Submitter : **Mr. John Houston** **Date: 06/28/2006**

Organization : **APEX Infusion Pharmacy**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See Attacment

CMS-1270-P-601-Attach-1.PDF

ATTACHMENT TO # 601

APEX Infusion Pharmacy

6/26/2006

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:

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

We are an Infusion Home Care Pharmacy located in Signal Hill California.

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

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

2. We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for infusion and enteral therapies, but urge CMS to recognize that Medicare payments both within and outside the competitive bidding program need to be at a level

sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. CMS should affirm this point in the final rule.

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

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

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

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

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

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

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

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 562 597-6800.

Sincerely,

John Houston
Manager

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

Submitter : **Ms. Marcia Nusgart** **Date: 06/28/2006**

Organization : **Coalitions of Enteral Nutrition, Wound Care Manufa**

Category : **Device Industry**

Issue Areas/Comments

Background

Background

CMS Should Issue the Final Rule as an Interim Final Rule with Comment Period

The Coalitions have been on the record at both the PAOC meetings and the open door meeting to address the proposed rule in complimenting the CMS staff for its hard work that it has devoted to this effort. However, it occurs not only to us but also to other associations that CMS has laid out a number of unanswered questions without the Agency committing to a concrete proposal on particular topics. The product selection
section of the regulation, which simply sets out general criteria for subsequent product selection, and the section regarding the application of competitively bid rates in other areas of the country, are two examples of this practice.

In addition, the quality standards that are extremely relevant to the competitive bidding program have not been released yet, even though both stakeholders and CMS would benefit from comments that reflect the application of the final quality standards to this program. At the PAOC meeting, CMS staff noted that the Agency had received over 5.000 comments on the quality standards and that they had been modified. It is imperative for stakeholders to see the final quality standards since they interrelate with key elements of the proposed rule due to their impact on the type and number of suppliers who may be able to submit, bids, the size of the suppliers, the construction of product categories and the appropriateness of the approach of the proposed rule s method for determining a single payment amount.

At this juncture, it is difficult to project what the final rule will look like on a number of important issues where CMS did not propose a specific course of action. For that reason, we suggest that CMS issue the final rule as an interim final rule with comment period, so that the public will see, for the first time, CMS decisions on an array of issues and thus will have an opportunity to comment on concrete proposals.
This would be more than good and fair policy. It also would be consistent with applicable law. Section 1871(a)(4) of the Social Security Act provides that a final rule will be treated as a proposed rule if it includes provisions that are not logical outgrowth(s) of a previously published notice of proposed rulemaking. Congress clearly was concerned about the type of situation where a proposed rule does not flesh out CMS intent with enough specificity so that the final rule s provisions surprise the public that commented on the proposed rule. The success of the CAP resides with defining and administering the details of the program. It is very difficult to comment if we do not know CMS thinking on various issues which are integral to the implementation of the program.

Testing if it works

The Coalitions of Enteral Nutrition Manufacturers, Respiratory Care Manufacturers, Wheelchair Seating Manufacturers and Wound Care Manufacturers (Coalitions)submit the following comments in response to the proposed rule on Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues, 71 F.R. 25654 (May 1, 2006) (the Proposed Rule).
The Coalitions would like to comment on the following issues:
" CMS should issue the final rule as an interim final rule with comment period
" Gap-Filling Proposal
" Criteria for Item Selection
" Exclusion of Surgical Dressings entirely from the competitive acquisition program (CAP)
" Exclusion of Enteral Nutrition from the first phase of the CAP
" Rebate Program

Gap-filling

Gap-filling

Gap-Filling Proposal
The Coalitions commend CMS recognition of the inadequacies of the gap-filling methodology. The gap-filling formula in antiquated and has become more problematic due to fee schedule freezes mandated by Congress. Moreover, the problem is intensified by the growing trend toward testing requirements and the SADMERC code verification of products.
CMS proposes to amend its current gap filling methodology for establishing fee schedule amounts for certain items of new DMEPOS and for readjusting fee schedules for some items of DMEPOS which had been previously established using gap filling. The proposed new procedure would include a technology assessment based on a comparison of three areas: function, price and medical benefit. CMS states that the Council on Technology and Innovation has endorsed this initiative in order to coordinate the activities of coverage, coding and payment and to coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

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

" What would trigger such an assessment?
" Which of the three areas of the assessment would be the first area of comparison?
" Which criteria would be used for assessment in each of the three areas?
" Which entities within CMS would participate and at what level?
" What is the role of the FDA?
" When and how would outside contractors be used?

" When and how would outside stakeholder opinions be solicited?

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

CMS also 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. The Coalitions strongly oppose this aspect of the proposal.

Since this new initiative is not required as part of the implementation for competitive bidding and is not mandated by either the MMA or the DRA, the Coalitions recommend:

" All references to the technology assessment as a part of gap filling should be removed from the final rule
" CMS develop an appeals process in situations where the manufacturer disagrees with the recommendation of a contractor and has data to support their opinion.
" CMS should publish this provision for comment as a separate proposed rule, with specific procedural requirements.

Submitter : **Mrs. Carolyn Busch** **Date: 06/28/2006**

Organization : **San Dimas Community Hospital**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Medicare patients who need specialized splinting for various diagnoses,such as rheumatoid arthritis, cerebrovascular accidents or wrist and hand injuries benefit from custom, readjustable splints that occupational therapists are qualified to fit and fabricate. We are trained to assess functional needs of these patients and can make orthotics that are less costly and more comfortable than many pre-fabricated splints. A patient who has a custom splint should return to the same therapist or facility for adjustment, since the professional who designed and fabricated the splint would be aware of possible problem areas.

CMS-1270-P-604 **Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues**

Submitter : Lois Carlson **Date & Time:** 06/28/2006

Organization : Lois Carlson

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-604-Attach-1.RTF

ATTACHMENT TO #604

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 Lois Carlson, 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 Connecticut, 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. 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,

Lois Carlson, OTR/L, CHT

Submitter : **Ms. Michelle McCarty** **Date: 06/28/2006**

Organization : **Physiotherapy Associates**

Category : **Occupational Therapist**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I am an occupational therapist specializing in the treatment of upper extremity disorders. I have specialized in this area for over 9 years. I am currently working in an outpatient therapy office, and frequently treat Medicare and Medicaid beneficiaries that require custom and off the shelf orthoses.

Therapists are unique from other suppliers of DMEPOS. We work as both a provider and a supplier, and it is difficult to divide the two aspects of our profession. As an upper extremity specialist, 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 and upper extremity 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.

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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.

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

Organization : **Brookfield Podiatry Center**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Dr. Thomas J. Mack

Foot Surgery and General Podiatry
9144 Broadway Avenue
Brookfield, Illinois 60513
(708) 387-0633

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,

Dr. Thomas J. Mack

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

Organization : Specialty Medical Sales

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-607-Attach-1.DOC

Comments: CMS 1270-P

"Conditions for awarding contracts"
Proposed 414.414 c. Quality Stds. & Accreditation "

The grace period for accreditation should consider the average length of time from preparation to survey date to final corrections to accreditation status. This is a major expense for the vast majority of DME suppliers and usually involves 4 to 6 months of preparation before survey date. The time frame should be 12 months in the bidding areas and those DME's going to bid should have a certified letter from one of the approved accreditation companies that shows a schedule / time frame. Staggering the rollout will allow CMS to correct problems before they become widespread and meet the demands of the MSA.

"Proposed 414.414 d Financial Standards"

The applicable financial standards should be defined before the RFP is issued to the DME's. Again, the smaller supplier may have excellent financials and a line of credit for servicing their historical growth but will need to secure additional sources to service the new capacity. If the supplier has shown a growth rate of 10 to 15% for the past 2 to 3 years is this sufficient to meet the forecasted capacity of the MSA? How will CMS determine the appropriate number of suppliers for a product category in each MSA? How is my capacity determined if my claims in a category are small as compared to the average? This could be by choice, referral contracting, better marketing all of which does not mean a supplier does not have capacity it is just underutilized capacity.

"Proposed 414.414 e Determine the Pivotal Bid "

There is no incentive to exclude extreme low bidders as they will be paid at the pivotal bid rather then there own bid. Recommend using a standard deviation from the median to disallow statistical outliers while ensuring sufficient capacity of suppliers. This would favor the smaller DME and balance program costs and savings.

"Opportunity for Participation by small Suppliers"

The model, most small DME's have followed (less then 10 employees), to compete against regional and national companies is by providing superior service and niche markets. . We do this by same day set up, follow up, educate and we live in the community. I concur with CMS recommendation on selecting of multiple suppliers

and allowing suppliers how many product categories we want to submit bids versus a single bidding competition for all items. This will favor the specialized supplier. Companies that are niche providers should have the option of becoming part of a network to compete in the bidding process as well as submitting a bid on their area of specialization. Just because a supplier may not be a one stop shop should not prevent them for servicing a MSA.

Quality Standards for Suppliers of DMEPOS.

Since 12/11/2000 suppliers have been required to meet Medicare enrollment standards at 424.57. Medicare states that there has not been sufficient oversight of suppliers related to the quality and provisions of their products. The OIG has conducted several investigations and uncovered many examples of fraud and abuse. Additional quality standards that address integrity, performance management, accountability and service to beneficiaries need to be **defined and be measurable. What constitutes the beneficiary satisfaction with the product and supplier?** More importantly, how will these standards be enforced if current manpower can't oversee the current system? Just because one is "deemed accredited "does not mean the company won't engage in questionable practices. I would start by not allowing REBATES from suppliers whose bid was lower then the established payment to the beneficiary. The savings is realized already by CMS and the primary concern of the beneficiary is quality of both product and service not the dollars. People need to be more responsible and accountable for there health care. You are asking suppliers to be more accountable, beneficiaries and rebates spells trouble.

Submitted by Tom Polston, President
Specialty Medical Sales
1702 S. Hwy. 121, 603
Lewisville, TX 75067

Submitter : Mrs. Peggy Walker **Date:** 06/28/2006

Organization : US Rehab

Category : Nurse

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

Competetive bidding will reduce the number of small suppliers and will basically put many small suppliers out of business. This also decreases patient service and care. Small suppliers take care of patients in rural areas & small towns which the competetive bid will harm. The patient will be the one in the end that will lose their right for patient choice.

Submitter : Mr. phil carter **Date:** 06/28/2006

Organization : wilcox pharmacy

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

This act will place an undue burden on the senior population, especially in rural america. The cost of doing business is much higher when your patient base is minimal, and is spread over many miles. Providers will be forced to decrease services such as delivery,and product choices (for the patient). The patient will also be denied provider choice simply because there will not be many independent providers left.The big national companiess tend NOT to be located in rural areas. Would you be pleased if your elderly parents have to drive 150 miles for healthcare supplies? In the rush to 'save money', this act is ill concieved without consideration of all of the true impacts it will bring.

Submitter : **Dr. Matthew Garoufalis** **Date: 06/28/2006**

Organization : **American Podiatric Medical Association**

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,

Matthew G. Garoufalis, DPM, FACFAS, FACFAOM, CWS

Submitter : **Ms. Janet Pedder** **Date: 06/28/2006**

Organization : **Meriter Hospital**

Category : **Nurse Practitioner**

Issue Areas/Comments

Issue

Issue

Making patients own oxygen equipment is absurd, let alone paying for maintenance....The fat cats in Washington just can't let go of their money, can they? I am infuriated that a bill is being passed to make oxygen equipment an ownership vs. rental so that the dme companies can continue servicing the equipment. Would you expect your parent to be doing this, given that they are on a limited salary?

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

Organization : Bachs Home Health Care Supply

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The concept of the ABN (Waiver) has not been addressed as to its proper usage in the future. It is possible for a vendor to base their award on a specific brand of product, but the patient may desire/physician require another updated or alternative model/brand. For instance, a mastectomy patient may be required to a winning provider who has based their bid on Product A, but the patient may want and be willing to pay for the upgrade to Product B. How does that get handled? Do they sign the ABN as before and pay the difference? Or, is the winning bidder not allowed to offer ugrades any longer? If that is so, where does the patient now go to get the product they desire WITHOUT costing the program any more outlay (ie, the patient pays the difference)
This concept can be applied to walkers, wheelchairs, etc... it is not specific to any category... In other words, everyone gets the cheapest models available under the winning bids, but those that can afford to upgrade should be allowed to....this concept is critical to determining a company's bid price ultimately.....
Sincerely,
Robert G Miller
Pres/CEO
908-813-3003

Submitter : Dr. Terry Ann Donovan

Date: 06/28/2006

Organization : Carolina Foot Care Associates, PLLC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

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

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

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

Submitter : Mr. Gerard McKeegan **Date:** 06/28/2006

Organization : Ross Park Home Infusion Services

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1270-P-614-Attach-1.DOC

Ross Park Home Infusion Services
Ross Park Pharmacy Inc.
380 Summit Avenue
Steubenville OH 43952
rphis@trinityhealth.com
"Keeping you at home, where you belong"

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:

Ross Park Home Infusion Services is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

We are a small home infusion company with three full-time employees serving rural and urban areas of mid-Eastern Ohio and the West Virginia Panhandle bordering the Ohio River. We have been in business since 1998 and serve approximately sixty (60) patients of which twenty (20) are Medicare patients and another 25 are Hospice patients.

