Submitter : Ms. N. Lois Adams **Date:** 06/28/2006

Organization : Cystic Fibrosis Pharmacy, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Specialty pharmacies which serve only one or two orphan disease modalities and which only sell medical supplies and equipment germaine to those modalities, should be permitted to continue to serve their patients. They could then be assigned a reimbursement level equal in amount to that accepted by CMS from larger providers.

Submitter : Mr. WILLIAM CONN **Date:** 06/28/2006

Organization : MED EMPORIUM

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-690-Attach-1.TXT

The following list of comments is submitted in response to the Proposed Rule for Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DEMPOS) and Other Issues.

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

2.) "General"-CMS Must Publish An Updated Implementation Timeline. CMS must publish an implementation timeline that at a minimum identifies the following steps and expected completion dates: a.) Publication of Supplier Standards; b.) Approval of accrediting organizations; c.) Issuance of final regulation; d.) Publication of final 10 MSAs and product categories; e.) Commencement of bid solicitations; f.) Conclusion of bid solicitations; g.) Announcement of winning bidders; h.) Education of beneficiaries and medical community; and i.) Implementation within each MSA. It is expected that the publication of such a timeline will highlight the significant problems that lie ahead based on an overly aggressive implementation plan.

3.) "General"- The Program Advisory And Oversight Committee (PAOC) Must Be Included By CMS In The Review Of Public Comments And The Development Of The Final Rule. CMS must include the Program Advisory and Oversight Committee in the review of the public comments received during the 5/1/06 through 6/30/06 comment period and the development of the Final Rule. To not do so excludes the important counsel and advice of key stakeholders in a critical process and goes against the very intent of establishing the PAOC. G. Program Advisory and Oversight Committee. CMS website "for the public to have access to all PAOC presentations, minutes, and updates for the Medicare DMEPOS Competitive Bidding Program.) does not exist. When the address is entered an error message appears, therefore, there is not adequate information available for the public to monitor the information.

4.) "Conditions for Awarding Contracts" (proposed §414.414) "Quality Standards and Accreditation for Suppliers of DMEPOS"- Only Companies That Are Accredited Should Be Eligible To Bid. Only accredited providers should be eligible to submit bids. CMS should not proceed with competitive bidding until it is sure that this is possible. CMS needs to identify the criteria it will use to identify the accrediting bodies now. CMS should grandfather all providers accredited by organizations that meet the criteria CMS identifies. CMS should also allow additional time for providers to analyze the quality standards in conjunction with the

NPRM rule. The quality standards will affect the cost of servicing beneficiaries and are an integral part of the bid process.

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

6.) "Conditions for Awarding Contracts"- Competitive Bidding Must Be Competitive And Sustainable. CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS has not identified any process through which it will seek to determine that the bids are either.

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

8.) "Competitive Bidding Areas"- Do Not Extend Competitive Bidding Beyond Defined MSA Boundaries. The proposed rule refers to the possibility of extending the implementation of competitive bidding to areas adjacent to selected MSAs. This is not provided for in the legislation and should not be done.

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

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

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

12.) "Determining Single Payment Amounts for Individual Items"- Provide More Details On The "Composite Bid" Calculation. The NPRM describes a methodology of creating a "composite" score to compare suppliers' bids in a category using weighting factors to reflect the relative market importance of each item. CMS should provide suppliers with the weighting factors it will use to evaluate the bids in each MSA so that suppliers are able to determine how best to bid each HCPCS item within a category.

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

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

15.) "Conditions for Awarding Contracts"- Financial Standards Must Be Clearly Defined And Evaluated Prior To Consideration Of Any Bid. (proposed §414.414(d)) Specific steps need to be established to allow a consistent evaluation of all companies and audited financial statements should not be required.

16.) "Conditions for Awarding Contracts"- A Bidding Company Should Be Required To Submit Specific Financial Information To Verify Financial Capability Review. This information should consist of: (a.) Two year comparative financial statements prepared in accordance with Generally Accepted Accounting Principles (GAAP). The financial statements must be accompanied by a "compilation", "review", or

"audit" report from an independent Certified Public Accountant. (b.) Certificate of Insurance verifying a minimum of $1,000,000 in general liability coverage and listing other appropriate insurance policies in force. (c.) Letter from primary institutional lender verifying current lending relationship. (d.) Letters from three primary product suppliers outlining purchasing volume over the last two years and its credit and payment history. (e.) Credit report from recognized credit rating organization. Once received, CMS should (a.) review all submitted documentation for completeness and appropriateness; and (b.) calculate basic business ratios to verify company's financial stability to consist of "Debt to Equity Ratio" and "Current Assets to Current Liabilities".

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

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

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

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

21.) "Terms of Contract"- Eliminate Requirement That Winning Supplier Must Repair Patient-Owned Equipment. (proposed §414.422(c)) The current reimbursement rates for service and repair are inadequate and it is impossible for a bidding supplier to factor these costs into their bids.

22.) "Terms of Contract"- Eliminate Limitation That Only Winning Suppliers May Repair Patient-Owned Equipment. (proposed §414.422(c))

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

24.) "Terms of Contract"- Do Not Require Wining Suppliers To Take On Beneficiaries That Are Currently Using Capped Rental Equipment From Another Supplier. (proposed §414.422(c)) Under a capped rental scenario, accepting a new beneficiary transfer after several months of rental with another supplier is unrealistic. It is impossible for a bidding supplier to factor in the cost of taking on beneficiaries that began service with another Medicare Supplier. If this requirement is to remain, then a new rental period should start when the beneficiary begins to receive an item from a wining supplier.

25.) "Opportunity for Participation by Small Suppliers"- Require That A Minimum Number Of Small Suppliers Be Included In The Wining Contract Suppliers. ("Opportunity for Participation by Small Suppliers) At a minimum, small business suppliers in an amount equal to the number of winning bidders should be allowed to participate in the contract assuming they submitted a bid at or below the current allowable amount.

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

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

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

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

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

31.) "Gap-filling"- Develop More Equitable System To Price HCPCs Changes. CMS proposes that when revisions to HCPCS codes for items under a competitive bidding program occurs in the middle of a bidding cycle and a single HCPCS code for two or more similar items is divided into two or more separate codes, the payment amount applied to these codes will continue to be the same payment amount applied to the single code until the next competitive bidding cycle. This is not equitable solution and a more appropriate procedure must be developed.

Submitter : Mr. Daniel Shields **Date:** 06/28/2006

Organization : The Carington Health Center at Carlton Cove

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-691-Attach-1.PDF

CMS-1270-P-691-Attach-2.PDF

CMS-1270-P-691-Attach-3.PDF

THE CARINGTON
HEALTH CENTER AT CARLTON COVE

June 28, 2006

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

To whom it may concern:

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

I am the Executive Director at The Carington Health Center at Carlton Cove Inc, a not-for-profit CCRC located at 1 Crown Circle, Huntsville, Alabama 35802. Our three year old community offers 162 independent living units and 105 skilled nursing beds. We employ over 160 individuals and continue to grow as our census increases.

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

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

I appreciate your attention to this matter.

Sincerely,

Daniel Shields, CNHA
Executive Director

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HEALTH CENTER AT CARLTON COVE

June 28, 2006

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Daniel Shields, CNHA
Executive Director

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I appreciate your attention to this matter.

Sincerely,

Daniel Shields, CNHA
Executive Director

Submitter : **Mrs. gloria machalk** **Date: 06/28/2006**

Organization : **louisville drug co.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam,
Thank you for this opportunity. I am strongly oppose to requiring patients to obtain supplies from certain providers, it takes away the patients choice therefore restrict his access to needed items which may compromise the patients health.
I urge you to keep small suppliers and allow the same payment options so patients may continue having these valuable services.

Thanks,
Gloria Machalk

Submitter : Mrs. Ruth Griffin **Date:** 06/28/2006

Organization : Denman Services, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

Background

Background

The proposed rule indicates that quality standards are being developed as required by the Medicare Modernization Act to address suppliers' accountability, business integrity, provision of quality products to beneficiaries, and performance management.

We believe the detail of these standards needs to be available to suppliers at least six months in advance to submitting a competitive bid. This information would be necessary for a supplier to determine costs associated with accreditation and compliance with the standards. It would not be fair to suppliers to submit a competitive bid without a full understanding of administrative costs.

Conditions for Awarding Contracts

Conditions for Awarding Contracts

In section 3, page 25675, Keith needs to comment on the items required to evaluate financial status for the bid selection process. What documents would we want to submit-most notably a business plan would be labor intensive.

In 4b, John should comment on the composite bid proposal (how to weight individual items within a product category) page 25676.

In 4f, we are concerned that it is too early in the competitive bidding project to limit the number of contracted suppliers to just meet the need. There is no reliable information available to determine the number of suppliers that may lose their contracts leaving concerns about access for Medicare beneficiaries. It is also unrealistic for some suppliers to assume unplanned volumes in short periods of time.

Section H describes the method for determining single payment amounts for individual items as the median of the suppliers' bids that are at or below the pivotal bid. We feel the median bid will set artificially low reimbursement for suppliers who submitted their bids based on their actual costs. The purpose of 'bidding' is to offer the price one will accept. We are in favor of awarding contracts based on the actual bids submitted.

We also object to the proposed 'rebate option'; this offers an unfair advantage to the larger volume distributors. In addition there is no precedence in health care that indicates this is even appropriate for this market. If the bid is determined to cover the suppliers' costs and profit margin then the deductible should be reduced for all beneficiaries regardless of the supplier who is servicing the beneficiary.

GENERAL

GENERAL

We respectfully ask how a supplier can furnish equipment and supplies to beneficiaries on 'travel status.' We ask the CMS define documentation required for travel status to protect the interests of the supplier.

To protect both beneficiaries and suppliers from supplying items in error where no reimbursement to the supplier can be made, that CMS provide a local toll free number that beneficiaries can access to easily find suppliers who can furnish an item included in the competitive bidding area in which the beneficiary permanently resides.

1. Pivotal Bid calculation: This process proposes that the array be determined from the lowest bidder up. We believe it is in the best interest of the program to arrive at the bid price versus capacity from the mean bid price moving up and down equally until capacity is met and or exceeded. By 'setting' the price from the middle the bid process attempts to assure adequate funding for services with assumed quality standards and not on a 'lowest bidder' model.

2. Rebate program: The process asks for comments on process for rebates in excess of beneficiaries 20% co-pay obligation. This assumes a greater than 20% reduction from current Medicare rates for specific HCPC items. Our comment is that if a bidder exceeds the 20% threshold on discount that that bid be rejected as unsound and unsustainable. The concept of rebate or giveback dollars in this environment is not in the best interest of the program or the patient. Providers leveraging operational efficiencies while maintaining quality standards may use this operating margin to expand their services and or improve patient education, quality, and service. In any event, no rebate should be considered until the bidding provider has been adequately measured for compliance to measurable quality standards within their accrediting body's performance measures reporting.

3. Terms of Contract: We believe contracted bidders must have the ability to exit the program with notice (90 days). This will allow the bidders who may have failed to meet the quality standards and market expectations for the patient to exit in a business like manner.

4. Administration or Judicial Review: If program safeguards remain in place to hold providers accountable for accurate records and compliance, then all current abilities to defend the provider's processes through the various reviews and submission of support documentation must be kept in place, up to and including the ALJ level.

5. Accreditation of bidders: We suggest that not only must the bidders be accredited by an approved agency, but the grace period be denied and the bidders be fully accredited at the time the bid is submitted for consideration. To not do so presents an unequal environment for the bidders related to cost and operating an HME within the accreditation body's framework of quality standards.

Hospital Based DME:

Bidder Selection Process--Individual hospital and hospital system based HME's will be included in the MSA's selected if they are appropriately accredited and meet the bid levels for the items/product groups selected. Hospital based HME's are an integral part of the acute site patient throughput and exclusion from this program will create patient access issues due to bed availability, acute site network stability, and adverse patient and physician satisfaction to the acute hospitals and or systems affected.

Issue

Issue

We agree that beneficiaries should decide whether they would like to continue renting from suppliers with whom they have been renting prior to competitive bidding. We recommend a supplier be given adequate time to arrange for transfer to another provider when the beneficiary elects a new supplier or in the event a supplier loses their contract status in the competitive billing program. This time frame to transition a beneficiary to a new supplier should be at least 60 days.

The proposal that grandfathered suppliers be paid single payment amounts for items that require substantial servicing, as well as oxygen equipment instead of fee schedule amounts may not adequately reimburse suppliers for beneficiaries that require frequent home visits and deliveries to meet their needs. We would suggest items that fall into this category for grandgathered suppliers directly tie to the number of physical contacts the suppliers have with the beneficiary. We would also like clarification on methods the DMERC will utilize to evaluate that items remain medically necessary in a grandfather supplier secnario. The grandfathering section does not address the beneficiary that already has rented equipment (example CPAP) in the home and now the physician has ordered additional equipment (example oxygen). If the beneficiary does not have the option of continuing with the supplier of the original equipment this could be burdensome for the beneficiary having to contend with more than one supplier and also pose a safety risk for the beneficiary.

Issue

Section C Payment Basis; 3. Special Rules (Grandfathering of Suppliers)

Regulatory Impact Analysis

Regulatory Impact Analysis

II. Provisions of the Proposed Regulation

Section B Implementation Contrator

Regulatory Impact Analysis

In light of the fact that CMS is attempting to decrease taxpayer expense with the DMEPOS competitive bidding program, using funds for another contractor is not a good use of resources. The alternatives described on page 25662 are viable and make use of resources already available.

Regulatory Impact Analysis

Regulatory Impact Analysis

Section C Payment Basis; 3. Special Rules (Grandfathering of Suppliers)

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

Although product categories allow providers a specialization niche as described in item 3, this will lead to fragmentation of services for beneficiaries who require several DMEPOS items that fall into a variety of product categories. Consider a beneficiary who requires oxygen, blood glucose reagent strips, wheelchair and air mattress. One single provider may not be a contracted provider for the services. This can cause confusion to the beneficiary as to who to call for assistance.

In item 4b we are concerned there is no explanation or definition of reasonable and necessary maintenance and servicing for beneficiary-owned DME.

It item 4e there is no rationale given for why the single payment amount for the rental of enteral nutrition equipment for months 4 through 15 would be less than months 1 to 3 as the cost for using these items and supplies remains the same. We feel the rental payment should be the same single payment amount for the entire 15 months prior to the beneficiary's decision to purchase new or used equipment.

Terms of Contracts

Terms of Contracts

In section 6, we should comment on what information we want collected from suppliers as well as terms and conditions of contract.

Submitter : **Dr. John Marzano** **Date: 06/28/2006**

Organization : **Westchester Podiatric Medicine, P.C.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Westchester Podiatric Medicine, P.C.

John C. Marzano DPM
200 N Central Avenue, Suite 210
Hartsdale, New York 10530
Web Page: www.westchesterpodiatric.com
Email: jmarzano@westchesterpodiatric.com
Email: drjcm@optonline.net
Telephone: 914-683-0600
Cellular Telephone: 914-424-8338
Fax: 866-549-2795

Wednesday, June 28, 2006
Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P

Dear Dr. McClellan:

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

I work as a podiatric wound healing specialist at St. John s Riverside Hospital in Yonkers and at office locations for Westchester Podiatric Medicine, P.C. 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. As a podiatric physician I understand the value of direct hands on management of these high risk and problematic people. Removing my ability to directly dispense and monitor the effects of vital DME products will most certainly endanger my patients. This will ultimately result in more ulcerations and subsequent medical and surgical treatment.

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. For example, many of my patients are suffering from diabetes and have undergone treatment for ulcerations including amputation of portions of their feet. Could there be anyone better suited to provide the correct protective foot devices than the podiatric physician treating those feet? As another example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries.

