative Remedies

CMS must include a procedure for debriefing suppliers who did not win a bid and an opportunity for a review to determine at a minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

Change of Ownership

It is reasonable for CMS to review a change of ownership to determine whether the buyer meets the quality standards and whether a buyer has, in the past before granting the new company contract supplier status. However, CMS cannot unreasonably withhold its approval of a change of ownership and should not deny winning-supplier status to a new owner on the basis that its capacity is not necessary within the competitive bidding area. CMS should approve a change of ownership if the new entity will meet all applicable quality standards and confirm to other requirements of competitive bidding. CMS approval should not be withheld based on a determination that the supplier's capacity was not necessary.

Participation of Small Suppliers

CMS has taken a **very narrow view** of its obligation to ensure that small suppliers are adequately represented among contract suppliers. CMS proposal for allowing networks does not consider the practical hurdles involved in creating new entity. Under the timelines that CMS has announced, it will be difficult to establish networks that can meet the eligibility requirements for submitting bids. Consequently, this may not be a viable option for most suppliers. CMS has also stated that the market share for supplier networks cannot exceed 20%. CMS should expand this to allow greater participation by small suppliers. CMS should also consider small supplier set asides in at least some MSAs. CMS has not provided for minority or female owned businesses to get any subcontracting rights.

Submitter : Dr. Craig Lang **Date:** 06/29/2006

Organization : MLG PODIATRY GROUP

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

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

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

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

If I see a patient who I diagnose with a fracture of the mid-foot, I may decide that it is medically necessary and appropriate to use a walking boot to treat my patient. I want to make sure the patient is not putting weight on the injured extremity and I need to make sure the walking boot fits properly for that patient. If I am not a supplier in the new program, I will not be able to do that and my patients will suffer.

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

Sincerely,

Submitter : Loraine Lovejoy-Evans **Date:** 06/29/2006

Organization : Independence Through Physical Therapy

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-840-Attach-1.DOC

6-29-06

RE: Proposed Rule for Competitive Acquisition of Certain DMEPOS

My name is Loraine Lovejoy-Evans, MPT, I work as a physical therapist in a private practice setting in Sequim, Washington. My primary case load is treating Medicare patients who are ambulatory, as Sequim is a retirement community. I am writing with concerns about the proposed rule for competitive acquisition of DMEPOS.

I would like to see CMS review the proposed regulations and establish a process that will enable physical therapists to continue to furnish orthotics that are important in patient care. As a therapist I and my colleagues are helping patients with adjustments to their orthotics and DME equipment with the knowledge we possess of anatomy and specific alignment issues to improve their functional abilities such as normalization of gait.

The current project being proposed to limit DMEPOS could obstruct our ability to furnish this equipment to a patient and limit their timely access. This could put a further negative impact on the patient's care and outcome potentially causing further injury without appropriate equipment in a timely manner, such as a fall with a hip fracture requiring a THR without appropriate equipment for safe ambulation.

It has been proposed that a certified orthotist would be the only one allowed to make adjustments to orthotics. However, a physical therapist has the training and capacity to make adjustments to equipment and this proposal would limit the ability to do so. In our area it often takes an orthotist 1-2 weeks to visit to be able to provide this service for the patient. Using equipment that is not fit properly can cause injury to the skin and breakdown of the tissues. In a body that is already compromised it can further limit mobility and healing if a wound occurs. This could put a patient who is ambulatory with an orthotic into a wheelchair virtually within days. A physical therapist who assesses an orthotic fit to be inappropriate and can make the necessary changes can help to keep the patient mobile and independent without causing medical injury.

CMS has indicated that physicians would be allowed to make recommendations for specific brand name products if an adverse event would occur without this product. I would like to see the same clarification made to allow physical therapists this ability. The physicians I work with typically defer to my understanding of this equipment. Allowing a physical therapist to recommend a specific brand name can be a cost savings for CSM, as our experience and expertise in this area is far greater than that of most physicians.

Physical therapists are educated in significant anatomy and physiology, functional mobility and healthy function of the human body and comprehensive patient care experiences as well as training in manufacturing orthotics and understanding how to fit these products and evaluate their effect on gait and appropriate posture in their education programs that are accredited by the Commission on Accreditation of Physical Therapy Education (CAPTE), which is recognized by the U.S. Department of Education and the Commission on Recognition in Postsecondary Accreditation (CORPA). Physical therapists as licensed professionals had to pass an examination to test their knowledge in fitting assistive equipment as well as orthotics and prosthetics and have a code of ethics and a practice act they follow to guide their practice and protect their patients. Each clinician is also required to carry liability insurance, I personally carry a 6-million dollar policy for my office. Physical therapists provide an evaluation and establish a plan of care for their patients and can include orthotics and prosthetics as part of this plan. Physical therapists are held to a high standard of quality when providing orthotics or prosthetics either in fabrication or fitting and training and as such should be allowed to continue to provide this service and not be limited by CSM. Thank you for your time in considering this matter on our behalf.

Very Truly Yours,
Loraine Lovejoy-Evans, MPT (lovejoyevans@hotmail.com)

Submitter : Mr. William Keel **Date:** 06/29/2006

Organization : Matrix Medical, LLC

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1270-P-841-Attach-1.DOC

Comments on the Notice of Proposed Rulemaking (NPRM) on Competitive Acquisition

Timing Concerns

Supplier Standards and Deficit Reduction Act Implementation

The information in the NPRM is inadequate to serve as a basis for public comments, especially because of the impact that the implementation of the Deficit Reduction Act of 2005 (DRA) will have on competitive bidding. Prior to implementing competitive bidding, CMS should issue an interim final rule to allow additional stakeholder comments.

In addition, because the NPRM raises more questions than it answers, does not identify the markets, or the products, and the final quality standards have not been published, we strongly urge that CMS also allow adequate time to schedule a meeting of the Program Advisory Oversight Committee (PAOC) after it publishes an interim final rule. This will allow CMS to have industry input one more time before publishing a final rule and initiating program implementation.

Opportunity to Comment on the Supplier Standards

CMS must allow all interested parties an opportunity to comment on the quality standards before they are finalized. Our understanding is that CMS received comments from 5600 organizations and individuals on the draft supplier standards, and the final standards will very likely differ significantly from the draft. If so, under principles of administrative law, CMS has an obligation to give stakeholders another comment period.

Moreover, an additional comment period is essential because CMS has chosen to by-pass the procedural protections of the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget that would otherwise be part of the rule-making process applicable to the quality standards.

It is critical that final supplier standards apply to every supplier desiring to submit a bid. Allowing an additional comment period is unlikely to have a substantial impact on the overall implementation time-line. Competitive bidding is a radical departure from traditional Medicare and this program is still mostly experimental (the two incomplete demonstrations notwithstanding); consequently, CMS should consent to reasonable delays and not rush to implement the quality standards or any other aspect of competitive bidding.

Overall Implementation Time-line

It is essential that CMS establish an implementation time-line that identifies all steps leading up to competitive bidding. Given the number of steps that must be commenced and completed, however, we advise CMS to adopt a realistic time-line and not rush through the process. Remaining steps include:

- Publication of the supplier standards
- Selection of the accrediting bodies
- Publication of interim final and final regulations
- Publication of the initial 10 MSAs and product categories
- Publication of the RFB
- Evaluation of bids and selection of contract suppliers
- Education of beneficiaries and referral sources
- Implementation within each MSAs

Payment Basis

Inflation Update
CMS states that providers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U, but providers have *no assurance* that Congress will not override the update through subsequent legislation in any given year. CMS must ensure that the inflation update to the competitive bid price will not be subject to subsequent freezes in the CPI-U. If CMS cannot provide this guarantee, then the only appropriate course of action is to instruct bidders to include an inflation adjustment in their bids.

Grandfathering Medicare Advantage
The NPRM does not address the impact of competitive bidding on Medicare Advantage patients who leave their plan to re-enter traditional Medicare. These patients may have a provider who is part of the MA plan network, but that may not be a contract supplier. What rules will apply to this patient population under competitive bidding? Will these patients have the opportunity to continue to use their existing supplier when they re-enter the traditional Medicare program? We recommend that patients moving from an MA plan to traditional Medicare be given the option of remaining with their existing providers under the grandfathering provisions proposed in the NPRM.

Beneficiary Switch to Contract Suppliers
The NPRM states that a beneficiary can decide to use a contract supplier at any time. Contract suppliers will be required to furnish capped rental or oxygen equipment to beneficiaries in the competitive bidding area regardless of the rental months remaining on the equipment. CMS states that suppliers must factor these additional costs into their bids. Suppliers will be unable to include these additional costs into their bids because it is not possible to predict whether beneficiaries may decide to switch to a grandfathered supplier and how many rental months remain on a piece of equipment. Moreover, CMS also states that suppliers may not submit bids higher than the current fee schedule amount for an item. This artificial ceiling on the bids further complicates bidding under this scenario. We appreciate CMS desire to preserve the beneficiarys freedom to change suppliers even under a competitive bidding program. We recommend that CMS initiate a new period of continuous use if a beneficiary decides to switch from a grandfathered supplier to a contract supplier.

Application of DRA to Oxygen Patients
It is unclear from the NPRM how CMS intends to apply the DRA provisions on oxygen to grandfathered suppliers and beneficiaries. Will the grandfathered relationship terminate at the conclusion of 36 months? As noted above, the implementation of the DRA forced ownership provisions on oxygen and capped rental equipment have important ramifications for competitive bidding. Stakeholders cannot provide meaningful comments on many issues in the NPRM without understanding how CMS will administer the DRA requirements. Consequently, it is important that CMS publish an interim final rule before it publishes the final rule on competitive bidding.

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

Limitation on Beneficiary Liability
We understand that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. Under current Medicare

rules, a supplier may furnish the beneficiary with an ABN notifying him that Medicare will not pay for an item. Other portions of the NPRM specifically state that ABNs will be permitted under a competitive bidding program, and the MMA requires that CMS continue to allow suppliers to use ABNs. CMS must clarify what it means when it states that a beneficiary will have no financial liability to a non-contract supplier for competitively bid items furnished by that supplier.

Competitive Bidding Areas

Staggered Implementation

The NPRM is silent on whether CMS will commence competitive bidding in 10 MSAs at the same time, or stagger the initial implementation of competitive bidding in 2007. We recommend that CMS phase-in the first 10 MSAs; we also strongly recommend that select only one MSA per state when implementing the first 10. This will allow CMS to identify and correct problems as competitive bidding commences before the problems become widespread; selecting only one MSA per state will also minimize negative impacts on beneficiaries until problems can be solved.

Nationwide or Regional Mail Order Competitive Bidding Program

It is unclear why CMS proposes a separate competitive bidding program for mail order suppliers in 2010. Because mail order suppliers are not excluded from participating in competitive bidding during 2007 and 2009, a separate program for them in 2010 is unnecessary. In addition, there is no definition for a mail order supplier under Medicare program rules. Many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes.

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

While mail order is an appropriate and cost effective vehicle for delivery of some replacement supplies such as test strips and lancets, it may not meet the needs of all beneficiaries who require such supplies. Mail order, while efficient, is subject to the ability to get the supplies to the beneficiary by commercial carrier. Whether or not a beneficiary receiving such supplies lives in a competitive bidding MSA, they should have the option of being able to obtain these supplies locally. The Medicare program must allow multiple distribution channels to meet beneficiary needs.

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

Establishing the Competitive Bidding Area

CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established ***in*** an MSA. CMS must identify the MSAs in which it will commence competitive bidding in 2007 in an interim final rule.

Criteria for Item Selection

Items Included in Competitive Bidding

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

are not included in competitive bidding under 1847(a)(2).

Potential for Savings
CMS has an obligation to explain and clarify what specific measures will be used to decide an items potential savings as a result of competitive bidding. CMS must address the following:

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

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

CMS must publish the items it will include in the initial competitive bidding program in an interim final rule. CMS should solicit additional public comment after it announces the product selections.

Brand-Specific Requirements

The NPRM proposes to allow physicians and practitioners to prescribe a specific brand or type of equipment. According to CMS, this type of provision would preserve beneficiary access to equipment. Although contract suppliers will not be required to carry all brands/models of equipment included in competitive bidding, if a physician orders a brand/model the supplier does not carry, the supplier must choose whether to fill the order, refer the beneficiary to another supplier, or ask the physician to change the order. Medicare will not pay for another item if the supplier failed to provide the brand name item the doctor ordered.

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

Coding Issues and Item Selection

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

Product Categories for Bidding Purposes

General Issues

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

Requirements to Bid on all Products in a Category

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

- Power wheelchair codes are in the process of being revised. A high probability exists for compromise of patient care due to the breadth of the category combined with the complexity of needs for the high-end rehab patient. Complex Rehab wheelchairs are predominantly custom-configured, and they utilize a minimal amount of standard in-stock components. Due to the high probability of inappropriate equipment being provided to the complex Rehab patient in the first level of review as well as subsequent provision of appropriate equipment, it is highly probable that a categorical bidding process will be more costly in the long run for complex Rehab and Assistive Technology.
- Manual wheelchairs HCPCS codes will be subjected to a similar recoding process beginning in 2007. Because of its greater breadth as a category, manual wheelchairs will probably cost more to bid categorically for similar reasons. Complex Rehab Technology patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the proposal in the NPRM, a provider who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. In many cases complex Rehab manual wheelchairs require multiple components from multiple manufacturers to achieve appropriate fit and function for the individual.
- Those providers who are awarded a winning bid in a category for Wheelchairs could end up not being a winning bidder for the associated seating. In effect, many patients may need to deal with two or more providers for a single rehab wheelchair. This situation could lead to access issues in areas of the country where a winning provider is not equipped to provide the complexity of multiple seating and positioning services required in that area.

- Current HCPCS codes are too broad, encompassing items that represent vastly different technologies. CMS should develop narrow product categories so that providers may submit proposals for more standard bases with general purpose seating and positioning products compared to high end complex rehab technology services. It is dangerous to the end user for non-qualified providers to be submitting bids for services that they do not provide.

Conditions for Awarding Contracts

Quality Standards and Accreditation

The NPRM states that CMS will allow a grace period during which unaccredited providers can participate in the bidding process. Unaccredited providers who are winning bidders may complete accreditation during the unspecified "grace period." Winning bidders who do not become accredited during the "grace period" will loose the contract supplier status. Because the overwhelming majority of DME suppliers are small businesses, it is likely that many will not be accredited at the time they are awarded contracts. As a result, bids from providers who are ultimately disqualified will be considered in the determination of the pivotal bid and single payment amount. By definition, *only* accredited suppliers should be eligible to bid. CMS should not proceed with competitive bidding until it is sure that all suppliers who may want to submit bids have had an opportunity to get accredited.

Further, the evaluation of the suppliers' financial stability must take place before the bid prices are arrayed and the pivotal bid is selected. Bids from disqualified providers should not be considered in selecting the winning bid point or setting the payment amount. CMS should consider the following evidence of suppliers' financial stability:

- D & B report
- Insurance Certificates
- Trade References
- Income / Balance Sheets
- Letters of Credit

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

Market and Supplier Capacity

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

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

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

Assurance of Savings

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Instead, CMS should adopt the methodology used in the demonstrations. CMS should look for savings in the overall product category even though a single payment amount for a specific item may be higher than its current fee schedule amount.

Determining the Single Payment Amount

CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the winning suppliers. This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects. We believe Congress did not have this methodology in mind when it authorized competitive bidding under the MMA.

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

Rebate Program

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

Specifically, 1128A(a)(5) prohibits the offering or transfer of remuneration when an individual or entity knows or should know that it is likely to influence the beneficiary's selection of a provider or supplier. Remuneration includes anything of value and would apply to the rebate proposed by CMS. While the statute contains exceptions to the definition of the term remuneration, the rebate program proposed in the NPRM does not fit any of the statutory exceptions. For example, remuneration does not include unadvertised waivers of coinsurance or deductible amounts for individuals who have been determined

to be in financial need. The rebate offered by contract suppliers under the CMS program would not fit into this exception. We are also unaware of any guidance from the Office of Inspector General (OIG) of the Department of Health and Human Services that would authorize the program CMS proposes. In light of the statutory prohibitions of 1128A(a)(5), CMS lacks the authority to implement a rebate program. Consequently, CMS should withdraw the proposal.