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

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

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

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

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

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

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

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

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

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to 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 800-655-5332.

Sincerely,

Gerard M. Mc Keegan, R. Ph.
Pharmacy Manager

c.c.: Gerald, John, Executive Director, Tri-State Health Services
John Stoll, RN, Director of Clinical Services
Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

Submitter : **Dr. Andrew Boulton** **Date: 06/28/2006**

Organization : **Dr. Andrew Boulton**

Category : **Physician**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

see attachment

CMS-1270-P-615-Attach-1.DOC

28th June 2006

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

Dear Sirs

RE: CMS 1270-P

I am writing to you as a clinically active Professor of Medicine who also leads a large clinical research group in diabetic foot problems. The questions raised by CMS 1270-P give rise to some concern: if I am interpreting this correctly, then for wound care and advanced modalities, this might have the unexpected consequence of somewhat limiting our choice for evidence-based treatment of complex diabetic foot ulceration. In this regard I am referring to negative pressure wound therapy (NPWT). According to my interpretation of recent developments regarding a complicated formula to pick 10 MSAs for competitive bidding, then it appears that NPWT will possibly end up as being one of the categories that is competitively bid. Thus there will be 2 potential treatments here that are a) VAC therapy (KCI) and b) Versatile 1 therapy (BlueSky).
Might I point out that these 2 devices are extremely different and do not work in an identical way. VAC therapy is a good example of what we should be practicing today – that is, evidence-based therapy. Numerous publications have confirmed the efficacy of this device, the most important being a recently published randomized controlled trial in the Lancet (November 2005) which demonstrated that NPWT using the VAC was associated with a faster wound healing time and a trend towards a reduction in re-amputations in patients with post-operative complex diabetic foot wounds. In contrast, the other device which is the Versatile 1 therapy, to my knowledge has no randomized controlled trials to support its use. Moreover the VAC therapy (KCI) can be used on an outpatient basis thereby reducing costs as the patient can be treated at home and remain mobile.
Whilst I firmly believe that competition is healthy, and often results in innovation and may improve overall patient care, I would wish to point out to you that in this particular case, in view of the differences between these 2 devices, this is not true competition.
Might I please suggest to you that because of the marked differences between these 2 devices, it would be premature to include them in this stage of competitive bidding: this might have the potential to have an adverse overall effect on the clinical management of complex diabetic foot wounds.

Yours sincerely

Andrew JM Boulton MD DSc (Hon) FRCP
Professor of Medicine, University of Miami, Fl and
University of Manchester, UK.
Chair, Foot Council, American Diabetes Association.
Director for Advanced Clinical Postgraduate Courses in
Developing Countries for EASD/ADA/IDF.
Email: aboulton@med.miami.edu

Submitter : **Dr. Craig Breslauer** **Date: 06/28/2006**

Organization : **South Florida Orthopaedics**

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:

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. Any action short of that would be discriminatory based on medical degree not on the training and the excellence of medical care podiatrists provide.

Sincerely,

Craig Breslauer, DPM, FACFAS

Submitter : **Dr. Richard Recko** **Date: 06/28/2006**

Organization : **Dr. Richard Recko**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

I request that the CMS modify the physician definition used for the new competitive acquistions program from 1861(r)(l)to 1861(r). I am a podiatric physician who prescribes and supplies 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 Metropoltan 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 standars. 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. Our practice also includes many wound care patients and there are many high tech dressings which need to be available through multiple vendors.

Please change the physician definition from 1861(r)(l) 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,
Richard R. Recko, D.P.M.

Submitter : **Dr. William Simon** **Date: 06/28/2006**

Organization : **Atlantic Foot & Ankle Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 28, 2006

William H. Simon, D.P.M.
1788 Republic Road

Suite 300
Virginia Beach, VA. 23454
(757) 481-0898

Mark B. McCelellan, 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 recently been notified that CMS is considering the new competitive acquisition program 1861(r). I would like to inform you of a similar program that was tried in the Tidewater area by a local insurance carrier. I am a Podiatrist that treats all medial and surgical conditions of the foot & ankle. My patient presented with an ankle fracture in which I wanted to correctly fit and dispense a fracture brace, but this Insurance carrier would not let us supply the fracture brace for this patient. She was sent out of my office with out any protection to go to a local DME contracted supplier. This patient ended up falling and sustained further injury to herself breaking her arm and sustaining a closed head injury.

This has lead to a legal nightmare for me, the insurance carrier and my practice. As a physician who treats all aspects of foot & ankle injuries I urge CMS to change the definition from 1861(r) to 1861(r) (3). Have we not forgotten that we treat our patients with their best interest in mind?

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) (3) definition of physician in finalizing its regulations.

Thank You,
William H. Simon, D.P.M.

Submitter : **Dr. Ronald Cervetti** **Date: 06/28/2006**

Organization : **Cedar Valley Podiatry**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 28, 2006

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

Dear Dr. McClellan:

We are writing to urge the Centers for Medicare and Medicaid Services 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)(l) to 1861(r).

As podiatric physicians in practice for nearly three decades we have a practice that has been dedicated to serve the needs of our patients, and a large part of that practice includes the Medicare and Medicaid population. Our patients rely on our judgment and skills to provide them with the best possible foot and ankle care. This would include the ability to provide certain DMEPOS items for which we evaluate the patients need and make appropriate recommendations and fit at the time they are seen, thus providing the most cost effective and best continuity of ongoing care.

Additionally, we are required to maintain a valid supplier number and adhere to all of the current supplier standards. We are subject to the Stark laws and other Federal and State regulatory requirements with is not different than that of any MD or DO.

We again urge you to consider the negative impact that forcing patients to seek care from multiple providers/suppliers would have from submission of multiple billings and forcing the patients to go between the physician and supplier and back again to maintain the accuracy and fit of any given appliance or supply.

We thank you for your attention to this most important issue.

Sincerely,

Ronald G. Cervetti DPM William E. Knudson, DPM

Philip J. Morreale DPM

CVP/ccb

Date: 06/28/2006

Submitter : **Dr. Thomas Pfennigwerth**

Organization : **Venango Foot and Ankle**

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,

Thomas Pfennigwerth, DPM

Submitter : **Dr. Howard Schultheiss** **Date: 06/28/2006**

Organization : **Dr. Howard Schultheiss**

Category : **Other Health Care Provider**

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 taking time from my busy schedule, providing care in the form of medical services and supplies to medicare patients, 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 supplies are dispensed at the time of the visit ensuring compliance, convinience and quality 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 as we have received legal recognition as physicians.

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 CMS forces me not to be able function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries. The distinct possibility of litigation could not be ruled out.

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 the best medical care to my patient's which includes supplying medically necessary DMEPOS items at the time of their visit, 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 severly negatively impacted.

Sincerely,

Dr. Howard L. Schultheiss Jr., DPM
Diplomat, ACCPPS
Fellow, APWCA

Submitter : **Dr. Kim Gauntt** **Date: 06/28/2006**

Organization : **Dr. Kim Gauntt**

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. Diabetic patients will also be negatively effected by having to go to outside vendors, who are simply "in it for the profit", for their diabetic shoes.

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,

K.G. Gauntt, DPM Oregon

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

Organization : **Paris Health**

Category : **Other Health Care Professional**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

une 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 Paris Health & Rehabilitation. It is a 140 bed nursing home in Paris.

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 Paris Health & Rehab 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,
Randy McChristian

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

Organization : Mr.

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

As an occupational therapist specializing in Hand therapy, I would oppose any legislation that would takes the assesment and treatment control out of my hands and put it in the hands of the "lowest bidder." As an example, there are literally hundreds of "wrist splints" out there classified under the same L code. However, splint construction varies widely among the different brands and models, with tremendously varying results. If I cannot recommend a specific splint make and model and know that that patient is going to get that exact splint, then I cannot treat the patient effectively, and the patient will have an adversly affected outcome.

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

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Opportunity for Networks

Opportunity for Networks

There is not adequate time for form networks, and networks are not the whole answer for allowing small business to play in this game. Eliminate the need to provide product in all areas of MSA, so small providers are viable.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

See attachment

CMS-1270-P-625-Attach-1.DOC

Wilcox Pharmacy Inc.

Wilcox Pharmacy, Wilcox LTC Pharmacy, and Option Care
252 Stratton Road, Rutland, Vt 05701 (802) 775-3351
400 Cornerstone Dr., Suite 130, Williston, VT 05495 (802) 879-1782

June 28, 2006

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

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

Wilcox Pharmacy and Option Care is a small rural provider of home medical equipment, supplies, and pharmacy products in Vermont. We do provide many of the products and services that may be included in the competitive bidding program, have been doing so for 20 years, and wish to comment on several issues in the proposal. Please note that we limit our comments to only several major points in order to add emphasis, but do find many other areas of concern.

1. Quality First. Setting quality standards in a lowest cost provider scenario is a critical protection for the beneficiaries, and should be completed prior to starting the process. Allowing a grace period for bidders to come up to speed would seem to be risky and irresponsible. Complete the required standards, allow stakeholders to comment, allow time for everyone to meet those standards, then start the competitive bidding, with safety first.

2. Get It Right. Protect the beneficiaries. This is a major change in the delivery of health care to a population at risk. Two partial demonstration projects do not adequately prepare CMS for administering a large scale process in 10 of the largest MSAs. Staggered entry into this project, to allowing time for learning the right ways to assure that beneficiaries are not adversely effected, would seem prudent.

3. Eliminate Rebates- This is wholly contrary to Medicare policies on inducement of services and is a potential risk to the integrity of this program.

4. Protect small business. Small business is the backbone of American business and is put at risk in this industry by these rules. Look carefully at the financial requirements (audited financials as an example) that are prohibitive for small business. Change the requirement that a provider must supply the whole MSA, to allow small providers to play in this game. Allow more time for small providers to form networks, as the time available currently is inadequate.

5. Eliminate home infusion and custom rehab from consideration. These are service intensive areas where significant cuts to reimbursement could lead to risks to beneficiaries. Often these patients are the most at risk, and their safety should be considered above some level of cost savings and cuts.

Thank you for the opportunity to comment on these important issues. I hope CMS thoughtfully and completely considers all the comments being made, and that this program offers both cost savings and protection for all beneficiaries.

Sincerely,

Richard J Wilcox,
President, Wilcox Pharmacy

Submitter : Ms. Joan Schafer **Date:** 06/28/2006

Organization : ASHT/ProMedica Health Care

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

As an Occupational Therapist with close to 40 years experience,as well as a Certified Hand Therapist and a soon to be consumer, I urge CMS to be careful in it's plan to limit patient access to splints/orthosis to a limited DME source.
Trauma patients, post operative patients and cumulative patients are just some of the general users of splints/orthoses. Often they are fit in conjunction with therapy or to allow them early re-entry to their work/home/leisure pursuits armed with improved knowledge of their condition, healing and safety issues.
Often they have a specific medical diagnosis that requires a specific orthosis for their size, work needs, home needs or continued protection. Orthoses are fit to protect as well as to enhance function. A clerk working for a DME company lacks the clinical expertise to determine these needs. An orthotist lacks this knowledge also and in fact, these issues are not within their scope of practice.
Keeping costs down is important, I realize. So is acceptable patient care. I have seen many patients who have received splints from DME providers who have failed to medically improve because of faulty fit and because the splint/orthosis did not fit, it also was often not used. Daily functional ability suffered. Pain continued. Delay in receiving the proper splint caused worsening of symptoms and required further medical/theraeutic intervention.
We need to find a reasonable way to cut costs without compromising reasonable patient care.
Ask yourself: would I want my " mother, father, wife, husband or child" to receive this type of care? Do I want myself impacted by delayed healing, compromised function, increased frustration and pain?
You have medical specialists: Occupational Therapists, Certified Hand Therapists, Orthopedic Physical Therapy specialists and doctors who want to see patients receive appropriate care while at the same time keeping costs reasonable. I urge you to include these specialists in your panels and forums while trying to find a reasonable solution to the ongoing dilema of spiralling medical costs.
Respectfully,
Joan E Schafer, OTR/L CHT
7746 Greenville Crossing
Waterville, Ohio, 43566
Ohio License # 00084

Issue

Issue

Proposed Rule for Competitive Acquisition of Certain DMEPOS CMS 1270 P

Submitter : Mr. Edward Callahan **Date:** 06/28/2006

Organization : Premier Home Care,Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

As part owner of a small HME company I have some major concerns regarding competitive bidding.1.competitive bidding essentially eleminates the medicare patient's right to choose a homecare provider and puts the responcibility of care and maintance in the hands of the patient.
2. The quality of home medical equipment provided to medicare patients
will be significantly diminished as companies that win a bid will be forced to provide basic equipment to their medicare patients.
4. Also this will eleminate competition thus putting a hault to advancement and improvement in home medical equipment
5. Competitive bidding has the potential to destroy small HME companies as sthe will lose many of their medicare patients and will not be able to compete with the larger national companies.
6. Competitive bidding along with rising gas prices (nearing $3.00 per gallon) will greatly diminish the service afforded to the medicare patients.