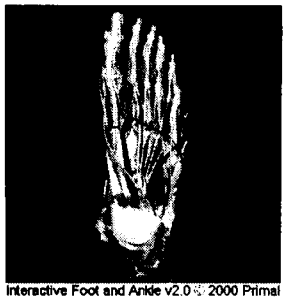
I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r)(3) before finalizing the regulations for the competitive acquisition program. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan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

Respectfully,
John C. Marzano DPM

CMS-1270-P-694-Attach-1.DOC

CMS-1270-P-694-Attach-2.DOC

Westchester Podiatric Medicine, P.C.


Interactive Foot and Ankle v2.0 © 2000 Primal Pictures Ltd.

John C. Marzano DPM
200 N Central Avenue, Suite 210
Hartsdale, New York 10530
Web Page: www.westchesterpodiatric.com
Email: jmarzano@westchesterpodiatric.com
Email: drjcm@optonline.net
Telephone: 914-683-0600
Cellular Telephone: 914-424-8338
Fax: 866-549-2795

Friday, June 30, 2006

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

Dear Dr. McClellan:

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

I work as a podiatric wound healing specialist at St. John's Riverside Hospital in Yonkers and at office locations for Westchester Podiatric Medicine, P.C. 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. As a podiatric physician I understand the value of direct hands on management of these high risk and problematic people. Removing my ability to directly dispense and monitor the effects of vital DME products will most certainly endanger my patients. This will ultimately result in more ulcerations and subsequent medical and surgical treatment.

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. For example, many of my patients are suffering from diabetes and have undergone treatment for ulcerations including amputation of portions of their feet. Could there be anyone better suited to provide the correct protective foot devices than the podiatric physician treating those feet? As another example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries.

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

Respectfully,

John C. Marzano DPM

Westchester Podiatric Medicine, P.C.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John C. Marzano DPM
200 N Central Avenue, Suite 210
Hartsdale, New York 10530
Web Page: www.westchesterpodiatric.com
Email: jmarzano@westchesterpodiatric.com
Email: drjcm@optonline.net
Telephone: 914-683-0600
Cellular Telephone: 914-424-8338
Fax: 866-549-2795

Friday, June 30, 2006

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

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

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

Respectfully,

John C. Marzano DPM

Submitter : **Date: 06/28/2006**

Organization : **Orthopaedic & Hand Specialists, PA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1270-P-695-Attach-1.DOC

Comments on CMS 1270-P

Proposed Regulations on Competitive Acquisition of DMEPOS

Subject: Prosthetics and Orthotics

I am the administrator of an orthopaedic hand surgical practice, which also employs hand therapists and physical therapists, makes extensive use of custom orthotics that are specifically fabricated for the patients, and occasional use of "off the shelf" (OTS) orthotics. I participated in your teleconference on May 23, and downloaded the proposed regulations. Thank you for restricting competitive bidding to only "off the shelf" (OTS) products. However, it was clear from the teleconference that the proposed regulation still is not grounded in how OTS orthotics are used in physician offices, nor in how hand therapy is practiced.

FIRST: Page 64 of the proposed regulation still refers to "adjustments that can only be made by a *certified orthotist* (emphasis added)" as the criterion that will distinguish between OTS orthotics and custom orthotics. This is an incorrect distinction, as it presumes, incorrectly, that a certified orthotist is the only health care professional capable of fabricating a customized orthotic. In our practice, **the occupational therapists/Certified Hand Therapists are all specifically trained and certified in fabrication of custom splints, and are fully capable and qualifed. The orthotist is not the only qualified practitioner, and any definition that specifically refers to only certified orthotists should and must be modified to include other qualified practitioners.**

SECOND: We have but a small Medicare population, so we do not have a large financial ax to grind. But **it appears that the proposed regulation, without the changes suggested below, will substantially inconvenience Medicare patients, disrupt care in a way that has the potential to harm the patients, while saving precious little money to the Medicare system.** In fact, without the changes suggested below, Medicare may pay more for other clinical services, specifically casting and strapping, and thus have a net increase in outlays across the combined "physician" and "DME" components. **I have suggested a methodology that will help you achieve your financial goal while not inconveniencing patients or physicians**, but you will have to see if this methodology will work within the regulatory structure. You may wish to work with your Congressional contacts if changes in legislation are needed in order to implement the suggestions below.

We use OTS orthotics for short-term protection and stabilization of a joint or limb while the patient is considering whether to have surgery; or to determine whether an orthotic will provide the patient pain relief before we subject the patient (and the payor) to the cost of a custom orthotic. The use of the orthotic is part and parcel of the Evaluation and Management of the patient. It is categorically NOT the dispensing of a product or supply item. The patient has come to us in pain. It would be an extraordinary inconvenience to send the patient, in pain, to a "low bid" provider elsewhere in the community for such a

small saving. It would also be clinically inappropriate, because the orthopaedic surgeon, while adjusting the OTS orthotic, is also evaluating the patient's pain, range of motion, compliance and understanding, etc. In other words, adjusting of the OTS orthotic is a teaching moment between the physician and patient, with an importance in the care of the injury or condition that transcends simply "dispensing a product."

These OTS orthotics are inexpensive to us, and are inexpensive to the Medicare program when billed to you. For example, we charge a mere $18.00 on L3908, a prefabricated OTS wrist forearm splint. You stated in the teleconference and in the document that the expected savings by competitive bidding were 25%, only $4.50 in this example. By the way, the Medicare allowable for L3908 is $44.14, but when we fit one of these splints for joint protection pending further evaluation we do not even charge the allowable. We charge a much lower $18.00 for the supply plus the fitting plus the education. This is more than reasonable, given that various web site mail order operations charge $8.99 plus shipping for similar items, without the on-site fitting and education that we provide.

We also may use OTS orthotics in the hand therapy department when, in the considered opinion of the orthopaedic surgeon or hand therapist, a custom orthotic is not necessary for the patient's condition. However, the OTS orthotic is again used as a stabilizing and protecting device while the hand therapist may also be showing the patient exercises to be performed periodically when the orthotic is removed. Again, the use of the orthotic is inherent in the exercise or range of motion program. It is not simply "dispensing a product."

During the teleconference, a podiatrist called in and asked whether he could continue to dispense an adjustable OTS brace that he used to stabilize acute fractures. The answer was that he could not, unless he engaged in the competitive bidding process and won a bid. **It is simply unacceptable to expect any patient, especially an elderly patient, to leave a physician's office with an acute fracture, and travel to another provider, perhaps waiting until the next day or over a weekend, in order to have an OTS brace adjusted. It might be considered malpractice for the provider to send that patient out without the fracture being stabilized. (EMTALA regulations make transferring or discharging a patient with an unstabilized fracture from an Emergency Department for financial reasons a potentially criminal violation – yet you stated that the podiatrist would not be allowed, for financial reasons created by the Medicare program, to properly stabilize a Medicare patient's fracture in the office. This is inconsistent, illogical, and certainly not the intent of the CAP/DMEPOS legislation.)**

If orthopaedic surgeons and podiatrists are not permitted to stabilize joints or acute fractures with OTS orthotics, then we will be forced to revert to the old practice of casting the injured limb. This will NOT save the Medicare program any money. Thus, the Medicare allowables in North Carolina are as follows: L3908 prefab splint, $44.14; 29125 short arm splint, $56.91; 29085, apply hand/wrist cast, $77.32 plus the charge for the materials. We fail to understand how Medicare expects to actually save any money,

when all is said and done, with some percentage of the patients receive both casting and then possibly subsequent splints through a "preferred" vendor.

Thus, **we strongly suggest that you exempt most of these low cost – low allowable L codes for prefabricated upper extremity splints i.e. L3908 through L3954, as items exempted for lack of significant saving.**

We strongly suggest that you exempt upper extremity fracture orthoses L3980 – L3985 because these are used immediately by the clinicians for post-fracture care after the initial cast has been removed. It is inappropriate, unsafe, and potentially malpractice for a patient to have a cast removed, and then be referred, unprotected, to another provider.

Ideally, because we believe that the provision and fitting of OTS orthotics is an integral part of the orthopaedic practice, we would like to see physicians offices that are also registered as DME suppliers to be exempt from the regulations concerning OTS orthotics. Table 4 on page 68 shows that in 2003, allowed charges for OTS upper extremity orthotics in 2003 were $29 million dollars, a mere 0.3% of Medicare's DME expenses in that year. Given the clinical interaction between the physician or therapist and the patient during the fitting process, the malpractice issue, and the probably increase in casting charges due to the malpractice issue, it would be in Medicare's interest to exempt physician offices from the orthotics bidding process.

THIRD: If Medicare feels that it must have a "competitive bidding model" for OTS orthotics, in spite of the low value and high difficulty to patients and providers, then you already have a more effective and patient-sensitive model which can be applied to OTS orthotics. This is the model used for competitively bid but locally administered oncology (and similar) drugs. Rather than force physicians to commit malpractice, and force patients to see two different providers, you could certify certain large-scale vendors of OTS orthotics through a competitive bid process, and simultaneously set a price for the orthotics. The physician's or therapist's office could obtain the OTS orthotic from one of the certified vendors, and Medicare would allow that vendor to bill for the product only, while the physician or therapist would bill a fitting charge, similar if not identical to CPT code 97703 or 97504. This would be different from Medicare's current practice of bundling the value of the fitting with the value of the product, but it is logical and consistent with the similar change made by Medicare in the payment for high-cost intravenous oncology drugs. Alternatively, if I understand the oncology drug program correctly, the physician or therapist could elect to bill for both the supply item (at the new allowable, derived from competitive bidding) and the fitting, if that provider could obtain the supply item at a sufficiently discounted price that it made economic sense to bill the Medicare program. This model provides the maximum flexibility to all providers, does not discriminate against small providers, largely eliminates the issue of "networks" (a concept that has fallen out of favor in health care), largely eliminates the need for "accreditation" of suppliers for this category of product, and, most importantly, supports proper care of the injured or infirm patient.

We strongly urge you to consider, and then implement, the proposals discussed above, and thank you for the opportunity to submit this comment.

Submitter : Dr. Eric Hubbard **Date:** 06/28/2006

Organization : APMA

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 : **Dr. Michael Frank** **Date: 06/28/2006**

Organization : **Dr. Michael Frank**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

June 28, 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 Frank, DPM

Submitter : Steven Pardi **Date:** 06/28/2006

Organization : The Medicine Shoppe#1579 Ilion New York

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

As a pharmacist-owner of a community pharmacy, I respectfully request that diabetes testing supplies (meters, test strips, lancets, etc) be excluded from the Competitive DME Bidding process. On a daily basis we spend a considerable consulting patients with diabetes about proper use of their testing kits, interpertation of their blood sugar readings, correct use of and understanding of their medications, etc. These patients need a knowledgeable professional who is readily accessable in their local community - not a toll-free support line that connects to a help desk overseas. Please consider the negative ramifications on patient care - often patients are confused and overwhelmed with the rigorous monitoring routines for properly managing diabetes - they do not need any more confusion or "hassle" added to their lives.
Thank you for your sincere consideration. Steve Pardi, R.Ph. Ilion NY

Submitter : **Date: 06/28/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 28, 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,

Scott A. Hamilton , DPM
Coastal Podiatry
8141 Rourk St
Myrtle Beach, SC 29572
843-449-8079

Submitter : **Mr. Todd Manley** **Date: 06/28/2006**

Organization : **Mosso's Medical Supply Company**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1270-P-700-Attach-1.DOC

Mosso's Medical Supply Co.

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:

Mosso's Medical Supply Company 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.

Mosso's M edical S upply Company is a D urable M edical E quipment c ompany offering Clinical RT Services that employ 140 professionals and serves approximately 7,000 patients. As General Manager, I will tell you that our organization and its employees prides itself with providing only the highest level of care to our patients. Implementing competitive bidding in my estimation will only diminish customer service to an extremely dangerous level. Individuals count on us everyday to be there for them when needed. While CMS has considered the quality standards in its process, there are different levels of quality in our industry. The competitive bidding process only gives an edge to the providers that provide less service. Is this the type of service or customers deserve? I like to think not.

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 b ut a lso t o o ther D MEPOS it ems t hat w ill c ontinue t o b e r eimbursed 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 inf usion therapy is no w div ided between P art B and t he ne w P art D p rescription dr ug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

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

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

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

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

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

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 724-537-9377

Sincerely,

Todd Manley
General Manager, Mosso's Medical Supply Company

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

Submitter : Mrs. Julie Richburg **Date:** 06/28/2006

Organization : Luverne Health and Rehabilitation, LLC

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

June 28, 2006

Dept. 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 CMS competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies.

I am the Administrator at Luverne Health and Rehabilitation, LLC in Luverne, Alabama. LH&R is a skilled nursing facility with 151 beds and 150 employees. We offer Speech, Occupational, and Physical therapies here in Luverne.

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 PartB reimbursements for certain DMEPOS items could directly impact our ability to provide the best possible care to residents.

Medicare Part B resident often are 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 our residents need and deserve.

At Luverne Health and Rehabilition, LLC we have so many residents whose care could be interrupted as a result of the implementation- jeopardizing their health and safety. The proposed rule has the potential to compromise a residents acess to specific services and products, resulting in long-term increased cost of care.

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

I appreciate your attention to this matter

Sincerely,
Julie Richburg RN, Nursing Home Administrator

Submitter : Mr. Paul Lowry **Date:** 06/28/2006

Organization : Lowry Drug Company, Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

Issue

Issue

I have another issues and concern regarding the competivie bidding process. Will medicare recipiants that do not want to be supplied from the "cheapest" bidder be able to select another provider and have a ABN applied and pay the difference to upgrade to a high quality of service and or equipment? Will that provider be paid at eh competivie price and still be able to collect the ABN amount.

Another issue is will there be an allowance for after hours service calls, or will providers simply tell the paitent to go to the hospital which happens now by the "cheaper" providers.

Submitter : **Mr. Clark Vaughan** **Date: 06/28/2006**

Organization : **Mr. Clark Vaughan**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

June 28, 2006

Dear Sir or Madam:

I am a physical therapist working in an outpatient clinic. My patients sometimes need orthoses in order to assist with walking, rolling, or transferring from lying to sitting to standing. The orthosis may be applied to the ankle, foot, trunk, or virtually any joint. Sometimes the orthosis is to discourage movement and sometimes it is to encourage movement. For instance, a patient that has had a fracture of the elbow may acquire stiffness that needs the gradual pressure of a brace to increase the motion. This brace may need occasional adjustments to increase the motion. Similarly, an orthosis for a foot may need adjusting as the patient gets use to the brace. These adjustments cannot be made by the supplier. Additionally, the patient may have other musculoskeletal problems that contribute to his/her problem. The prescription as well as the adjustment of the orthosis may change as musculoskeletal conditions are treated. This is best done by the physical therapist.

With these points in mind, I hope that physical therapists can continue to provide off the shelf orthotics and assistive devices that require minimal adjustment as well as more custom-made ortheses.

Respectfully.

Clark Vaughan, PT, OCS, FAAOMPT

Submitter : Mr. Tomas Perez **Date:** 06/28/2006

Organization : The ORsini Group

Category : Health Care Provider/Association

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

The proposed oxygen concentrator purchase is not practicle for us as a company or for the pateints. First of all the patients family will try to sell the equipment at garage sales, ebay, or the flea market, making them "Drug" dealers. Oxygen is a Drug and anyone that sells or rents concentrators would be considered dealers. Secondaly, all concentrators will require some sort of maintenace, this must be performed to keep oxygen purity at it higest level.

This proposed action will harm the patient and cause more health issues than money you think you will save.

Submitter : **Date: 06/28/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 28, 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,
Joseph J Menn, DPM
Coastal Podiatry Associates
8141 Rourk St
Myrtle Beach, SC 29572
843-449-8079

Submitter : **Date: 06/28/2006**

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

The competitive bidding process that is being proposed takes away choices for Medicare recipients by decreasing the number of providers able to service patients which can lead to reduced quality care. Currently, if a patient is dissatisfied with the service they receive from a provider they can go somewhere else. With competitive bidding a winning bid can put many providers out of business if a provider can't accept the winning bid amount, which gives the winning provider the ability to put patient care to a minimum.