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

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

Bulletin at 1.

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

Once an inducement is in the public domain, its harmful effects cannot be contained, even with the safeguards CMS intends to implement. The fact that a provider does not actively promote an inducement does not change the illegal nature of the activity or the disruptive repercussions it has on competition and quality of care. The OIG would be unlikely to approve of a rebate program like the one CMS proposes even if the supplier did not advertise the rebate:

The inducement element of the offense is met by any offer of valuable ... goods and services as part of a marketing or promotional activity, regardless of whether the marketing or promotional activity is active or passive. For example, even if a provider does not directly advertise or promote the availability of a benefit to beneficiaries, there may be indirect marketing or promotional efforts or informal channels of information dissemination, such as word of mouth promotion by practitioners or patient support groups.

Bulletin at 5 (Emphasis supplied).

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

Terms of Contract

Repair or Replacement of Equipment

CMS will require contract suppliers to accept all beneficiaries within the competitive bidding area. CMS will also require contract suppliers to repair or replace beneficiary owned equipment under the

competitive bidding program. As we mentioned above, we recommend that CMS allow a new period of continuous use to begin when a beneficiary switches to a contract supplier. This preserves the beneficiary's choice and protects the contract supplier who may have to furnish equipment to the beneficiary without adequate compensation for the item or the service it requires. The repair of patient owned equipment should be treated as a separately bid item on the RFB. In other words, CMS should solicit bids for the repair of patient owned equipment. We assume that replacement equipment will be provided and paid for in an amount equal to the single payment amount for the items or the contract suppliers bid, depending on the payment methodology CMS adopts in the final rule.

Termination of Contract

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

Judicial and Administrative Remedies

CMS should include a procedure for debriefing suppliers who did not win a bid and an opportunity for a review to determine at a minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

Change of Ownership

It is reasonable for CMS to review a change of ownership to determine whether the buyer meets the quality standards and whether a buyer has, in the past before granting the new company contract supplier status. However, CMS cannot unreasonably withhold its approval of a change of ownership and should not deny winning-supplier status to a new owner on the basis that its capacity is not necessary within the competitive bidding area. CMS should approve a change of ownership if the new entity will meet all applicable quality standards and confirm to other requirements of competitive bidding. CMS approval should not be withheld based on a determination that the supplier's capacity was not necessary.

Participation of Small Suppliers

CMS has taken a very narrow view of its obligation to ensure that small suppliers are adequately represented among contract suppliers. CMS proposal for allowing networks does not consider the practical hurdles involved in creating new entity. Under the timelines that CMS has announced, it will be difficult to establish networks that can meet the eligibility requirements for submitting bids. Consequently, this may not be a viable option for most suppliers. CMS has also stated that the market share for supplier networks cannot exceed 20%. CMS should expand this to allow greater participation by small suppliers. CMS should also consider small supplier set asides in at least some MSAs.

Submitter : **Dr. Thomas Werner** **Date: 06/29/2006**

Organization : **Arkansas Podiatrist**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Dear Dr. McClellan:

I want to request that the Centers of Medicare and Medicaid Services modify the physician definition for the new competetive acquisition program from 1861(r)(1) to 1861(r). I am an Arkansas podiatrist and I prescribe and supply durable medical equipment , orthotics and supplies (DMEPOS items) to my patients only. If I am instead required to bid to supply to an entire area, my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me. I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

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

Sincerely,

Thomas G. Werner, D.P.M.

Submitter : Ms. JANE BOREN **Date:** 06/29/2006

Organization : GATEWAY MEDICAL EQUIPMENT

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

I am opposed to the implementation of "Competetive Bidding" for several reasons:
1. Competetive Bidding seems to be based on the supposition that durable medical equipment(DME) is a commodity only. The fact is that the business of providing DME is much more than drop-shipping a piece of equipment to a customer. A great deal of service (including delivery, set-up, patient education, equipment maintenance and service, provision of back-up equipment, etc.) goes into providing a safe and effective service for the patient.
2. Medicare already has the ability to set the rates they pay for items and services. It is not necessary to implement competitive bidding which will discriminate against and likely eliminate smaller service providers.
3. Competitive bidding stifles marketplace competition. Smaller companies cannot compete on the price of commodities with nationwide suppliers. However, where we excel and do compete is in service.
4. Competitive bidding does not reward quality of products or services.
5. This legislation goes against the intent of the Medicare program as it was originally established which was that Medicare beneficiaries were guaranteed the right to chose their provider from the pool of providers enrolled in the program.

I am a small business owner. I employ eleven people. If competitive bidding [which I believe to be a misnomer] is implemented, I expect it likely that I will lose this business which constitutes my life-savings. I believe that our company does a much better job of providing service than a big company would.

These are not only quality-of-life issues for our patients. They also present a potential for serious financial outcomes for the Medicare program. As the CMS tinkers with the Medicare program, it is prudent to be cautious not to so seriously cut the smaller cost programs such as durable medical equipment (which lacks the strong lobby of the pharmaceutical companies, hospitals and physicians) without consideration of the negative outcomes that will befall Medicare beneficiaries and the negative financial outcomes for the Medicare program. In addition, the CMS needs to realize that the potential for savings in establishing a program with another overlay of bureaucracy is very unlikely and in the long run will probably result in vastly increasing costs as competetion is stifled and larger providers gain a stranglehold on the Medicare program.

Submitter : **Dr. Jason Novick** **Date: 06/29/2006**

Organization : **Dr. Jason Novick**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

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

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

In my practice, I use a variety of DMEPOS items. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries.

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

Sincerely,

Dr. Jason Novick, D.P.M.

Submitter : Mr. Scott Williamson **Date:** 06/29/2006

Organization : Am. Board for Cert. in Orthotics and Prosthetics

Category : Other

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Attached please find our comments.

CMS-1270-P-845-Attach-1.PDF

American Board for Certification in Orthotics and Prosthetics, Inc.

330 John Carlyle St., Suite 210 • Alexandria, Virginia 22314 • (703) 836-7114 • FAX (703) 836-0838 • www.abcop.org

June 29, 2006

VIA ELECTRONIC MAIL and OVERNIGHT MAIL

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

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

Dear Dr. McClellan,

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

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

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

Quality Standards and Accreditation

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

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

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

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

> (ii) A supplier satisfies paragraph (c)(2)(i) of this section if it –
> - Is accredited in good standing by an organization that CMS designates as a CMS-approved accreditation organization under §424.58 of this chapter, and
> - Received an on-site survey conducted in-person by trained and qualified surveyors.

Accreditation

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

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

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

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

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

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

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

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

Specifically, we recommend adding:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

Jeffrey J. Yakovich, CO
President

Exhibit 1

Categorization of Orthotic HCPCS Codes by Practitioner Skill Level

(Submitted August 8, 2005)

Introduction and Update of Terms
June 29, 2006

Introduction

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

Updated Term

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

Categorization of Orthotic HCPCS Codes by Practitioner Skill Level

(Revised August 8, 2005)

Executive Summary

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

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

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

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

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

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

Summary of Findings

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

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

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

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

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

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

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

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

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

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

Comprehensive Report

Mission Statement

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

Method

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

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

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

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

Procedure

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

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

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

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

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

Findings

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

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

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

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

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

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

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

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

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

*Diagnostic complexity will affect level of provider.

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

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

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

Table Three: Level of Independent Care Providers by Device Type

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

* Diagnostic complexity will affect level of provider.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Comments

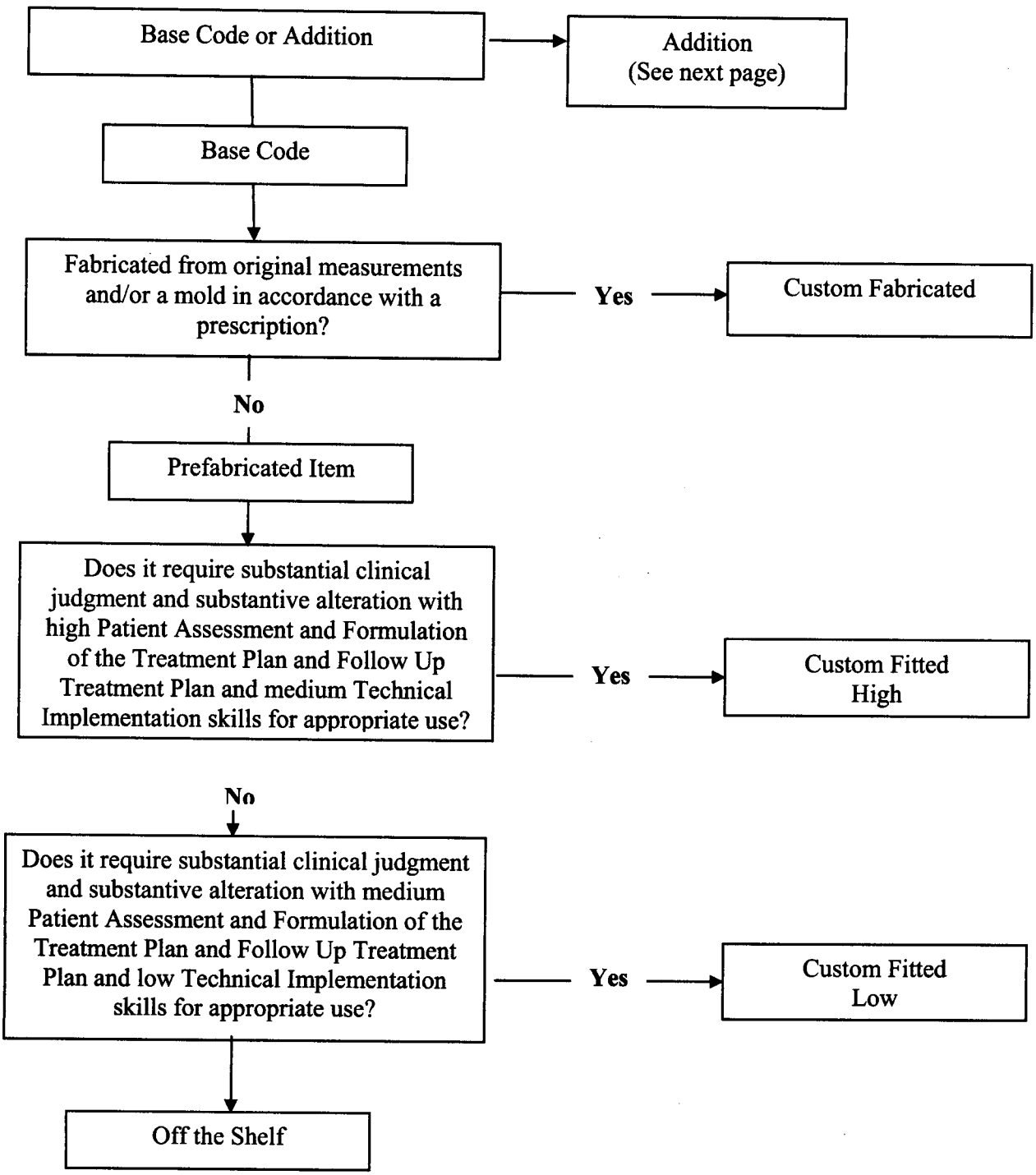
The group also agreed that three additional explanatory notes be included in this report, as follows:

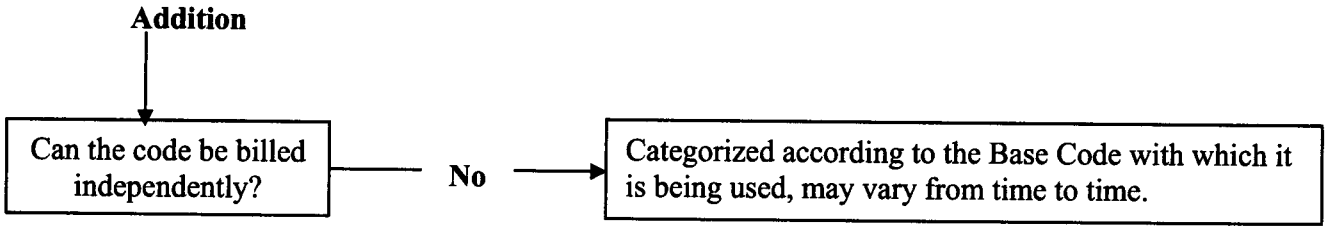
1. The devices/services referenced in this report are provided based upon a physician's written prescription.

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

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

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




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

Appendix B
Types of Devices

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

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

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

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

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

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

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

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

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

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

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

A. ABC Certified Orthotist and/or Prosthetist

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

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

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

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

    And
    - A 12-month NCOPE accredited residency program

2. Unique Qualifications Pathway

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

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

B. ABC Registered Assistant

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

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

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

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

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

C. ABC Registered Technician

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

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

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

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

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

D. ABC Registered Fitter-Orthotics

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

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

Registered Fitter Eligibility Pathways

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

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

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

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

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

Domains and Related Tasks:

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

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

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

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

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

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

- Consult technical component/material resources as required

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

- Modify and prepare patient model for fabrication

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Participate in education for residents, students, and trainees

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

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

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

Knowledge and Skill Statements

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

Knowledge of neuroanatomy

Knowledge of anatomical landmarks

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

Knowledge of normal human locomotion

Knowledge of normal and pathological gait

Knowledge of tissue characteristics/management

Knowledge of volumetric control

Knowledge of planes of motion

Knowledge of biomechanics

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

Knowledge of medical terminology

Knowledge of referral documents

Knowledge of procedures to record data

Knowledge of policies and procedures regarding privileged information

Knowledge of roles and responsibilities associated with other professions

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

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

Knowledge of universal precautions, including sterile techniques and infection control

Knowledge of ethical standards regarding proper patient management

Knowledge of scope of practice related to orthotic/prosthetic credentials

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

Knowledge of orthotic/prosthetic design

Knowledge of orthotic/prosthetic fitting criteria

Knowledge of trimlines

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

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

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

Knowledge of measurement tools and techniques

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

Knowledge of materials science

Knowledge of componentry

Knowledge of alignment devices and techniques

Knowledge of hand and power tools

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

Knowledge of care and maintenance of orthoses/prostheses

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

Knowledge of item warranty and warranty limitations

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

Knowledge of research methodology and literature

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

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

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

Skill in interpreting referral documents (including X-rays)

Skill in interviewing patients and referral sources

Skill in taking histories and performing physical examinations

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

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

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

Skill in normal and pathological gait/motion analysis

Skill in orthotic/prosthetic gait/motion analysis

Skill in managing patients relative to their condition

Skill in impression-taking/measuring for orthoses/prostheses, including upper limb, lower limb, spinal

Skill in using mechanical measuring devices

Skill in using electrical measuring devices

Skill in using computer-based measuring devices

Skill in patient delineation rectification and/or patient model modification

Skill in orthotic/prosthetic fabrication

Skill in use of safety equipment

Skill in using hand and power tools

Skill in use of materials and components

Skill in use of alignment devices

Skill in cosmetic finishing

Skill in evaluating fit and function of an orthosis/prosthesis

Skill in maintaining and repairing components

Skill in restoring optimal fit and function of orthoses/prostheses

Skill in solving patient's problems related to ADLs (e.g., dressing, driving)

Skill in documentation

Appendix E
Categorization of Orthotic & Prosthetic HCPCS Payment Codes by Practitioner Skill Level