Submitter : Mr. wallace pollard **Date:** 06/28/2006

Organization : comfortcare medical supply

Category : Health Care Provider/Association

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

looks as if the "small" or "new" supplier is going to be left out in the cold again. oh well,we can always file for bankruptcy and cost the government more money!!

Regulatory Impact Analysis

Regulatory Impact Analysis

how much is the loss of jobs, taxes, etc,and re-training people going to cost the government when half of the dme workforce has been laid off their jobs?

Submitter : Mrs. Angella Mattheis **Date:** 06/28/2006

Organization : Agnesain HealthCare

Category : Individual

Issue Areas/Comments

Administrative or Judicial Review

Administrative or Judicial Review

Administrative or Judicial Review

We are asking for clarification of the last words in this section this Rule . It is unclear at what level reviews will be denied. We strongly disagree with the inability to tell our story. Removing administrative or judicial review takes away our freedom of speech which is clearly unconstitutional under the Equal Protection law.

Opportunity for Networks

Opportunity for Networks

Opportunity for Networks

Why do you limit a network to have 20% of the Medicare market within a competitive bidding area yet a single large company can have 80% of the Medicare market share?

The statement that each member of the network must be independently eligible to bid defeats the entire purpose of networking. If we had the ability to service the entire MSA we would not rely on networking.

We strongly disagree with the primary legal entity being responsible for billing Medicare and receiving and distributing payment. Why must we adjust our entire billing process if we want to network and participate in competitive bidding? We want to be responsible for our own financials.

We strongly suggest that if CMS needs to decrease cost then simply lower the allowables and monitor the compliance of the current 21 standards. This would simplify this very complex, cumbersome and unfair Competitive Bidding Proposal.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

We strongly disagree with using the SBA s definition of small business. This definition puts small businesses under the definition of $6 million in annual sales. This section clearly states that 90% of DMEPOS suppliers had Medicare allowed charges of less than $1 million in 2003. If you increase this number to include all payers it would still be much less than $3 million. This is a clear contradiction to the SBA s definition of small business.

Small businesses will have to endure large expenses in order to participate in Medicare billing, with 90% of us having less than $1 million in Medicare allowed charges this will put many of us out of business. Is your purpose to wean out small business?

You have rejected the carving out of areas for small businesses because it could lead to confusion for the beneficiary if faced with multiple competitive bidding sub-areas. The entire concept of competitive bidding will do just that. Our beneficiaries may have to go to three different locations to obtain oxygen, a hospital bed and a wheelchair. This will also cause a tremendous burden on our discharge planners trying to coordinate these services before discharge. The ultimate burden may lie on the hospital with extended
inpatient days.

You claim to recognize the importance that small business plays in this industry yet you only propose two ideas to protect us, multiple winners and separate bidding competitions for product categories. There needs to be much more emphasis to protect those who do less than 3 million in sales a year. Things such as:
" Implementing partial SBA
" Allowing the small business owner to continue to service their area by accepting the current bid without having to participate in the bidding process.
" Recognize the tremendous cost involved in the accreditation process and preparing for competitive bidding.
" Redefining small business definition to under 3 million

You must remember that eliminating the small businesses will affect our country negatively with a rise in both unemployment and public aide.

Submitter : Mr. Sergio Silva **Date:** 06/28/2006

Organization : Medi-Source Home Medical Inc. DME

Category : Device Industry

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

A small DME like ourselves does not have a chance to bid and obtain an award. How can we possibly compete with a large company that will take a dive just to be awarded and then save on services and provide cheap equipment? Since the proposed awards are by category, even if we were to win in a category we would not stand a chance of staying in business without being able to provide the full line of DME products. We constantly have customers that start with one item then need more items as time goes by. How could we serve these customers? There are very few customers that need only one item. Competitive bidding is the dumbest way to save money. Why not just do a fair competitive analysis of the current pricing versus equipment cost and other costs and simply re-adjust the compensation per code? If it is done fairly at least existing DME will have a choice of continuing to provide services under the new pricing or simply go out of business. At least this would be a gradual thing, the way it is now proposed we will be put out of business from one day to the next. Grandfathering existing contracts will not help if new business can't be procured.

GENERAL

GENERAL

Small DME companies have been providing the lyon's share of the services to the Medicare recipients, now this proposed docket will mean the end of these operators and the squandering of their patients.

Opportunity for Networks

Opportunity for Networks

Networking doesn't work. In the trial areas no one networked and the reason is simple. If a local DME becomes part of a network, then they lose their right to bill Medicare directly, and they must rely on an organization called network to provide the billing and revenues back to the DME. This would add cost and it brings a host of other issues into play such as inventory, services, billing , write offs, collections etc. A network won't work so the bidding will go to the biggest cheapest company out there and the small operators will all go out of business.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

CMs 1270 P if implemented will put thousands of proud honest DME operators out of business. We make an honest living by offering personal service to the elderly population in need of DME equipment and someone with the patience to talk to them. The bidding program will mean that small DME's will be outbid and therefore will not be under contract with Medicare. The least you should do is allow non contract DME companies to continue to offer services and bill Medicare at prices determined by the bidding process. The aging population needs our services, we are local and within short distances from our customers. Our customers are people not just numbers. With the new enactement of this ACT patients will become numbers. If the act is being enacted in order to save money then in a justifiable way why not review the compensation by code and period you have accomplished what you want. This way the DME that elects to go out of business at least can do so at their own pace and of their own free will. The way you are proposing to do it now is to put them out of business from one day to the next and get them replaced with a large company that will not in a million years be able to provide the personal services we provide. And by the way there ar thousands of honest DME service providers like our company. We will be replaced by large not caring money grabbinbg large companies.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

We are being told that accreditation is a process that will cost over $7000.00. We are a small company with only three people, but we are proud of the work we do and the services we provide, and so are our customers. Why not just do a survey of DME customers? you will soon find out what DME should be forced to change or the be accredited. This accreditation business is creating a bonanza for companies that supposedly will do the work. I can't imagine what they can possibly need to do that will take 7 months and cost $7000.00. Why is it that the cost of accreditation is the same whether you are a three man outfit or a 50 man outfit????? This is just simply wrong.

Submitter : Mr. Jack Hogan **Date:** 06/28/2006

Organization : Health Complex Medical

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

I have many concerns regarding the ruling for Competitive Bidding. One general one is the timeline. October 2007 is not far off. CMS needs to make sure that they have accounted for all concerns before implementation. Suppliers are still in the dark on many issues, product selection, accreditation requirements, MSA determinations, etc.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

CMS needs to be aware of the quality of service that the small suppliers provide to Medicare beneficiaries. Don't make it hard for small suppliers to participate. The proposal for small providers to form a network is not a viable alternative. CMS should consider that a certain percentage of small providers be awarded the bids.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

My comment regarding the accreditation of suppliers is that the standards be in place before the process of competitive bidding begins. Adequate time need to be given for suppliers to become accredited. A final rule needs to be developed very soon. CMS should also grandfather those suppliers who are currently accredited. The process of accrediting again with a new body will prove to be an unnecessary financial burden on businesses.

Submitter : **Dr. Scott Schroeder** **Date: 06/28/2006**

Organization : **Dr. Scott Schroeder**

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,

Scott A. Schroeder, DPM, FACFAS

Submitter : Ms. Heather Allan **Date:** 06/28/2006

Organization : Florida Association of Medical Equipment Services

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : **Ms. Laura Blum** **Date: 06/28/2006**

Organization : **JCAHO**

Category : **Private Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-634-Attach-1.PDF

Joint Commission

Setting the Standard for Quality in Health Care

June 30, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-1850
CMS-1270-P

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

The Joint Commission on Accreditation of Healthcare Organizations appreciates the opportunity to comment on the proposed rule on "Competitive Acquisition for Certain Medical Equipment, Prosthetics, Orthotics, and Suppliers (DMEPOS) and Other Issues for the Medicare Program." Established in 1951, the Joint Commission is an independent, not-for-profit organization that evaluates and accredits nearly 15,000 healthcare organizations in the United States. Nearly 3,800 of Joint Commission-accredited entities provide home care services—1,326 of whom provide home medical equipment services in over 4,150 locations.

In 1988, the Joint Commission became the first entity to offer accreditation for suppliers of home medical equipment (HME). Today, the Joint Commission accredits more than 10% of the nation's HME suppliers through three service distinctions—HME accreditation with clinical respiratory services (50%), HME "stand-alone" accreditation (25% of the Joint Commission accredited HME organizations), and HME accreditation with rehabilitation technology (25%).

It is evident that in the course of drafting the proposed rule, CMS staff had to address a myriad of complex issues associated with implementing competitive bidding programs for certain covered items of durable medical equipment, prosthetics, orthotics, and supplies in a safe and efficient manner.

This letter addresses provisions in the following subparts:

- Opportunity for participation by small suppliers
- Quality standards and accreditation for suppliers of DMEPOS
- Conditions of awarding contracts: *§414.414 (b)(2)(i) and (ii)*
- Accreditation: *§414.414 (c)(2)(i)*
- Submission of bids under a competitive bidding program and expected savings: *§414.412(e) and §414.414 (f)*
- Sufficient number of suppliers: *§414.414 (g)*
- Determination of competitive bidding payment amounts: rebate: §414.416 (c)
- Accreditation:
    - Validation survey: §424.58 (2)
    - Discovery of a deficiency: §424.58 (b)(3)
    - Validation survey: 424.58 (d)(2)
    - Withdrawal of approval: §424.58(4)(i)

If you have any questions or require additional information regarding the comments provided below, please contact Laura Blum, Associate Director of Federal Relations, at lblum@jcaho.org. Laura can be reached by telephone at 202.783.6655.

Opportunity for Participation by Small Suppliers

CMS is required to ensure that small suppliers of items have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program.

Joint Commission Comment: The Joint Commission supports CMS' proposal to use the SBA definition and allow networks of providers to bid in an effort to include small suppliers in the competitive bidding project. As discussed in section §414.414 (g), awarding contracts to all eligible suppliers that submit an acceptable bid in a product category would encourage the participation of the small suppliers. The Joint Commission would strongly object to the dispensation of the small supplier from the requirements for meeting the quality standards and being accredited.

Quality Standards and Accreditation for Suppliers of DMEPOS

Any supplier seeking to participate in the Medicare DMEPOS Competitive Bidding Program will need to satisfy the quality standards.

Joint Commission Comment: The Joint Commission suggests that the review and modification of the quality standards should be part of a formally established process. Since the DMEPOS quality standards will not codified through the federal rule making (or a similarly established) process, it is unclear how CMS will develop, update and implement these requirements. It is essential to the promotion of quality services to the Medicare beneficiary that there be comprehensive vetting of the quality standards to assure that they are reasonable and appropriate. This vetting should include thorough discussion by the Program Advisory Committee and a public comment period. The Joint Commission suggests that CMS staff review the fate of the Quality Improvement System for Managed Care (QISMC) to better understand how quality requirements, that are not part of the rule making (or similar) process, can be difficult to sustain.

Conditions for Awarding Contracts: §414.414 (b)(2)(i) and (ii)
The proposed rule states that each bidding supplier must certify in its bid that it, its high level employees, chief corporate officers, Board of Director members, and the bidding supplier's subcontractors are not now and was not sanctioned by any government agency or accreditation or licensing organization or disclosure information about any prior or current legal actions, sanctions, or debarments by any Federal, State or local program, including actions against any members of the Board of Directors, chief corporate officers, high-level employees, affiliated companies, and subcontractors.

Joint Commission Comment: The term "sanctioned" can be interpreted in many different ways by the entities suggested in the proposed rule – governmental agency, accreditation, or licensing organization. The Joint Commission suggests that CMS detail what specific types of "sanctions" should be included in the disclosure. It is also important to define the expectation for "certify". Does CMS intend for a simple attestation or a prescribed legal signed statement testifying to the veracity of the disclosures or lack of disclosures?

Accreditation: §414.414 (c)(2)(i)
CMS states in the proposed rule that all bidding suppliers must be accredited by a CMS-approved accreditation organization, as defined under §424.57(a).

Joint Commission Comment: The Joint Commission supports the requirement that suppliers meet quality standards and that bidding suppliers are accredited by a CMS-approved accreditation organization. However, the quality standards have not been finalized. Similarly, the application procedure for the naming of the approved accreditation organizations has not been finalized. To complete the bidding process in the first competitive bidding areas by 2007, it is likely that the demand for accreditation by not-yet-accredited suppliers will place an undue burden on the approved accreditation organizations to complete the accreditation process before the bid is submitted. The Joint Commission suggests an alternative for the first group of suppliers that are in the competitive bidding areas named for 2007. This alternative allows any supplier to submit a bid regardless of accreditation status, with the caveat that no supplier should be designated as a contract supplier if they are not accredited. In other words, CMS could allow the bid to be submitted but would not award a contract supplier designation without evidence of meeting the quality standards and accreditation. All bidding suppliers should be required to show evidence that they have at least applied for accreditation to a CMS approved accreditation organization. However, allowing any grace period does have inherent risk. Specifically, the bid submitted by an unaccredited supplier has not factored in all the quality standards requirements and therefore may not be reflective of all the costs associated with the provision of an item. This could skew the pivotal bid and provide an unrealistic payment depending on the number of unaccredited suppliers in any given region, or for any given product category. The risk of accepting bids from non-accredited suppliers in 2007 could be minimized if the bids were recalculated and ranked a second time by dropping out the information from those non-accredited suppliers before determining the final payment The Joint Commission does not support a designated grace period (e.g., six months) by each competitive bidding program. It is unwieldy and time consuming to administer for the Competitive Bidding Implementation Contractors (CBIC) and the accrediting organizations.