It should be mandatory that businesses prove they meet all quality standards before they are included in the bidding process to ensure the validity of the bid and not skew the process for the legitimate provider's bids.

How can providers be expected to submit realistic bids when the regions and equipment categories are not yet available and the time frame to start is 2007. Providers need at least a year to do cost analysis to submit appropriate bids.

The offering of rebates goes against everything Medicare has tried to alleviate with kickbacks and inducements.

CMS already controls the pricing for Medicare why spend all the additional money to come full circle just to lower allowables?

Submitter : **Ms. Sharon Cheng** **Date: 06/28/2006**

Organization : **Medicare Payment Advisory Commission**

Category : **Federal Government**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-707-Attach-1.DOC

MEDPAC Medicare Payment Advisory Commission

601 New Jersey Avenue, N.W. • Suite 9000
Washington, DC 20001
202-220-3700 • Fax: 202-220-3759
www.medpac.gov

Glenn M. Hackbarth, J.D., Chairman
Robert D. Reischauer, Ph.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

June 28, 2006

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Box 8013
Baltimore, Maryland 21244-8013

RE: file code CMS-1270-P

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on CMS's proposed rule entitled: *Medicare program; Competitive acquisition for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and other issues.* [CMS-1270-P] Federal Register, May 1, 2006. We appreciate your staff's ongoing efforts to administer and improve the payment system for durable medical equipment, prosthetics, orthotics, and supplies, particularly considering the agency's competing demands.

We support the use of competitive bidding in the Medicare fee-for-service program for DMEPOS. By giving suppliers an incentive to offer prices close to their costs, competitive bidding has the potential to give CMS better price signals for rate setting and to improve the value of beneficiary and program spending. Your final report on the competitive bidding demonstrations noted that they generated substantial savings without adversely affecting quality or access.

We note that the proposed rule pays due attention to the need for transition policies and for ongoing monitoring of access and quality. Transition policies, for example, those in the proposed rule allowing some beneficiaries to maintain established relationships with some suppliers who do not win contracts, will be important to minimize disruption for beneficiaries. The proposed rule also anticipates a role for an ombudsman and a system for addressing beneficiary complaints and appeals. We support these provisions of the proposed rule.

Payment basis

Payment adjustment to account for inflation

CMS proposes that the competitively determined item prices be increased annually over the three year life of the contract by the CPI-U as are payment rates in the fee schedule. We suggest that you eliminate any automatic payment adjustment.

Establishing an automatic annual update makes it possible for prices to rise faster within the competitive bidding areas (CBAs) than in areas using the fee schedule in the event of a payment freeze or a payment reduction. If the prices rise within the CBAs, it is possible that they could overtake fee schedule prices and result in higher spending in CBAs than outside them. There are alternatives to automatic updates.

One alternative is bidding a single price for the term of the contract. This would require the bidders to estimate the rate at which their own costs will rise over the contract period and set their bid prices accordingly. This alternative could result in higher savings for the program if some bidders can not only offer lower prices in year one than their competition, but also lower cost growth over time. However, it is possible that removing the annual payment adjustment could result in higher bids in year one if bidders build in a substantial hedge against future cost increases.

As another alternative, CMS could allow each bidder to either specify an annual adjustment or propose bids for each item for each year of the contract. CMS would then use a discount rate to reduce all bids to a base year for comparison. This alternative would give suppliers the most freedom in designing their bids.

Authority to adjust payments in other areas

CMS asked for comments on how information from competitive bidding for DMEPOS should be incorporated into the fee schedule for areas outside of CBAs. We support using the price signals from competitive bidding to inform the fee schedule in all areas. For items whose bid prices converge across CBAs, CMS could change national or regional fee schedules fairly rapidly. For prices that do not converge, CMS should identify market characteristics that are related to price differences and use these analytical results to determine how rates for items in other areas should be adjusted.

Competitive bidding areas

MSAs for 2007

CMS asked for comments on the selection method for the ten MSAs in which the competition will occur in 2007. The method proposed in this rule would rank MSAs based on their total population, total DMEPOS charges, charges per beneficiary, and the number of DMEPOS

suppliers per DMEPOS users. These selection criteria are well suited to ranking and selecting MSAs in which competitive bidding is most likely to generate the most substantial savings and to offset the costs of implementing the competitive bidding program.

In addition to ranking MSAs on the total number of DMEPOS suppliers, we suggest that CMS also consider the numbers of suppliers of constituent categories of DMEPOS; for example, oxygen and supplies or hospital beds. If there are enough suppliers to support competition in each of the constituent markets within an MSA, then it should be included in the competitive bidding process. Otherwise, it should not be selected. Our research on this topic showed that the constituent markets can differ from the total DMEPOS market.

Establishing the competitive bidding areas for 2007 and 2009
The proposed rule contemplates setting competitive bidding areas as equal to MSAs, larger than MSAs, or smaller than MSAs. At least for the first round of competition, we suggest that CMS define CBAs to be equal to MSA boundaries. MSAs are well defined and known to bidders. For simplicity and transparency, those definitions should be used without alteration. In addition, because CMS is choosing bidding areas based on MSA characteristics, this would seem to be the relevant area. In future rounds of competition, a larger area could be considered if those areas equate better with markets and are used to define and choose competitive areas.

Submission of bids under the competitive bidding program
Physicians
CMS needs to clarify how physicians will provide DME in CBAs. The self-referral law that prohibits physicians from supplying most DME items seems to conflict with the proposed rule's requirement that all bidders must bid on all items within a category of DME. It appears that physicians cannot be bidders.

We suggest that CMS allow physicians in CBAs to continue to supply the limited range of items currently allowed under law and not require them to bid. However, physicians in CBAs should be reimbursed at the competitively determined prices. Prohibiting physicians from supplying DME to their own patients might substantially inconvenience beneficiaries—for example, not being able to provide crutches to a beneficiary whose leg has just been placed in a cast.

Conditions for awarding contracts
Assurance of savings
CMS solicited comments on the various methods for assuring savings under the competitive bidding program. In the proposed rule, two different methods are proposed: One method would reject any bid that includes any item priced above the current fee schedule price. The other method is indifferent to the prices of individual items so long as the amount to be paid

under the bid for the entire category is less than it would have been if each item in the category were priced at the current fee schedule. The proposed rule favors the former interpretation.

We would propose that the program should accept bids that include some items with prices above the current fee schedule so long as the total bid would result in lower spending than the current fee schedule. Allowing this variation is likely to give CMS the most accurate price signals for both over- and under-priced items. Improving accuracy can remove incentives to over- or under-provide products or services depending upon the relative profitability of the products and ameliorate access problems that beneficiaries may have if they seek less profitable products. Also, in the specific case of competitive bidding, if the bidders are not permitted to bid a higher price for items that cost them more to supply than the current fee schedule allows, then they will not offer the program substantial discounts on the items that are currently priced too high.

We note that in the competitive bidding demonstrations, the program achieved substantial savings even though several of the items in each of the categories were priced through the bidding process above the fee schedule amount.

Determining single payment amounts for individual items

Rebate program

CMS solicited comments on the proposed rebate program. Although the goal of sharing potential provider profit with the beneficiaries is laudable, it is preferable to obtain the best price through competition not through a rebate. Adding a rebate program would not be advisable. A rebate program will complicate the design and administration of the program and possibly induce additional demand for DME, as well as raise the risk of fraud and abuse as noted in the proposed rule. The proposed rule would prohibit advertising of rebates, yet at the same time require a supplier provide rebates for all beneficiaries if any beneficiary received one. Enforcing either of these provisions would complicate administration of the program. If a beneficiaries' cost sharing were reduced or eliminated, demand for DME may be induced (allowing a beneficiary to be paid to purchase DME if the rebate exceeded cost sharing would be even worse). Demand could also be channeled to more expensive substitute items if rebates made those items less expensive for the beneficiary. Induced demand and item substitution could increase rather than decrease Medicare spending. Beneficiaries will already get the benefit of reduced cost sharing as rates go down. Competition should also reduce the opportunity for rebates over time.

Fee schedule for home dialysis supplies and equipment

CMS proposes to establish a fee schedule for home dialysis supplies and equipment furnished by DME suppliers (also referred to as the method II payment option). Currently, CMS pays suppliers for home dialysis supplies and equipment on a reasonable charge basis that

cannot exceed the national median payment (composite rate) that CMS would have paid to hospital-based facilities. (CMS calls the composite rate paid to dialysis facilities the method I payment option.) The agency proposes to derive the fee schedule from charge data for allowed services furnished by suppliers in 2005 and to maintain the cap under which monthly payments to suppliers cannot exceed the composite rate for hospital-based facilities. CMS's proposal continues to pay suppliers up to 30 percent more than dialysis facilities for furnishing one form of home dialysis—continuous cycling peritoneal dialysis (CCPD).

We are concerned that the payment rate for CCPD paid to DME suppliers does not reflect efficient suppliers' costs. There is no evidence to suggest that suppliers incur higher costs to furnish CCPD than dialysis facilities incur. The Office of Inspector General (OIG) (2003) reported that Medicare paid $15.3 million more and beneficiaries paid an additional $3.1 million to DME suppliers compared with payments to dialysis facilities for CCPD in 2000.

CMS should consider revising the payment provisions so that payment does not vary between DME suppliers and dialysis facilities. The OIG recommended that CMS limit suppliers' payment rate for CCPD items to equal the rate paid to dialysis facilities. Doing so would decrease spending for beneficiaries and the Medicare program. Paying the same rate for the same services across different settings would lessen CMS's administrative burden.

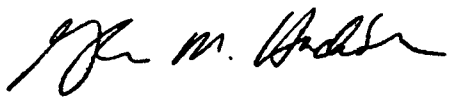
The Commission is considering ways to improve payment for home dialysis. Competitive bidding may be one potential way to encourage efficiency. In future work, we plan to consider ways for Medicare to modernize payment for home dialysis services.

Conclusion

MedPAC appreciates the opportunity to comment on the important policy proposals crafted by the Secretary and CMS. The Commission also values the ongoing cooperation and collaboration between CMS and MedPAC staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact Mark Miller, MedPAC's Executive Director.

Sincerely,



Glenn M. Hackbarth, J.D.
Chairman

Submitter : **Dr. Christopher Attinger** **Date: 06/28/2006**

Organization : **Georgetown University Hospital**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

From:
Christopher Attinger, MD
Georgetown University Wound Center
Georgetown University Hospital
Washington, DC, 20007, USA

Subject: Placing the VAC dressing up for competitive bidding

I am a Plastic Surgeon who is the medical director of the Georgetown University Hospital Wound and Limb Salvage Service. We have a team approach to Limb Salvage involving Orthopedic Surgery, Vascular Surgery, Infectious Disease, Endocrinology, Podiatry, Plastic Surgery, Nephrology, Physical Therapy, Psychiatry, Pedorthics And Prosthetics. Our focus is on salvage of threatened diabetic limbs. We see 12,000 patients a year and perform over 1,600 cases per year. Our clinical decision tree is guided solely by evidence-based studies. We have achieved the highest reported limb salvage rate in the country using this approach: a primary amputation rate of 2.7% and secondary amputation rate 1.3%. This compares with the national primary amputation rate of 23%.

The VAC has played an integral part in helping us achieve such a high salvage rate. We use it in the following manner. The diabetic patients come in with ulcers +/- gangrene and +/- osteomyelitis. The ulcers are initially dibrided. The leg is revascularized if necessary. The patient is then sent out on appropriate antibiotics and a VAC dressing. The VAC stimulates rapid formulation of granulation tissue while keeping the wound clean. We monitor the wounds closely with visiting nurses. We see the patients regularly in the office. When the wound has turned the corner and has a healthy granulating base, we can then consider reconstructing the foot. By using this careful measured approach to these extremely difficult wounds and using the VAC as a critical part of the treatment, we have been able avoid major amputations and achieve the high limb salvage rates mentioned above. We have been able to do this largely on an outpatient basis because of the reliability of the VAC as a dressing. This has helped keep the cost of limb salvage down without detrimentally affecting patient care.

Indeed, the use of the VAC nationally and internationally has now become clinically accepted as part of routine wound healing therapy. In a recent supplement of Plastic and Reconstructive Surgery (Volume 117:725 June 2006), the role of the VAC in wound healing is fully delineated. Its use is pervasive in wound care including wound bed preparation, skin graft immobilization, and revascularization of collagen matrix. In terms of diabetic limb salvage, a prospective randomized study (Lancet 366:1704, 2005) showed the VAC was instrumental in preserving limbs. This study nicely reflects our own experience. Indeed the success of the VAC in treating wounds is such that is now become routine in the care of the wounded combat troops in Iraq and Afghanistan.

The reason the VAC has been so successful is because of its patented design. It delivers negative pressure via a sponge that can evenly transmit the pressure on the wound surface. The resulting deformation of the cytoskeleton of surrounding wound surface cells stimulates cellular duplication and formation of granulation tissue. It also can deliver the negative pressure via an on and off cycle that helps maintain increased blood flow. There is nothing currently on the market that resembles the VAC.

I am very concerned the VAC may be put up for competitive bidding. The question is with what? There is currently nothing on the market to compete with it or that has been validated with a randomized trial. Until that data is available and the results are comparable, the VAC should never be put up for competitive bidding. I feel it would do a disservice to all diabetic patients if the VAC were put up for bidding and an unproven device were substituted because of price considerations. I cannot strongly urge you enough to avoid putting the VAC up for competitve bidding until prospective randomized studies show that a viable alternative exists.

Submitter : **Date: 06/28/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 27, 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 since 1983, 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,

Gary A Raymond DPM, FACFAS
Advanced Regional Canter for Ankle and Foot Care

CMS-1270-P-709-Attach-1.DOC

Advanced Regional Center for Ankle and Foot Care

711 Logan Blvd
Altoona, PA 16602
814-943-3668

927 West High Street
Ebensburg, PA 15931
814- 472-4303

220 Regent Court
State College, PA 16801
814-231-1566

June 27, 2006

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

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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,

Gary A Raymond DPM, FACFAS
Advanced Regional Canter for Ankle and Foot Care

Submitter : **Dr. Duane Brown** **Date: 06/28/2006**

Organization : **Brown Podiatry**

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,

Duane A. Brown, DPM

Submitter : **Dr. Anothony Scroggins** **Date: 06/28/2006**

Organization : **Brown Podiatry**

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

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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.

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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. Anthony Scroggins, DPM

Submitter : Mr. Fred Mathews RRT **Date:** 06/28/2006

Organization : AARC

Category : Other Practitioner

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As a respiraory therapist I feel that not all companies are created equal. In regards to oxygen therapy I certainly do not want to tell my patients that the only company you can get your oxygen from is located 2-3 hours away and you are ready to go home but we have to wait for the provider to get the oxygen set up. I understand that the system needs to control costs so lower the rates. At this time in Iowa CMS is paying $200.32 per month for a concentrator lower it to $160,if the providers want to stay in business they will if not well at least it is not because CMS forced them out because of limiting who can provide the service.Also I know the Veterans Administration utilized this process for providing oxygen, there are some very unfortunates stories related to that process of delivering oxygen. Units being shipped home with the patient on the transit van with the patient being responsible for unloading it and the service showing up two days later to see if it is working properly. If you want to see how low the bids can go fine but once the low bid is established let everybody have the right to participate.
Thank You Fred Mathews RRT

Submitter : Archie Chapman **Date:** 06/28/2006

Organization : Chapman Healthcare Center

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1270-P-713-Attach-1.TXT

CHAPMAN HEALTHCARE CENTER, INC.
3701 DADEVILLE ROAD
ALEXANDER CITY, AL 35010
PHONE (256) 234-6366
FAX (256) 234-2366

June 28, 2006

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

To Whom It May Concern:

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

I am the administrator at Chapman Healthcare Center, located in Alexander City, AL. We are licensed for 212 beds. I have 239 employees at the present time. We offer Physical, Occupational, and Speech Therapy at our facility.