HCPCS Code		
A5500	For Diabetics Only, Fitting (Including Follow-Up), Custom Preparation And Supply Of Off-The-Shelf Depth-Inlay Shoe Manufactured To Accommodate Multi-Density Insert(S) Per Shoe	Custom Fitted, High
A5501	For Diabetics Only, Fitting (Including Follow-Up), Custom Preparation And Supply Of Shoe Molded From Cast(S) Of Patients Foot (Custom Molded Shoe), Per Shoe	Custom Fabricated
A5508	For Diabetics Only, Deluxe Feature Of Off-The-Shelf Depth-Inlay Shoe Or Custom Molded Shoe, Per Shoe	Custom Fabricated
A5510	For Diabetics Only, Direct Formed, Compression Molded To Patient's Foot Without External Heat Source, Multiple Density Insert(S), Prefabricated, Per Shoe	Custom Fitted, High
K0628	For Diabetics Only, Multiple Density Insert, Direct Formed, Molded To Foot After External Heat Source Of 230 Degrees Fahrenheit Or Higher, Total Contact With Patient's Foot, Including Arch, Base Layer Minimum Of ¼ Inch Material Of Shore A 35 Durometer Of 3/16 Inch Material Of Shore A 40 Durometer (Or Higher), Prefabricated, Each	Custom Fitted, High
K0629	For Diabetics Only, Multiple Density Insert, Custom Molded From Model Of Patient's Foot, Total Contact With Patient's Foot, Including Arch, Base Layer Minimum Of 3/16 Inch Material Of Shore A 35 Durometer Or Higher, Includes Arch Filler And Other Shaping Material, Custom Fabricated, Each	Custom Fabricated
K0630	Sacroiliac Orthosis, Flexible, Provides Pelvic-Sacral Support, Reduces Motion About The Sacroiliac Joint, Includes Straps, Closures, May Include Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, low
K0631	Sacroiliac Orthosis, Flexible, Provides Pelvic-Sacral Support, Reduces Motion About The Sacroiliac Joint, Includes Straps, Closures, May Include Pendulous Abdomen Design, Custom Fabricated	Custom Fabricated
K0632	Sacroiliac Orthosis, Provides Pelvic-Sacral Support, With Rigid Or Semi-Rigid Panels Over The Sacrum And Abdomen, Reduces Motion About The Sacroiliac Joint, Includes Straps, Closures, May Include Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
K0633	Sacroiliac Orthosis, Provides Pelvic-Sacral Support, With Rigid Or Semi-Rigid Panels Placed Over The Sacrum And Abdomen, Reduces Motion About The Sacroiliac Joint, Includes Straps, Closures, May Include Pendulous Abdomen Design, Custom Fabricated	Custom Fabricated
K0634	Lumbar Orthosis, Flexible, Provides Lumbar Support, Posterior Extends From L-1 To Below L-5 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Pendulous Abdomen Design, Shoulder Straps, Stays, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, low
K0635	Lumbar Orthosis, Sagittal Control, With Rigid Posterior Panel(S), Posterior Extends From L-1 To Below L-5 Vertebrae, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Stays, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted High

HCPCS Code	CMS Description	Custom Fitted
K0636	Lumbar Orthosis, Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From L-1 To Below L-5 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
K0637	Lumbar-Sacral Orthosis, Flexible, Provides Lumbo-Sacral Support, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Stays, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
K0638	Lumbar-Sacral Orthosis, Flexible, Provides Lumbo-Sacral Support, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Stays, Shoulder Straps, Pendulous Abdomen Design, Custom Fabricated	Custom Fabricated
K0639	Lumbar-Sacral Orthosis, Sagittal Control, With Rigid Posterior Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Stays, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
K0640	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Disks, Includes Straps, ...** .... Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment **Per SADMERC, Should Read "Sagittal Control", Not "Sagittal-Coronal Control" And Should Have The Phrase "Closures, May Include Padding, Shoulder Straps," Inserted At Asterisk.**	Custom Fitted, High
K0641	Lumbar-Sacral,Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Custom Fabricated **Per SADMERC, Should Read "Sagittal Control", Not "Sagittal-Coronal Control."**	Custom Fabricated
K0642	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Posterior Frame/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Stays, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
K0643	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Posterior Frame/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Stays, Shoulder Straps, Pendulous Abdomen Design, Custom Fabricated	Custom Fabricated

HCPCS Code	CMS Description	Product Category
K0644	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Lumbar Flexion, Rigid Posterior Frame/Panels, Lateral Articulating Design To Flex The Lumbar Spine, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Anterior Panel, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
K0645	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Lumbar Flexion, Rigid Posterior Frame/Panels, Lateral Articulating Design To Flex The Lumbar Spine, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Anterior Panel, Pendulous Abdomen Design, Custom Fabricated	Custom Fabricated
K0646	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
K0647	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Custom Fabricated	Custom Fabricated
K0648	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Rigid Shell(S)/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xiphoid, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Overall Strength Is Provided By Overlapping Rigid Material And Stabilizing Closures, Includes Straps, Closures, May Include Soft Interface, Pendulous Abdomen Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
K0649	Lumbar-Sacral Orthosis, Sagittal-Coronal Control, Rigid Shell(S)/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xiphoid, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Overall Strength Is Provided By Overlapping Rigid Material And Stabilizing Closures, Includes Straps, Closures, May Include Soft Interface, Pendulous Abdomen Design, Custom Fabricated	Custom Fabricated
L0100	Cranial Orthosis (Helmet), With Or Without Soft Interface, Molded To Patient Model	Custom Fabricated
L0110	Cranial Orthosis (Helmet), With Or Without Soft Interface, Non-Molded	Custom Fitted, High
L0112	Cranial Cervical Orthosis, Congenital Torticollis Type, With Or Without Soft Interface Material, Adjustable Range Of Motion Joint, Custom Fabricated	Custom Fabricated
L0120	Cervical, Flexible, Non-Adjustable (Foam Collar)	Off the Shelf

HCPCS Code		
L0130	Cervical, Flexible, Thermoplastic Collar, Molded To Patient	Custom Fabricated
L0140	Cervical, Semi-Rigid, Adjustable (Plastic Collar)	Custom Fitted, Low
L0150	Cervical, Semi-Rigid, Adjustable Molded Chin Cup (Plastic Collar With Mandibular/Occipital Piece)	Custom Fitted, Low
L0160	Cervical, Semi-Rigid, Wire Frame Occipital/Mandibular Support	Custom Fitted, Low
L0170	Cervical, Collar, Molded To Patient Model	Custom Fabricated
L0172	Cervical, Collar, Semi-Rigid Thermoplastic Foam, Two Piece	Custom Fitted, Low
L0174	Cervical, Collar, Semi-Rigid, Thermoplastic Foam, Two Piece With Thoracic Extension	Custom Fitted, Low
L0180	Cervical, Multiple Post Collar, Occipital/Mandibular Supports, Adjustable	Custom Fitted, High
L0190	Cervical, Multiple Post Collar, Occipital/Mandibular Supports, Adjustable Cervical Bars (Somi, Guilford, Taylor Types)	Custom Fitted, High
L0200	Cervical, Multiple Post Collar, Occipital/Mandibular Supports, Adjustable Cervical Bars, And Thoracic Extension	Custom Fitted, High
L0210	Thoracic, Rib Belt	Custom Fitted, Low
L0220	Thoracic, Rib Belt, Custom Fabricated	Custom Fabricated
L0430	Spinal Orthosis, Anterior-Posterior-Lateral Control, With Interface Material, Custom Fitted (Dewall Posture Protector Only)	Custom Fitted, Low
L0450	TLSO, Flexible, Provides Trunk Support, Upper Thoracic Region, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Disks With Rigid Stays Or Panel(S), Includes Shoulder Straps And Closures, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L0452	TLSO, Flexible, Provides Trunk Support, Upper Thoracic Region, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Disks With Rigid Stays Or Panel(S), Includes Shoulder Straps And Closures, Custom Fabricated	Custom Fabricated
L0454	TLSO, Flexible, Provides Trunk Support, Extends From Sacrococcygeal Junction To Above T-9 Vertebra, Restricts Gross Trunk Motion In The Sagittal Plane, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Disks With Rigid Stays Or Panel(S), Includes Shoulder Straps And Closures, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, low
L0456	TLSO, Flexible, Provides Trunk Support, Thoracic Region, Rigid Posterior Panel And Soft Anterior Apron, Extends From The Sacrococcygeal Junction And Terminates Just Inferior To The Scapular Spine, Restricts Gross Trunk Motion In The Sagittal Plane, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Disks, Includes Straps And Closures, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0458	TLSO, Triplanar Control, Modular Segmented Spinal System, Two Rigid Plastic Shells, Posterior Extends From The Sacrococcygeal Junction And Terminates Just Inferior To The Scapular Spine, Anterior Extends From The Symphysis Pubis To The Xiphoid, Soft Liner, Restricts Gross Trunk Motion In The Sagittal, Coronal, And Transverse Planes, Lateral Strength Is Provided By Overlapping Plastic And Stabilizing Closures, Includes Straps And Closures, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High

HCPCS Code		
L0460	TLSO, Triplanar Control, Modular Segmented Spinal System, Two Rigid Plastic Shells, Posterior Extends From The Sacrococcygeal Junction And Terminates Just Inferior To The Scapular Spine, Anterior Extends From The Symphysis Pubis To The Sternal Notch, Soft Liner, Restricts Gross Trunk Motion In The Sagittal, Coronal, And Transverse Planes, Lateral Strength Is Provided By Overlapping Plastic And Stabilizing Closures, Includes Straps And Closures, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0462	TLSO, Triplanar Control, Modular Segmented Spinal System, Three Rigid Plastic Shells, Posterior Extends From The Sacrococcygeal Junction And Terminates Just Inferior To The Scapular Spine, Anterior Extends From The Symphysis Pubis To The Sternal Notch, Soft Liner, Restricts Gross Trunk Motion In The Sagittal, Coronal, And Transverse Planes, Lateral Strength Is Provided By Overlapping Plastic And Stabilizing Closures, Includes Straps And Closures, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0464	TLSO, Triplanar Control, Modular Segmented Spinal System, Four Rigid Plastic Shells, Posterior Extends From Sacrococcygeal Junction And Terminates Just Inferior To Scapular Spine, Anterior Extends From Symphysis Pubis To The Sternal Notch, Soft Liner, Restricts Gross Trunk Motion In Sagittal, Coronal, And Transverse Planes, Lateral Strength Is Provided By Overlapping Plastic And Stabilizing Closures, Includes Straps And Closures, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0466	TLSO, Sagittal Control, Rigid Posterior Frame And Flexible Soft Anterior Apron With Straps, Closures And Padding, Restricts Gross Trunk Motion In Sagittal Plane, Produces Intracavitary Pressure To Reduce Load On Intervertebral Disks, Includes Fitting And Shaping The Frame, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0468	TLSO, Sagittal-Coronal Control, Rigid Posterior Frame And Flexible Soft Anterior Apron With Straps, Closures And Padding, Extends From Sacrococcygeal Junction Over Scapulae, Lateral Strength Provided By Pelvic, Thoracic, And Lateral Frame Pieces, Restricts Gross Trunk Motion In Sagittal, And Coronal Planes, Produces Intracavitary Pressure To Reduce Load On Intervertebral Disks, Includes Fitting And Shaping The Frame, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0470	TLSO, Triplanar Control, Rigid Posterior Frame And Flexible Soft Anterior Apron With Straps, Closures And Padding, Extends From Sacrococcygeal Junction To Scapula, Lateral Strength Provided By Pelvic, Thoracic, And Lateral Frame Pieces, Rotational Strength Provided By Subclavicular Extensions, Restricts Gross Trunk Motion In Sagittal, Coronal, And Transverse Planes, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Disks, Includes Fitting And Shaping The Frame, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0472	TLSO, Triplanar Control, Hyperextension, Rigid Anterior And Lateral Frame Extends From Symphysis Pubis To Sternal Notch With Two Anterior Components (One Pubic And One Sternal), Posterior And Lateral Pads With Straps And Closures, Limits Spinal Flexion, Restricts Gross Trunk Motion In Sagittal, Coronal, And Transverse Planes, Includes Fitting And Shaping The Frame, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High

HCPCS Code		
L0480	TLSO, Triplanar Control, One Piece Rigid Plastic Shell Without Interface Liner, With Multiple Straps And Closures, Posterior Extends From Sacrococcygeal Junction And Terminates Just Inferior To Scapular Spine, Anterior Extends From Symphysis Pubis To Sternal Notch, Anterior Or Posterior Opening, Restricts Gross Trunk Motion In Sagittal, Coronal, And Transverse Planes, Includes A Carved Plaster Or Cad-Cam Model, Custom Fabricated	Custom Fabricated
L0482	TLSO, Triplanar Control, One Piece Rigid Plastic Shell With Interface Liner, Multiple Straps And Closures, Posterior Extends From Sacrococcygeal Junction And Terminates Just Inferior To Scapular Spine, Anterior Extends From Symphysis Pubis To Sternal Notch, Anterior Or Posterior Opening, Restricts Gross Trunk Motion In Sagittal, Coronal, And Transverse Planes, Includes A Carved Plaster Or Cad-Cam Model, Custom Fabricated	Custom Fabricated
L0484	TLSO, Triplanar Control, Two Piece Rigid Plastic Shell Without Interface Liner, With Multiple Straps And Closures, Posterior Extends From Sacrococcygeal Junction And Terminates Just Inferior To Scapular Spine, Anterior Extends From Symphysis Pubis To Sternal Notch, Lateral Strength Is Enhanced By Overlapping Plastic, Restricts Gross Trunk Motion In The Sagittal, Coronal, And Transverse Planes, Includes A Carved Plaster Or Cad-Cam Model, Custom Fabricated	Custom Fabricated
L0486	TLSO, Triplanar Control, Two Piece Rigid Plastic Shell With Interface Liner, Multiple Straps And Closures, Posterior Extends From Sacrococcygeal Junction And Terminates Just Inferior To Scapular Spine, Anterior Extends From Symphysis Pubis To Sternal Notch, Lateral Strength Is Enhanced By Overlapping Plastic, Restricts Gross Trunk Motion In The Sagittal, Coronal, And Transverse Planes, Includes A Carved Plaster Or Cad-Cam Model, Custom Fabricated	Custom Fabricated
L0488	TLSO, Triplanar Control, One Piece Rigid Plastic Shell With Interface Liner, Multiple Straps And Closures, Posterior Extends From Sacrococcygeal Junction And Terminates Just Inferior To Scapular Spine, Anterior Extends From Symphysis Pubis To Sternal Notch, Anterior Or Posterior Opening, Restricts Gross Trunk Motion In Sagittal, Coronal, And Transverse Planes, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0490	TLSO, Sagittal-Coronal Control, One Piece Rigid Plastic Shell, With Overlapping Reinforced Anterior, With Multiple Straps And Closures, Posterior Extends From Sacrococcygeal Junction And Terminates At Or Before The T-9 Vertebra, Anterior Extends From Symphysis Pubis To Xiphoid, Anterior Opening, Restricts Gross Trunk Motion In Sagittal And Coronal Planes, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L0700	Cervical-Thoracic-Lumbar-Sacral-Orthoses (CTLSO), Anterior-Posterior-Lateral Control, Molded To Patient Model, (Minerva Type)	Custom Fabricated
L0710	CTLSO, Anterior-Posterior-Lateral-Control, Molded To Patient Model, With Interface Material, (Minerva Type)	Custom Fabricated
L0810	Halo Procedure, Cervical Halo Incorporated Into Jacket Vest	Custom Fitted, High
L0820	Halo Procedure, Cervical Halo Incorporated Into Plaster Body Jacket	Custom Fabricated
L0830	Halo Procedure, Cervical Halo Incorporated Into Milwaukee Type Orthosis	Custom Fabricated