Submission of bids under a competitive bidding program §414.412(e) and Expected Savings §414.414 (f)

In §414.412(e), CMS outlines the submission of bids under a competitive bidding program including that "a bid must include all costs related to furnishing an item, including all services directly related to the furnishing of an item." In §414.414(f), it states that CMS does not award a

contract unless it determines that the amounts be paid to a contract supplier for an item under a competitive bidding program are expected to be less than the amounts that would be otherwise be paid for the same item under subparts C or D.

Joint Commission Comment: The Joint Commission suggests that this method of awarding a contract (i.e., the amount to be paid for an item is less than the amounts that would otherwise be paid for the same item) contradict the proposed requirement that a bid must include all costs related to furnishing an item, including all services directly related to the furnishing of the item. The imposition of quality standards and accreditation has added requirements for all suppliers that are not likely included in the current payment determinations for such items. Market forces should be allowed to play out for a true determination of competitive bidding by allowing the suppliers to determine their affordable cost to furnish an item and array the bids, determine the pivotal bids as outlined in the legislation, and award the payments.

The Joint Commission recognizes CMS' mandate to achieve cost savings to the Medicare program for these items. However, the cost savings should be viewed in totality. For example, a reduction in the number of suppliers is anticipated, and some products may show appreciable savings and others may have none.

Sufficient Number of Suppliers: §414.414 (g)

As proposed, CMS will award at least two contracts for the furnishing of that product category under a competitive bidding process.

Joint Commission Comment: The Joint Commission expresses serious reservations with respect to the determination of supplier capacity and ability to meet projected increases in beneficiary demand. Our extensive industry experience suggests that suppliers would have little factual criteria, and no control over external circumstances to base their assumptions of expansion plans. For example, while any business may wish to expand and pre-determine their staffing needs, manpower shortages may prevent the execution of the plan. In order to assure beneficiary access to necessary items and services we would suggest that any qualified, accredited supplier be eligible for a contract award at the specified payment. This methodology would, again, allow

market forces to increase or decrease businesses within a competitively bid area instead of unduly restricting small businesses from competing, and eliminate the need for an elaborate selection of new suppliers after the bidding period. It would assure beneficiaries' access to necessary items in a period when there may be limited number of suppliers.

Determination of competitive bidding payment amounts- rebate: §414.416 (c)

The proposed rule states that a contract supplier that submitted a bid for an item, in an amount that is below the single payment amount calculated by CMS for that item, may elect to issue a rebate. The intended purpose for allowing these contract suppliers to offer rebates is "...to allow beneficiaries to ability to realize additional savings." As part of this proposed plan, a contract supplier may not advertise that it issues a rebate for any item furnished under this subpart.

Joint Commission Comment: The Joint Commission does not support the establishment of any "rebate" program. The proposed methodology suggests that if a winning bidder submits a bid lower than the established price, the difference between that bid price and the award price could be returned to the beneficiary. Patients may perceive an advantage and select a supplier who offers a rebate over one who does not – therefore, the potential for solicitation of business based on a CMS-sanctioned rebate is high. Also, if bids are realistic, the dollar amount of the rebate will not be significant to most patients. Lastly, the inherent risk of fraud and abuse in this area is evident. A contract supplier may not advertise, but there is no prohibition against informing patients and referral sources through other means that the patients served by his/her organization will receive a rebate. An unscrupulous DMEPOS supplier could game the system for increased market share within the MSA. The costs of monitoring a rebate program outweigh the benefits that could be gained by the Medicare program or its beneficiaries.

Validation survey: § 424.58 (2)

As proposed, CMS would conduct a survey of an accredited supplier for validation purposes or a representative sample basis in response to a substantial allegation.

Joint Commission Comment: The proposed process for the validation survey of suppliers should be outlined in greater detail in the regulation's preamble to include the survey frequency, who will perform the surveys, and the methodology used to determine the validation sample.

Discovery of a deficiency: §424.58 (b)(3)

The proposed provision states that if CMS discovers a deficiency and determines that the DMEPOS supplier is out of compliance with Medicare supplier quality standards, CMS may revoke the suppliers' billing number or require the accreditation organization to perform a subsequent full accreditation survey at the accreditation organization's expense.

Joint Commission Comment: The Joint Commission has several comments regarding this section. First, it seems redundant and confusing to specify "If CMS discovers a deficiency and determines that the DMEPOS supplier is out of compliance with Medicare quality standards,.." A finding of noncompliance would be based on a deficiency; the provision would have more clarity if it simply stated: "If CMS determines noncompliance...."

Second, it is unclear what is meant by "a subsequent full accreditation survey." Does this refer to the next accreditation survey that is due, or any subsequent survey (e.g., some other future or subsequent survey), or is there an expectation that this would be an additional survey that would occur during some as yet unspecified time period? It is also necessary to define what is meant by "full accreditation survey."

Finally, we are unaware of any statute or other authority that would permit CMS to specify that the accreditation organization perform a survey at its own expense, and believe that CMS should cite that authority.

Validation survey: §424.58 (d)(2)

This section of the proposed rule describes CMS oversight of approved accrediting organizations and proposes that CMS or its designated survey team may conduct a survey of an accredited DMEPOS supplier, examine the results of an accreditation organization's survey or observe the accreditation survey to validate the accreditation process. This section of the proposed rule also

describes those circumstances that might trigger a notice of intent to withdraw approval, specifically: --a disparity rate of 10% for non immediate jeopardy deficiencies; --any disparity on standards that constitute immediate jeopardy, or -- widespread or systemic problems in an accreditation organization's process.

Joint Commission Comment: The oversight provisions should be clarified to describe: who is eligible to be "a designated survey team"; the percent of the validation surveys per CMS-approved accrediting organizations; the methodology for selecting suppliers for CMS survey; and the detailed information on how the disparity rate will be calculated. In addition, for clarity, we suggest revising 424(d) (2) (ii) to describe what is meant by "disparity between findings....on standards that constitute immediate jeopardy." Finally, CMS should clarify the phrase "widespread or systemic problems in an organization's process" to specify the types of issues being referenced.

Withdrawal of approval: §424.58(4)(i)

CMS may withdraw its approval of an accreditation organization at any time if CMS determines that accreditation by the organization no longer guarantees that the suppliers of DMEPOS and other items and services are meeting the supplier quality standards, and that failure to meet those requirements could jeopardize the health or safety of Medicare beneficiaries and could constitute a significant hazard to the public health.

Joint Commission Comment: The use of the term "guarantees" should be replaced by "adequate assurance" as specified in §424.58(d)(2)(iii). This latter term more appropriately represents the process of accreditation in that accreditation can provide such assurance that the quality standards are met, but can not "guarantee" such an assertion.

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

Organization :

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-635-Attach-1.DOC

SUMMARY OF COMMENTS
Notice of Proposed Rulemaking (NPRM) on Competitive Acquisition

Timing Concerns

Supplier Standards and Deficit Reduction Act Implementation

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

Opportunity to Comment on the Supplier Standards

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

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

Overall Implementation Timeline

CMS needs to establish an implementation timeline that identifies the critical steps leading-up to competitive bidding. However, given the number of steps that must be commenced and completed, we urge CMS to adopt a realistic timeline and not rush through the process. The remaining steps include:

- Publication of the supplier standards
- Selection of the accrediting bodies

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

Payment Basis

Inflation Update

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

Grandfathering Medicare Advantage

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

Beneficiary Switch to Contract Suppliers

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

Application of DRA to Oxygen Patients

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

Authority to Adjust Payment in Other Areas

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

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

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

Limitation on Beneficiary Liability

We understand that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. Under current Medicare rules, a supplier may furnish the beneficiary with an ABN notifying him that Medicare will not pay for an item. Other portions of the NPRM specifically state that ABNs will be permitted under a competitive bidding program, and the MMA requires that CMS continue to allow suppliers to use ABNs. CMS should

clarify what it means when it states that a beneficiary will have no financial liability to a non-contract supplier for competitively bid items furnished by that supplier.

Competitive Bidding Areas

Staggered Implementation

The NPRM is silent on whether CMS will commence competitive bidding in 10 MSAs at the same time, or stagger the initial implementation of competitive bidding in 2007. We recommend that CMS phase-in the first 10 MSAs. This will allow CMS to identify and correct problems as competitive bidding commences before the problems become widespread.

Nationwide or Regional Mail Order Competitive Bidding Program

It is unclear why CMS proposes a separate competitive bidding program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in competitive bidding during 2007 and 2009, a separate program for them in 2010 would be unnecessary. Further, there is no definition for a "mail order" supplier under Medicare program rules. Many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes. As a result, we are unsure who would qualify to participate in a national competition for mail order supplies.

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

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

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

Establishing the Competitive Bidding Area

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

Criteria for Item Selection

Items Included in Competitive Bidding

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

Potential for Savings

CMS should explain and clarify what specific measures will be used to decide an item's potential savings as a result of CB. Specifically, CMS should address the following:

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

Additional Criteria for Item Selection

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

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

Brand-Specific Requirements

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

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

Coding Issues and Item Selection

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

Product Categories for Bidding Purposes

General Issues

Clear definition of the product categories must be outlined for bidding suppliers. All HCPCS codes and their typical quantities should be identified for each product category that the supplier bids. For example, glucose monitors and supplies should include glucose monitors, test strips, lancets, lancing device, and replacement batteries.

Glucose monitors for visually impaired (i.e.: E2100) should be identified and bid separately as the cost is drastically different. If the bid pricing is related to the product category and not each HCPCS code that makes up the category, then it may be cost prohibitive to service visually impaired beneficiaries with the monitors resulting in service issues for beneficiaries.

Requirements to Bid on all Products in a Category

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

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

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.

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

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

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.

Bulletin at 1.

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

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

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

Bulletin at 5 (Emphasis supplied).

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

Terms of Contract

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.

Termination of Contract

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

Judicial and Administrative Remedies

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

Change of Ownership

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

Participation of Small Suppliers

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

Submitter : Mrs. Stephanie Williams **Date:** 06/28/2006

Organization : Twin Co. Regional Hospital

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am a hand therapist in a rural area of Southwest Virgina. Many times a patient will come in needing a splint to support their hand or wrist in order for them to gain independence with everyday tasks. More often than not, they have no idea what type of splint would assist them the most, or how to know if it is a proper fit. In order to provide good care, therapists need the ability to make a judgement call with their individual patients as to what type of splint would be in their best interest. In addition, time is usually of the essence. If someone has to go looking for a splint (under the proposed rule), they are usually delayed in receiving the care they need, potentially costing more healthcare dollars due to complications/additional therapy visits in the long run. The margin of profit is very low with orthotics, however it is a service that we have found is vital to provide our patients with the best care.Please reconsider the rule, and allow us to practice hand therapy in the manner that benefits are patients,is cost effective, and doesn't penalize our patients.

Submitter : **Ms. Lauren Yee** **Date: 06/28/2006**

Organization : **Head 2 Toe Physical Therapy**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-637-Attach-1.DOC

Lauren Yee
Head 2 Toe Physical Therapy
210 N. Aviation Blvd., Ste B
Manhattan Beach, CA 90266

June 28, 2006

To Whom It May Concern:

This letter is in regards to the "Proposed Rule for Competitive Acquisition of Certain DMEPOS". I am an outpatient physical therapist and am not in favor of the proposed rule.

With recent Medicare coverage changes, prescription drug changes, and the monetary cap on Physical Therapy services, our patients are increasingly challenged to obtain services. The ability for physical therapists to furnish off-the shelf orthotics, wheelchairs, ambulatory assistive devices, and other items to patients is imperative. If this changes, it will be difficult for some patients to locate a specific supplier as well as access transportation to pick it up once they find one. These patients may not get the proper equipment, compromising their safety and progress. I strongly believe the ability of the physical therapist to supply equipment to patients is more efficient, safe, and practical.

Thank you for your consideration of the above comments.

Sincerely,

Lauren Yee MPT, OCS

Submitter : Ms. MARYANN LARGEN **Date:** 06/28/2006

Organization : MED EMPORIUM

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-638-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 : **Dr. Paul Bishop**

Organization : **Centers For Foot and Ankle Surgery**

Category : **Physician**

Date: 06/28/2006

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,
Paul Bishop, DPM, FACFAS

Submitter : Dr. Michael Ward

Organization : Dubuque Podiatry, PC

Category : Physician

Date: 06/28/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-640-Attach-1.WPD

DUBUQUE PODIATRY, P.C.
Michael W. Ward D.P.M.
Timothy J. Quagliano D.P.M.
Robert S. Kelsey D.P.M.
Michael Arnz D.P.M.
1500 Delhi St., Suite # 2200
Dubuque, Iowa 52001

Phone: 563-557-5930
Fax: 563-557-5936

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 ®(1) to 1861®(3).