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

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

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

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

I appreciate your attention to this matter.

Sincerely,

Archie J. Chapman Administrator
Chapman Healthcare Center, Inc.

Submitter : Ms. denise edman **Date:** 06/28/2006

Organization : home air joliet

Category : Health Care Provider/Association

Issue Areas/Comments

Payment Basis

Payment Basis

I BELIEVE THAT THIS NEW LAW WITH CAPPED RENTAL CONCENTRATORS WILL BE TO HARD FOR THE SENIORS TO TAKE CARE OF.I FEEL THAT THEY WON'T TAKE CARE OF THEIR EQUIPMENT PROPERLY AND WILL RESULT IN MORE HOSPITAL STAYS.

Submitter : Dr. Eric White **Date:** 06/28/2006

Organization : Integrated Care Systems

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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 : Mrs. Joyce Yeary

Organization : Orthopaedic Associates

Category : Occupational Therapist

Date: 06/28/2006

Issue Areas/Comments

GENERAL

GENERAL

RE: Proposed Rule for Competitive Acquisition of Certain DMEPOS CMS-1270-P
Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiares in their care without additional constraints.
My name is Joyce Yeary OTR/L CHT and I am an occupational therapist and certified hand therapist specializing in the treatment of upper extremity disorders. I work in a outpatient therapy clinic and frequently treat Medicare beneficiaries. As a hand therapist orthoses are a critical part of patient treatment. A patient is frequently seen in the clinic postoperatively. The cast is removed, wound care is done, and a protective splint must be applied immediately to protect the surgical repair. The patient must leave the clinic with the splint on or risk injury. There is no time for competitive bidding. Splints also need to be custom fabricated to help increase motion of a joint and must be fitted precisely with just the correct angles to achieve increased joint motion. The therapist working with the patient has a good knowledge of their medical conditions and can make changes to the splint as therapy progresses. Requirements for patients to obtain bids for equipment would negatively affect their rehabilitation process and could even cause the patient to sustain injury. Therapists are unique from other suppliers of DMEPOS. We work as both a provider and a supplier, and it is difficult to divide the two aspects of our profession. In conclusion, I request that Medicare revise the proposed regulation to allow therapist to continue to supply critical OTS orthoses unimpeded by a competive bidding process.

Sincerely,

Joyce Yeary OTR/L CHT

Submitter : **Dr. Greg Geiger** **Date: 06/28/2006**

Organization : **Integrated Care Systems**

Category : **Pharmacist**

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

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. Kathryn Holtfreter** **Date: 06/28/2006**

Organization : **Traverse Bay Hand Therapy**

Category : **Occupational Therapist**

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Concerning DMEPOS - CMS-1270-P. I have been an Occupational Therapist for 21 years and a Certified Hand Therapist for 12 years. My focus of study for the last 18 years has been in Orthopedics. Having worked in this field for this long I have seen the effects of improper selection of orthoses or adaptive equipment for patients. My focus is on treating each individual case as unique and tailoring the treatment/equipment to meet the patients' needs. The clientele I work with primarily will be coming to me after a surgical procedure and decisions on protective devices need to be made at that time with consideration to a variety of factors, i.e. stable protective positioning, edema, functional needs for home or jobs. By knowing what precautions need to be taken I am better able to judge what orthotic to use, or how to modify an orthotic if need be. There have been too many times that I have evaluated a patient who has been in an inappropriate orthotic that has caused problems that need addressing in addition to the original injury which required the orthotic in the first place. Examples include: increased distal edema, shortened ligaments due to improper positioning of fingers, nerve compression syndromes due to tight bindings, decreased function of hand due to distal border of splints. When necessary I have asked permission to "do surgery" on the splint, which is usually readily given, and I then modify the splint as possible.(by this time the patient is already complaining of numbness or swelling and s/he is quite happy to have the situation corrected.) If I am allowed to fit the patient in the first place the above problems can be more easily avoided.

I fully support a move towards cost containment but not at the expense of a patients overall treatment outcome. Please allow me to use my expertise and years of experience to service my patients needs.

Sincerely,

Kathryn Holtfreter OTR/CHT

Traverse Bay Hand Therapy, 214 N. Division, Traverse City, MI 49684

Submitter : Ms. Carrie Baer

Date: 06/28/2006

Organization : The Therapy Center

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-719-Attach-1.DOC

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

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

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

My name is Carrie Baer, and I am an occupational therapist specializing in the treatment of upper extremity disorders. I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the exam. I am currently working in Oklahoma City, Oklahoma, and frequently treat Medicare and Medicaid beneficiaries that require custom orthoses.

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

Hand therapists typically treat very acute patients, and the need to be able to immediately dispense and adjust an orthosis is crucial to the final outcome of these patients. In the course of treatment of these patients, we will often see changes in stability, edema, inflammation, and wound healing that require immediate attention. This regulation, as stated, could significantly interfere with my ability to react to these changes, putting repairs and patients at risk.

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

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

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

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

Sincerely,

Carrie Baer, OTR/L, CHT

Submitter : **Dr. James Sudberry** **Date: 06/28/2006**

Organization : **Advanced Foot and Ankle Care Centers**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am urging CMS to revise the physician definition from 1861(r)(l) to 1861 (r) to allow podiatric physicians to bid to supply DMEPOS items to our patients only and execute physician authorizations, as DO's and MD's will be allowed to do. We use DMEPOS items in the same fashion as DO's and MD's as important treatments in certain foot and ankle pathologies, and are subject to the same state and federal regulations regarding their use. Requiring our patients to travel elsewhere to obtain these protective devices would put them at further risk for injury, as it would for patients of DO's and MD's as well. Again, I urge you to revise the physician definition to 1861(r).

Thank you for the work that you do in the interest of our patients.

Sincerely,

Dr. James A. Sudberry
Smyrna, Tennessee

Submitter : **Dr. Dvaid Taylor** **Date: 06/28/2006**

Organization : **APMA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 28, 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,

David T. Taylor, DPM

Submitter : **Dr. John M. Snyder** **Date: 06/28/2006**

Organization : **Academy of Podiatry**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 28, 2006

Mark. B. McClelland, 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, 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,

John M. Snyder, DPM

Submitter : **Dr. James Elipas** **Date: 06/28/2006**

Organization : **Ankle and Foot Specialists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Ankle and Foot Specialists
7437 N. Harlem Ave.
Niles, IL 60714
Phone: 847-588-3338
Fax: 847-588-3341

James G. Elipas DPM, PC
John T. Flanagan DPM

June 28, 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,

James G. Elipas DPM, PC
Member IPMA #5002

Submitter : **Dr. Aaron Solomon** **Date: 06/28/2006**

Organization : **APMA**

Category : **Physician**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

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. Our practice dispenses a large amount of DMEPOS items to patients. This includes but is not limited to diabetic shoes and CAM walkers. In the case of CAM walkers, under the bidding proposal, our practice would be unable to dispense a device that is NEEDED at that time to treat a severe injury. Forcing a patient to go untreated for an additional amount of time, risk and cost to the patient to go to another location to receive their CAM walker. In all of this time the patient could be in their device receiving the necessary care that they need. This proposal would force podiatric physicians to tiptoe along the lines of the standard of care by not being able to properly treat our patients by being unable to dispense the necessary DMEPOS item.

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. This professional discrimination against podiatric physicians only hurts our patients. We provide care for their lower extremity problems, and we are being told that we cannot do this any more. Our fear is that these services will be put into the hands of those who have limited expertise in the diagnosis and treatment of problems of the foot and ankle. We would be able to continue to provide the EXPERT care that we have been providing for our patients all along.

Sincerely,

Aaron Solomon, DPM

Date: 06/28/2006

Submitter : Mr. Brian Sigman

Organization : Board of Education and Services for the Blind

Category : State Government

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

Dear Sir or Madam,

I am writing to request that the Department of Health and Human Services reconsider the proposed language regarding the exclusion for coverage of low vision aids and closed circuit televisions, and that you fully assess the impact that such an exclusion could have on the lives of people who are legally blind before proceeding any further. It is acknowledged in the Notice of Proposed Rulemaking that three United States district courts have found that section 1862(a)(7)of the Act does NOT prohibit payment for video magnifiers. Therefore, the question arises as to why such an action is proposed to definitively state in regulation that these devices are not allowable when three separate courts have ruled to the contrary. It is greatly concerning to find such a notice of proposed rulemaking, that could result in health and safety concerns for individuals whose vision is greatly reduced, and who must utilize magnifying devices to maintain some degree of useable vision to remain independent within the home and community. I request that the Department of Health and Human Services first assess the health and safety impact, and that the results of this assessment be published before proceeding further with implementation of this proposed regulation.

Sincerely,

Brian S. Sigman,
Executive Director,
State of Connecticut,
Board of Education and Services for the Blind

Submitter : Dr. Mark Gagnon

Date: 06/28/2006

Organization : Dr. Mark Gagnon

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-726-Attach-1.DOC

ATTACHMENT TO #726

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,
Mark J. Gagnon, DPM

Submitter : Dr. H. R. Hadden **Date:** 06/28/2006

Organization : Midstate Podiatry Associates Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I AM REQUSTING THAT 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 DO PRESCRIBE AND SUPPLY DURABLE MEDICAL EQUIPMENT SUCH AS WALKING BRACES AND THERAPEUTIC SHOES. IF I AM REQUIRED TO BID TO SUPPLY TO AN ENTIRE METROPOLITAN STATISTICAL AREA, MY PATIENTS MAY NO LONGER BE ABLE TO GET THE MEDICALLY APPROPRIATE AND NECESSARY ITEMS FROM ME EVEN THOUGH THEY ARE INTEGRAL TO THE CARE I AM PROVIDING.

IN ADDITION, I WANT TO BE ABLE TO EXECUTE A PHYSICIAN AUTHORIZATION WHEN I DETERMINE A PARTICULAR BRAND IS NECESSARY.

I AM REQUIRED TO OBTAIN A VALID SUPPLIER NUMBER AND MUST ADHERE TO ALL OF THE CURRENT SUPPLIER STANDARDS TO WHICH AN MD OR DO MUST ADHERE, AND I AM SUBJECT TO STATE LAWS AND OTHER FEDERAL AND STATE REGULATIONS. IF CMS PLANS TO MAKE SPECIFIC ALLOWANCES FOR PHYSICIAN SUPPLIERS, PODIATRIC PHYSICIANS MUST BE INCLUDED.

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 MY PATIENTS, MY PATIENTS WILL NEED TO GO ELSEWHERE TO OBRTAIN THE DME THEY NEED, WHICH CAN RESULT IN INCREASED RISK TO THE PATEINT BECAUSE THEY COULD NOT OBTAIN THE NECESSARY DME AT THE TIME IT WAS NEEDED.

I HAVE BEEN IN PRACTICE FOR OVER 40 YEARS, AND HAVE TREATED MANY INJURIES OF THE FOOT AND ANKLE. IF I SEE A PATIENT WITH A FRACTURE, AND I DECIDE IT IS MEDICALLY NECESARY TO USE A WALKING BOOT TO TREAT THE PATIENT, I NEED TO MAKE SURE THE BOOT FITS PROPERLY. IF I AM NOT A SUPPLIER IN THE NEW PROGRAM, I WOULD NOT BE ABLE TO DO THAT.

AGAIN, I REQUEST YOU CHANGE THE DEFINITION FROM 1861(r)1) TO 1861(r) SO THAT I AM ELIGIBLE TO SUPPLY ITEMS TO MY PATIENTS ONLY, AND EXECUTE PHYSICIAN AUTHORIZATIONS. IF I AM REQUIRED TO INSTEAD BID TO SUPPLY THE ENTIRE MSA, MY PATIENTS WILL MOST CERTAINLY BE NEGATIVELY IMPACTED.

SINCERELY,

H. R. HADDEN, D.P.M.

Submitter : **Dr. Kelly John** **Date: 06/28/2006**

Organization : **Rockford Orthopedic 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,

Kelly J. John, DPM
535 Roxbury Road
Rockford, IL 61107
(815)398-9491

Submitter : **Dr. Warren L. Simmonds** **Date: 06/28/2006**

Organization : **Dr. Warren L. Simmonds**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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,who has been in practice for 46 years, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. This relationship enhances a more beneficial outcome for the patient. 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,

Warren L. Simmonds, DPM
1111 Kane Concourse, Suite 111
Bay Harbor, Florida 33154

Submitter : Dr. Thomas Rappette **Date:** 06/28/2006

Organization : Podiatrist

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-730-Attach-1.DOC

CMS-1270-P-730-Attach-2.DOC

ATTACHMENT 1 TO #730

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,

Thomas Rappette
654 West Veterans Parkway
Yorkville, IL 60560

ATTACHMENT 2 TO #730

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,

Thomas Rappette
654 West Veterans Parkway
Yorkville, IL 60560

Submitter : **Stuart Codron** **Date: 06/28/2006**

Organization : **Stuart Codron**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 28, 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,

Stuart Codron, DPM

Submitter :

Date: 06/28/2006

Organization :

Category : **Other Practitioner**

Issue Areas/Comments

Issue

Issue

I believe that people with diabetes, who happen to be covered by Medicare, should be given a choice of which blood glucose meter / meter test supplies will be covered by medicare. I believe simply making people have to take the "least expensive" meter will do a diservice to patients. For example some people need a meter with large print and others do not, some people will need a meter which is very simple in terms of sequence (because of a stroke, for example) while others will not, still others make have a nuerological tremor in their hands where a meter that allows for test strips to be applied to the drop of blood then put back in the meter would be a better choice for them, others may have another medical problem where issues relating to hematocrit might make it important for that patient to have one meter rather than another. Choice of blood glucose meter can be a lot more complex than a "one meter fits all" approach to Medicare patients. Choice of meters can be important to patients and have an impact on medical decisions that are made. This may be a less appropriate way of wringing savings out of medicare. The Medicare act should be ammended to allow the government to bargain with pharmaceutical and durable medical equipment manufactures to lower the prices of medications and durable medical equipment for medicare patients.

Submitter : John R. Hedding **Date:** 06/28/2006

Organization : John's Med Hill Pharm PC / supplier #1260350001

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I believe that instead of competitive bidding, CMS should remain open to the idea of small, local DME suppliers, rather than only allowing large DME clearinghouses. Local suppliers can do a better and more timely job of supplying the needs of their familiar customers, as well as saving CMS money. For our local customers to be required to deal with a DME provider who is perhaps hundreds of miles away, whose only job is to "sell" and who will NEVER see the beneficiary is not in the best interest of anyone, except perhaps the companies with the winning bids.

I urge CMS to set fair payment amounts for all covered items. As all are aware, fee schedules often don't cover even the cost of the item, not to mention shipping charges, nor the time involved to get all necessary documentation in place, arrange for the procurement and perhaps delivery of the item, and then to process the billing.

By keeping fee schedules in line with actual expenses incurred in providing DME, small suppliers may be able to continue to serve the needs of the Medicare/Medicaid populations in their areas. If the bidding process insures that DME supplies can only come from certain suppliers (in an effort to control costs), the effect on those populations, in remote areas such as ours, may be that beneficiaries won't receive supplies for diabetic testing, ostomy and urological supplies, as well as aids to daily living, in a timely fashion.