HCPCS Code		
L1000	Cervical-Thoracic-Lumbar-Sacral Orthosis (CTLSO) (Milwaukee), Inclusive Of Furnishing Initial Orthosis, Including Model	Custom Fabricated
L1005	Tension Based Scoliosis Orthosis And Accessory Pads, Includes Fitting And Adjustment	Custom Fitted, High
L1200	Thoracic-Lumbar-Sacral-Orthosis (TLSO), Inclusive Of Furnishing Initial Orthosis Only	Custom Fabricated
L1300	Other Scoliosis Procedure, Body Jacket Molded To Patient Model	Custom Fabricated
L1310	Other Scoliosis Procedure, Post-Operative Body Jacket	Custom Fabricated
L1500	Thoracic-Hip-Knee-Ankle Orthosis (THKAO), Mobility Frame (Newington, Parapodium Types)	Custom Fitted, High
L1510	THKAO, Standing Frame, With Or Without Tray And Accessories	Custom Fitted, High
L1520	THKAO, Swivel Walker	Custom Fitted, High
L1600	Hip Orthosis, Abduction Control Of Hip Joints, Flexible, Frejka Type With Cover, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, low
L1620	Hip Orthosis, Abduction Control Of Hip Joints, Flexible, (Pavlik Harness), Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1630	Hip Orthosis, Abduction Control Of Hip Joints, Semi-Flexible (Von Rosen Type), Custom-Fabricated	Custom Fabricated
L1640	Hip Orthosis, Abduction Control Of Hip Joints, Static, Pelvic Band Or Spreader Bar, Thigh Cuffs, Custom-Fabricated	Custom Fabricated
L1650	Hip Orthosis, Abduction Control Of Hip Joints, Static, Adjustable, (Ilfled Type), Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1652	Hip Orthosis, Bilateral Thigh Cuffs With Adjustable Abductor Spreader Bar, Adult Size, Prefabricated, Includes Fitting And Adjustment, Any Type	Custom Fitted, High
L1660	Hip Orthosis, Abduction Control Of Hip Joints, Static, Plastic, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1680	Hip Orthosis, Abduction Control Of Hip Joints, Dynamic, Pelvic Control, Adjustable Hip Motion Control, Thigh Cuffs (Rancho Hip Action Type), Custom Fabricated	Custom Fabricated
L1685	Hip Orthosis, Abduction Control Of Hip Joint, Postoperative Hip Abduction Type, Custom Fabricated	Custom Fabricated
L1686	Hip Orthosis, Abduction Control Of Hip Joint, Postoperative Hip Abduction Type, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1690	Combination, Bilateral, Lumbo-Sacral, Hip, Femur Orthosis Providing Adduction And Internal Rotation Control, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1700	Legg Perthes Orthosis, (Toronto Type), Custom-Fabricated	Custom Fabricated
L1710	Legg Perthes Orthosis, (Newington Type), Custom Fabricated	Custom Fabricated
L1720	Legg Perthes Orthosis, Trilateral, (Tachdijan Type), Custom-Fabricated	Custom Fabricated
L1730	Legg Perthes Orthosis, (Scottish Rite Type), Custom-Fabricated	Custom Fabricated
L1750	Legg Perthes Orthosis, Legg Perthes Sling (Sam Brown Type), Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low

HCPCS Code		
L1755	Legg Perthes Orthosis, (Patten Bottom Type), Custom-Fabricated	Custom Fabricated
L1800	Knee Orthosis, Elastic With Stays, Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L1810	Knee Orthosis, Elastic With Joints, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L1815	Knee Orthosis, Elastic Or Other Elastic Type Material With Condylar Pad(S), Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L1820	Knee Orthosis, Elastic With Condylar Pads And Joints, With Or Without Patellar Control, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L1825	Knee Orthosis, Elastic Knee Cap, Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L1830	Knee Orthosis, Immobilizer, Canvas Longitudinal, Prefabricated, Includes Fitting And Adjustment	Custom Fitted,Low
L1831	Knee Orthosis, Locking Knee Joint(S), Positional Orthosis, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L1832	Knee Orthosis, Adjustable Knee Joints, Positional Orthosis, Rigid Support, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L1834	Knee Orthosis, Without Knee Joint, Rigid, Custom-Fabricated	Custom Fabricated
L1836	Knee Orthosis, Rigid, Without Joint(S), Includes Soft Interface Material, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L1840	Knee Orthosis, Derotation, Medial-Lateral, Anterior Cruciate Ligament, Custom Fabricated	Custom Fabricated
L1843	Knee Orthosis, Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint, Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1844	Knee Orthosis, Single Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint, Medial-Lateral And Rotation Control, With Or Without Varus/Valgus Adjustment, Custom Fabricated	Custom Fabricated
L1845	Knee Orthosis, Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint, Medial-Lateral And Rotation Control, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1846	Knee Orthosis, Double Upright, Thigh And Calf, With Adjustable Flexion And Extension Joint, Medial-Lateral And Rotation Control, Custom Fabricated	Custom Fabricated
L1847	Knee Orthosis, Double Upright With Adjustable Joint, With Inflatable Air Support Chamber(S), Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1850	Knee Orthosis, Swedish Type, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L1855	Knee Orthosis, Molded Plastic, Thigh And Calf Sections, With Double Upright Knee Joints, Custom-Fabricated	Custom Fabricated
L1858	Knee Orthosis, Molded Plastic, Polycentric Knee Joints, Pneumatic Knee Pads (CTI), Custom-Fabricated	Custom Fabricated
L1860	Knee Orthosis, Modification Of Supracondylar Prosthetic Socket, Custom-Fabricated (Sk)	Custom Fabricated
L1870	Knee Orthosis, Double Upright, Thigh And Calf Lacers With Knee Joints, Custom-Fabricated	Custom Fabricated

HCPCS Code		
L1880	Knee Orthosis, Double Upright, Non-Molded Thigh And Calf Cuffs/Lacers With Knee Joints, Custom-Fabricated	Custom Fabricated
L1900	Ankle Foot Orthosis, Spring Wire, Dorsiflexion Assist Calf Band, Custom-Fabricated	Custom Fabricated
L1901	Ankle Orthosis, Elastic, Prefabricated, Includes Fitting And Adjustment (E.G. Neoprene, Lycra)	Off the Shelf
L1902	Ankle Foot Orthosis, Ankle Gauntlet, Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L1904	Ankle Foot Orthosis, Molded Ankle Gauntlet, Custom-Fabricated	Custom Fabricated
L1906	Ankle Foot Orthosis, Multiligamentus Ankle Support, Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L1907	Ankle Foot Orthosis, Supramalleolar With Straps, With Or Without Interface/Pads, Custom Fabricated	Custom Fabricated
L1910	Ankle Foot Orthosis, Posterior, Single Bar, Clasp Attachment To Shoe Counter, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L1920	Ankle Foot Orthosis, Single Upright With Static Or Adjustable Stop (Phelps Or Perlstein Type), Custom-Fabricated	Custom Fabricated
L1930	Ankle Foot Orthosis, Plastic Or Other Material, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1932	Ankle Foot Orthosis, Rigid Anterior Tibial Section, Total Carbon Fiber Or Equal Material, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1940	Ankle Foot Orthosis, Plastic Or Other Material, Custom Fabricated	Custom Fabricated
L1945	Ankle Foot Orthosis, Plastic, Rigid Anterior Tibial Section (Floor Reaction), Custom-Fabricated	Custom Fabricated
L1950	Ankle Foot Orthosis, Spiral, (Institute Of Rehabilitative Medicine Type), Plastic, Custom-Fabricated	Custom Fabricated
L1951	Ankle Foot Orthosis, Spiral, (Institute Of Rehabilitative Medicine Type), Plastic Or Other Material, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1960	Ankle Foot Orthosis, Posterior Solid Ankle, Plastic, Custom-Fabricated	Custom Fabricated
L1970	Ankle Foot Orthosis, Plastic With Ankle Joint, Custom-Fabricated	Custom Fabricated
L1971	Ankle Foot Orthosis, Plastic Or Other Material With Ankle Joint, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L1980	Ankle Foot Orthosis, Single Upright Free Plantar Dorsiflexion, Solid Stirrup, Calf Band/Cuff (Single Bar 'BK' Orthosis), Custom-Fabricated	Custom Fabricated
L1990	Ankle Foot Orthosis, Double Upright Free Plantar Dorsiflexion, Solid Stirrup, Calf Band/Cuff (Double Bar 'BK' Orthosis), Custom-Fabricated	Custom Fabricated
L2000	Knee Ankle Foot Orthosis, Single Upright, Free Knee, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs (Single Bar 'AK' Orthosis), Custom-Fabricated	Custom Fabricated
L2005	Knee Ankle Foot Orthosis, Any Material, Single Or Double Upright, Stance Control, Automatic Lock And Swing Phase Release, Mechanical Activation, Includes Ankle Joint, Any Type, Custom Fabricated	Custom Fabricated
L2010	Knee Ankle Foot Orthosis, Single Upright, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs (Single Bar 'AK' Orthosis), Without Knee Joint, Custom-Fabricated	Custom Fabricated

HCPCS Code	[illegible]	[illegible]
L2020	Knee Ankle Foot Orthosis, Double Upright, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs (Double Bar 'AK' Orthosis), Custom-Fabricated	Custom Fabricated
L2030	Knee Ankle Foot Orthosis, Double Upright, Free Ankle, Solid Stirrup, Thigh And Calf Bands/Cuffs, (Double Bar 'AK' Orthosis), Without Knee Joint, Custom Fabricated	Custom Fabricated
L2035	Knee Ankle Foot Orthosis, Full Plastic, Static (Pediatric Size), Without Free Motion Ankle, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L2036	Knee Ankle Foot Orthosis, Full Plastic, Double Upright, Free Knee, With Or Without Free Motion Ankle, Custom-Fabricated	Custom Fabricated
L2037	Knee Ankle Foot Orthosis, Full Plastic, Single Upright, Free Knee, With Or Without Free Motion Ankle, Custom-Fabricated	Custom Fabricated
L2038	Knee Ankle Foot Orthosis, Full Plastic, Without Knee Joint, Multi-Axis Ankle, Custom-Fabricated	Custom Fabricated
L2039	Knee Ankle Foot Orthosis, Full Plastic, Single Upright, Poly-Axial Hinge, Medial Lateral Rotation Control, With Or Without Free Motion Ankle, Custom-Fabricated	Custom Fabricated
L2040	Hip Knee Ankle Foot Orthosis, Torsion Control, Bilateral Rotation Straps, Pelvic Band/Belt, Custom Fabricated	Custom Fabricated
L2050	Hip Knee Ankle Foot Orthosis, Torsion Control, Bilateral Torsion Cables, Hip Joint, Pelvic Band/Belt, Custom-Fabricated	Custom Fabricated
L2060	Hip Knee Ankle Foot Orthosis, Torsion Control, Bilateral Torsion Cables, Ball Bearing Hip Joint, Pelvic Band/ Belt, Custom-Fabricated	Custom Fabricated
L2070	Hip Knee Ankle Foot Orthosis, Torsion Control, Unilateral Rotation Straps, Pelvic Band/Belt, Custom Fabricated	Custom Fabricated
L2080	Hip Knee Ankle Foot Orthosis, Torsion Control, Unilateral Torsion Cable, Hip Joint, Pelvic Band/Belt, Custom-Fabricated	Custom Fabricated
L2090	Hip Knee Ankle Foot Orthosis, Torsion Control, Unilateral Torsion Cable, Ball Bearing Hip Joint, Pelvic Band/ Belt, Custom-Fabricated	Custom Fabricated
L2106	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Cast Orthosis, Thermoplastic Type Casting Material, Custom-Fabricated	Custom Fabricated
L2108	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Cast Orthosis, Custom-Fabricated	Custom Fabricated
L2112	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Orthosis, Soft, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L2114	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Orthosis, Semi-Rigid, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L2116	Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Orthosis, Rigid, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L2126	Knee Ankle Foot Orthosis, Fracture Orthosis, Femoral Fracture Cast Orthosis, Thermoplastic Type Casting Material, Custom-Fabricated	Custom Fabricated
L2128	Knee Ankle Foot Orthosis, Fracture Orthosis, Femoral Fracture Cast Orthosis, Custom-Fabricated	Custom Fabricated
L2132	KAFO, Fracture Orthosis, Femoral Fracture Cast Orthosis, Soft, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L2134	KAFO, Fracture Orthosis, Femoral Fracture Cast Orthosis, Semi-Rigid, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L2136	KAFO, Fracture Orthosis, Femoral Fracture Cast Orthosis, Rigid, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High

HCPCS Code	CMS Description	Custom Fabricated
L3000	Foot, Insert, Removable, Molded To Patient Model, "UCB" Type, Berkeley Shell, Each	Custom Fabricated
L3001	Foot, Insert, Removable, Molded To Patient Model, Spenco, Each	Custom Fabricated
L3002	Foot, Insert, Removable, Molded To Patient Model, Plastazote Or Equal, Each	Custom Fabricated
L3003	Foot, Insert, Removable, Molded To Patient Model, Silicone Gel, Each	Custom Fabricated
L3010	Foot, Insert, Removable, Molded To Patient Model, Longitudinal Arch Support, Each	Custom Fabricated
L3020	Foot, Insert, Removable, Molded To Patient Model, Longitudinal/ Metatarsal Support, Each	Custom Fabricated
L3030	Foot, Insert, Removable, Formed To Patient Foot, Each	Custom Fabricated
L3040	Foot, Arch Support, Removable, Premolded, Longitudinal, Each	Off the Shelf
L3050	Foot, Arch Support, Removable, Premolded, Metatarsal, Each	Off the Shelf
L3060	Foot, Arch Support, Removable, Premolded, Longitudinal/ Metatarsal, Each	Off the Shelf
L3070	Foot, Arch Support, Non-Removable Attached To Shoe, Longitudinal, Each	Custom Fitted, Low
L3080	Foot, Arch Support, Non-Removable Attached To Shoe, Metatarsal, Each	Custom Fitted, Low
L3090	Foot, Arch Support, Non-Removable Attached To Shoe, Longitudinal/Metatarsal, Each	Custom Fitted, Low
L3100	Hallus-Valgus Night Dynamic Splint	Off the Shelf
L3140	Foot, Abduction Rotation Bar, Including Shoes	Custom Fitted, High
L3150	Foot, Abduction Rotation Bar, Without Shoes	Custom Fitted, High
L3160	Foot, Adjustable Shoe-Styled Positioning Device	Custom Fitted, High
L3170	Foot, Plastic Heel Stabilizer	Off the Shelf
L3201	Orthopedic Shoe, Oxford With Supinator Or Pronator, Infant	Custom Fitted, Low
L3202	Orthopedic Shoe, Oxford With Supinator Or Pronator, Child	Custom Fitted, Low
L3203	Orthopedic Shoe, Oxford With Supinator Or Pronator, Junior	Custom Fitted, Low
L3204	Orthopedic Shoe, Hightop With Supinator Or Pronator, Infant	Custom Fitted, Low
L3206	Orthopedic Shoe, Hightop With Supinator Or Pronator, Child	Custom Fitted, Low
L3207	Orthopedic Shoe, Hightop With Supinator Or Pronator, Junior	Custom Fitted, Low
L3208	Surgical Boot, Each, Infant	Custom Fitted, Low
L3209	Surgical Boot, Each, Child	Custom Fitted, Low
L3211	Surgical Boot, Each, Junior	Custom Fitted, Low
L3212	Benesch Boot, Pair, Infant	Custom Fitted, Low
L3213	Benesch Boot, Pair, Child	Custom Fitted, Low
L3214	Benesch Boot, Pair, Junior	Custom Fitted, Low
L3215	Orthopedic Footwear, Ladies Shoes, Oxford	Custom Fitted, Low
L3216	Orthopedic Footwear, Ladies Shoes, Depth Inlay	Custom Fitted, Low
L3217	Orthopedic Footwear, Ladies Shoes, Hightop, Depth Inlay	Custom Fitted, Low
L3219	Orthopedic Footwear, Men's Shoes, Oxford	Custom Fitted, Low
L3221	Orthopedic Footwear, Men's Shoes, Depth Inlay	Custom Fitted, Low
L3222	Orthopedic Footwear, Men's Shoes, Hightop, Depth Inlay	Custom Fitted, Low
L3230	Orthopedic Footwear, Custom Shoes, Depth Inlay	Custom Fabricated