As a podiatric physician, of over 30 years, 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®(1) to 1861®(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,

Michael W. Ward, DPM,FACFAS

Submitter : Ms. Deborah Hartenstein **Date:** 06/28/2006

Organization : Vermont Sports Medicine Center

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

As an Occupational Therapist and Certified Hand Therapist, I am opposed to the pending rule for orthoses. A focused concern is the timing for patients to access the needed splints, the availability of specific and particular needs for individual medical problems and the customization requirements which are so often necessary. Often, patients who are referred to my clinic and come in with a prefabricated orthoses is less than satisfied with the fit and comfort as well as achieving the desired outcome. Patients have invested time and a lot of money to have their problems surgically repaired and medically managed. Hand surgeons require and expect specificity and refinement to meet individual needs to protect repairs, prevent further injury and damage, and provide the needed personalized education for use, application, activity restrictions and potential complications. Custom splint fabrication assures the necessary treatment link between the treating surgeon/physician and hand therapist while keeping the individual at the center of care while simultaneously promoting the best performance and functional outcomes. I am in hopes that CMS will reconsider this rule for the sake of patients.

Submitter : Jody Strain

Date: 06/28/2006

Organization : Nutrishare, Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Submitter : **Dr. Paul Peicott** **Date: 06/28/2006**

Organization : **Dr. Paul Peicott**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 26, 2006

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

RE: Competitive Bidding Program for DMEPOS

Dear Dr. McClellan:

As a podiatrist I am writing to you to urge CMS to modify the physician definition from 1861(r)(1) to 1861(r) before finalizing the regulations for a competitive acquisition program. The proposed rules do not allow a podiatrist to be excluded from competitive acquisition programs for durable medical equipment and supplies (ie: walking boots, air casts, prosthetics, etc.). This is a patient safety issue and would force me to send patients out of my office to an offsite location to be fitted for walking casts and prosthetics and to purchase other medical supplies.

There are many situations in my office where this would become a problem for a patient. For example, a diabetic patient that presents with an ulceration on his/her foot. After diagnosing then debriding the wound I will apply the appropriate dressing having taken it from the shelf in my office. This allows the patient to see how to apply the site-specific dressing as well as ask any questions. After application, the patient is then given the remaining dressings for immediate and continued at-home dressing changes allowing the wound to heal optimally until they return for follow up 2-3 weeks later.

Another example is when a patient comes in with a fracture or injury I may dispense a walking boot/cast. In this case I am able to fit it properly at the time of the visit and insure that they get the appropriate device whether it be a short walker, air cast, nonpneumatic, etc. The patient also does not have to walk on the injured foot to go to a supply house to pick up a device.

Again, I urge you to change the proposed rule regarding the Competitive Bidding for DMEPOS items so that podiatric physicians can be given the same consideration given to the MD and DO suppliers. Thank you, in advance, for your consideration in this matter.

Sincerely,

Paul S. Peicott, DPM

Submitter : Dr. Timothy Quagliano

Organization : Dubuque Podiatry, PC

Category : Physician

Date: 06/28/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-644-Attach-1.DOC

CMS-1270-P-644-Attach-2.DOC

DUBUQUE PODIATRY, P.C.
Michael W. Ward D.P.M.
Timothy J. Quagliano D.P.M.
Robert S. Kelsey D.P.M.
Michael Arnz D.P.M.
1500 Delhi St., Suite # 2200
Dubuque, Iowa 52001

Phone: 563-557-5930
Fax: 563-557-5936

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 ®(1) to 1861®(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®(1) to 1861®(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,

Michael W. Ward, DPM,FACFAS

Submitter : Ms. N. Lois Adams

Organization : Freedom Pharmacy

Category : Pharmacist

Date: 06/28/2006

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

It is CMS who should be setting pricing criteria because it is CMS ALONE which has the requisite knowledge to accurately formulate what it wishes to pay for services, DME, etc.

Recent history in Florida has taught us that, in the health care industry, competitive bidding often does not result in actual cost savings.

First, by its nature, competitive bidding often effectively eliminates the smaller provider. These companies include minority and woman-owned businesses. And, by narrowing the field to the larger purveyors, you are then dealing with companies many of whom are owned by vertically-integrated manufacturing/benefit management companies - and some of these have recently come under fire by the U.S. Attorney General and various state governments because of unfair business practices.

For the Medicare system to realize true cost savings, it should continue to be the author of those savings. CMS should determine a realistic reimbursement for products and services for items covered under Medicare B and then permit any company which meets the guidelines promulgated by CMS for participation to participate.

The U.S. was founded on open competition. Narrowing the playing field is in no one's best interest.

Submitter : Mr. Richard Hartig

Date: 06/28/2006

Organization : Hartig Drug Co., and Finley-Hartig Homecare

Category : Pharmacist

Issue Areas/Comments

Opportunity for Networks

Opportunity for Networks

Our firm provides oxygen and medical equipment and supplies to primarily rural areas in Iowa, Illinois, and Wisconsin. I am concerned about patient access, response times, and emergency service given our geography and low population(s).

Submitter : **Dr. Glenn Weinfeld**

Organization : **Foot & Ankle Podiatry Associates, PC**

Category : **Physician**

Date: 06/28/2006

Issue Areas/Comments

GENERAL

GENERAL

June 5, 2006

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

Dear Dr. McClellan:

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

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

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

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

Sincerely,

Glenn D. Weinfeld, DPM, AACFAS

Submitter : **Dr. michael hattan**

Organization : **Dr. michael hattan**

Category : **Physician**

Date: **06/28/2006**

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 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 resident physician and will 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 when done with my residency to provide medically necessary and appropriate care to the patients I will serve.

Sincerely,

Michael J. Hattan, DPM

Submitter : **Dr. Dale Smith** **Date: 06/28/2006**

Organization : **PBA Health**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-649-Attach-1.DOC

CMS-1270-P-649-Attach-2.DOC

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)

Dr. McClellan:

PBA Health 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.

PBA Health is comprised of 1000 independent pharmacy owners in 14 states. The majority of these small businesses have sold diabetes supplies and small amounts of medical equipment to Medicare beneficiaries for many years. Patients find it convenient to purchase such items from their local pharmacist who takes the time to educate, train and answer questions they may have. CMS-1270-P if enacted as written will threaten this relationship and will drive more of these small pharmacies out of business.

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 diabetic supplies and aids to daily living (crutches, canes, wheel chairs) covered under the durable medical equipment benefit. 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

Community Pharmacy 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 a comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.**

2. **We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for Pharmacies that are also doing large amounts of DME business 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. **The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.**

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

5. **It is important to remove diabetic supplies and strips from the list of DME that requires accreditation. Independent pharmacies selling small amounts of diabetic supplies and DME will not choose to go through the costly accreditation process.**

6. **CMS states that in 2010 they intend to move diabetic testing supplies to national mail order suppliers. This would be inconvenient for Medicare beneficiaries and devastating to our independent pharmacy members. I have experience with patients who continue to receive supplies that they no longer need but are unable to get the mail order company to stop sending them. State Pharmacy Laws prevent prescriptions being returned once dispensed. This will result in great waste of dollars to the Medicare program. And our pharmacist will be asked to fill correct supplies but will have to charge the patient because the mail order has already billed Medicare.**

Expecting national, regional or small chains – some with thousands of outlets – to seek accreditation for an important but small part of their business or to comply with the additional quality standards when they are already subject to comprehensive pharmacy law requirements is simply unrealistic. Accrediting agencies will face significant hurdles in accrediting all these pharmacies, and some pharmacies believe that the cost of accreditation – both in time and resources – is too burdensome. This process could disrupt the important access that Medicare beneficiaries have had to items such as diabetic testing supplies and other health care items, and the critical coordination of receiving their prescription drugs for diabetes and other disease conditions from their community pharmacy. Plenty of time should be given to pharmacies become accredited.

Many of the organizations pushing the accreditation process are charging $5-15,000 to go through this process. A small pharmacy billing less than $100,000 a year for such sales cannot afford to pay this amount every three years just to do Medicare business at a very low profit margin.

Not to mention the cost to keep up with policies and procedures. Any hospital in the U.S. will tell you that they have had to add a large staff just to comply with Joint Commission's requirements to remain accredited. This is an additional cost that is not compensated by insurance or federal insurance programs. These are costs the small business owner cannot afford.

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 816-245-5740.

Sincerely,

Dale E. Smith, R.Ph., M.A.
Director of TriNet Third Party
PBA Health
1575 N. Universal Avenue
Kansas City, MO 64120

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)

Dr. McClellan:

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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 diabetic supplies and aids to daily living (crutches, canes, wheel chairs) covered under the durable medical equipment benefit. 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.

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Community Pharmacy 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 a comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.**

2. **We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for Pharmacies that are also doing large amounts of DME business 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. **The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.**

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

5. **It is important to remove diabetic supplies and strips from the list of DME that requires accreditation. Independent pharmacies selling small amounts of diabetic supplies and DME will not choose to go through the costly accreditation process.**

6. **CMS states that in 2010 they intend to move diabetic testing supplies to national mail order suppliers. This would be inconvenient for Medicare beneficiaries and devastating to our independent pharmacy members. I have experience with patients who continue to receive supplies that they no longer need but are unable to get the mail order company to stop sending them. State Pharmacy Laws prevent prescriptions being returned once dispensed. This will result in great waste of dollars to the Medicare program. And our pharmacist will be asked to fill correct supplies but will have to charge the patient because the mail order has already billed Medicare.**

Expecting national, regional or small chains – some with thousands of outlets – to seek accreditation for an important but small part of their business or to comply with the additional quality standards when they are already subject to comprehensive pharmacy law requirements is simply unrealistic. Accrediting agencies will face significant hurdles in accrediting all these pharmacies, and some pharmacies believe that the cost of accreditation – both in time and resources – is too burdensome. This process could disrupt the important access that Medicare beneficiaries have had to items such as diabetic testing supplies and other health care items, and the critical coordination of receiving their prescription drugs for diabetes and other disease conditions from their community pharmacy. Plenty of time should be given to pharmacies become accredited.

Many of the organizations pushing the accreditation process are charging $5-15,000 to go through this process. A small pharmacy billing less than $100,000 a year for such sales cannot afford to pay this amount every three years just to do Medicare business at a very low profit margin.

Not to mention the cost to keep up with policies and procedures. Any hospital in the U.S. will tell you that they have had to add a large staff just to comply with Joint Commission's requirements to remain accredited. This is an additional cost that is not compensated by insurance or federal insurance programs. These are costs the small business owner cannot afford.

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 816-245-5740.

Sincerely,

Dale E. Smith, R.Ph., M.A.
Director of TriNet Third Party
PBA Health
1575 N. Universal Avenue
Kansas City, MO 64120

Submitter : **Ms. katherine fiscina** **Date: 06/28/2006**

Organization : **country south inc diabetic supply of america**

Category : **Health Care Industry**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Competitive Bidding will only allow for the "big guys" to remain in the healthcare arena such as Liberty Medical which have already repaid the Federal government over $25,000,000.00 in fines after an F.B.I. investigation but,Libert Medical admitted "no wrongdoing". Ask yourselves this would you pay $25,000,000.00 if you had done nothing wrong?

Honest, hardworking, providers like myself do not have the resources that huge industry has to compete and win. Liberty Medical has purchased their own manufacturing company to produce their own brand name, diabetic testing supplies, can the average business owner compete with that?

America is "supposed to" be the land of opportunity but, for whom corporate America or the average business owner and their employee's?

If this program does continue to move forward as presented in this proposal an enormous amount of American's will be forced to close their business and an enormous amount of American's will be without jobs.

If the government wants to make competition why can't those companies which have already been accused of defrauding our government be excluded from the selection process?

Do companies that have proven to be the culprit in invading our Medicare system really have the right and privledge to throw there hat in the ring?

Sincerely,
Katherine Fiscina
Controller
Country South Inc. dba Diabetic Supply Of America

Submitter : Ms. Lori DeMott **Date:** 06/28/2006

Organization : Physiotherapy Associates American Society of Hand

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-651-Attach-1.DOC

CMS-1270-P-651-Attach-2.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 Lori DeMott, 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 outpatient orthopedics, 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. 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,

Lori DeMott OTR/L, CHT
Clinic Director
Eastside Hand

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

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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,

Lori DeMott OTR/L, CHT
Clinic Director
Eastside Hand

Submitter : Dr. Joseph Grillo **Date:** 06/28/2006

Organization : American Podiatric Medical Association

Category : Physician

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Dr McClellan,
Podiatrists ARE physicians and to classify them as otherwise is ridiculous.We admit patients,perform surgery and DAILY prescribe shoes,orthotics and other durable medical equipment and to exclude as physicians is predjudicial and an insult to myself and my patients.
All this is is another assault on patient rights. Imagine if you walked into your doctors office,had a fracture or Charcot joint and had to go to another provider to get what you need to get better. I firmly oppose CMS attempt to put this up for contractual bidding and predjudicial exclusion of podiatrists from taking care of patients as we know best how to do. Sincerely,Joseph Grillo DPM-Ft. Myers,FL

Submitter : **Ms. Deanne Birch** **Date: 06/28/2006**

Organization : **Infusion Innovations**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-653-Attach-1.DOC

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

June 28, 2006

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:

Infusion Innovations 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.