Submitter : Mr. Robert Miller **Date:** 06/28/2006

Organization : Bachs Home Health Care Supply

Category : Pharmacist

Issue Areas/Comments

Physician Authorization/Treating Practitioner

Physician Authorization/Treating Practitioner

It is NOT possible for a physician to determine the brand or model of a product ordered in a bid situation. As a vendor, we have obviously done outreach to our manfuacturers to determine the best possible price in order to be in the bid arena in the first place. CMS cannot then allow a physician to determine the brands of products ordered and require us to provide them.
Example: Stomahesive paste for ostomy care has been overpriced for years. If this product is a bid item, we as vendors will do outreach to other manufacturers to find a low cost alternative. That is what bidding is all about. Consequently we will then bid a price for that alternative. If we must through vague regulation dispense the BRAND name product for some unknown reason, then the concept of bidding is flawed. How can we be expected to control costs in that manner. It also should not be expected for us as providers to HOPE that most physicians will not demand, nor patient or therapists, the brand name product (the old win some lose some attitude). That is poor business logic.
Sincerely,
Robert G Miller, BS,RPh
Pres/CEO

Submitter : Ms. Cynthia Mathis

Organization : Ms. Cynthia Mathis

Category : Other Practitioner

Date: 06/29/2006

Issue Areas/Comments

GENERAL

GENERAL

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

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

I have been an occupational therapist specializing in the treatment of upper extremity disorders for over 10 years. I am also a certified hand therapist with specialized training and experience in treating patients with upper extremity problems. By the time a patient sees me, that patient has dealt with a problem that causes pain and limits in motion. Both of these decrease function such as the ability to brush teeth or unbutton pants to go to the bathroom. Part of the overall treatment plan may include a splint that either protects or assists in these functional activities.

Off the shelf splints at a discount store are cheaper, but cost more in the longterm. If the wrong splint is issued by someone who can provide cheap splints but doesn't have the experience to properly fit the splint or the opportunity to correctly adjust the splint as swelling or motion changes, then therapy will take longer and cost more. The therapist's input and expertise in the supply of an off the shelf orthosis saves money in treatment cost.

For my patients functional outcome, I request that Medicare revise the proposed regulation to allow therapists to continue to supply critical OTS orthoses unimpeded by the competitive bidding process.

Thank you for the opportunity to comment on this proposed regulation.

Sincerely,

Cynthia Mathis, OTR/L, MOT, CHT

Submitter : Dr. Stephen Levin **Date:** 06/29/2006

Organization : Dr. Stephen Levin

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

This is to comment on the definition of physician in regards to the competitive bidding process for DME supplies

CMS-1270-P-736-Attach-1.DOC

CMS-1270-P-736-Attach-2.DOC

ATTACHMENT 1 TO #736

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 have been practicing podiatric medicine for 8 and since obtaining my degree and residency I have always been considered a physician by my peers and my local hospitals. 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. I am astonished that even more restrictions are being placed on patients that translate into poor medicine and possibly harm to patients as well.

Sincerely,

Stephen F. Levin, DPM

ATTACHMENT 2 TO #736

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 have been practicing podiatric medicine for 8 and since obtaining my degree and residency I have always been considered a physician by my peers and my local hospitals. 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. I am astonished that even more restrictions are being placed on patients that translate into poor medicine and possibly harm to patients as well.

Sincerely,

Stephen F. Levin, DPM

Submitter : **Dr. Franklin Kase** **Date: 06/29/2006**

Organization : **Dr. Franklin Kase**

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. Franklin Kase

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 bec

Submitter : **Mrs. Elizabeth Burrows-Hight** **Date: 06/29/2006**

Organization : **MVP PT OT Hand Therapy, Lakewood Clinic**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS CMS-1270-P,

I am writing in effort to have Medicare revise the proposed regulation to establish a proces that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

My name is Elizabeth Burrows-Hight and I am an occupational therapist specializing in the treatment of hand therapy/upper extremity disorders for 8 years and frequently treat Medicare/Medicaid patients that require custom and off the shelf splints that require adjustment by the therapist. I am writing to request that Medicare revise the proposed regulation to allow therapists to continue to supply over the counter orthoses unimpeded by a competitive bidding process. As a hand therapist, I make decisions to issue a particular splint to a patient based on the nature of their diagnosis and take into account their range of motion, swelling, skin integrity, pain and comfort. I work with a variety of suppliers and also fabricate splints depending on the patient's needs. The provision of a splint is part of my profession and complete treatment plan and the competitve bidding regulation would pose a serious threat to my ability to effectively treat my patients in that it could mean that the particular supplier that wins the bid may not be the suitable type of splint that the patient is in need of, thereby jeapardizing the patient's care. In addition, should the patient be issued a prefabricated splint and it not fit properly, as a therapist I question whether it would be considered legal or ethical if the therapist adjusts the splint when the therapist isn't the one who prescribed the splint in question. It is the therapist that is trained in higher education and clinical experience that should be the one to decide on which splints would benefit the patient and need to be adjusted, not the highest bidder of a durable medical equipment supply company that is out to make a profit.

In conclusion, I request that Medicare revise the proposed regulation to allow therapists to continue to utilize their educational and clinical expertise in supplying OTS orthosis unimpeded by a competitive bidding process. Thank you for your attention and for giving me the opportunity to comment on this proposed regulation.

Sincerely,

Elizabeth Burrows-Hight

Submitter : **Dr. Russell Barone** **Date: 06/29/2006**

Organization : **Hendersonville Podiatry**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 28, 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.

I have been in practice for 27 years at the same location in Hendersonville, North Carolina. 75% of the patient population of my practice in Hendersonville is of geriatric age. They are very well aware of my existence and the services I provide including the diabetic shoe program. It is much more convenient for my patients to have access at my office location for DMEPOS than to be sent to another location.

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,

Russell J. Barone, DPM

Submitter : **Dr. Joseph Setter** **Date: 06/29/2006**

Organization : **Midstate Podiatry Associates, LTD**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 28,2006

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

Dear Dr. McClellan:

I am a Podiatric Specialist in Bloomington, IL. I request that the Centers for Medicare & Medicaide Services (CMS) modify the Physician definition used for the new competitive acquisition program from 1861 (r) (l) to 1861 (r) . I prescribe and supply select durable equipment , prosthetics, orthotics and supplies (DMEPOS) items tomy patients only. If I am instead required to bid to supply an entire metropolitan Statistical Area (MSA), my patients may no longer be able to acquire medically appropriate and necessary DMEPOS items from me though they are an integral to the care I provide.

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

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 the other suppliers, including the ability to bid to supply select DMEPOS items to my patients only and the right to execute a physician authorization.

For example, a patient treated by me for an ankle injury would be in need of an ankle brace to stabilize the ankle and crutches to off-weight the extremity in the course of my treatment of this patient. 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, that particular patient would need to go elsewhere to obtain the medically necessary equipment. So, that patient would risk converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications. In Medicine, time is golden.

So I ask you to please change the physician definition from 1861(r) (l) to 1861(r) so that I and other Podiatric physicians would be 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.

Fraternally,

Joseph R. Setter, DPM, FACFAS

Submitter : **Dr. Michael Sabia** **Date: 06/29/2006**

Organization : **Stamford Podiatry Group**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-741-Attach-1.PDF

STAMFORD PODIATRY GROUP, P.C.

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

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

June 28, 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:

We 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). We are podiatric physicians who prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to our patients only. If we are required to bid to supply to an entire Metropolitan Statistical Area (MSA), our patients may no longer be able to get medically appropriate and necessary DMEPOS items from us even though they are integral to the care we provide.

Additionally, we want to be able to execute a physician authorization when we determine that a particular brand of item is necessary for our patients.

Similar to MD and DO suppliers, we am required to obtain a valid supplier number and must adhere to all of the current supplier standards. We are 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. Our use of DMEPOS items as an integral part of patient care is no different than that of our MD and DO colleagues.

For example, if we treat a patient with an ankle injury, we may determine that an ankle brace is necessary to stabilize the ankle and crutches are necessary to limit weightbearing on the injured extremity. If we are not a DMEPOS supplier in the new competitive acquisition program because we were unsuccessful in competing to bid to supply to the entire MSA rather than just to our 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 we are eligible to bid to supply items to our patients only and execute physician authorizations. We want to be able to continue to provide medically necessary and appropriate care to the patients we serve.

Sincerely,

Michael L. Sabia, Jr., DPM

Marissa Girolamo, DPM

Rui DeMelo, DPM

Francisco Lago, DPM

Submitter :

Date: 06/29/2006

Organization :

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-742-Attach-1.DOC

ATTACHMENT TO #742

ROSS PRODUCTS DIVISION * ABBOTT LABORATORIES

625 CLEVELAND AVENUE * COLUMBUS, OHIO 43215-1724 * 614-624-7677

June 19, 2006

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

Dear Customer:

Abbott's Ross Products shares with you the common goal of providing quality products and services to patients who rely on enteral nutrition therapy to manage their health and well being.

With this in mind, we want to make you aware that the Centers for Medicare and Medicaid Services ("CMS") recently issued the above-referenced proposed rule that will require Medicare Part B suppliers of certain DMEPOS items, possibly including enteral nutrition, to submit bids and be awarded a contract in order to remain a supplier and receive reimbursement. This includes suppliers who provide enteral nutrition products and services to Medicare Part B patients in a skilled nursing facility setting. **This is a significant change to the current "any willing provider" environment, and means skilled nursing facilities will be required to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items provided to their own patients.**

In addition to making you aware of this proposed rule we are sending a list of key concerns regarding how this could potentially affect patient access and care in your facility. If you share in our concerns we urge you to send CMS a letter to that fact including these key concerns and any more that you may have.

Time is running out as the open public comment period for this rule closes June 30, 2006. Please take the time to write your letter and mail it as soon as possible. Comments can be electronically to http://www.cms.hhs.gov/eRulemaking or mail one original and two copies to:

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

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

You can obtain a copy of the competitive bidding proposed rule at:
http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/06-3982.pdf

Sincerely,

Maureen Doyle-Scharff
Director, Health Education, Policy & Programs

Submitter : Ms. Toni-Ann Esposito

Date: 06/29/2006

Organization : Toni

Category : Health Care Provider/Association

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Please do not proceed with this billing for DME
THe affect for the benificary is horrfic as the services
that go along with OXYGEN and other medical equipment will be
eliminated. The rebate clause is a clear inducement to the process
and must be eliminated at all costs
And access to patients must be addressed
The reprecusions to small providers appears to be restraint of trade
This system did not work on it's piolet trials it can not succeed
as it is written!
Be advised and I would be most happy to comment further
THANK YOU FOR THIS OPPORTUNITY
Toni Esposito RN<BSN

Submitter : **Dr. Harry Goldsmith** **Date: 06/29/2006**

Organization : **Dr. Harry Goldsmith**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

After reviewing the CMS proposal for competitive bidding, I have a significant concern regarding the methodology that could be used to equate (even reasonably) items included in a single product group.

CMS-1270-P-744-Attach-1.DOC

CMS-1270-P-744-Attach-2.DOC

ATTACHMENT 1 TO #74

Harry Goldsmith, DPM

13337 E. South St. #325
Cerritos, CA 90703
562 402-0789 hgfca@gte.net

June 27, 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: Proposed Rule - Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

To Whom It May Concern:

I appreciate the opportunity to comment on the above proposed rule regarding competitive acquisition of certain DMEPOS. After reviewing the text of the proposed rule, I have several concerns.

As a podiatrist, I am concerned over the methodology that was/is used to assign items to any given product group or product category. While I appreciate and agree with the development of what appears to be mutually exclusive product categories (e.g., oxygen, wheelchairs, hospital beds/accessories, negative pressure wound therapy devices, walkers, diabetic supplies, etc.), I have a concern that items assigned to specific product groups – in some cases – may not be all that "equal or comparable" when closely examined. Specifically, I am concerned that items of unequal overall quality, proven efficacy, product support capabilities, etc. are being lumped together, regardless, for the primary purpose of effecting a cost saving. While I am very much in favor of fair and reasonable pricing for DMEPOS, I am very much against placing two items which have not been shown to be equal and comparable into the competitive bidding process.

For example, while one could rather easily make the case that all "folding wheeled walker without seat" or "lancets, box of 100" or "stationary liquid oxygen" items within their respective product groups are more or less equal and comparable, items assigned within a product group such as negative pressure wound therapy (NPWT) may not be. Using the NPWT example (I believe the current HCPCS code is E2402), if two companies have products which are negative pressure wound therapy devices, but Company 1's product (VAC Therapy, KCI, San Antonio, TX) has widely been used within the United States (and around the world) for years to successfully close wounds in setting such as hospitals, other health facilities, in patients' homes (with the assistance of home health nursing), and in physician offices, and Company 2, (Blue Sky Versatile 1) relatively new to NPWT, does not enjoy the same experience; if Company 1 can present a number of clinical studies and peer-reviewed articles validating the efficacy and value of not only NPWT as a treatment modality, but also validating the efficacy and value their specific products on a variety of wound types, and Company 2 cannot; if Company 1 has a nationwide network of sales, education, training, and support personnel to assist healthcare professionals in filling their prescription demands for the product, ensuring

the proper use of their units, and providing a national network of 24/7 technical/repair support, and Company 2 does not – how can it be reasonably presumed that Company 1 and Company 2's products are equal, comparable, and will share similar cost profiles? And if one cannot equate the findings of their clinical trials, the efficacies of their products, and their commitment to providing product support, how can one expect to offer them within a single category for competitive bidding and be "comparable"?

I would think that, unlike "lancets, box of 100" or "foldable walkers without a seat" which one could reasonably argue are, within their respective product groups, uniformly equal, product items assigned to the negative pressure wound therapy devices group may not be comparable and equal. I believe to consider them to be comparable and equal by lumping them into a competitive bidding process would be patently unfair, potentially offering patients a CMS-approved product that does not, and has not had to meet the same standards - efficacy and support – that a competing company meets. This is potentially risking unintended negative outcomes for affected patients due to this process.

I would urge you to consider carefully reviewing all the factors regarding items (especially if there are very few competing items) included within any given product group to ensure that the competitive bidding process is truly fair. For the purposes of this competitive bidding proposal, I suggest that the NPWT category be removed from this process, or at the very least delayed until more information is available to substantiate that the product offerings are comparable.

Thank you for the opportunity to comment.

Harry Goldsmith, DPM

ATTACHMENT 2 TO #74-F

Harry Goldsmith, DPM

13337 E. South St. #325
Cerritos, CA 90703
562 402-0789 hgfca@gte.net

June 27, 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: Proposed Rule - Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

To Whom It May Concern:

I appreciate the opportunity to comment on the above proposed rule regarding competitive acquisition of certain DMEPOS. After reviewing the text of the proposed rule, I have several concerns.

As a podiatrist, I am concerned over the methodology that was/is used to assign items to any given product group or product category. While I appreciate and agree with the development of what appears to be mutually exclusive product categories (e.g., oxygen, wheelchairs, hospital beds/accessories, negative pressure wound therapy devices, walkers, diabetic supplies, etc.), I have a concern that items assigned to specific product groups – in some cases – may not be all that "equal or comparable" when closely examined. Specifically, I am concerned that items of unequal overall quality, proven efficacy, product support capabilities, etc. are being lumped together, regardless, for the primary purpose of effecting a cost saving. While I am very much in favor of fair and reasonable pricing for DMEPOS, I am very much against placing two items which have not been shown to be equal and comparable into the competitive bidding process.

For example, while one could rather easily make the case that all "folding wheeled walker without seat" or "lancets, box of 100" or "stationary liquid oxygen" items within their respective product groups are more or less equal and comparable, items assigned within a product group such as negative pressure wound therapy (NPWT) may not be. Using the NPWT example (I believe the current HCPCS code is E2402), if two companies have products which are negative pressure wound therapy devices, but Company 1's product (VAC Therapy, KCI, San Antonio, TX) has widely been used within the United States (and around the world) for years to successfully close wounds in setting such as hospitals, other health facilities, in patients' homes (with the assistance of home health nursing), and in physician offices, and Company 2, (Blue Sky Versatile 1) relatively new to NPWT, does not enjoy the same experience; if Company 1 can present a number of clinical studies and peer-reviewed articles validating the efficacy and value of not only NPWT as a treatment modality, but also validating the efficacy and value their specific products on a variety of wound types, and Company 2 cannot; if Company 1 has a nationwide network of sales, education, training, and support personnel to assist healthcare professionals in filling their prescription demands for the product, ensuring

the proper use of their units, and providing a national network of 24/7 technical/repair support, and Company 2 does not – how can it be reasonably presumed that Company 1 and Company 2's products are equal, comparable, and will share similar cost profiles? And if one cannot equate the findings of their clinical trials, the efficacies of their products, and their commitment to providing product support, how can one expect to offer them within a single category for competitive bidding and be "comparable"?