HCPCS Code	CMS Description	[illegible]
L3250	Orthopedic Footwear, Custom Molded Shoe, Removable Inner Mold, Prosthetic Shoe, Each	Custom Fabricated
L3251	Foot, Shoe Molded To Patient Model, Silicone Shoe, Each	Custom Fabricated
L3252	Foot, Shoe Molded To Patient Model, Plastazote (Or Similar), Custom Fabricated, Each	Custom Fabricated
L3253	Foot, Molded Shoe Plastazote (Or Similar) Custom Fitted, Each	Custom Fitted, High
L3260	Surgical Boot/Shoe, Each	Custom Fitted, Low
L3265	Plastazote Sandal, Each	Custom Fitted, High
L3485	Heel, Pad, Removable For Spur	Off the Shelf
L3650	Shoulder Orthosis, Figure Of Eight Design Abduction Restrainer, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3651	Shoulder Orthosis, Single Shoulder, Elastic, Prefabricated, Includes Fitting And Adjustment (E.G. Neoprene, Lycra)	Custom Fitted, Low
L3652	Shoulder Orthosis, Double Shoulder, Elastic, Prefabricated, Includes Fitting And Adjustment (E.G. Neoprene, Lycra)	Custom Fitted, Low
L3660	Shoulder Orthosis, Figure Of Eight Design Abduction Restrainer, Canvas And Webbing, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3670	Shoulder Orthosis, Acromio/Clavicular (Canvas And Webbing Type), Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3675	Shoulder Orthosis, Vest Type Abduction Restrainer, Canvas Webbing Type Or Equal, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3677	Shoulder Orthosis, Hard Plastic, Shoulder Stabilizer, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3700	Elbow Orthosis, Elastic With Stays, Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L3701	Elbow Orthosis, Elastic, Prefabricated, Includes Fitting And Adjustment (E.G. Neoprene, Lycra)	Off the Shelf
L3710	Elbow Orthosis, Elastic With Metal Joints, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3720	Elbow Orthosis, Double Upright With Forearm/Arm Cuffs, Free Motion, Custom-Fabricated	Custom Fabricated
L3730	Elbow Orthosis, Double Upright With Forearm/Arm Cuffs, Extension/ Flexion Assist, Custom-Fabricated	Custom Fabricated
L3740	Elbow Orthosis, Double Upright With Forearm/Arm Cuffs, Adjustable Position Lock With Active Control, Custom-Fabricated	Custom Fabricated
L3760	Elbow Orthosis, With Adjustable Position Locking Joint(S), Prefabricated, Includes Fitting And Adjustments, Any Type	Custom Fitted, High
L3762	Elbow Orthosis, Rigid, Without Joints, Includes Soft Interface Material, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3800	Wrist Hand Finger Orthosis, Short Opponens, No Attachments, Custom-Fabricated	Custom Fabricated
L3805	Wrist Hand Finger Orthosis, Long Opponens, No Attachment, Custom-Fabricated	Custom Fabricated
L3807	Wrist Hand Finger Orthosis, Without Joint(S), Prefabricated, Includes Fitting And Adjustments, Any Type	Custom Fitted, High

HCPCS Code	CMS Description	[illegible]
L3900	Wrist Hand Finger Orthosis, Dynamic Flexor Hinge, Reciprocal Wrist Extension/ Flexion, Finger Flexion/Extension, Wrist Or Finger Driven, Custom-Fabricated	Custom Fabricated
L3901	Wrist Hand Finger Orthosis, Dynamic Flexor Hinge, Reciprocal Wrist Extension/ Flexion, Finger Flexion/Extension, Cable Driven, Custom-Fabricated	Custom Fabricated
L3902	Wrist Hand Finger Orthosis, External Powered, Compressed Gas, Custom-Fabricated	Custom Fabricated
L3904	Wrist Hand Finger Orthosis, External Powered, Electric, Custom-Fabricated	Custom Fabricated
L3906	Wrist Hand Orthosis, Wrist Gauntlet, Custom-Fabricated	Custom Fabricated
L3907	Wrist Hand Finger Orthosis, Wrist Gauntlet With Thumb Spica, Custom-Fabricated	Custom Fabricated
L3908	Wrist Hand Orthosis, Wrist Extension Control Cock-Up, Non Molded, Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L3909	Wrist Orthosis, Elastic, Prefabricated, Includes Fitting And Adjustment (E.G. Neoprene, Lycra)	Off the Shelf
L3910	Wrist Hand Finger Orthosis, Swanson Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3911	Wrist Hand Finger Orthosis, Elastic, Prefabricated, Includes Fitting And Adjustment (E.G. Neoprene, Lycra)	Off the Shelf
L3912	Hand Finger Orthosis, Flexion Glove With Elastic Finger Control, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3914	Wrist Hand Orthosis, Wrist Extension Cock-Up, Prefabricated, Includes Fitting/Adjustment	Off the Shelf
L3916	Wrist Hand Finger Orthosis, Wrist Extension Cock-Up With Outrigger, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3917	Hand Orthosis, Metacarpal Fracture, Orthosis, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3918	Hand Finger Orthosis, Knuckle Bender, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3920	Hand Finger Orthosis, Knuckle Bender With Outrigger, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3922	Hand Finger Orthosis, Knuckle Bender, Two Segment To Flex Joints, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3923	Hand Finger Orthosis, Without Joint(S), Prefabricated, Includes Fitting And Adjustments, Any Type	Custom Fitted, High
L3924	Wrist Hand Finger Orthosis, Oppenheimer, Prefabricated, Includes Fitting And Adjustable	Custom Fitted, High
L3926	Wrist Hand Finger Orthosis, Thomas Suspension, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3928	Hand Finger Orthosis, Finger Extension, With Clock Spring, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3930	Wrist Hand Finger Orthosis, Finger Extension, With Wrist Support, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3932	Finger Orthosis, Safety Pin, Spring Wire, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low

HCPCS Code	CMS Description	Device Category
L3934	Finger Orthosis, Safety Pin, Modified, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3936	Wrist Hand Finger Orthosis, Palmer, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3938	Wrist Hand Finger Orthosis, Dorsal Wrist, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3940	Wrist Hand Finger Orthosis, Dorsal Wrist, With Outrigger Attachment, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3942	Hand Finger Orthosis, Reverse Knuckle Bender, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3944	Hand Finger Orthosis, Reverse Knuckle Bender, With Outrigger, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3946	Hand Finger Orthosis, Composite Elastic, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3948	Finger Orthosis, Finger Knuckle Bender, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L3950	Wrist Hand Finger Orthosis, Combination Oppenheimer, With Knuckle Bender And Two Attachments, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3952	Wrist Hand Finger Orthosis, Combination Oppenheimer, With Reverse Knuckle And Two Attachments, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3954	Hand Finger Orthosis, Spreading Hand, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3960	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning, Airplane Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3962	Shoulder Elbow Wrist Hand Orthosis, Abduction Positioning, Erbs Palsey Design, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3963	Shoulder Elbow Wrist Hand Orthosis, Molded Shoulder, Arm, Forearm And Wrist, With Articulating Elbow Joint, Custom-Fabricated	Custom Fabricated
L3980	Upper Extremity Fracture Orthosis, Humeral, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3982	Upper Extremity Fracture Orthosis, Radius/Ulnar, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3984	Upper Extremity Fracture Orthosis, Wrist, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, High
L3985	Upper Extremity Fracture Orthosis, Forearm, Hand With Wrist Hinge, Custom-Fabricated	Custom Fabricated
L3986	Upper Extremity Fracture Orthosis, Combination Of Humeral, Radius/Ulnar, Wrist, (Example--Colles' Fracture), Custom Fabricated	Custom Fabricated
L4350	Ankle Control Orthosis, Stirrup Style, Rigid, Any Type Interface (E.G. Pneumatic, Gel) Prefabricated, Includes Fitting And Adjustment	Off the Shelf
L4360	Walking Boot, Pneumatic With Or Without Interface Material, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L4370	Pneumatic Full Leg Splint, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L4380	Pneumatic Knee Splint, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low

HCPCS Code	CMS Description	Medicare Payment
L4386	Walking Boot, Non-Pneumatic, With Or Without Joints, With Or Without Interface Material, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L4396	Static AFO, Including Soft Interface Material, Adjustable For Fit, For Positioning, Pressure Reduction, May Be Used For Minimal Ambulation, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low
L4398	Foot Drop Splint, Recumbent Positioning Device, Prefabricated, Includes Fitting And Adjustment	Custom Fitted, Low

Note: All prosthetic devices are custom fabricated.
Orthotic repair codes L4000 through L4210 are considered custom fabricated.

Submitter : Ms. SUSAN BECKER **Date:** 06/29/2006

Organization : CHRISTUS HOSPITAL - ST. ELIZABETH

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

Having potentially low-cost providers offering generic equipment and little training or support to patients would actually lead to higher long-term costs for CMS. Poor equipment and training leads to lowe patient adherence to glucose monitoring and overall treatment guidelines, leading to more long-term complications, more ER visits, and higher overall costs.

Submitter : **Mrs. Esther Pedroso** **Date: 06/29/2006**

Organization : **Mrs. Esther Pedroso**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

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

Attention: CMS-1270-P

Opposed to Definition of Prefabricated Orthoses

Opposed to Competitive Bidding for Prefabricated Orthoses

Dear Administrator:

I would like to take this opportunity to comment on the proposed rule CMS-1270-P. I am currently receiving occupational therapy at a hand therapy facility. I can see that orthoses are a large part of the treatment for these patients. While most are custom fabricated, prefabricated orthoses are also supplied. When a therapist supplies a prefabricated orthoses, they also instruct the patient in precautions, use, timetables for changes, wound care, disease process, etc. They frequently change the angle of the orthoses, add custom components, adapt these orthoses for wounds, and otherwise customize these prefabricated orthoses for the patient s individual needs. I do not feel that this type of customization could be preformed by a non-therapist that was not aware of all the aspects of my care.

In addition, my therapist expresses doubt about her ability to win a competitive bid. She has a small facility, and stocks only those items needed in her practice. While she has a variety of orthoses specific to her practice, I have been told that she would be unable to stock large amounts of goods outside of her expertise. As she stocks the devices that she feels will work best (not necessarily the most inexpensive), she has a very small profit margin with these goods and will be unable to bid significantly under the current reimbursement. I am concerned that a supply facility will stock the most inexpensive orthoses in order to ensure a margin of profit, regardless of my needs.

I also have concerns re: the need to go to another facility for my prefabricated orthoses. Hand therapists work with very acute patients, who frequently need immediate protection. Are these patients supposed to get in their car and drive to another facility unprotected, and then possibly have to wait for an appropriate device that may or may not be stocked? And what about the instruction that a therapist typically gives when a splint is placed? It goes beyond how to put on and take off the device. Will I have to go back to the therapist, possibly incurring another charge for evaluation and treatment, in order to get the advice that would have been given to me for free if I had received the orthosis in the therapist s office?

Finally, under the definition of custom orthoses, you did not mention occupational and physical therapists. Since they are currently supplying these orthoses, I strongly disagree with the wording of this definition. These therapists routinely supply custom orthoses that are critical to the effective treatment of the upper extremity patient.

Please consider exempting therapists from the competitive bidding program. I fear that you will loose a very valuable professional in the distribution of prefabricated orthoses through this program, the hand therapist that has an in depth and intimate understanding of my injury and orthotic needs.

Thank you for your consideration.

Submitter : **Mrs. Phyllis Cummings** **Date: 06/29/2006**

Organization : **Mrs. Phyllis Cummings**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

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

Attention: CMS-1270-P

Opposed to Definition of Prefabricated Orthoses

Opposed to Competitive Bidding for Prefabricated Orthoses

Dear Administrator:

I would like to take this opportunity to comment on the proposed rule CMS-1270-P. I am currently receiving occupational therapy at a hand therapy facility. I can see that orthoses are a large part of the treatment for these patients. While most are custom fabricated, prefabricated orthoses are also supplied. When a therapist supplies a prefabricated orthoses, they also instruct the patient in precautions, use, timetables for changes, wound care, disease process, etc. They frequently change the angle of the orthoses, add custom components, adapt these orthoses for wounds, and otherwise customize these prefabricated orthoses for the patient s individual needs. I do not feel that this type of customization could be preformed by a non-therapist that was not aware of all the aspects of my care.

In addition, my therapist expresses doubt about her ability to win a competitive bid. She has a small facility, and stocks only those items needed in her practice. While she has a variety of orthoses specific to her practice, I have been told that she would be unable to stock large amounts of goods outside of her expertise. As she stocks the devices that she feels will work best (not necessarily the most inexpensive), she has a very small profit margin with these goods and will be unable to bid significantly under the current reimbursement. I am concerned that a supply facility will stock the most inexpensive orthoses in order to ensure a margin of profit, regardless of my needs.

I also have concerns re: the need to go to another facility for my prefabricated orthoses. Hand therapists work with very acute patients, who frequently need immediate protection. Are these patients supposed to get in their car and drive to another facility unprotected, and then possibly have to wait for an appropriate device that may or may not be stocked? And what about the instruction that a therapist typically gives when a splint is placed? It goes beyond how to put on and take off the device. Will I have to go back to the therapist, possibly incurring another charge for evaluation and treatment, in order to get the advice that would have been given to me for free if I had received the orthosis in the therapist s office?

Finally, under the definition of custom orthoses, you did not mention occupational and physical therapists. Since they are currently supplying these orthoses, I strongly disagree with the wording of this definition. These therapists routinely supply custom orthoses that are critical to the effective treatment of the upper extremity patient.

Please consider exempting therapists from the competitive bidding program. I fear that you will loose a very valuable professional in the distribution of prefabricated orthoses through this program, the hand therapist that has an in depth and intimate understanding of my injury and orthotic needs.

Thank you for your consideration.

Submitter : **Mrs. Eva Lafferty** **Date: 06/29/2006**

Organization : **Mrs. Eva Lafferty**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

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

Attention: CMS-1270-P

Opposed to Definition of Prefabricated Orthoses

Opposed to Competitive Bidding for Prefabricated Orthoses

Dear Administrator:

I would like to take this opportunity to comment on the proposed rule CMS-1270-P. I am currently receiving occupational therapy at a hand therapy facility. I can see that orthoses are a large part of the treatment for these patients. While most are custom fabricated, prefabricated orthoses are also supplied. When a therapist supplies a prefabricated orthoses, they also instruct the patient in precautions, use, timetables for changes, wound care, disease process, etc. They frequently change the angle of the orthoses, add custom components, adapt these orthoses for wounds, and otherwise customize these prefabricated orthoses for the patient s individual needs. I do not feel that this type of customization could be preformed by a non-therapist that was not aware of all the aspects of my care.

In addition, my therapist expresses doubt about her ability to win a competitive bid. She has a small facility, and stocks only those items needed in her practice. While she has a variety of orthoses specific to her practice, I have been told that she would be unable to stock large amounts of goods outside of her expertise. As she stocks the devices that she feels will work best (not necessarily the most inexpensive), she has a very small profit margin with these goods and will be unable to bid significantly under the current reimbursement. I am concerned that a supply facility will stock the most inexpensive orthoses in order to ensure a margin of profit, regardless of my needs.

I also have concerns re: the need to go to another facility for my prefabricated orthoses. Hand therapists work with very acute patients, who frequently need immediate protection. Are these patients supposed to get in their car and drive to another facility unprotected, and then possibly have to wait for an appropriate device that may or may not be stocked? And what about the instruction that a therapist typically gives when a splint is placed? It goes beyond how to put on and take off the device. Will I have to go back to the therapist, possibly incurring another charge for evaluation and treatment, in order to get the advice that would have been given to me for free if I had received the orthosis in the therapist s office?

Finally, under the definition of custom orthoses, you did not mention occupational and physical therapists. Since they are currently supplying these orthoses, I strongly disagree with the wording of this definition. These therapists routinely supply custom orthoses that are critical to the effective treatment of the upper extremity patient.