Infusion Innovations is a locally owned Home Infusion Provider for the States of Utah, Idaho, and bordering counties. We are located in Salt Lake City and employ over 40 employees. We are just entering our 8th year of business and currently serve, on average, over 250 patients each month. Over 25% of these are Medicare Enteral Nutrition patients. We have a complete nutrition program including a Registered Dietician to oversee our patient's medical needs, ensure they are receiving adequet nutrition and obtaining/maintaining their nutritional goals, and provide ongoing support for their particular disease. This is a group of people that can no longer obtain their nutrition orally – like you and I. In order for these patients to survive they must be fed either enterally via a feeding tube, or intravenously on Total Parenteral Nutrition. Our patients are contacted and followed monthly, and when appropriate our Dietician will contact their physician to make recommendations. The scope of service we provide to our enteral patients is very clinical in nature and much more than delivery of DME.

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

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

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

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

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

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

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

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

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

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify

reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 801.908.6100. or toll free 1.800.322.8695.

Sincerely,

Deanne Birch
Managing Member
Director of Reimbursement
Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

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

Organization : Sandcreek Medical

Category : Other Health Care Provider

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

I am bothered by the fact that CMS does not have any concrete timetable set that they have to follow. The deadline for the DME companies is looming and CMS has not issued the final, and acceptable, set of standards. Dealing with Medicare and the complex rules/laws associated with Medicare is like walking through a maze. You can come up with a great sounding idea, then you realize that it will not work for many different reasons. The idea is not bad, it just needs to be rethought. CMS must leave adequate time after issuing their standards for the industry to digest them and use their expertise, to respond on what standards will not work the way CMS wants. This is a complex issue and it cannot be rushed.

Also, I believe that CMS and Congress think that having supplier standards will make every one honest. With in the last few months a national respiratory company agreed to pay somewhere around 14 million dollars in fines, but, they admitted to no wrong doing. This company is an accredited company.

CMS cannot drag this out to the point small business do not have adequate time to become accredited. If this happens, only the large companies will be able to bid. Small providers will be squeezed out by the system.

My last thought about having stringent and finite standards. You can go to any McDonalds in America and have a Big Mac. I am sure that the Big Mac will taste about the same at all the restaurants. I am also sure that it will not be the best hamburger you have ever had.
Stringent rules do not make everything perfect.

Submitter : **Ms. Lauri Maier** **Date: 06/28/2006**

Organization : **Rainier Long Term Care Pharmacy**

Category : Nurse

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

The comp. bidding program should include unique products that can easily be provided by a central supplier. (Beds, WC, motorized equip.) Keep the common DMEPOS supplies locally (diabetic supplies, wound and inc. products, enterals, O2)

Education and Outreach

Education and Outreach

I appreciate CMS's commitment in providing a proactive ed. approach. Providing suppliers with bidding timelines, program requirements, instructions and the opportunity to attend conferences well in advance of deadlines is much appreciated.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

I urge CMS to take steps to ensure that small suppliers can participate in the competitive bidding.
Once the single payment amount is determined for each DMEPOS, suppliers currently providing DMEPOS who are willing to accept that payment amount should be allowed to join the competitive bidding program.

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

Submission of bids are to include all costs related to furnishing the item (del. setup, training, maint.) Using the CPI-U to increase annually will not cover the costs to provide the services. (gasoline, salaries)
I object to suppliers being able to submit bids for only the products they want to specialize in. Specialization will force beneficiaries to shop with a number of vendors instead of having just one provider for everything. Speicalization will also force small suppliers who have a limited profit margin on some items to loose that market to it's competitor who just offers that one product.

Submitter : Mr. Adrian Asencio
Organization : Carnahan Therapy
Category : Occupational Therapist

Date: 06/28/2006

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 : Jackie Bolt

Date: 06/28/2006

Organization : Carolina Homecare

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1270-P-657-Attach-1.DOC

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

Dear Sir/Madam:

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

Payment Basis

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

We also need information on how DRA provisions are going to be implemented for oxygen patients. We cannot provide meaningful comments or make recommendations without sufficient information. We also certainly cannot estimate costs and provide realistic bids without a significant amount of information that is currently missing in this proposed rule. It is disconcerting to think that CMS truly believes that providers can make viable, stable business decisions with the huge amount of information that is lacking in this proposed rule.

The proposed rule also does not address Medicare Advantage patients and how they will be handled under competitive bidding. I am sure that CMS is aware that on a very frequent basis, beneficiaries "flip" between traditional Medicare and the Medicare Advantage program. Our company deals with reimbursement issues every day as a result of these beneficiary decisions. The proposed rule should have addressed rules that would apply to these beneficiaries that leave the Medicare Advantage plan and reenter

traditional Medicare. I recommend that the same grandfathering provisions would apply to them.

Competitive Bidding Areas

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

It is also recommended that New York, Los Angeles and Chicago be top priorities in the 2009 phase of implementation due to the potential for significant cost savings to the Medicare program. Even though these are large areas, the experience gained during implementation of the first 10 MSAs should prepare CMS for these areas and they should be implemented first during the second phase due to the large cost savings that should be realized according to CMS projections.

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

Criteria for Item Selection

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

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

Submission of Bids under the Competitive Bidding Program

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

Conditions for Awarding Contracts

Only accredited providers should be eligible to submit bids. CMS should not proceed with competitive bidding until it is sure that this is possible. CMS needs to identify the criteria it will use to identify the accrediting bodies now and publish that criteria. CMS should grandfather all providers accredited by organizations that meet the criteria that CMS identifies. CMS should allow additional time for providers to analyze the quality standards in conjunction with the NPRM. The quality standards will have a significant impact on the cost of servicing our beneficiaries. Until these quality standards have been released and providers can implement them, as well as see the costs of becoming accredited (both internal costs and the actual cost of the accreditation process), then it is impossible to prepare bid pricing. Companies that have not gone through the accreditation process can submit unrealistic bid prices due to the fact that they have not completed the process nor obtained accreditation. These low bids can significantly impact final pricing. And if these companies choose not to get accredited and drop out of the contract supplier group, they have lowered pricing for these products.

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

It is also important to note that the timelines that CMS are considering for implementation of competitive bidding are unrealistic based on accreditation requirements. For the majority of companies in this industry, they have not prepared for nor gone through the accreditation process. This is a time-consuming process and one that many companies do not want to prepare for until they have all the answers. Providers want to see final quality standards and then a list of the accrediting bodies recognized by CMS before they begin the lengthy, expensive process of accreditation. It requires a

minimum of 6 months to prepare for your initial survey plus the majority of accreditation bodies require that companies be in compliance with quality standards for a minimum of 4 months prior to survey. So, realistically, providers going through accreditation for the first time will need 10-12 months to complete that process. Add on to that timeframe another 4-8 weeks after the survey before the accreditation body notifies the provider of the "official" results of their survey. So, it is important to realize that on average, CMS should expect it to take a minimum of one year to complete the accreditation process and become officially accredited. This doesn't even take into consideration the tremendous backlog that all accrediting bodies are going to face once quality standards are finalized and accreditation organizations are selected. It is unrealistic to think that this won't add additional time to the already lengthy process.

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

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

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

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

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

Determining Single Payment Amount for Individual Items

The NPRM describes a rebate program that allows contracted suppliers to rebate the difference between their bid and the established payment amount to the beneficiaries.

Providing rebates is contrary to laws applicable to the Medicare program such as the Anti-Kickback statute and the Beneficiary Inducement Statute. This rebate program could take fraud and abuse to a whole new level in our industry and would be almost impossible for CMS to oversee and regulate. This entire provision needs to be eliminated from the final rule.

Terms of Contracts

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

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

Opportunity for Participation by Small Suppliers

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

Opportunity for Networks

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

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

and what they should be, etc. Providers need detailed information so they can use this data to determine suitable partners for networks.

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

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

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

Sincerely,

Jackie Bolt
Owner
Carolina Homecare
1136 Grove Road
Greenville, SC 29605

Submitter : Dr. Stanley Bosta **Date:** 06/28/2006

Organization : Stanley Bosta, DPM, PC

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,

Stanley D. Bosta, DPM, PC

Submitter : **Mrs. Betty Ced** **Date: 06/28/2006**

Organization : **Cypress Mobility Inc**

Category : **Other Health Care Provider**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

We are in the process of acquiring our accreditation. However, we feel the competitive bid will put us at a severe disadvantage. All small companies like ours will be unable to compete with the large corporations and that is not right. Small companies will be put out of business if this goes into effect. As far as our company is concerned, we have the necessary financial ability to provide our clients with what they need as outlined in your supplier standards.

As a Medicare participating supplier of DME equipment, we ask that you please reconsider the competitive bid process.

Thank you

Submitter : Dr. George Williams **Date:** 06/28/2006

Organization : Ankle + Foot Center of Tampa Bay

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 have been in practice in Florida fro the last 4 years and 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 and surgeons 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 also routinely prescribe walking boots after certain surgical procedures and, of course, these patients cannot walk without further injuring their foot.

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

Professionally,

George Williams DPM, AACFAS

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

Organization : **John J. DiStazio, DPM, PC**

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,

John J. DiStazio, DPM, PC

Submitter : Mrs. Roselyn Brecher **Date:** 06/28/2006

Organization : Northport Health Services of Florida,LLL D/B/A Cry

Category : Health Care Professional or Association

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

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 Crystal River Health River Health and Rehabilitation a 150 bed facility located on 136 NE 12th Avenue in Crystal River, Florida. We employ 160 people and provide physical therapy, occupational therapy and speech therapy. Our nursing services include IV therapy, wound therapy, respiratory therapy, restorative care and
pain management.
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 Crystal River Health and Rehabilitation 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,

Roselyn(Lyn)Brecher, Administrator

Submitter : Mr. Michael Byington **Date:** 06/28/2006

Organization : Kansas Assn. f/t Blind and Visually Impaired

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

This proposed rulemaking codifies an exclusion for low vision aids. It refuses to acknowledge such aids as covered durable medical equipment. It equates such aids with the exclusion for the coverage of eye glasses.

This is equivelant logic to suggesting that prosthetic limbs should not be covered because standard shoes are not covered. Quite obviously, Medicare would not make such an exclusion for prosthetic limbs. It defies logic to make such an exclusion for visual aids.

The real issue here would appear to be that Medicare has declined to cover low vision aids as durible medical equipment at initial levels throughout its history. If one looks at Medicare's own functional definitions of such equipment, this has been a longstanding error on the part of Medicare. Medicare now faces the reality that a significant number of Medicare recipients who have low vision have appealed denials of coverage of low vision aids, such as closed circuit television magnification devices. Many administrative hearings officers in numerous jurisdictions have acknowledged that low vision aids should be covered as durible medical equipment, and have allowed such coverage at the end of a protracted appeals process. The result is that considerable case law is being established to the effect that low vision aids are durible medical equipment which in fact should be covered by Medicare on a regular basis. Appeals should not be necessary.

In proposing the rulemaking in the way that it has, CMS is attempting to invaladate a plethora of established case law through the making of one, broad rule of sloppy construction which says in layman's terms, "Well all of our other regulations and definitions make it seem as though low vision aids are durible medical equipment, so at this point we are going to specifically say that such things are not covered, even though in other rules, we imply that they are. Case law ratifying such an interpretation is thus nullified across the board."

This approach constitutes discrimination by class. If a person who can not move without a wheelchair can get help from Medicare to get the wheelchair for purposes of achieving functional movement, then a person who can not see without prosthetic visual aids of a specialized nature should be able to acquire such aids with Medicare assistance in order to restore functional vision.

It is most perplexing in the extreme to the members of the Kansas Association for the Blind and Visually Impaired, and certainly to myself as its President, that CMS proposes to further codify discrimination against low vision citizens when coverage is compared with that available for persons who have other physical dysfunctions. I trust the exclusion language for low vision aids will be withdrawn, and replaced with clear inclusion of low vision aids as a type of durible medical equipment.

Michael Byington, President
Kansas Association for the Blind and Visually Impaired.

Submitter : Dr. Stephen Kruljac **Date:** 06/28/2006

Organization : Stephen J Kruljac, DPM, PC

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,

Stephen J. Kruljac, DPM, PC

Submitter : **Dr. Rodger Kuhn** **Date: 06/28/2006**

Organization : **Rodger B Kuhn, DPM, PC**

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).

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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,

Rodger B. Kuhn, DPM, PC

Submitter : **Dr. William Lenz** **Date: 06/28/2006**

Organization : **William H. Lenz, DPM, PC**

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:

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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,

William H. Lenz, DPM, PC

Submitter : Mr. Herb Paserman **Date:** 06/28/2006

Organization : JAMES

Category : Health Care Provider/Association

Issue Areas/Comments

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

In the section labeled "Rebate Program" it is stated that suppliers who submitted bids below the single payment amount for a bid item could offer a rebate to their customers on the price difference, while other higher bidders could not. This offer constitutes a dangerously unethical precedence, encouraging monetary inducements which, once started could escalate into all types of illegal behavior. Providers who are prohibited from competing fairly, will find every possible way to survive and hold onto their business. The motivation and temptation to break the law will be too strong for many to resist, thereby degrading the program and eliminating anyone who tries to participate legally and fairly. Furthermore, those offering the rebates will be encouraged to accept dangerously high patient loads that would violate their own standards of care and jeopardize their accredited status. This could ultimately lead to a total meltdown in quality of service within the CBA and unjustified patient injury as well as significantly higher costs of care to the system, eradicating any savings from the competitve bidding program.