I would think that, unlike "lancets, box of 100" or "foldable walkers without a seat" which one could reasonably argue are, within their respective product groups, uniformly equal, product items assigned to the negative pressure wound therapy devices group may not be comparable and equal. I believe to consider them to be comparable and equal by lumping them into a competitive bidding process would be patently unfair, potentially offering patients a CMS-approved product that does not, and has not had to meet the same standards - efficacy and support – that a competing company meets. This is potentially risking unintended negative outcomes for affected patients due to this process.

I would urge you to consider carefully reviewing all the factors regarding items (especially if there are very few competing items) included within any given product group to ensure that the competitive bidding process is truly fair. For the purposes of this competitive bidding proposal, I suggest that the NPWT category be removed from this process, or at the very least delayed until more information is available to substantiate that the product offerings are comparable.

Thank you for the opportunity to comment.

Harry Goldsmith, DPM

Submitter : **Ms. Joseph Lewarski** **Date: 06/29/2006**

Organization : **Inogen, Inc.**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-745-Attach-1.DOC

ATTACHMENT TO # 745

inogen

Via Electronic Transmission

June 28, 2006

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

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

Inogen, Inc. an oxygen technology research, development and manufacturing organization, respectfully submits the following comments on the Centers for Medicare and Medicaid Services (CMS) notice for a proposed rule rulemaking (NPRM) identified as CMS-1270-P: Medicare Program; Competitive Acquisition for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues.

As a manufacturer of new and innovative home oxygen technologies, we have grave concerns regarding the ramifications surrounding the implementation a competitive bidding program as outlined in CMS-1270-P, with emphasis on its impact on patient access to medically prescribed and appropriate home medical equipment. We believe that the inclusion of medically complex respiratory technologies, including oxygen therapy devices is inappropriate. Technologically and clinically complex respiratory therapies, including but not limited to oxygen therapy, sleep therapy and mechanical ventilation require detailed technical and professional support at the initiation of use and periodically throughout the period of medical necessity. These complex technologies are inappropriate for competitive bidding as the potential for poor outcomes exists by not considering the need for the availability of skilled services required for education, ongoing monitoring, follow-up and identification of additional medical needs. These concerns were echoed in previous comments regarding competitive bidding previously submitted by professional clinical organizations.[1]

As a general statement, we find the NPRM entirely too ambiguous with key elements of the program not included in the document. The following outline our specific comments regarding the proposed rule:

[1] American Association for Respiratory Care (AARC) comments to CMS on the clinical and patient safety ramifications of competitive bidding of respiratory technologies.

PAYMENT BASIS

Inflation Update

CMS states that providers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U. Providers have no assurance that Congress will not override the update through subsequent legislation in any given year. CMS needs to address how it plans to assure providers that the inflation update to the competitive bid price will not be subject to subsequent freezes in the CPI-U. If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids.

Beneficiary Switch to Contract Suppliers

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

Application of DRA to Oxygen Patients

It is unclear from the NPRM how CMS intends to apply the DRA provisions on oxygen to grandfathered suppliers and beneficiaries. Will the "grandfathered" relationship terminate at the conclusion of 36 months? 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.

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. The ABN process has been somewhat ambiguous to date and needs to be clarified in policy to ensure that providers and beneficiaries can effectively utilize the ABN process to gain access to products and services determined to be non-covered as a result of the bid implementation.

CRITERIA FOR ITEM SELECTION

Items Included in Competitive Bidding

Homebound Medicare patients with Chronic Obstructive Pulmonary Disease (COPD – i.e., emphysema and chronic bronchitis) and other pulmonary diseases require a range of equipment

including oxygen cylinders, flow meters, oxygen regulators, liquid oxygen systems, oxygen concentrators, and mechanical ventilators. Since these items require periodic performance checks and maintenance, the professional clinical support and the technical service component tied to this equipment is indispensable. Medically complex respiratory patients rely on the continued use of this equipment in order to live or, at the very least, maintain their quality of life. These patients depend on clinical and technical equipment services. Not recognizing and accounting for this need compromises patient safety and quality of care. Therefore, we strongly recommend that technologically complex respiratory devices, including oxygen, CPAP, invasive and non-invasive ventilation devices be excluded from the competitive bidding program.

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

Coding Issues and Item Selection

The methodology that CMS proposes for item selection relies on historical data and does not take into account recent changes in a benefit that will affect utilization. For power wheelchairs, recent changes in the HCPCS codes, a new LCD, and new fee schedules will significantly change utilization for these items. Specifically, CMS would lack the cost and volume data required under the formula in the NPRM to select an item. CMS would be unable to determine which codes within this product category are the highest cost and highest volume for Medicare using current data. The generic HCPCS coding system is simply too ambiguous. There is significant variance of device cost, quality and capabilities within the same product code. This statement is supported by findings from the Government Accounting Office (GAO).[2]

Current HCPCS codes are simply too broad, encompassing items that represent vastly different technologies. CMS should develop narrow product categories with appropriately stratified HCPCS codes so that providers may submit proposals specific to the unique components of the technology and its applications versus grouping widely diverse products into very narrow codes. Failure to appropriately define and stratify the HCPCS codes will likely result in restricted beneficiary access to medically appropriate and innovative home medical technologies.

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 suppliers will not be accredited at the time they are awarded contracts. As a result, bids from providers who are ultimately disqualified will be considered in the determination of the pivotal bid and single payment amount. By definition, *only* accredited suppliers should be eligible to bid. CMS should not proceed with competitive bidding until it is sure that that all suppliers who may want to submit bids have had an opportunity to get accredited.

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[2]GAO Report to Congressional Committees. "Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment & Supplies." Publication GAO-04-765 Sept 2004

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

Market and Supplier Capacity

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

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 Amount

CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the "winning suppliers". This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due

to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects. More importantly, we believe Congress did not have this methodology in mind when it authorized competitive bidding under the MMA.

CMS should set the payment amount at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This method was used in the two demonstration projects. 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.

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

TERMS OF CONTRACT

Repair or Replacement of Equipment

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

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.

SUMMARY

The most basic of economic principles play a central role in the respiratory device manufacturers' development and the home medical equipment (HME) providers' adoption of new technologies in the home care market. Free market competition, company differentiation and positioning are key drivers that stimulate HME providers to investment in and implement new and innovative home respiratory technologies. In the absence of local market competition, commodity pricing models, along with the elimination of physician, referral and patient choice of HME provider will rapidly

diminish the demand for new and innovative respiratory technologies, as many HME providers will be forced to focus their attention primarily on the acquisition price of the equipment.

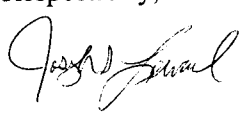
A major challenge to technology innovation is the generic and often ambiguous nature of the current HCPCS coding system as it applies to home respiratory technologies. Items must be billed through a complex system that typically uses generic codes that can represent myriad products. In a report to Congress, the *Government Accounting Office* noted there is significant variance of device cost, quality and capabilities within the same product code and that expansion of the coding system is needed to better identify and stratify the various technologies.[3]

Technology has evolved since the demonstration projects and new technology is essential to meet the clinical needs of all beneficiaries. HIPAA requires standardized coding among all payors, which means that even outside of the Medicare and Medicaid programs the impact of the coding deficiencies will affect patient access to new technologies. Efficient coding is critical to ensuring patient access to evolving technology. As HME providers are faced with the requirement to bid these HCPCS codes simply on price, the likely result will be use of the least costly alternative within the specific equipment HCPCS codes. This was evidenced during the competitive bid demonstration projects, where there was a noted decrease in the use of innovative and newer ambulatory oxygen technologies among the bid winners.

The implementation of competitive bidding and continued payment reductions for respiratory technologies will produce a domino effect as the deleterious impact migrates throughout the supply chain. The net effect will be the significant reduction or elimination of innovation efforts as manufacturers shift their resources and efforts to producing low-cost, commodity devices that will likely be in higher demand. This perpetuates the need for American manufacturers to move operations off-shore to remain competitive.

We thank you for the opportunity to submit comments and hope that our comments, in conjunction with others, will serve as a guide for the implementation of the competitive bidding program.

Respectfully,



Joseph Lewarski, BS, RRT, FAARC
Vice President of Clinical
& Governmental Affairs

[3]GAO Report to Congressional Committees. "Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment & Supplies." Publication GAO-04-765 Sept 2004

Submitter : Mrs. Beth Wood **Date:** 06/29/2006

Organization : na

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I have some concern about the competitive bid ruling regarding UE braces and splints/orthotics. I have been a practicing therapist for 26 years and am a Certified Hand Therapist. I weekly am faced w/ a patient who was given an off the shelf brace from their doctor or picked up one at Wal-mart. They don't fit,have rubbed sores and in some cases are being applied backwards causing further pain and injury. I routinely remove the metal supports, remodel them or replace them w/ thermoplastic stays in order to provide adequate support in the proper position. Pt's are overjoyed w/ the comfort and reduced pain when fit properly. Because of the high mark up on braces by the hospital I work for I do not routinely issue the brace but I fit the patient in a variety I keep on hand and then give them a picture in a catalog w/ several competing options and direct them to the internet if they have that option. In some cases where immediate harm would befall them by the delay in securing the brace I will provide them in the clinic. If a prefabricated brace is not an option due to swelling, nontraditional hand size, etc. I make them a custom splint. This is especially true w/ finger splints as they almost routinely have to be customized in order to have a good close fit that does not restrict other functioning unnecessarily. I have concern the wording of this bill proposed would compromise patient care. I am equally concerned about controlling medical costs. I have tried hard over the years to minimize costs to patients. I encourage home made weights and therapy equipment, garage sale bedside commodes and bath benches. When I had my own practice my fees were far below the average. I like the concept of competitive bidding, as this drives down costs usually, but what about requiring a therapist to make an assessment for determining what kind is purchased. Otherwise I fear the pt will still have a selection under their beds w/ none of them fitting properly. My husband has recently completed a book about the Health Care System
called 'Sharks on the Wounded Fish'. It deals w/ his experiences as having been a patient (quadraplegic) and later an Occupational Therapist. Costs out of control are addressed and how the patient needs to be the one calling the shots but they are fearful of alienating their doctors or health care providers. If there is a way for the patient to drive the purchase and be educated on the profit margins some providers/ manufactures have set, this may better keep costs under control. Perhaps a centralized information bank where they can look at a provider network and chose the type of prefabricated brace they want. The need for customized vs prefabricated is a tougher issue and probably caps are the only way to stop abuse. A public listing for patients to see costs comparisons might also be employed. This would be cumbersome to keep updated. I have always thought a pt should receive a pre estimate and a post treatment bill and that all medical supplies should have price tags on them just like in a shoe store. This allow patients to have more say so about what they wished to be charged for and be empowered to refuse medications. etc to opt for less expensive ones that are not the latest pharmacy companies promotion. Well enough of soap box. Thanks for considering my thoughts. Beth A. Wood, OTR/L CHT

Submitter : **Dr. Barnett Fung** **Date: 06/29/2006**

Organization : **Dr. Barnett Fung**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am writing to urge CMS to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain DMEPOS from 1861(r)(1) to 1861(r)
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 MSA my patients will be negatively impacted. My patients rely on me as their podiatric physician to use my best medical judgement and clinical skills in treating them, should they have to go elsewhere to obtain their DMEPOS, it will bring undue hardship for them and will further incurred additional expenses for them. Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to our patients only 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.
Sincerely,

Dr. Barnett Fung

Submitter : Dr. Angelina Colton-Slotter **Date:** 06/29/2006

Organization : Dr. Darla R. Miller & Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 28,2006
Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-1270-P

Dear Dr. McClellan,
I am writing to urge CMS to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain DME, prosthestics, orthotics, and supplies from 1861(r)(l) to 1861(r).
As a podiatric physician, I prescribe and supply DMEPOS to my Medicare beneficiaries as an integral part of patient care. I am required to 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 supply select DMEPOS items to only my patients and the right to execute a physician authorization.
In my practice, I commonly prescribe and dispense diabetic extra depths and other diabetic products such as wound care medications and dressings. Due to a large portion of my practice catering to diabetics it would put my patients at a disadvantage to have to travel further to get the needed wound care supplies. Diabetic wounds can deterioate very quickly if the patient is on his/her feet traveling for what they need. This is only one example of a situation that would put patients at risk for traveling for their supplies, etc.
I strongly urge CMS to modify the physician definition from 1861 (r)(l) to 1861 (r). I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.
Thank you.
Sincerely,
Angelina M. Colton-Slotter, DPM

Submitter : Dr. Jean M deLeon **Date:** 06/29/2006

Organization : Baylor Health Care System

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-749-Attach-1.TXT

CMS-1270-P-749-Attach-2.TXT

ATTACHMENT TO # 749

June 28. 2006

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

Dear CMS:

I am a wound care physician in the Baylor Health Care System in Dallas, Texas. I run the inpatient wound care unit as well as an outpatient wound care center for the system. As a member of the Alliance of Wound Care Stakeholders, representing the Academy of Physical Medicine and Rehabilitation, I participated in a lively discussion of possible changes that could seriously affect the care of my patients under the proposed "Competitive Bidding" process. My understanding of the process is that approximately ten categories of medical devices and products would be competitively bid upon by at least two suppliers starting in October of 2007. The concept of delivering healthcare at the lowest cost possible is part of Baylor's overall goal of providing safe, timely, effective, efficient, equitable, patient centered care (STEEEP®). This effort to improve healthcare, however, is based on achieving the highest quality clinical outcomes. The "Quality Standards and Accreditation" section does not give any qualifying criteria for suppliers who submit a bid in a particular category. I believe this opens the door for suppliers to cut corners in an effort to submit the lowest bid. Education programs, clinical studies on safety and efficacy, and incentives to evolve and improve technology are reduced when there are no standards or rewards for achieving a better outcome or a superior product. Life frequently shows us that you get what you pay for.

The Baylor Health Care System has made efforts to evaluate 'best practice" and then to raise the bar on clinical outcomes throughout the system. We believe the financial costs involved in this effort are for the benefit of all patients, not just the Medicare population. If the products made available to the Medicare population are chosen on cost only without adequately factoring in efficacy and safety, then the Medicare population would not be receiving equitable care. Depending on the category, that care may not be the safest, most effective care, tailored for their needs. How can the six sigmas of quality only apply to certain patient populations and only in certain healthcare settings?

I believe that a 'Best Bid" concept would offer a reasonable approach to reducing healthcare cost. Simply stated, each supplier submitting a bid must provide information on their item that reflected some basic quality assurance. These categories, for instance, would include: safety features; reports of adverse events; breadth of product line and ability to accommodate variable patient needs; clinical and bench research to support efficacy; educational and service support. Each category would receive an assigned weighted score based on the information provided by each supplier. Just as some of the large GPOs approach bids, this non-financial score can be combined with a financial score to determine the top two bids. If the supplier can not meet the minimum set of non-financial criteria which ensures a minimum level of quality, then the bid is not considered. Subsequently, suppliers who have neglected doing any safety or efficacy trials on their device / product or suppliers who have put no resources into meeting the

Baylor Specialty Hospital
3504 Swiss Avenue
Dallas, Texas 75204
jeande@baylorhealth.edu

needs of a particular patient population would not be able to game the system with a low dollar bid.