Please consider exempting therapists from the competitive bidding program. I fear that you will loose a very valuable professional in the distribution of prefabricated orthoses through this program, the hand therapist that has an in depth and intimate understanding of my injury and orthotic needs.

Thank you for your consideration.

Submitter : **Ms. Marilyn Ruffing** **Date: 06/29/2006**

Organization : **Ms. Marilyn Ruffing**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

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

Attention: CMS-1270-P

Opposed to Definition of Prefabricated Orthoses

Opposed to Competitive Bidding for Prefabricated Orthoses

Dear Administrator:

I would like to take this opportunity to comment on the proposed rule CMS-1270-P. I am currently receiving occupational therapy at a hand therapy facility. I can see that orthoses are a large part of the treatment for these patients. While most are custom fabricated, prefabricated orthoses are also supplied. When a therapist supplies a prefabricated orthoses, they also instruct the patient in precautions, use, timetables for changes, wound care, disease process, etc. They frequently change the angle of the orthoses, add custom components, adapt these orthoses for wounds, and otherwise customize these prefabricated orthoses for the patient s individual needs. I do not feel that this type of customization could be preformed by a non-therapist that was not aware of all the aspects of my care.

In addition, my therapist expresses doubt about her ability to win a competitive bid. She has a small facility, and stocks only those items needed in her practice. While she has a variety of orthoses specific to her practice, I have been told that she would be unable to stock large amounts of goods outside of her expertise. As she stocks the devices that she feels will work best (not necessarily the most inexpensive), she has a very small profit margin with these goods and will be unable to bid significantly under the current reimbursement. I am concerned that a supply facility will stock the most inexpensive orthoses in order to ensure a margin of profit, regardless of my needs.

I also have concerns re: the need to go to another facility for my prefabricated orthoses. Hand therapists work with very acute patients, who frequently need immediate protection. Are these patients supposed to get in their car and drive to another facility unprotected, and then possibly have to wait for an appropriate device that may or may not be stocked? And what about the instruction that a therapist typically gives when a splint is placed? It goes beyond how to put on and take off the device. Will I have to go back to the therapist, possibly incurring another charge for evaluation and treatment, in order to get the advice that would have been given to me for free if I had received the orthosis in the therapist s office?

Finally, under the definition of custom orthoses, you did not mention occupational and physical therapists. Since they are currently supplying these orthoses, I strongly disagree with the wording of this definition. These therapists routinely supply custom orthoses that are critical to the effective treatment of the upper extremity patient.

Please consider exempting therapists from the competitive bidding program. I fear that you will loose a very valuable professional in the distribution of prefabricated orthoses through this program, the hand therapist that has an in depth and intimate understanding of my injury and orthotic needs.

Thank you for your consideration.

Submitter : Mr. Donald Lowe **Date:** 06/29/2006

Organization : Mr. Donald Lowe

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

Attention: CMS-1270-P

Opposed to Definition of Prefabricated Orthoses

Opposed to Competitive Bidding for Prefabricated Orthoses

Dear Administrator:

I would like to take this opportunity to comment on the proposed rule CMS-1270-P. I am currently receiving occupational therapy at a hand therapy facility. I can see that orthoses are a large part of the treatment for these patients. While most are custom fabricated, prefabricated orthoses are also supplied. When a therapist supplies a prefabricated orthoses, they also instruct the patient in precautions, use, timetables for changes, wound care, disease process, etc. They frequently change the angle of the orthoses, add custom components, adapt these orthoses for wounds, and otherwise customize these prefabricated orthoses for the patient s individual needs. I do not feel that this type of customization could be preformed by a non-therapist that was not aware of all the aspects of my care.

In addition, my therapist expresses doubt about her ability to win a competitive bid. She has a small facility, and stocks only those items needed in her practice. While she has a variety of orthoses specific to her practice, I have been told that she would be unable to stock large amounts of goods outside of her expertise. As she stocks the devices that she feels will work best (not necessarily the most inexpensive), she has a very small profit margin with these goods and will be unable to bid significantly under the current reimbursement. I am concerned that a supply facility will stock the most inexpensive orthoses in order to ensure a margin of profit, regardless of my needs.

I also have concerns re: the need to go to another facility for my prefabricated orthoses. Hand therapists work with very acute patients, who frequently need immediate protection. Are these patients supposed to get in their car and drive to another facility unprotected, and then possibly have to wait for an appropriate device that may or may not be stocked? And what about the instruction that a therapist typically gives when a splint is placed? It goes beyond how to put on and take off the device. Will I have to go back to the therapist, possibly incurring another charge for evaluation and treatment, in order to get the advice that would have been given to me for free if I had received the orthosis in the therapist s office?

Finally, under the definition of custom orthoses, you did not mention occupational and physical therapists. Since they are currently supplying these orthoses, I strongly disagree with the wording of this definition. These therapists routinely supply custom orthoses that are critical to the effective treatment of the upper extremity patient.

Please consider exempting therapists from the competitive bidding program. I fear that you will loose a very valuable professional in the distribution of prefabricated orthoses through this program, the hand therapist that has an in depth and intimate understanding of my injury and orthotic needs.

Thank you for your consideration.

Submitter : Mr. Michael Flores

Organization : Huntleigh Home Medical, Ltd

Category : Other Health Care Provider

Date: 06/29/2006

Issue Areas/Comments

Background

Testing if it works

See Attached

CMS-1270-P-852-Attach-1.DOC

CMS-1270-P-852-Attach-2.DOC

Comments on the Notice of Proposed Rule Making of Competitive Acquisition

1. There are too many unkowns
    a. We don't know which DME items are being considered
    b. Which providers will be subject to competitive bidding process
    c. We don't know anything about what the quality standards are going to be.

2. Test Project Incomplete
    a. CMS/HCFA was supposed to have done three test project, they only did two and they didn't even finish those.
    b. The results were not tabulized. They only saw, on paper (in theory), that savings could be done, but they were not factored in with the cost of implementation and the impact of services to beneficiaries. This behavior is reckless and unlawful!!!

3. Weakens Competition and promotes BIG Business and not small Business
    a. Fewer suppliers have strength to control pricing.
    b. Competitive Bidding favors large corporations with deep pockets by allowing them to purposefully underbid. This will enable them to gain contracts then wield control over the market.

4. Quality Standards are Important and Supported
    a. But how can we make comments on substance that doesn't exist yet?

5. Rebates
    a. Opens the door for fraud and abuse…lets keep honest people honest.

Submitter : **Miss. jan lipstreuer** **Date: 06/29/2006**

Organization : **Miss. jan lipstreuer**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

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

Attention: CMS-1270-P

Opposed to Definition of Prefabricated Orthoses

Opposed to Competitive Bidding for Prefabricated Orthoses

Dear Administrator:

I would like to take this opportunity to comment on the proposed rule CMS-1270-P. I am currently receiving occupational therapy at a hand therapy facility. I can see that orthoses are a large part of the treatment for these patients. While most are custom fabricated, prefabricated orthoses are also supplied. When a therapist supplies a prefabricated orthoses, they also instruct the patient in precautions, use, timetables for changes, wound care, disease process, etc. They frequently change the angle of the orthoses, add custom components, adapt these orthoses for wounds, and otherwise customize these prefabricated orthoses for the patient s individual needs. I do not feel that this type of customization could be preformed by a non-therapist that was not aware of all the aspects of my care.

In addition, my therapist expresses doubt about her ability to win a competitive bid. She has a small facility, and stocks only those items needed in her practice. While she has a variety of orthoses specific to her practice, I have been told that she would be unable to stock large amounts of goods outside of her expertise. As she stocks the devices that she feels will work best (not necessarily the most inexpensive), she has a very small profit margin with these goods and will be unable to bid significantly under the current reimbursement. I am concerned that a supply facility will stock the most inexpensive orthoses in order to ensure a margin of profit, regardless of my needs.

I also have concerns re: the need to go to another facility for my prefabricated orthoses. Hand therapists work with very acute patients, who frequently need immediate protection. Are these patients supposed to get in their car and drive to another facility unprotected, and then possibly have to wait for an appropriate device that may or may not be stocked? And what about the instruction that a therapist typically gives when a splint is placed? It goes beyond how to put on and take off the device. Will I have to go back to the therapist, possibly incurring another charge for evaluation and treatment, in order to get the advice that would have been given to me for free if I had received the orthosis in the therapist s office?

Finally, under the definition of custom orthoses, you did not mention occupational and physical therapists. Since they are currently supplying these orthoses, I strongly disagree with the wording of this definition. These therapists routinely supply custom orthoses that are critical to the effective treatment of the upper extremity patient.

Please consider exempting therapists from the competitive bidding program. I fear that you will loose a very valuable professional in the distribution of prefabricated orthoses through this program, the hand therapist that has an in depth and intimate understanding of my injury and orthotic needs.

Thank you for your consideration.

Submitter : Mr. Allyn Lipstreuer **Date:** 06/29/2006

Organization : Mr. Allyn Lipstreuer

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

Attention: CMS-1270-P

Opposed to Definition of Prefabricated Orthoses

Opposed to Competitive Bidding for Prefabricated Orthoses

Dear Administrator:

I would like to take this opportunity to comment on the proposed rule CMS-1270-P. I am currently receiving occupational therapy at a hand therapy facility. I can see that orthoses are a large part of the treatment for these patients. While most are custom fabricated, prefabricated orthoses are also supplied. When a therapist supplies a prefabricated orthoses, they also instruct the patient in precautions, use, timetables for changes, wound care, disease process, etc. They frequently change the angle of the orthoses, add custom components, adapt these orthoses for wounds, and otherwise customize these prefabricated orthoses for the patient s individual needs. I do not feel that this type of customization could be preformed by a non-therapist that was not aware of all the aspects of my care.

In addition, my therapist expresses doubt about her ability to win a competitive bid. She has a small facility, and stocks only those items needed in her practice. While she has a variety of orthoses specific to her practice, I have been told that she would be unable to stock large amounts of goods outside of her expertise. As she stocks the devices that she feels will work best (not necessarily the most inexpensive), she has a very small profit margin with these goods and will be unable to bid significantly under the current reimbursement. I am concerned that a supply facility will stock the most inexpensive orthoses in order to ensure a margin of profit, regardless of my needs.

I also have concerns re: the need to go to another facility for my prefabricated orthoses. Hand therapists work with very acute patients, who frequently need immediate protection. Are these patients supposed to get in their car and drive to another facility unprotected, and then possibly have to wait for an appropriate device that may or may not be stocked? And what about the instruction that a therapist typically gives when a splint is placed? It goes beyond how to put on and take off the device. Will I have to go back to the therapist, possibly incurring another charge for evaluation and treatment, in order to get the advice that would have been given to me for free if I had received the orthosis in the therapist s office?

Finally, under the definition of custom orthoses, you did not mention occupational and physical therapists. Since they are currently supplying these orthoses, I strongly disagree with the wording of this definition. These therapists routinely supply custom orthoses that are critical to the effective treatment of the upper extremity patient.

Please consider exempting therapists from the competitive bidding program. I fear that you will loose a very valuable professional in the distribution of prefabricated orthoses through this program, the hand therapist that has an in depth and intimate understanding of my injury and orthotic needs.

Thank you for your consideration.

Submitter : Dr. Gerald Rogan **Date:** 06/29/2006

Organization : Rogan Consulting

Category : Physician

Issue Areas/Comments

Conditions for Awarding Contracts

Conditions for Awarding Contracts

Recommendations for Incorporation into Final Rule CMS-1270:
1. '414.414: Conditions for awarding contracts.: (c) Quality standards and accreditation.
a. Recommendation: Add an additional section (3) Compliance program. All bidding suppliers must include in their bid a compliance program designed to assure that the items provided to beneficiaries are reasonable and necessary consistent with the purpose for which the item is prescribed by the referring (treating) practitioner.
b. CMS should consider whether to specify in the regulation that --- CMS reserves the right to consider factors other than price to award a contract (e.g. the quality of a compliance program: the likelihood that a bidder s compliance program will assure services provided are reasonable and necessary).

2. '414.422: Terms of contracts.:
Recommendation: Add to (a) A contract supplier must comply with all terms of its contract, including any option exercised by CMS, including but not limited to contract award conditions specified in '414.414(c), for the full duration of the contract period.

Rationale: These proposals may further effectuate the intent the following goals articulated in the regulation:
' Improve the efficient interaction among manufacturers, providers of services, suppliers, and individuals;
' Increase oversight of product provision in an efficient manner that includes provider innovations consistent with sound business practices and recommendation of the OEI/OIG;
' In addition to requiring specified quality standards and accreditation , provide for additional accountability and business integrity through a readily auditable program to assure that the items supplied to beneficiaries are reasonable and necessary;
' Encourage DME suppliers to optimize information management techniques that meet these goals;
' Encourage and reward DME suppliers that contribute to an improvement of net health outcomes by facilitating the communication of the results of diagnostic tests (performed with DME supplies) to the referring practitioner to support superior decision-making;
' Assure that DME supplier eligibility fulfills the OEI/OIG recommendations that CMS supports: those that are likely to help assure DME items supplied to beneficiaries are reasonable and necessary (i.e. are not compromised by fraud, abuse, or waste);

In order to assure savings under the Medicare DMEPOS Competitive Bid Program, CMS should consider whether a bidder s robust compliance program, fully effectuated and proven effective by independent audit, may substantially assure the affected DME items provided are reasonable and necessary, even when the payment for a few individual items within a product category is higher than the allowable established by the Pivotal Bid. If CMS agrees with this intent, the Final Rule should permit CMS to consider the value of a provider s compliance program designed to assure statutory reasonable and necessary requirements are met . CMS may wish to consider non-price variables when awarding contracts for certain DMEPOS items.

For example, the Final Rule should allow CMS to consider the value of innovative business models that are likely to assure that DME supplies provided to beneficiaries are reasonable and necessary , including:
a. Assurance that DME supplies for self-administered tests are used by the beneficiary for illness management;
b. Assurance the practitioner who orders the supplies is regularly informed of the beneficiary s self-management test activity; and
c. A method by which DHHS agencies may readily audit the activities of the DME supplier to assure its compliance with contract requirements.

ABt Associates recommended parameters of (1) business quality standards and (2) product quality standards. I believe the ABt recommendations do not go far enough to meet the needs of program integrity outlined by the OEI/OIG and agreed upon by the Agency. The OEI/OIG recommends a voluntary DME compliance program.

Terms of Contracts

Terms of Contracts

Recommendations for Incorporation into Final Rule CMS-1270:
1. '414.414: Conditions for awarding contracts.: (c) Quality standards and accreditation.
a. Recommendation: Add an additional section (3) Compliance program. All bidding suppliers must include in their bid a compliance program designed to assure that the items provided to beneficiaries are reasonable and necessary consistent with the purpose for which the item is prescribed by the referring (treating) practitioner.
b. CMS should consider whether to specify in the regulation that --- CMS reserves the right to consider factors other than price to award a contract (e.g. the quality of a compliance program: the likelihood that a bidder s compliance program will assure services provided are reasonable and necessary).

2. '414.422: Terms of contracts.:
Recommendation: Add to (a) A contract supplier must comply with all terms of its contract, including any option exercised by CMS, including but not limited to contract award conditions specified in '414.414(c), for the full duration of the contract period.

Rationale Summary: Competitive bidding will reduce the overpayment driver of waste, abuse, and fraud. Mandatory compliance will increase effective program safeguards.

See attached file for full explanation.