Submitter : **Mrs. Elizabeth Redick** **Date: 06/28/2006**

Organization : **Webb City Health and Rehabilitation**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

June 28th, 2006

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

To Whom it may concern:

I am writing to expres my concerns regarding the Center for Mediare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEOS").

I am the Administrator at Webb City Health and Rehabilitation of a 120 bed skilled nursing facility in Webb City, Missouri.

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 abilitiy 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 speciality items, existing care plans could be interrupted, thereby affecting our ability to provide the car seniors need and deserve.

At Webb city Health and Rehab we have numerous residents whose care could be interrupted as a result of this implementation-jeopardizing their health and safety. Ths proposed rule has the potential to compromise a residents access to specific services and products, resulting in long-term increased costs of care.

I feel it 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,

Elizabeth Redick
Administrator

Submitter : Ms. Dee Simons **Date:** 06/28/2006

Organization : Roche Diagnostics

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : Mr. Sam Jarczynski

Organization : Rx Stat, Inc.

Category : Other Health Care Provider

Date: 06/28/2006

Issue Areas/Comments

GENERAL

GENERAL

Attachment of comments.See attachment.

CMS-1270-P-670-Attach-1.DOC

Rx Stat, Inc.
Comments on the Notice of Proposed Rulemaking (NPRM) on Competitive Acquisition

Timing Concerns

Supplier Standards and Deficit Reduction Act Implementation

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

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

Opportunity to Comment on the Supplier Standards

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

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

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

Overall Implementation Time-line

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

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

Payment Basis

Inflation Update

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

Grandfathering Medicare Advantage

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

Beneficiary Switch to Contract Suppliers

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

Application of DRA to Oxygen Patients

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

Authority to Adjust Payment in Other Areas

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

Limitation on Beneficiary Liability

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

Competitive Bidding Areas

Staggered Implementation

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

Nationwide or Regional Mail Order Competitive Bidding Program

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

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

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

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

Establishing the Competitive Bidding Area

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

Criteria for Item Selection

Items Included in Competitive Bidding

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

products and supplies are not durable medical equipment and consequently do not meet the definition of covered items as defined under 1834(a)(13). CMS must confirm that ostomy products and supplies are not included in competitive bidding under 1847(a)(2).

Potential for Savings

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

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

Additional Criteria for Item Selection

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

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

Brand-Specific Requirements

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

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

competitive bidding. Inasmuch as CMS authority to implement this requirement is discretionary under the MMA, we strongly recommend that CMS *not* include this provision in the final rule.

Coding Issues and Item Selection

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

Product Categories for Bidding Purposes

General Issues

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

Requirements to Bid on all Products in a Category

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

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

issues in areas of the country where a winning provider is not equipped to provide the complexity of multiple seating and positioning services required in that area.

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

Conditions for Awarding Contracts

Quality Standards and Accreditation

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

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

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

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

Market and Supplier Capacity

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

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

that the competitive bidding payment amounts are sustainable over time.

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

Assurance of Savings

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

Determining the Single Payment Amount

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

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

Rebate Program

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

Specifically, 1128A(a)(5) prohibits the offering or transfer of remuneration when an individual or entity knows or should know that it is likely to influence the beneficiary's selection of a provider or supplier. Remuneration includes anything of value and would apply to the rebate proposed by CMS. While the statute contains exceptions to the definition of the term remuneration, the rebate program proposed in

the NPRM does not fit any of the statutory exceptions. For example, remuneration does not include unadvertised waivers of coinsurance or deductible amounts for individuals who have been determined to be in financial need. The rebate offered by contract suppliers under the CMS program would not fit into this exception. We are also unaware of any guidance from the Office of Inspector General (OIG) of the Department of Health and Human Services that would authorize the program CMS proposes. In light of the statutory prohibitions of 1128A(a)(5), CMS lacks the authority to implement a rebate program. Consequently, CMS should withdraw the proposal.

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

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

Bulletin at 1.

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

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

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

Bulletin at 5 (Emphasis supplied).

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

Terms of Contract

Repair or Replacement of Equipment

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

Termination of Contract

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

Judicial and Administrative Remedies

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

Change of Ownership

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

Participation of Small Suppliers

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

Submitter : Mrs. Marcie Parker **Date:** 06/28/2006

Organization : Healthwise Pharmacy of Greenville, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1270-P-671-Attach-1.TXT

June 28, 2006

To: CMS

Dear Sir:

Thank you for the opportunity to comment on the competitive bidding proposal. I would like to make a few points.

1. Competitive bidding is not in the best interest of Medicare beneficiaries when it comes to small rural communities. The bidding process will eliminate small independent pharmacies from providing much needed supplies that we have been providing for years. Our customers depend on the local Pharmacist for counseling and professional help with health related issues. Where will the patients get that special one on one attention they have been getting at their local pharmacy when they are in need? Hospitalization costs will soar as a result of the local pharmacist not being included in the patients overall health care plan.

2. Diabetic supplies being done through mandatory mail order is a terrible idea that may appear to save money, but will actually lead to rising costs with Emergency Room visits and also hospitalization costs as a result of complications of lack of blood sugar control. There are many complicating factors such as changes in a beneficiary's level of supply needs that may inhibit the supplier's ability to get reorder supplies to a beneficiary within the required time frame. With glucose monitors, the type/brand that a beneficiary is initially prescribed may change based on the beneficiary's medical status and required changes in the brand of test strips supplied. For example, a beneficiary may develop arthritis and be unable to open the packages of test strips requiring that they be switched to a different brand in order to comply with the prescribed testing.

3. Quality standards is a good idea, but should be put in place gradually to allow for small businesses such as independent pharmacies to adjust to the new standards and be allowed adequate time to become accredited.

4. Competitive bidding should not be allowed in MSA's with less than 500,000 people. This would help keep small business owners in rural communities open and therefore beneficiary access in these areas will not be compromised.

Thanks:

Marcie Parker, PharmD, RPh, MBA
HEALTHWISE PHARMACY
615-B South Memorial Drive
Greenville, NC 27834
252-752-0338

Submitter : **Dr. Charlotte Reisinger** **Date: 06/28/2006**

Organization : **American Podiatric Medical Association**

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.

Respectfully,

Charlotte A. Reisinger, DPM, AACFAS

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

Organization : Kentucky Medical Supply, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

It seems a bit like "putting the cart before the horse". National accrediation and previously proposed standard updates need to be established prior to beginning the competitive bidding process. Otherwise bids might be submitted by suppliers who cannot or will not be able to supply beneficiaries with quality products or service. The proposed quality standards will affect the cost of servicing beneficiairies, which will thereby, affect the bid itself. To the best of my knowledge not only have the proposed standards not reached final approval, but the accreditation process has not been established. Suppliers do not have a clue at this point what procedures will be acceptable by CMS. What establishes a supplier as a qualified or eligible bidder? CMS should publish the quality standards in order to facilitate comment on them, before the implementation of such standards on the industry. Previously proposed standard updates were available for comment, but again I have not seen anything since commenting on them. Accreditation firms or processes should be identified and time allowed for businesses to secure accreditation, or at a very minimum be in the process of receiving accreditation. It is my understanding the process can be quite lengthy and costly. For the small durable medical equipment business, I am concerned the research and cost required would be prohibitive. However, some standard must be in place prior to soliciting bids to assure the bids made would be cost efficient for the Medicare program and still provide the beneficiary with quality of product and care. In my opinion the first step should be creating the guidelines which establish a qualified or eligible supplier. This step is the most important. It is the foundation for all other elements of the process. Guidelines need to be created and implemented before the bidding begins to guarantee the bidding process. It also ensures the quality of the bid itself. It would certify the bidding process by assuring only those bidders who can and/or do meet the specific guidelines for operation of their business. Competitive bidding should mean exactly what it says. Bidding should be based on an amount the supplier is willing to provide a particular item/service for x number of customers. As I understand it, bids above the current fee schedule would be disqualified. However, some items within the current fee schedule are bare minimum with little or no profit margin for the supplier, especially the small business owners who cannot afford to surplus order items. Businesses are expected to show a profit; if they do not show a profit, they will eventually be forced to close their doors. If CMS receives fifty bids for same or similar service, but only needed five contracted suppliers to provide for the beneficiaries within the metropolitan area, would bidder five have the winning bid? What if bidder five's bid was substantially lower than the median of the fifty submitted bids? It appears the payment method would be the median of the contracted suppliers, or in the case of the above example the payment would be the median bid of the five suppliers. And what about the other 45 bidders, are they just out of luck? Will they be forced to eventually close their doors because they cannot accept new beneficiaries for these services? Suppose bidder #30 has several Medicare beneficiaries as customers, will the customers be transferred to another supplier? If so, how doews the business make up for that lost revenue? Or what happens when the payment period has reached the maximum for those beneficiaries, but the company could not keep building its business? Bidding should be truly competitive and affordable for all parties. The winning bid should be the average bid for the group of products within the particular location. All bids should be taken into consideration and the median of those bids should be the amount of the winning bid.

Submitter : **Dr. Dusky Farmer** **Date: 06/28/2006**

Organization : **American Podiatric Medical Association**

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)(3).

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)(3) 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,

Dusky R. Farmer, DPM, AACFAS

Submitter : Mr. Gary Glisson **Date:** 06/28/2006

Organization : Ward Drug Company

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-675-Attach-1.TXT

June 28, 2006

To: CMS

Dear Sir:

Thank you for the opportunity to comment on the competitive bidding proposal. I would like to make a few points.

1. Competitive bidding is not in the best interest of Medicare beneficiaries when it comes to small rural communities. The bidding process will eliminate small independent pharmacies from providing much needed supplies that we have been providing for years. Our customers depend on the local Pharmacist for counseling and professional help with health related issues. Where will the patients get that special one on one attention they have been getting at their local pharmacy when they are in need? Hospitalization costs will soar as a result of the local pharmacist not being included in the patients overall health care plan.

2. Diabetic supplies being done through mandatory mail order is a terrible idea that may appear to save money, but will actually lead to rising costs with Emergency Room visits and also hospitalization costs as a result of complications of lack of blood sugar control. There are many complicating factors such as changes in a beneficiary's level of supply needs that may inhibit the supplier's ability to get reorder supplies to a beneficiary within the required time frame. With glucose monitors, the type/brand that a beneficiary is initially prescribed may change based on the beneficiary's medical status and required changes in the brand of test strips supplied. For example, a beneficiary may develop arthritis and be unable to open the packages of test strips requiring that they be switched to a different brand in order to comply with the prescribed testing.

3. Quality standards is a good idea, but should be put in place gradually to allow for small businesses such as independent pharmacies to adjust to the new standards and be allowed adequate time to become accredited.

4. Competitive bidding should not be allowed in MSA's with less than 500,000 people. This would help keep small business owners in rural communities open and therefore beneficiary access in these areas will not be compromised.

Thanks:

Gary Glisson, RPH
PO Box 400
Nashville, NC 27856
252-459-2202

Submitter : J. Harris Morgan **Date:** 06/28/2006

Organization : Option Care of Camilla, Inc.

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

durable medical equipment, orthotics, infusion therapy, enteral nutrition therapy, and supplies.

Submitter : **Mrs. Tara Hensley** **Date: 06/28/2006**

Organization : **Mason City Clinic**

Category : **Physician Assistant**

Issue Areas/Comments

GENERAL

GENERAL

I work in an Orthopedic dept where we need to apply splints and instruct patients on a daily basis. It is important that we have access on site to these splints and that we can have a variety as we treat many patients and conditions. Patients that have fractures should not be going somewhere else to get a splint- this is poor patient care and could damage the care of the fracture and patient. You cannot grossly generalize the use of our splints, suppliers, and our access. Patients are more complient if we can show them how to use the splints and if we can fit them. There needs to be some changes or special accomadations for clinics and departments such as ours to the proposed rule. Please keep these things in mind. Thank you.

Submitter :

Date: 06/28/2006

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1270-P-678-Attach-1.PDF

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. Lawrence Wayne **Date:** 06/28/2006

Organization : Valley Infusion Care

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-679-Attach-1.PDF

Valley Infusion Care
Provide of Quality, Personalized Pharmaceutical Care
1815 W. Diehl Rd., Ste 900
Naperville, Illinois 60563

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:

Valley Infusion Care 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.

Valley Infusion Care is a home infusion therapy company located in Naperville, Illinois, that first cared for patients in July 1999. We treat approximately 30 – 45 patients per week at home. Therapies include: intravenous antibiotics, Total Parenteral Nutrition, hydration therapy, chemotherapy and pain management.

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

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

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

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

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

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

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

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

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

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

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

8. The private sector, only allows home infusion to be provided to their insured by accredited o rganizations and s ome ins urance c ompanies w ill o nly a ccept J oint Commission accreditation. Currently this is NOT the standard with CMS. Quality and Safety need to be concerns of the CMS as far as home infusion is concerned. Participation of home infusion providers in Part B only will help to assure this.

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 630-355-5630.