Negative pressure wound therapy is a particular area that I have discussed with CMS on previous occasions. In this category, the VAC device is the only proven, safe, negative pressure wound healing device currently on the market. The suction device that recently received the same code under this category has no randomized controlled studies and merely uses research on the VAC to support it's efficacy. As I have discussed with CMS earlier this year, I will not bring the suction device into the Baylor Health Care System because of significant safety issues as well as clearly inferior healing rates. Any "competitive bidding" process should uncover these deficits and inspire the supplier to invest in improving the safety features as well as efficacy to better serve the Medicare population. Given the complexity of wounds that I treat in the Long Term Acute Care as well as the Acute Care settings with the VAC, I would need to extend inpatient hospital stays for Medicare patients to safely transition them to the home setting if the suction device was the only option for Medicare patients. The outpatient and home health settings would certainly be prolonged using a less effective device. My Medicare patients are some of the most fragile patients that I care for and could develop more complications during that prolonged closure and require more admissions to the hospital. The intended benefit of choosing a less expensive device in this case would result in more expense in other areas and possible harm to the patient. Quality standards should keep these unintended consequences from occurring. The most expensive device or product is not necessarily the most efficacious but nor is the least expensive item. Therefore the "Competitive Bidding" process should be the "lowest best bid" to ensure quality and contain cost.

Unfortunately, even with the most well researched guidelines there is no one drug or one treatment strategy that will work for all patients. Guidelines cannot replace thinking. I must treat my patients using the best available data and my physician-patient relationship. If I know that one particular device or product is needed to heal my patient, then I hope that Medicare patients will not be prevented from accessing this care with proper documentation and justification on my part.

I hope that you consider these comments and continue to support the six sigmas of quality for patient care. Please feel free to contact me with any questions or comments.

Respectfully,

Jean M. de Leon, MD

Baylor Specialty Hospital
3504 Swiss Avenue
Dallas, Texas 75204
jeande@baylorhealth.edu

needs of a particular patient population would not be able to game the system with a low dollar bid.

Negative pressure wound therapy is a particular area that I have discussed with CMS on previous occasions. In this category, the VAC device is the only proven, safe, negative pressure wound healing device currently on the market. The suction device that recently received the same code under this category has no randomized controlled studies and merely uses research on the VAC to support it's efficacy. As I have discussed with CMS earlier this year, I will not bring the suction device into the Baylor Health Care System because of significant safety issues as well as clearly inferior healing rates. Any "competitive bidding" process should uncover these deficits and inspire the supplier to invest in improving the safety features as well as efficacy to better serve the Medicare population. Given the complexity of wounds that I treat in the Long Term Acute Care as well as the Acute Care settings with the VAC, I would need to extend inpatient hospital stays for Medicare patients to safely transition them to the home setting if the suction device was the only option for Medicare patients. The outpatient and home health settings would certainly be prolonged using a less effective device. My Medicare patients are some of the most fragile patients that I care for and could develop more complications during that prolonged closure and require more admissions to the hospital. The intended benefit of choosing a less expensive device in this case would result in more expense in other areas and possible harm to the patient. Quality standards should keep these unintended consequences from occurring. The most expensive device or product is not necessarily the most efficacious but nor is the least expensive item. Therefore the "Competitive Bidding" process should be the "lowest best bid" to ensure quality and contain cost.

Unfortunately, even with the most well researched guidelines there is no one drug or one treatment strategy that will work for all patients. Guidelines cannot replace thinking. I must treat my patients using the best available data and my physician-patient relationship. If I know that one particular device or product is needed to heal my patient, then I hope that Medicare patients will not be prevented from accessing this care with proper documentation and justification on my part.

I hope that you consider these comments and continue to support the six sigmas of quality for patient care. Please feel free to contact me with any questions or comments.

Respectfully,

Jean M. de Leon, MD

Baylor Specialty Hospital
3504 Swiss Avenue
Dallas, Texas 75204
jeande@baylorhealth.edu

Submitter : Dr. T. Eric Siceloff **Date:** 06/29/2006

Organization : Dr. T. Eric Siceloff

Category : Physician

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I am writing to request that the Centers for Medicare & Medicaid Services revise the definition being used in the proposed rule regarding competitve bidding for certain durable medical equipment from 1861(r)(1) to 1861(r)(3).

As a podiatric physician I prescribe and dispense DMEPOS items to Medicare beneficiaries as an important part of patient care. These patients rely on me to have the judgement to treat their condition and supply the necessary equipment to treat them appropriately. Referring the patient to another DMEPOS supplier could jepordize their condition and create further disability.

I current maintain a supplier number and adhere to the current supplier standards in order to supply my patients with the items they require based on medical necessity. This is intregal to my patient's care and podiatric physicians MUST be included. I believe my patient's will be negatively impacted if they have to seek items from the low bidder in the Metropolitan Statistical Area.

Please change the current physician definition so that I may continue to provide quality care to all of my Medicare beneficiaries.

Sincerely,

T. Eric Siceloff, D.P.M.

Submitter : Dr. Regis Boudreau **Date:** 06/29/2006

Organization : American Podiatric Medical Association

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am writing to urge CMS to revise the physician definition used in the proposed rule that would establish a competative aquisition 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 patients rely on me to use my best judgement and clinical skills in treating them. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. Podiatric phycicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to my patients only and the right to execute a physician authorization.

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

Sincerely,

Regis Boudreau, DPM

Submitter : **Dr. Michael Carroll** **Date: 06/29/2006**

Organization : **Friendly Foot Care**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 28, 2006

Mark B. McClellan, MD, PhD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1270-P

Electronic Comments

Dear Dr. McClellan:

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

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

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

For example, if I treat a patient with an ankle injury, I may determine that an ankle brace is necessary to stabilize the ankle and crutches are necessary to limit weightbearing on the injured extremity. If I am not a DMEPOS supplier in the new competitive acquisition program because I was unsuccessful in competing to bid to supply to the entire MSA rather than just to my patients, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

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

Sincerely,

Dr. Michael Carroll

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

Organization : Foot Care Center, PLC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

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)(3).

As a podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. These individuals are my patients and they rely on me to use my best medical 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)(3) before finalizing the regulations for the competitive acquisition program. I want to be able to continue to supply DMEPOS
items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

Sincerely,

James I Lewis, DPM

Submitter : **Dr. Joseph Kiefer** **Date: 06/29/2006**

Organization : **Dr. Joseph Kiefer**

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,

Joseph E. Kiefer, DPM

Submitter : Mrs. kerry demers **Date:** 06/29/2006

Organization : Mrs. kerry demers

Category : Occupational Therapist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

This is another ridiculous bureaucratic scheme to drive healthcare costs up and further inconvenience patients. Don't you people have anything better to do? I believe our country's healthcare system has greater priorities than to further complicate our senior citizens' health care system.

Submitter : **Dr. Stephen Bennett** **Date: 06/29/2006**

Organization : **APMA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Dear Mr McClellan,

I am writing to object to the fact that the proposed competitive acquisition program for certain DME and supplies fails to include doctors of podiatric medicine along with other physicians.

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 see alot of traumatic injuries that require immoblization and compression. If I were unable to supply my patients with the immediate care that is medically warrented, and instead was forced to send patients off site, to g.. knows where, to obtain the proper fitting device, further injury would be possible and questions would arise to my competence. Furthermore, after some in office surgeries, where bones are cut, immobilization devices are dispensed, to keep the bones in there proper alignment. If I prescribe the device before the surgery, the time it takes for the patient to aquire it may postpone the surgery and place further disability and discomfort on the patient.

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 Stephen J Bennett

Submitter : Mrs. ROSIE RAY **Date:** 06/29/2006

Organization : JIM DANDY MEDICAL

Category : Health Care Provider/Association

Issue Areas/Comments

Gap-filling

Gap-filling

There should be three categories for the bidding of Power chairs and Scooters to save the government money, allow small business s to stay in business and to better provide for the beneficiary.

The 3 separate categories for Powerchairs and Scooters should be:

1. New machines only, off the shelf so to speak. (Scooter Store) will probable get this bid in most cities.

2. Used machines only . Keeps the small business s going. The market is brimming over with a abundance of slightly used or demo machines. We refuse buying them every day. Lets put them to use and save some money. The machines are too expensive to be treated as if they are disposable.

" Used Powerchairs and Scooters bid amount should be at least 75% below the winning bid for new equipment.

" To encourage beneficiary s to accept used equipment offer them a 100 dollar rebate and the fact they are sharing in protecting the Medicare Trust Fund.

" Set strict standards for the selling of used equipment. I can suggest many.

" Encourage doctors to prescribe used equipment in cases that:

1. The beneficiary s condition may worsen rapidly to the point they can not handle the equipment.

2. Their life expectance may not be over 2 years.

3. Custom machines as determined by their doctor, for those that s health could be damaged if put in standard equipment. This is much needed and not well addressed at the time. A small business can give these beneficiary s the special attention they require. Their needs are more complex and their condition sometimes more lengthy. (MS for an example) The company winning this bid should furnish a loaner when needed, keep parts in stock, and have a fast response time. They could use the services of a physical therapist when needed. Manufactures offer very good training on seating. We have found physical therapist and occupational therapist to be well trained on the beneficiary s medical needs and limitations but know absolutely nothing about what equipment is available on the market. They frequently request us to do a in-service to enlighten them. We know at least one rehabilitation center that gives the beneficiary physical therapy regardless if its helpful or not(some times even harmful) and then sends them to a DME owned by them, for a machine. Two hits on Medicare at one time.

My suggestions are for the good of all Medicare The beneficiary- and lastly the Compliant Provider and there are some out there even if not recognized.

My company would be willing to test pilot the used equipment or
the custom equipment in San Antonio Tx. I am sure many providers would bite the bullet and follow suit.

ROSIE RAY DREYER
owner Jim Dandy Medical

Submitter : Dr. Roberto Araujo **Date:** 06/29/2006

Organization : Senior Campus Physicians

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1270-P-758-Attach-1.RTF

ATTACHMENT TO #758

June 23, 2006

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

Attention: CMS-1270-P Electronic Comments

Dear Dr. McClellan:

I am writing to urge the Centers for Medicare & Medicaid Services (CMS) to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) from 1861(r)(1) to 1861(r)(3). As a podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. These individuals are my patients and they rely on me to use my best medical 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 provide care at one of the 17 current campuses of Erickson Retirement Communities, namely Riderwood Village. 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 also dispense shoes under the diabetic therapeutic shoe bill, therefore helping prevent complications to the feet of several diabetics on this campus. These complications could lead to unnecessary hospitalizations, amputations, and even death. I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r)(3) before finalizing the regulations for the competitive acquisition program. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted. Thank you for your attention to this matter.

Sincerely yours,

Dr. Roberto Araujo
Senior Campus Physicians, Podiatry
Erickson Retirement Communities
Riderwood Village Campus
3110 Gracefield Road
Silver Spring, MD 20904
301-572-8340

Submitter : Mr. joey tart **Date:** 06/28/2006

Organization : family medical supply inc.

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Gap-filling

Gap-filling

The provision for replacing the Gap Filling methodology for setting fees for new DMEPOS items is inappropriate for inclusion in the Competitive Acquisition NPRM. There can be no assurance that suppliers would submit bids for new technologies at the level that would be inferred through Gap Filling. Rather, issues of Gap Filling should be addressed in a separate NPRM and/or special competitive acquisition process.

The three methodologies proposed to replace Gap Filling are not objective and not directly related to price/value assessment. In addition, none of the methodologies appear to involve the manufacturer and his/her health economic or other support data. Rather, functional and medical benefit assessments would be conducted by CMS contractors who may or may not have expertise in the technology/therapeutic area. The proposal to use these methods to adjust prices that were established using Gap Filling at any time after January 1, 2007 makes it all the more important to include the manufacturer in the process.

Issue

Issue

Competitive Bidding

Issue

The core problem with the NCB program is that we are bidding on products only and CMS refuses to acknowledge the service part of the DME Industry. If prices continue to be cut it will affect the service the patient receives. When service deterorates the patient will be left to fend for themselves and will end up in an institution instead of at home and this will in turn cost the country more money to care for the elderly in institutions rather than at home which is the most cost effectice mode of care.

Opportunity for Networks

Opportunity for Networks

Providers have not had ample time to set up networks in order to bid the contracts. Once the MSA's are anounced then there will not be sufficient time to set up a network. Also an individual provider may want to submit an individual bid as well as bid with a network. I understand a provider not being able to participate in a network and as an indivdual provider, but they should be able to bid both ways.
Does the network itself have to seek accreditation?

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

One of the problems with the NCB program is that it does not encourage competition at all. It will actually eliminate competition. There should be a provision to allow the small provider to survive or CMS will be left with only a few large providers which will then be able to raise their prices in the next round of bidding. I believe that when the bids are awarded their should be a requirement to have a certain percentage of smaller providers awarded bids.

Physician Authorization/Treating Practitioner

Physician Authorization/Treating Practitioner

The NPRM proposes to allow physicians to prescribe a specific brand or type of equipment.

The bidding process is not designed to bid on specific brands, it is designed to find the cheapest item possible to meet the need. Physicians should be allowed to specify the type of equipment but not the brand. If physicians are allowed to write orders for specific brands then the representatives for the manufacturers will be calling on the doctors and trying to persuade them to write orders for their equipment. This also will allow manufacturers to entice Doctors to order their equipment and then set up agreements with only certain providers so that they can capture the market in that MSA.
If it is possible for a physician to require the providers to deliver a particular brand then we should be bidding on particular brands and there should be one price for one brand and another price for another brand.

Quality Standards and Accreditation for Supplies of

Submitter : Dr. Benjamin Hockin

Date: 06/29/2006

Organization : Complete Foot Care L.L.C.

Category : Physician

Issue Areas/Comments

Physician Authorization/Treating Practitioner

Physician Authorization/Treating Practitioner

I am Podiatric Physician currently treating a great number of diabetic patients in need of protective shoes and inserts.

Less experienced personnel (pharmacists, nurses, orthotists) who fit diabetics for foot wear, put the patient at greater risk of infection and ulceration when improper fitting occurs. The reasoning is that they are untrained in identiying and/or treating these conditions as they arise. In my experience, diabetic shoe fitting should be done under the direct supervision of a podiatrist being that we treat these conditions daily.

To allow suppliers with minimal expertise (including pharmacies, nurses, or orthotists) in the pathology of the foot and ankle, would do a great disservice to the Diabetic Shoe Program and put patients at further potential risk.

Diabetic shoe/insert fitting has a great potential for complications if done improperly in my experience. Therefore, it should be performed mainly by podiatrists or inexperienced personnel under the direct supervision of a podiatrist. It is also important that podiatric physicians do not get 'lumped' into a bidding competition with non-physician suppliers for this reason.

Benjamin J. Hockin D.P.M.
Board Certified, ABPOPPM

Submitter : Mr. Banji Adereti **Date:** 06/29/2006

Organization : Elim Pharmacy

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I strongly object to CMS alternative proposal that will limit beneficiaries choice of DME providers this porposal will severely restrict beneficiaries' access to needed items and supplies. limiting beneficairies choice/access to mandatory mail service is not apporpriate for DME like Lancets and Glucose testing strips- items that beneficiaries need convenient and frequent access to.

Criteria for Item Selection

Criteria for Item Selection

The competitive bidding program should not include common DMEPOS supplies such as diabetic testing supplies. These are items that beneficiaries always got from thier pharmacies along with thier other medications.

Submitter : **Dr. Diane Krasner** **Date: 06/29/2006**

Organization : **Wound & Skin Care Consultant**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

Dr. Diane L. Krasner
PhD RN CWCN CWS BCLNC FAAN
"""""""
Wound & Skin Care Consultant

212 East Market Street
York, PA 17403 USA
Phone 717.812.1734 " FAX 717.812.0135
e-mail dlkrasner@aol.com

June 29, 2006

Centers for Medicare & Medicaid Services
Department of Health ad Human Services
File: CMS-1270-P

I am a board certified wound, ostomy, continence nurse, a certified wound care specialist and the lead co-editor of the text Chronic Wound Care: A Clinical Source Book for Healthcare Professionals (3rd edition, 2001). I practice as a Wound, Ostomy, Continence Nurse at St. Agnes Hospital here in Baltimore. I would like to comment on the effect the proposed rule for competitive bidding would have on Negative Pressure Wound Therapy (E2402).