CMS-1270-P-855-Attach-1.DOC

Submitter : DOUG TARCHALSKI **Date:** 06/29/2006

Organization : HURON VALLEY HOME-CARE SUPPLY, INC.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

6-29-06
I AM VERY OVERWELMED BY THIS ENTIRE THING OF COMPETITIVE BIDDING. WE ARE A PRIVATE, ONE LOCATION DME COMPANY. WE HAVE BEEN SUPPLYING DME TO THE AREA NOW FOR 25 YEARS. WE HAVE APROX 100 OXYGEN PATIENTS THAT WE TAKE CARE OF. I DO NOT SEE ANY WAY THAT WE WILL BE ABLE TO SURVIVE THIS. WE DON'T HAVE THE RESORCES TO PUT INTO WHAT IT WILL TAKE. WE ARE HARDLY MAKING IT NOW WITH ALL OF THE CUTBACKS IN ALLOWABLES. ALSO, THE MANDATORY ACCREDITATION IS SOMETHING THAT I DON'T KNOW IF WE CAN AFFORD TO IMPLEMENT. I DON'T KNOW WHERE THE MONEY WILL COME FROM TO DO THIS AND PREPARE. I BELIEVE THAT THIS WILL PUT US OUT OF BUISNESS AND SEND OUR CURRENT PATIENTS SCRAMBLING TO GET SERVICED. THEY DEPEND ON US FOR THEIR HOME CARE EQUIPMENT AND SUPPLIES.
PLEASE GRANDFATHER US SMALL DME COMPANIES SO THAT WE CAN MATCH WHATEVER THE WINNING BID IS, AND ALSO CONTINUE TO SUPPLY OUR AREA WITHOUT HAVING TO BECOME ACCREDITED. WE HAVE BEEN DOING THIS FOR 25 YEARS AND ARE VERY GOOD AT WHAT WE DO. WE HAVE NEVER HAD A PROBLEM OR HAVE NEVER BEEN SUED. NEVER !.
PLEASE DELAY THE IMPLEMENTATION OF THIS. PLEASE DON'T RUSH IT.
YOU ARE MOVING MUCH TOO QUICKLY. OUR PEOPLE ARE AT RISK.
THE ACCREDITATION SHOULD BE IN PLACE FIRST, AHEAD OF COMETITIVE BIDDING.
PLEASE TAKE INTO CONSIDERATION THE END USERS. THEY WILL SUFFER OVER THIS.
MAKE IT EASY FOR US PROVIDERS TO SELL OUR BUISNESSES. MANY OF US WILL HAVE TO.
THE REBATE PORTION OF THIS IS CONFUSING AND GOES AGAINST THE ANTI-KICKBACK LAWS WE ABIDE BY.
YOU HAVE TO CLARIFY THE PRODUCT SELECTION.
THE BIDDING PROCESS MUST BE MADE EASIER FOR US SMALLER SUPPLIERS.
PLEASE MAKE IT EASIER FOR SMALLER SUPPLIERS TO GAIN ACCESS.
CMS SHOULD HAVE TO CLARIFY THE POTENTIAL SAVINGS THEY EXPECT TO GAIN FROM THIS, AND EXPLAIN THE METHODOLOGY WICH THEY USE TO DETERMINE THEM.
CMS SHOULD MAKE IT EASY FOR US SMALL DME'S TO NETWORK AND SUB-CONTRACT WITH OTHER DME'S. THIS MAY BE THE ONLY WAY WE CAN SURVIVE THIS MESS.
OUR BUISINESSES ARE IN DANGER HERE ALONG WITH THE SAFTEY AND WELL BEING OF OUR PATIENTS THAT WE LOVE AND HOLD SO DEAR.
PLEASE DO THIS RIGHT SO THAT EVERYONE INVOLVED IS TAKEN CARE OF AND NOBODY IS LEFT OUT. MOST IMPORTANTLY OUR PATIENTS.

PLEASE HELP US.

DOUGLAS AND ROBIN TARCHALSKI
OWNERS
HURON VALLEY HOME-CARE SUPPLY, INC.
HIGHLAND, MICHIGAN, 48356
248-887-4343

FOUNDED 7-1-81

Submitter : **Dr. Sandra Hudak** **Date: 06/29/2006**

Organization : **Tri-State Foot and Ankle Center / APMA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Dear Dr. McClellan,

I write to urge CMS to modify the physician definition from 1861(r) (1) to 1861(r) before continuing with any regulations regarding the new competitive aquisition program relative to DMEPOS related supplies.

PLEASE UNDERSTAND THIS: Podiatrists provide specialized foot and ankle care - in many cases, beyond the understanding of primary care physicians, beyond the initial care rendered in emergency rooms and urgent care centers, and beyond the knowledge of many orthotists/ prosthetists. To use a definition of physician that excludes podiatric physicians reveals a lack of knowledge of the podiatric profession and its integral role in today's society. Additionally, the training of podiatrists has continued to intensify, with many newer podiatric physicians having, like myself, at least three years of surgical training in foot and ankle procedures.

In taking away my ability to provide my patients with DME devices, CMS would cause not only a disruption in the continuity of their care, but could also directly jeopardize this care.

As podiatrists have specialized knowledge in foot and ankle pathology and/ or injury, we are best qualified to choose, make, or order the most appropriate devices for our patients. Requiring patients to obtain devices from those who may not concentrate /specialize in foot and ankle care can result in the inappropriate selection of such devices. This can set a patient back in their plan of care, which can lend to either having to order new devices (waste), or can lend to the need for prolonged care/ additional services, as well as directly impacting the patient's immediate care.

Secondly, in forcing patients to obtain needed items from secondary locations, the following scenario ensues (we currently accept some insurance plans which have already elected to force patients to secondary locations for DME products, and have inside knowledge on how this plays out) ..... There is a gap in communication between the prescription written by the physician and the staff of the facility or office where the patient needs to obtain the product. Often times, patients will return and say " they didn't have that in my size" - or, the quality of what they had is nothing comparable to what you wanted for me. I have had several patients have to drive to two or three facilities just to get what I finally ordered due to an inventory problem. If there is some benefit to Medicare, for instituting such a policy, it must be acknowledged as a MAJOR disservice to patients! If anything, DME devices relative to different specialties should ONLY BE DISTRIBUTED BY THE SPECIALIST - which STREAMLINES CARE, ELIMINATES ERROR AND WASTE, and MAKES SENSE.

Hundreds of thousands of patients' feet and limbs have been salvaged through the careful efforts of their podiatric physicians. As a physician yourself, I am sure that you can appreciate that political choice should fuse with the realities our patients face. YOU are in a position to achieve this!

As a physician participating in the Medicare program, I should have the same right to treat my patients and dispense the products necessary to treat them with the highest standard of care as would any other MD or DO participating physician. I therefore hope that your office will reconsider using 1861(r)(1) and will apply the broader definition, including podiatric physicians (1861(r)), and will allow us to competitively bid to supply DMEPOS - only to our patients, while abiding by all supplier standars, including Stark requirements.

I implore you to do the right thing!

Respectfully,

Sandra L. Hudak, DPM

Submitter : **Dr. Michael Robinson** **Date: 06/29/2006**

Organization : **Amer. Pod. Med Assoc.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

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

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

In my practice, I use a variety of DMEPOS items. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries.

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

Sincerely,

Michael A. Robinson, DPM, MPH

Submitter : **Dr. Arnold Zuckman** **Date: 06/29/2006**

Organization : **Dr. Arnold Zuckman**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

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

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

In my practice, I use a variety of DMEPOS items. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries.

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

Sincerely,

Arnold Zuckman DPM

Submitter :

Date: 06/29/2006

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I believe that customers should be able to receive their DME supplies from any pharmacy or supplier they choose. If competitive bidding is forced upon small suppliers, most of us would go out of business. This would leave customers with no choice but to hunt for another supplier, whose prices are probably high due to there only being large companies who supply DME.

It would truly be a shame for customers to lose the dedication and closeness they get from us because of competitive bidding. Our pharmacy will not be able to compete with large bidders who will have lower prices to begin with and as soon as small businesses close, because they can't compete, the large companies jack the prices up. It's a monopoly waiting to happen.

People appreciate being able to go just down the street for supplies vs. driving a long distance to stand in line or calling an 800 number to be placed on hold for any length of time. I also feel that people will be more likely to get DME prescribed to them if the equipment is at a local pharmacy or DME supplier.

At the least, I feel that there should be a different type of bidding process for small independently owned businesses.

For these reasons our pharmacy is against Competitive Bidding in Rural areas.

Submitter : Mrs. Kamela Yuricich **Date:** 06/29/2006

Organization : Ohio Association of Medical Equipment Services

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1270-P-861-Attach-1.DOC

OHIO ASSOCIATION OF
MEDICAL EQUIPMENT SERVICES

SUBMITTED ELECTRONICALLY

June 29, 2006

Mark McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

The Ohio Association of Medical Equipment Services (OAMES) is pleased to submit comments on CMS' Notice of Proposed Rulemaking (NPRM) for Competitive Acquisition for Certain DMEPOS and Other Issues. OAMES is a state trade association with over 200 company members representing home medical equipment providers, manufacturers, wholesalers, repair businesses, IT companies, billing agencies, consultants, law firms and others who serve Medicare beneficiaries in the state of Ohio.

OAMES is an active member of the American Association for Homecare (AAHomecare) and fully supports the detailed comments and concerns of this organization. The following pages summarize the association's key issues as they affect Ohio providers related to CMS' Notice of Proposed Rulemaking published May 1, 2006 in the *Federal Register* (71 *Federal Register* 25654), Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues.

OHIO ASSOCIATION OF MEDICAL EQUIPMENT SERVICES
17 South High Street, Suite 1000
Columbus, Ohio 43215
614/876-2424 phone ~ 614/228-7702

TIMING

Deficit Reduction Act

The information in the NPRM is inadequate to serve as a basis for public comments, especially with respect to the impact that the implementation of the Deficit Reduction Act of 2005 (DRA) will have on competitive acquisition.

Quality Supplier Standards

Without quality standards in place before the bidding process begins, bidding will not be done in the full and proper context of service expectations. Furthermore, CMS must allow stakeholders an opportunity to comment on the quality standards BEFORE they are finalized. OAMES strongly supports a requirement that all suppliers billing Medicare must meet quality standards. In fact in Ohio, we passed a strong licensure law in 2004 which mandates a certain level of business and patient care standards. However, for those states who don't, and until accreditation is in place for all companies, bid prices will not likely reflect the service component vitally important to providing care.

Realistic Timetable

There is genuine concern among home medical equipment providers in Ohio that the implementation schedule, what little is definitively known, is very aggressive and much too rushed to handle such a complete change in payment methodology to a vast community of providers and beneficiaries. We urge CMS to adopt a realistic timeline and not rush through the process which causes such a radical change impacting providers and consumers.

PAYMENT BASIS

There are a number of concerns related to payment issues first and foremost that this initiative, as it is developing, is becoming unbelievably complicated and is causing very grave concerns among our member companies. Here is a list of issues OAMES is concerned with as the rule impact reimbursement:

- Inflation Update - CMS states competitive bid prices will be updated by the CPI-U, however, there is no assurance that Congress will not over-ride this in any future legislation.

- Medicare Advantage - The rule does not address the impact of competitive bidding on Medicare Advantage patients who leave their plan to reenter traditional Medicare.

- Switching Providers - As described in the AAHomecare comments, the rule allows for beneficiaries to switch suppliers at any time. While we appreciate CMS' recognition that beneficiaries should have the freedom to change providers, there needs to be consideration for the billing processes that are interrupted when a switch occurs.

- DRA Impact on Oxygen Patients - The NPRM does not address the recently passed initiative in the DRA that forces the ownership of oxygen equipment and capped rental equipment. The implementation of this law will have ramifications for competitive bidding and it is important to understand how CMS will administer the DRA requirements. We urge CMS to publish an interim rule before it publishes a final competitive acquisition rule.

- Authority to Adjust Payments - AAHomecare provides a legal analysis of the NPRM as it relates to CMS' ability to use the payment information obtained through competitive bidding to adjust the payment amounts for those items in areas outside of the competitive bidding area. In implementing this authority, CMS should adhere to the inherent reasonableness (IR) methodology authorized by Congress under the Benefits Improvement and Patient Protect Act. This allows for procedural steps to protect stakeholders and requires an analysis of the basis to make a payment adjustment.

- Limitation on Beneficiary Liability - CMS should clarify what it means in rule when it states that a beneficiary will have no financial liability to a non-contract supplier for competitively bid items furnished by that supplier.

COMPETITIVE BIDDING AREAS

Implementation

OAMES recommends that the initial implementation of competitive bidding in the first ten MSAs be staggered. This would allow CMS to identify and correct problems as the program is rolled out before implementation is full-scale.

Mail Order

There is no definition of a "mail order" supplier under Medicare program rules thus we do not understand why a separate competitive bidding program is proposed in 2010. Many providers supply items to beneficiaries by mail order yet also provide retail or delivery services in the home. There are many factors that determine the appropriate delivery and distribution method including not only cost and efficiencies but changes in a beneficiary's supply needs, change in medical condition, etc. This initiative raises many questions and additional detail is necessary for further public comment.

Bid Areas

CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The Medicare Modernization Act is clear that the competitive acquisition areas will be established in an MSA. CMS needs to identify the MSAs they've selected for competitive bidding as soon as possible.

CRITERIA FOR ITEM SELECTION

Ostomy products and supplies are not "durable medical equipment" and therefore do not meet the definition of "covered items" as defined under §1834(a)(13). CMS needs to confirm that

ostomy products and supplies are not included in competitive bidding under §1847(a)(2).

Potential for Savings

There are many unanswered questions which we urge CMS to explain and clarify what specific measures will be used to decide an item's potential savings as a result of competitive bidding.

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

Criteria for Item Selection

One of the most prevalent concerns expressed by OAMES members is the criteria for selecting the items to competitive bid. The over-riding issue the industry historically has had with this payment model is the program appears to be driven by costs and utilization only. There is a real risk that by focusing exclusively on the commodity and not the service, CMS creates a benefit with the emphasis on the product and not patient care. An extreme yet logically consistent argument would be to pay for the heart patient's pacemaker, yet not the medical staff, operating room and other expenses associated with this treatment. We strongly urge CMS to consider clinical and service factors specific to products and the patient's prescribed medical care. CMS should publish the items it plans to competitive bid in an interim rule for further public comment.

Brand-Specific

We recommend that CMS not include this provision in the final rule. This requirement will promote a demand for premium or brand name items based on direct to consumer advertising, even though the "brand name" product has the same clinical benefit as other products. Physicians are often not current on the features and benefits of new technologies and rely on the homecare provider's expertise and clinical staff to help match the patient's needs to the equipment or supplies. Furthermore, the proposal is contrary to how suppliers do business, not only under the Medicare program, but with all payers. Providers carry items and equipment that the FDA deems to be functionally equivalent to other products. Having to carry all possible items and equipment is unreasonable, extremely costly and burdensome and will increase suppliers' costs, reducing potential savings from competitive bidding.

Coding Issues and Item Selection

We recommend that CMS not include power wheelchairs in the initial rounds of competitive bidding because it would lack recent data from which to determine the HCPCS codes that represent the highest costs and highest volume for CMS. The methodology that CMS proposes

for item selection relies on historical data and does not take into account recent changes in a benefit, particularly the most recent changes on power wheelchairs that effects utilization.

PRODUCT CATEGORIES FOR BIDDING PURPOSES

Overall, clear definition of the product categories must be outlined for bidding suppliers and all HCPCS codes and their typical quantities should be identified for each product category that the supplier bids.

Requirements to Bid on all Products in a Category

As described in the rule, providers may choose to bid on one, some, or all of the product categories, but if a provider bids on a category, that provider must bid on each item included in the category. This is a concern to OAMES members who represent a wide variety of business types and market diversity. CMS must define products categories narrowly, to make sure that they are consistent and representative of the products that a supplier might actually furnish. The American Association for Homecare provided considerable detail that OAMES supports regarding this rule. This is particularly problematic for more sophisticated products in rehab and assistive technology areas.

CONDITIONS FOR AWARDING CONTRACTS

OAMES membership participated in an OAMES-sponsored educational teleconference call on June 23 to be educated on the proposed rules for the competitive bidding program as proposed by CMS in the NPRM. Without question, this area of the rule was one of the most confusing and troubling sections discussed since it has the potential for the greatest impact on the traditional consumer-to-provider relationship.

Quality Standards and Accreditation

CMS should not proceed with competitive bidding until it is sure that that all suppliers who may want to submit bids have had an opportunity to get accredited. Furthermore, CMS should promote an aggressive accreditation campaign to assure that providers in any MSA with a competitive bidding program are accredited *before* the bid solicitations are published. First and foremost, CMS needs to identify the criteria it will use to select accrediting bodies *now*. While OAMES supports the quality initiative driving this process, there are practical and logistical concerns about having providers accredited and ready to submit bids when the organizations that would do the accrediting have not been selected. We recommend that CMS "fast track" accreditation in the manner that was suggested by the PAOC so that CMS can publish a notice soliciting public comments on the organizations that are seeking designation as an accrediting body.

Market and Supplier Capacity

The NPRM states that CMS will evaluate market capacity and supplier capacity to determine the number of suppliers necessary to service beneficiaries in an MSA. OAMES agrees that CMS must carefully evaluate capacity issues to ensure adequate access to DMEPOS items in a competitive bidding area. This is another fundamental flaw to a competitive bidding model which erodes competition by guaranteeing exclusivity to limited bidders. Under the

methodology proposed in the NPRM, CMS would array the composite bids from lowest to highest and count up from the bottom until it identifies the point where the bidders' cumulative capacity is sufficient to service the MSA. This will be the winning, or "pivotal" bid, however, this methodology does not include any mechanism to "rationalize" the bids to ensure that there are no unreasonably low bids. Although competitive bidding is premised on the theory that suppliers will submit their "best bid," in fact there will be suppliers with small individual capacity who may submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity.

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

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

Assurance of Savings

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Instead, CMS should adopt the methodology used in the demonstrations. CMS should look for savings in the overall product category even though a single payment amount for a specific item may be higher than its current fee schedule amount.

Determining the Single Payment Amounts for Individual Items

Based on the rule, CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the "winning suppliers". This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also significantly different than the method used in the Polk County, Florida, and San Antonio, Texas, demonstration projects. Therefore, we believe CMS should set the payment amount at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This was the method used in the two demonstration projects.

Rebate Program

This initiative was a complete surprise and is fundamentally flawed. CMS proposes to make the rebate program voluntary, however, would not allow suppliers to advertise the rebate to beneficiaries. Instead, CMS would distribute program materials in the competitive bidding area that would identify contract suppliers that offer rebates. OAMES has serious concerns about the program integrity ramifications this proposal would create and questions how CMS can reconcile a rebate program of this type with the statutory prohibition on beneficiary inducements under §1128A(a)(5) of the Act. We fully support the legal concerns described in AAHomecare's comments on this initiative.

TERMS OF CONTRACT

Repair or Replacement of Equipment

CMS will require contract suppliers to accept all beneficiaries within the competitive bidding area. CMS will also require contract suppliers to repair or replace beneficiary owned equipment under the competitive bidding program. As previously mentioned, we recommend that CMS allow a new period of continuous use to begin when a beneficiary switches to a contract supplier. This preserves the beneficiary's choice and protects the contract provider who may have to furnish equipment to the beneficiary without adequate compensation for the item or the service it requires. This is especially a concern since the senior population is often mobile and may vacation through winter far away from their place of residence ("snow-birds"). We recommend the repair of patient owned equipment be treated as a separately bid item on the RFB.

Termination of Contract

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

Judicial and Administrative Remedies

CMS should include a procedure for debriefing suppliers who did not win a bid and an opportunity for a review to determine at a minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

Change of Ownership

It is sensible for CMS to review a change of ownership to determine whether the buyer meets the quality standards before granting the new company contract supplier status. However, CMS cannot unreasonably withhold its approval of a change of ownership and should not deny winning supplier status to a new owner on the basis that its capacity is not necessary within the competitive bidding area. CMS should approve a change of ownership if the new entity will meet applicable quality standards and confirm to other requirements of competitive bidding. CMS approval should not be withheld based on a determination that the supplier's capacity was not necessary.

Opportunity for Participation of Small Suppliers

CMS has taken a very narrow view of its obligation to ensure that small providers are adequately represented among contract suppliers. This was a top concern to OAMES members who are overwhelmingly small, community-based businesses.

Opportunity for Networks

CMS' proposal for allowing networks does not consider the business development logistics in creating a new entity and under the timelines that CMS has announced, it will be difficult to establish networks that can meet the eligibility requirements for submitting bids. As such, this may not even be a viable option for most providers and does little, if anything to "protect" small business. CMS has also stated that the market share for supplier networks cannot exceed 20%. CMS should expand this to allow greater participation by small suppliers and also consider small provider set asides in at least some of the MSAs.

* * * * *

Thank you for the opportunity to provide comments on this important proposed regulation. Please contact Kam Yuricich at 614/876-2424 or by mail at kam@oames.org if you have any questions.

Sincerely,

Kam Yuricich

Kamela Yuricich
Executive Director
Ohio Association of Medical Equipment Services

Submitter : Dr. Timothy Scott **Date:** 06/29/2006

Organization : Dr. Timothy J. Scott,DPM,FASFAS

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

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

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

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

For example, if I treat a patient with an ankle injury, I may determine that an ankle brace is necessary to stabilize the ankle and crutches are necessary to limit weightbearing on the injured extremity. If I am not a DMEPOS supplier in the new competitive acquisition program because I was unsuccessful in competing to bid to supply to the entire MSA rather than just to my patients, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

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

Sincerely,
Dr. Timothy J. Scott DPM,FACFAS

Submitter : **Beverly Andersen** **Date: 06/29/2006**

Organization : **Highline Hand Therapy**

Category : **Occupational Therapist**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

see attachment

GENERAL

GENERAL

See attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Ms. Nancy Schlichting **Date:** 06/29/2006

Organization : Henry Ford Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-864-Attach-1.DOC

Office of The President & CEO
One Ford Place
Detroit, MI 48202
313-876-8708

June 29, 2006

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

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

Dear Sir or Madam,

Thank you for the opportunity to comment on proposed rule-making concerning competitive bidding for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). This proposal is of great interest to the Henry Ford Health System (HFHS) because it contains the potential to disrupt a continuum of care and services that we have constructed over a period of years for our patients and will adversely impact the continuity of care for all of our post-acute patients. We believe the rule should be revised to recognize the efforts and good progress many large health systems have made in filling gaps in service through the creation of home-based and other types of post-acute care.

Our comments identify the key problem areas. We also include suggested amendments to the proposed rule that would overcome these concerns. We believe the proposed rule-making creates a structure that interferes with efficient and high quality discharge planning, creates new burdens for patients and their families, and adversely affects costs. We strongly recommend that the proposed rule be amended to allow those DME companies owned and operated by health systems (like HFHS) to continue to serve Medicare patients, using the pricing that emerges from competitive bidding and complying with all quality standards.

We are very concerned that our own hospital-based DME company is not structured to compete for all patients in the region and thus may be excluded from serving our own patients. Michigan is fortunate to have a number of large integrated health systems

which have developed DME and other patient support services in an effort to coordinate care and improve cost and patient satisfaction over the full continuum of care. Our hospital-based companies serve both Medicare and non-Medicare patients. However, it is not likely any can survive without the volume associated with Medicare patients.

Henry Ford Health System is a large, integrated health system with more than 65,000 inpatient admissions annually, more than 2.5 million outpatient visits to the Henry Ford Medical Group (an 800 physician group practice) annually, and more than 50,000 outpatient surgical procedures performed annually. More than 1 million residents of Southeast Michigan receive care from HFHS. Fully 20% of the ambulatory care and 12% of the acute care market in Southeastern Michigan is provided by HFHS. Patients 65 and older constitute 24% of HFHS patient visits. We are one of the nation's leading comprehensive, integrated health systems, providing acute, specialty, primary and preventive care services, backed by excellence in research and education. HFHS serves a diverse patient population from both urban and suburban areas, including a wide range of low income and affluent communities, as well as ethnic and racial diversity. Our uncompensated care is running between $115 million and $125 million per year.

HFHS also owns Health Alliance Plan (HAP), Michigan's largest provider-based HMO. HAP participates in Medicare Advantage, and serves more than 3,000 employer groups and 540,000 members throughout Southeastern Michigan. Much of our innovation in coordinating care beyond the hospital setting has been driven by the managed care initiatives of HAP.

Over the years, Henry Ford Health System has built the capacity to integrate services for a wide range of patients and has continually sought out innovative ways to coordinate care across the full spectrum of care. With our network of hospitals and the Henry Ford Medical Group as core providers, we have also developed a number of companies and programs that provide home-based and other support services especially helpful for and valued by our post-acute care patients, particularly our Medicare patients. We estimate that close to 75,000 Medicare patients receive care from HFHS, with approximately 50,000 of these patients consistently choosing HFHS as their main provider.

One of these companies is HealthCore, a medical supply entity that is owned and operated by the HFHS. HealthCore functions in unison with other HFHS owned home care entities, including Home Health Care, Home Infusion, Hospice, Extended Care and the Center for Senior Independence. These business entities operate as a single, comprehensive, home care services unit called "Henry Ford at Home." This integrated business model greatly enhances hospital discharge and home delivery efficiencies, and allows HFHS physicians and other care-givers greater ability to assist and advocate for the best care for our patients. A physical presence for these business entities within all Henry Ford hospitals is part of the health system's strategic plan.

The proposed rule-making on competitive bidding jeopardizes our ability to sustain HealthCore with adequate volume over time. This goes in the wrong direction and would prove detrimental to stated goals of CMS and Congress to increase integration and

coordination of care. The advantages of integrated post-acute services that would be adversely affected by the proposed rule are:

Length of Stay. The availability of various in-home services and equipment for Henry Ford patients at time of discharge allows our physicians and care team to meet real time service and product needs on demand. Occupying space within our own hospitals, HealthCore and the other providers of home care services through "Henry Ford at Home" maximizes our capacity for optimal communication between discharge planners and the physician and other care-givers with the most time sensitive and cost efficient strategies to meet patient needs.

If the rule is adopted as proposed, a re-coordination of processes will need to be implemented throughout Henry Ford Health System in order to allow for the considerable increase in response time from external providers, many of whom will prove to be unprepared or unable to deliver a diverse product line. In many cases, more than one provider will need to be called in. It is unrealistic to expect patients and their families to do the necessary coordination that assures patient needs are met post discharge.

Cost Increases. Although pricing may initially be standardized through the competitive bidding structure, the loss of hospital-based suppliers and hospital-based discharge planning capability will generally reduce competition at the local level and increase overall patient care costs. For the large health systems, like HFHS, there will be increased costs in the form of lost efficiencies and reliability that is currently associated with in-house full-range suppliers. In addition, savings to Medicare achieved through moderating costs of medical equipment may also be lost, exponentially, due to late or delayed discharges.

Quality of Care. One of the many benefits provided to a patient who has made a decision to seek their medical care through HFHS or other similar integrated health system is that seamless care does not stop when they leave the hospital. Quality health care and patient satisfaction is produced by continued oversight, good planning and selection of appropriate health care services, once the patient is home. An integrated system is engineered to communicate and coordinate services with physicians, nurses and technicians, avoiding waste and improper timing of services and using experience with established patterns of care to anticipate needs of patients on a timely basis. The quality improvements are experienced as lower readmissions, better control of chronic conditions, optimal partnerships with family care-givers and timely adjustments to various medications and supplies, depending upon the needs of the patient. Costs are significantly reduced, redundancies are eliminated, and patient information can be protected within the single health system.

If patients of integrated health systems are forced to utilize external DMEPOS providers, the overall results will most likely prove to be quite contrary to intent. External providers who are selected through the lowest bid will not have the quality and service guarantees that come with an in-house supplier or much incentive to become integrated into the HFHS continuum of care. We also fear that external unknown DMEPOS suppliers may

respond to incentives to provide the lowest possible bid and then provide services that mirror their bid. Cut rate services at cut rate prices will eventually increase opportunities for avoidable emergency visits and hospital re-admits.

Access to Care. Competitive bidding without fine tuning to allow the hospital-based companies to participate will eventually create pressures to reduce not only the quality of services rendered, but also the number of providers able to render those services. Without the smaller, hospital-based companies, a type of monopoly develops which places a fully integrated health system in a position of having to accept an unacceptable level of service for our patients, with little leverage to affect either price or quality of these outside providers.

Recommendations. We respectfully submit the following for consideration:

1. Allow hospital-owned and operated DMEPOS suppliers the option to participate at the winning bid rate. This would enable hospital-owned and operated suppliers to serve patients and it would also meet CMS' goal of addressing cost-savings concerns that the competitive bidding process is intended to address. Maintaining local competition in the form of hospital-based companies strengthens goals of the rule without creating a bonus or monopoly for lowest bidders. Local competition moderates incentives to file artificially low bids that can result in low quality services and supplies. This can be accomplished by modifying the definition of the term "Contract Supplier" in the proposed rule to include all hospital-owned and operated DMEPOS suppliers. The expanded definition would assure hospital-owned suppliers the continued ability to maintain access to their patients throughout the entire continuum of care.

Specifically, this modification can be accomplished by amending the proposed Section 414.402 "Definitions" as set forth below:

> "Contract supplier means an entity that is awarded a contract by CMS to furnish a competitive bidding program **or an entity that is owned and operated by a hospital system.**" (new language in bold type)

2. Quality standards must be established prior to a supplier being allowed to participate in the bidding process. The issue of credentialing DMEPOS suppliers becomes more important if competition at the local level is destroyed by eliminating the hospital-based companies, which currently are included in various accreditations and credentialing required of the sponsor hospital and health system. Price is one consideration, but quality is equally important to a hospital or health system seeking to provide cost-effective care.

3. Eliminate the rebate proposal. A structure that allows beneficiaries the option to receive services from suppliers that can offer rebates introduces opportunity for fraud and abuse, which becomes very difficult to monitor or control. Opportunities for the misappropriation of government funds are similarly difficult to control under a rebate

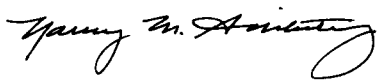
structure, and a perception of providers "incentivizing" patients may be unavoidable where rebates are allowed.

Henry Ford Health System is one of the nation's premier health care organizations well-known for high quality and service to patients. We are a major employer in the State of Michigan and major provider of health care services to patients. Our flagship institution, Henry Ford Hospital, and the Henry Ford Medical Group are consistently ranked at the top in national surveys for expert care, safety and quality improvement. Henry Ford Hospital is ranked among the top 50 hospitals in America by AARP, which reviews more than 4,500 hospitals nationwide based on factors such as death rates, physician ratings, accreditation scores and training programs. We want to continue to be a premier medical resource to the people of Detroit, the state of Michigan, and patients who come from virtually every state in the nation. In order to continue to meet the challenges of cost and quality improvement, HFHS must be able to manage all the elements of care along the full continuum of care.

By allowing the hospital-based companies to continue to participate in Medicare and serve patients of the parent health care system, the likelihood of disruptions in patient care and in functionality of entire integrated health care systems can be avoided. In preserving the benefits the hospital-based companies bring to patients, CMS has an opportunity to strengthen competition and introduce economies of scale, while at the same time encouraging the integrated health systems to function at the peak of efficiency. A provision within the competitive bidding program for preserving DMEPOS businesses that are owned and operated by a hospital system will preserve gains made by the integrated systems in the form of reduced LOS, well-planned and timely discharges, and a seamless, high quality continuum of care. Protecting these efficiencies and the savings they provide can only enhance the overall strategy to improve performance through the DMEPOS competitive bidding process. We strongly urge you to amend the proposed rule to allow hospital-based DME providers to continue to serve our Medicare patients.

Thank you for the opportunity to submit comments. Please address any questions about our comments to me or to Steven Serra, Vice President, HealthCore at 248-304-4526 or sserra1@hfhs.org.

Sincerely,



Nancy M. Schlichting
President & CEO
Henry Ford Health System