The proposed rule assumes that all the devices within a HCPCS code are comparable in their safety and efficacy. In the case of Negative Pressure Wound Therapy (E2402), this is not the case. If the proposed rule were implemented, patients requiring VAC Therapy would not have access to that therapy. This is a serious concern given that VAC Therapy is the standard of care for patients with certain types of very serious wounds, including dehisced surgical wounds, open amputations, necrotizing fasciitis wounds, serious traumatic wounds and so on.

For many of my patients with life-threatening wounds, the VAC is a life-saving device. The alternative, Blue Sky, is in no way a comparable therapy. It is just like the wall suction devices we rigged up 25 years ago to deal with copious drainage when we didn t have anything better. Comparing the VAC and Blue Sky is like comparing apples and oranges.

Please feel free to contact me if you would like to discuss this matter further with a locally-based clinician. My office number at St. Agnes Hospital is 410.368.3034. My home phone is 410.321.4994. My cell number is 717.781.5955.

Sincerely,
Diane L. Krasner

CMS-1270-P-762-Attach-1.DOC

Dr. Diane L. Krasner
PhD RN CWCN CWS BCLNC FAAN
•••••••
Wound & Skin Care Consultant

212 East Market Street
York, PA 17403 USA
Phone 717.812.1734 • FAX 717.812.0135
e-mail dlkrasner@aol.com

June 29, 2006

Centers for Medicare & Medicaid Services
Department of Health ad Human Services
File: CMS-1270-P

I am a board certified wound, ostomy, continence nurse, a certified wound care specialist and the lead co-editor of the text Chronic Wound Care: A Clinical Source Book for Healthcare Professionals (3rd edition, 2001). I practice as a Wound, Ostomy, Continence Nurse at St. Agnes Hospital here in Baltimore. I would like to comment on the effect the proposed rule for competitive bidding would have on **Negative Pressure Wound Therapy (E2402).**

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For many of my patients with life-threatening wounds, the VAC is a life-saving device. The alternative, Blue Sky, is in no way a comparable therapy. It is just like the wall suction devices we rigged up 25 years ago to deal with copious drainage when we didn't have anything better. Comparing the VAC and Blue Sky is like comparing apples and oranges.

Please feel free to contact me if you would like to discuss this matter further with a locally-based clinician. My office number at St. Agnes Hospital is 410.368.3034. My home phone is 410.321.4994. My cell number is 717.781.5955.

Sincerely,

Diane Z. Kraoner

Submitter : **Ms. Kathy Pilon** **Date: 06/29/2006**

Organization : **Kalkaska Memorial Health Center**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-763-Attach-1.DOC

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

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

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

My name is Kathy Pilon, and I am an occupational therapist specializing in the treatment of upper extremity disorders. I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the exam. I am currently working in a rural health facility, and frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

Therapists are unique from other suppliers of DMEPOS. We work as both a provider and a supplier, and it is difficult to divide the two aspects of our profession. Orthotics are only one portion of the overall treatment plan. Hand therapists typically treat very acute patients, and the need to be able to immediately dispense and adjust an orthosis is crucial to the final outcome of these patients. In the course of treatment of these patients, we will often see changes in stability, edema, inflammation, and wound healing that require immediate attention. This regulation, as stated, could significantly interfere with my ability to react to these changes, putting repairs and patients at risk.

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

A patient's needs are thoroughly evaluated by a therapist to determine the appropriate orthosis for beneficiary use. In many cases, a specific brand may be the only one that will appropriately meet the needs of a patient. Should this rule be enforced as written, suppliers will not be required to bid on all brands of a certain orthosis. As a result, there is no guarantee that a beneficiary will be able to find a specific orthosis in their area, potentially limiting their access to an important orthosis. As a hand therapist, I have found the need to replace an inappropriate orthosis, fitted by by an orthotics provider, at great expense to Medicare to pay for both.

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

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

Sincerely,

Kathy Pilon, OTR, CHT

Submitter : **Dr. Paul Kesselman** **Date: 06/29/2006**

Organization : **Dr Paul Kesselman**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1270-P-764-Attach-1.DOC

CMS-1270-P-764-Attach-2.DOC

Paul Kesselman DPM FACFAS
980 East 12th Street
Brooklyn NY 11230
Tel 718-338-7878 Fax 718-338-7879

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

June 26 2006

Re: COMPETITIVE ACQUISITION FOR CERTAIN DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, and SUPPLIES

Dear Sir/Madam:

After a thorough review of the proposed "Competitive Acquisition Program, I am significantly troubled about the impact this will have on my patient's ability to receive and my ability as a podiatric physician to deliver effective and quality health care. There are several major areas of concern:

1) Podiatric Patients to Receive Prejudicial Treatment by CMS

During a recent meeting, CMS officials confirmed that podiatric physicians will be eligible to participate in the competitive bidding program, but these officials also indicated that CMS **DID NOT** use the 1861(r) definition of physician, which includes podiatric physicians, in defining individuals who may bid to supply DMEPOS to only their patients. Instead, CMS officials used the more restrictive 1861(r)(1) definition of physician, which restricts its definition of physician to MDs or DO's.

This does not allow podiatrists the same abilities as MD and DO physicians to competitively bid in order to supply DMEPOS items to their patients, and has the real potential to be a real and present danger to podiatric patients.

As a result, of using1861(r)(1) definition of physician, podiatric physicians will be expected to bid to supply DMEPOS items to an entire metropolitan statistical area (MSA) rather than their own patients. This will necessitate podiatric physicians to compete with large, traditional DMEPOS suppliers for the right to supply items to Medicare beneficiaries.

This is clearly biased against podiatrists and our patients. It has the potential to cause significant harm to our patients, both those who may be acutely injured, and cannot tolerate delays in obtaining care, and those who with chronic disease processes.

A daily example in my office is that of an acutely injured patient with a foot or ankle fracture that has been reduced and now requires immobilization. Instead of the patient receiving a cam walker and crutches from my office, under the proposed competitive bidding system, they may now be required to go cross town to obtain these medically necessary services. That same patient seen by an MD or DO physician would not face the potential harm solely created by a proposed new system of reimbursement, and not due to my level of expertise as a podiatric physician.

Podiatrists just as MD and DO physicians, primarily supply DME supplies only to their current patients. As physicians we do not generally advertise ourselves as DME suppliers to the general public and only offer DME products as services which are integral to their medical services.

Under the proposed system, patients of podiatric physicians, many of whom are poor and elderly would be unduly punished. These patients will now be required to make several visits to both their podiatrist and another supplier in order to be furnished with needed medical supplies. These same patients seeking similar care from an MD would not be so punished. Since many podiatric patients suffer from multiple diseases this will be create significant problems in acquiring medically necessary products which they would otherwise have unfettered access to from the physician who is treating them. This will certainly create logistical problems for the patients and their families, potentially resulting in further medical complications.

Federally funded transportation assistance is now the only way many of our patients obtain medical care. Should the podiatric physician not be unable to deliver their acutely required care, patients will be required to go to other providers in order to receive their DME items. This will result in the federal government paying for additional trips to multiple providers in order for patients to obtain necessary supplies. As a result the total cost of furnishing DME products to podiatric patients under the proposed system may exceed the current fee for service system, and would actually higher than that when provided by an MD/DO supplier. I do not believe that any of these scenarios were the intent of the original authors of the competitive bid system.

As a result of this bias, the physician definition selected by CMS officials will negatively impact podiatrists' ability to render both effective and quality medical care to our patients. I am therefore urging you to change the definition of physician within the proposed competitive bidding program to include podiatrists.

2) Physician Need to Participate in Competitive Bidding

A recent review of the 2004 data on DMEPOS services reveals that all physician categories (MD DPM DO) are responsible for less than 4% of the DMEPOS services provided. Creating more restrictions and burdens on these physician categories, many of whom are small businesses, will result in most electing not to participate in the competitive bidding process. This will certainly be to the detriment of patient care and will most certainly not be an effective means of cost containment. I therefore question the efficacy of requiring any physician group in participating in competitive bidding s as a means of reducing expenditures on DMEPOS.

3) Cost of Travel to obtain DMEPOS

Patients who require acutely injured and/or have other urgent medical needs are often in no position to travel to another provider after being initially assessed and immobilized. In particular, the elderly often have multiple co-morbidities and may have required special arrangements for transportation to get to their doctors' offices. Requiring these frail patients to go to another provider for services which otherwise are readily obtained at my and many other physicians' offices will create an undue stress for them and increase the real costs of delivering their health care. Many may select to delay medically necessary treatment, others will elect to go to emergency rooms, and others will select to go to another provider to obtain the necessary DMEPOS service, via publicly funded transportation as per the proposed guidelines. Any of these possibilities will increase the real costs of delivering any given DMEPOS.

Should the patient elect to delay seeking care, this will ultimately allow their wounds, fractures and other disease states to progressively worsen. The potential escalation for an inexpensive minor problem into one which would require additional and more expensive sophisticated medical/surgical services is especially problematic to me as a podiatric physician. Having thoroughly read the proposed competitive bid program, I see no evidence that this has been factored into any theoretical cost savings postulated by CMS.

Particularly troublesome is what factoring in transportation costs may do to the real costs of delivering inexpensive off-the-shelf devices and/or dressings with present reimbursements at under a few hundred dollars. Adding in transportation and aide costs funded through the federal Medicaid programs, as well as municipally assisted transportation services through "Access A Ride Programs" would cause the real costs of providing these services, all paid for, or subsidized by the Federal Government to be exorbitantly higher that at present.
This would also create an undue financial stress on already strapped local and state government budgets to meet any additional costs not already paid for by the Federal Government.

4) Additional Expenses for Rural Patients

Patients who live in rural areas could be required to travel long distances in order to obtain necessary services, which up to this time could have been provided for locally in their doctor's office. This too would create long delays in delivering effective and timely patient care. There would also be a disproportionate increase in the financial costs necessary to transport patients' long distances in these areas.

5) The end of the small DMEPOS Supplier and easy patient access

Podiatrists and other small DMEPOS suppliers cannot afford retaining cost consultants employed by many large DMEPOS suppliers in order to determine what might be a winning bid. This will effectively eliminate the ability of small companies providing easy access to patients out of business.
This will in the long run result in large corporations rendering ineffective less accessible care to those who most need it.
Impeding access to any medically necessary service, will ultimately in the long run, cost Medicare more money as complications from lack of easy access multiply.

6) The cost of monitoring bids

A competitive bidding system would invite more fraud and abuse by large DME dealers who could get the "inside tract" on bidding, identical to what transpires with many other publicly funded works projects. The cost of monitoring this bidding system would also create another financial burden for the government significantly reducing any projected savings otherwise created.

7) Generic vs. Brand Name Supplies

The ability of the DME service provider to provide a generic device due to cost/profit restrictions on bids, rather than what was originally prescribed for by the physician, may cause significant problems for patients.

In the case of specially required off the shelf devices for patients who would not fit into a generic device (i.e. an obese patient with a fracture would not be able to fit into most commercially available CAM walkers, and requires a more expensive type such as one of the Bledsoe devices). It is already almost impossible to fit patients like this at today's current rates, without the supplier taking an economic loss. Further rate reductions will either force suppliers to refuse supplying this type of patient, or force the supplier to ask for a prescription for a custom fracture brace, costing hundreds if not thousands of dollars more.

This will expose the patient to an increased risk of functional limb loss if they cannot find a suitable supplier as well as increased costs for those previously outlined in paragraphs 1-5 not yet factored in.

8. Therapeutic Foot Wear and Surgical Dressings.

Upon reviewing the proposal it appears that these two items are exempt from competitive bidding, I cannot find an exact resource which would specifically state these items are exempt. Despite assurances from Dr. Edwards the SADMERC director, to their exclusion, I would urge CMS to specifically state which product items, by category, are exempt. This should be posted not only in the Federal Register, but on a website which would be updated on a regular routine basis.

Therapeutic Shoes for diabetics require fitting by professionals who have an intimate knowledge of foot anatomy and diabetic foot pathology. Doctors of Podiatric Medicine treat millions of patients with diabetic foot pathology and have intimate knowledge of their patient's medical histories, pathologies far superior to medical suppliers. Doctors of Podiatric Medicine are in a unique position to determine which shoe would be most suitable for their patients' individual needs. Many podiatrists have unfortunately been witness to the devastating effects a poorly fitting shoe has caused by medical suppliers who are untrained in proper shoe fitting techniques. These often result in significant ulcerations, infections and limb loss, at a substantial cost to the Medicare program. Simultaneously we are aware of the significant preventative benefits appropriately fitted shoes can provide, and the millions of dollars in costs savings that this type of preventative care provides to the Medicare program. The American Podiatric Medical Association and I along with other professional organizations have been working for the last several years with SADMERC's medical director, Dr. Edwards to revamp the Medicare Therapeutic Shoe Bill to insure that patients receive shoes from qualified providers (such as podiatrists). The result to diabetic patients could be catastrophic if podiatrists were unable to continue to service these patients with appropriate therapeutic shoes and would certainly result in much higher financial expenditures for the Medicare program.

Surgical Dressings:
Similarly because of our ongoing treatment of diabetic foot ulcers, patients need to have easy access to dressings which are most efficacious for their specific wounds, and not driven solely by the profit motives of a large medical/surgical supplier. Doctors of Podiatric Medicine are in a unique position to understand the needs of their patients' wounds, and should be able to continue to provide their patients with the best surgical dressings available.

By allowing podiatrists, who generally have long term relationships with a higher level of responsibility level to their patients than paraprofessional DMEPOS suppliers, to continue to function as their patients' DMEPOS suppliers, patients can be assured that they are receiving the correct products based on medically necessity, and not motivated purely by profit.

Summary and Suggested Changes:

A) Summary

For the above stated reasons the competitive bidding process, particularly as it would apply to podiatric physicians is flawed. It is therefore my opinion that the proposed competitive system will most certainly result in a system which:

1) Will not realize the savings projected;
2) May result in higher expenditures than through the current system for many services;
3) Unduly interferes with the doctor patient relationship, particularly for podiatrists' and our patients;
4) Places patients in harms way solely based on a system of reimbursement, and not based on provider licensure or expertise.

Suggested Changes:

I am therefore urging you to implement the following changes to the competitive bidding system:

1) Podiatrists should be included in your definition of physician with regards to participation in the competitive bidding system, and all physician specialty types should be exempt from the requirement in participating in the competitive bidding process so long as they are only supplying their own patients.
2) Some safe harbor should be created for small suppliers in order to assure patients easy access in obtaining DMEPOS supplies.
3) An any willing provider ruling stipulating that any provider, so long as they have submitted a bid, may choose to accept the winning bid fee schedule in their area.
4) Podiatrists and other physicians should be exempt from the inventory, toll free and other high cost requirements of quality standards proposals and proposed competitive bidding system. The APMA AMA and other physician specialty societies should be entrusted with setting up standards in mutual cooperation with CMS that would be unique for physicians.
5) Insure that podiatrists and other physicians have the ability to provide necessary DME services within the legal scopes of their practices.
6) Exclude off the shelf devices such as therapeutic shoes, surgical dressings orthopedic immobilization devices including CAM Walkers, crutches, canes from the competitive bidding proposal.

I look forward to continuing this dialogue and am prepared to answer any further questions you may have.

Sincerely,

Paul Kesselman DPM FACFAS

Paul Kesselman DPM FACFAS

Submitter : Dr. Charles Morelli **Date:** 06/29/2006

Organization : Sound Shore Podiatry & Foot Surgery Center

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,

Charles Morelli DPM FACFAS
Mamaroneck, NY