Sincerely,

Lawrence J. Wayne, RPh
General Manager

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

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

Organization : The University of Michigan Health System

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-680-Attach-1.DOC

University of Michigan
Hospitals and
Health Centers

Accounting and Reimbursement Services
2500 Green Rd. Suite 100
Ann Arbor, Michigan 48105-1500
734-647-3321
734-647-0026 Fax

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

June 28, 2006

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

Dear Dr. McClellan:

The University of Michigan Health System (UMHS) welcomes this opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed rule to implement competitive bidding programs for certain covered items of DMEPOS.

CMS proposes that when implemented, items that are competitively bid will only be provided by winning bidders and this program will set reimbursement rates for certain items of durable medical equipment (DME) and off-the-shelf (OTS) orthoses based on that competitive bidding process. Further, reimbursement rates established under the competitive bidding program must be lower than what would have been paid under the established Medicare DMEPOS fee schedule.

The implementation of limited or "exclusive" provider panels that do not allow hospital entities to serve their own patient population often increase hospital re-admissions, increase length of stays and lead to a higher proportion of less favorable clinical outcomes. In addition, hospital costs rise as a result of increased administrative oversight and program management.

UMHS recommends that CMS allow hospitals currently providing the services/supplies included under the competitive bidding final rule to continue to be reimbursed for treating their own patient population.

REGULATORY IMPACT ANALYSIS

(Federal Register page 25690)

As mentioned above, UMHS strongly believes the implementation of this rule will result in an unfunded mandate on integrated health systems. It appears that CMS' impact analysis did not assess the additional costs associated with reduced patient access, choice, and service related to other areas of the hospital system and healthcare continuum. Factors including an increased length of stay in inpatient/acute care settings, increased patient re-admission frequency and/or severity of illness should be assessed in the impact analysis.

UMHS recommends that CMS review the pilot programs for the occurrence of increased costs in the tertiary inpatient and outpatient care settings. UMHS is concerned that savings resulting from the competitive bid program may result in unintended cost-shifts within the health care continuum.

UMHS strongly urges CMS to delay or reduce the scope of implementation of the competitive bidding program until further review of the effect of cost-shifts within the health care continuum can be assessed.

USE OF TERMS

(Federal Register page 25660)

Noncontract Supplier:

The term has been defined by the proposal as "a supplier that is located in a competitive bidding area or that furnishes items through the mail to beneficiaries in a competitive bidding area but that is not awarded a contract by CMS to furnish items included in the competitive bidding program for that area."

This definition does not address those suppliers that are physically located outside of a competitive bidding area yet provide services to beneficiaries whose permanent address is inside a CBA. Although implied, UMHS believes it is best to clarify the use of this term in order to avoid any confusion while implementing the competitive bidding program.

UMHS recommends that CMS update the "noncontract supplier" definition to "a supplier that furnishes items to beneficiaries in a competitive bidding area, but that is not awarded a contract by CMS to furnish items included in the competitive bidding program for that area."

Items:

This term has been defined by the proposal to include "(4) off-the-shelf orthotics, which are orthotics described in section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit a beneficiary."

The definition as stated should not be further defined by the provider who supplies these particular OTS services. UMHS requests further clarification of the term "minimal self-adjustment" as used in the definition. UMHS believes that this term should be limited to adjustments made by the beneficiary or caretaker, not requiring modifications made by an outside supplier. If any adjustments are made by an outside supplier, the item should be reconsidered as a custom-fitted orthosis, and therefore would not be included in this proposed regulation.

UMHS urges CMS to clarify the term "minimal self adjustment" used within the definition as "limited to modification made by the beneficiary or caretaker."

COMPETITIVE BIDDING AREAS

(Federal Register page 25665)

The Medicare Modernization Act (MMA) provides CMS with the authority to phase-in competitive bidding programs so the competition under the programs occurs in 10 of the largest Metropolitan Statistical Areas (MSAs) in 2007. CMS proposes to exclude the three largest MSAs (based on population) from consideration for competitive bidding until 2009 because of the logistics associated with the start-up of this new and complex program. This exclusion seems to violate the intent of the MMA since the allowable charges of these three MSAs represents 45% of the allowable charges of the top ten MSAs.

UMHS r ecommends i ncluding t he t op three M SAs i n t he c ompetitive b idding p rocess a nd reducing the scope of the competitive bidding program to no more than three product groups. This w ill allow f or an orderly roll out of the competitive bidding process f or 2007, allow providers, DMERCs and CMS to gain experience with the competitive bidding process in larger MSAs, and still generate savings to the Medicare program.

SUBMISSION OF BIDS UNDER THE COMPETITIVE BIDDING PROGRAM

(Federal Register page 25672)

CMS has proposed to allow Skilled Nursing Facilities (SNFs), which provide DMEPOS items included in the competitive bid program, to supply only their own residents if the SNF becomes a contracted supplier. UMHS agrees with CMS' approach and believes the same provisions should be applied to hospital providers.

UMHS recommends that CMS exempt hospitals from the requirement to provide services to the entire competitive bidding area.

CONDITIONS FOR AWARDING CONTRACTS

(Federal Register page 25674)

Quality Standards:

The Social Security Act specifies that a contract may not be awarded to any entity unless the entity meets applicable quality standards. A grace period may be granted for suppliers that have not had sufficient time to obtain accreditation before submitting a bid. If a supplier does not then successfully attain accreditation, CMS will suspend or terminate the supplier contract.

UMHS recommends that only bid submissions from suppliers and providers who are accredited at the time of bid submission should be included in the determination of the pivotal bid. This would safeguard the competitive bidding process from providers who submit artificially low bids to ensure inclusion in the program, ultimately driving the pivotal bid down for the CBA, and later decide the pivotal bid is too low and elect not pursue accreditation.

Evaluation of Bids:

It is imperative that CMS takes into consideration the product manufacturers within each specific product group before awarding contracts. Since a HCPCS code may contain many brand products made by a wide range of manufacturers, suppliers will choose to only offer certain brands of products within that HCPCS code. Beneficiaries whose permanent residence is within a designated CBA will have previously purchased DME items, such as infusion pumps, which will require the use of manufacturer specific supplies. To require a patient to convert to a new delivery system would be costly to the patient and/or the supplier, and negate the Medicare program savings intended to be obtained by the competitive bidding program.

In an effort to maintain patient access to quality care and ensure product availability, **UMHS recommends that CMS implement a provision to allow any willing accredited provider/supplier to service patients in a given CBA at the pivotal bid amount.**

As the specific "off-the-shelf orthotics" to be included in the competitive bidding program have not been defined by this proposed rule, it is UMHS' intent to ensure that items requiring any modifications that cannot be performed by the beneficiary or caretaker are not included in the final rule. It is imperative that CMS realize that some off-the-shelf orthotics are used for post-surgical support requiring precise modifications by a trained professional before patient use, and incorrect application of these items can cause damage to the surgical site and/or prolong post-surgery healing.

UMHS recommends that off-the-shelf orthotics included in the competitive bidding program be restricted to items used solely for the purpose of orthotically providing musculoskeletal support, with additional adjustment made by and limited to the beneficiary or caretaker.

DETERMINING SINGLE PAYMENT AMOUNTS FOR INDIVIDUAL ITEMS

(Federal Register page 25680)

CMS is proposing to allow contract suppliers that submitted bids for an individual item below the single payment amount to provide the beneficiary with a rebate. UMHS foresees the rebate option adding another layer of complexity to this already intricate program without achieving any additional savings. Rebates have the potential to encourage over utilization and may result in beneficiaries placing pressure on their provider to order unnecessary products and services.

UMHS is opposed to the proposal to allow contract suppliers to offer rebates to the beneficiary. However, if allowed, in order to reduce these potential risks, UMHS strongly recommends that under no circumstances should the rebate exceed the co-pay amount.

QUALITY STANDARDS AND ACCREDITATION FOR SUPPLIERS OF DMEPOS

(Federal Register page 25684)

CMS has proposed to add a new section §424.58 to address the requirements for CMS approved accreditation organizations in the application of the quality standards to suppliers of DMEPOS and other items.

UMHS recommends that CMS establish the objective and subjective criteria that will be used to select the accrediting bodies at least 90 days prior to the implementation of the competitive bidding program.

Once again UMHS would like to thank you for the opportunity to comment on the proposed rule to implement competitive bidding programs for certain covered items of DMEPOS. If you have any questions or would like clarifications please contact me at (734) 647-2579.

Sincerely,

Robert Reske

Robert Reske, Manager
Accounting and Reimbursement Services
University of Michigan Health System

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

Organization : Orthopaedic

Category : Physician

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

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.'

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.)

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

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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.

Opportunity for Networks

Opportunity for Networks

The "dispensing of products" is but a small part of most therapy practices and of orthopaedic practices, such as ours, that dispense products as an important component, but only a component, of our services. It is unreasonable to believe that the large majority of physicians and therapists will be able to create and then manage special networks that have no purpose other than to meet a Medicare rule. It is like telling an automotive dealership that while it can run a repair department, it has to create and join a network for only the purpose of selling brake parts.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

There is essentially no opportunity for small suppliers. Your own analysis indicates that 70 hours of paperwork will be required in order for a supplier to submit a bid. This alone will force most small suppliers out of the market. Yet, without small suppliers, there is no competition.

Please see also comment under "Opportunity for Networks."

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

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

Regulatory Impact Analysis

Regulatory Impact Analysis

Access to care in a safe and appropriate manner by Medicare enrollees

Regulatory Impact Analysis

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.

Use of terms

Use of terms

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

Submitter :

Date: 06/28/2006

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1270-P-682-Attach-1.DOC

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 would like to provide comments on the CMS proposed rule concerning durable medical equipment. 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), so I can continue to serve my patients.

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. The walking boot would help to immobilize the injured foot and prevent further trauma. I want to make sure the patient is not putting weight on the injured extremity. Also, 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 would have to refer my patient to an appropriate supplier. This would result in a delay of treatment which could result in an increased risk of complications. Complications will lead to increased pain and suffering for the patient. The eventual result is increased cost for CMS and with health care costs out of control this would not be the desired outcome.

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

Sincerely,
Gerard J. Busch, D.P.M.

Submitter : Mrs. Edna Diaz

Date: 06/28/2006

Organization : EBJ Orthotics

Category : Home Health Facility

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

See Attachment

CMS-1270-P-683-Attach-1.TXT

May 30, 2006

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

Dear Sir or Madame,

The following arguments should be taken under consideration to delay the Competitive Bidding Project scheduled for Puerto Rico:

1) The majority of the metropolitan areas in Puerto Rico have areas that are poorly accessible in respects for delivery, be it by mail or by personally. Example: streets with no names, no physical address given only a road and kilometer number. Topographically, they are rural areas within the metro area.

2) Puerto Rico is very prone to hurricanes and severe storms, which bring major flooding. This factor complicates the delivery of oxygen and other vital equipment if there are few suppliers because of the topography of the island and the slow removal of debris after disasters, slowing up deliveries considerably and puts in risk lives of the patients.

3) Spanish is the official language in Puerto Rico which slows the accreditation process and consequently the Competitive Bidding Program. The patient orientation, as well as the training to suppliers and employees become more time-consuming due to the translation of material. No accreditation body has any paperwork in Spanish or sufficient Spanish-speaking personnel.

4) Hispanics have a higher incidence of diabetes; therefore this justifies the higher rate of invoicing products related to diabetic patients.

5) Years ago, HCFA agreed to a higher fee-schedule for Puerto Rico and the Virgin Islands because they took into consideration that there are no medical equipment manufacturers here ocean or air freight must be paid on top of excise tax for the majority of equipment that comes into Puerto Rico, raising costs considerably. This factor has to be taken into consideration when checking for a higher "Fee for Service.

6) Considering the language and education level, we believe instruction should be "face-to-face" at the moment of the delivery of a glucose monitor and other vital medical equipment. This is feasible because Puerto Rico is only 100 x 35 miles. The company that will provide the service should be accessible to patient.

7) If we take into consideration the difficulties in the implementation of Part C &D to Puerto Rico, where there was no direction from the local CMS offices (with approximately 6-7 employees) until 2006 and the Social Security Administration was not involved in the process, only the Medical Health Plans with their Advantage Coverage. The same company that had the economical interest was the only ones that informed the patient. When CMS got involved, their intervention was limited due to the lack of personnel and economical resources. This situation brought on fraud, confusion and lack of clarity in the instruction to the patient to the point of having mass media coverage and local government involvement. If this happened, what would be the effects of the implementation of Competitive Bidding in Puerto Rico?

8) We live in a culture which is not familiarized with the use of rebates. Companies that are U.S. based, and do business locally, do not implement the marketing strategies that they utilize states-wide, because of the cultural difference. The use of the implementation of rebate will cause confusion of fraud because there is no knowledge of the functions of this.

9) We support that for the implementation of Competitive Bidding in Puerto Rico the latest data available be used. We understand that this is fundamental in order to understand the reality of the present moment.

   In Puerto Rico, for the above mentioned reasons, the impact and penetration of the Medicare Advantage Plan market has been much greater than that states-side (almost double), as per data provided by CMS of Puerto Rico dated Feb., 2006. Consequently, we understand the number of patients under "Fee for Service" the quantity of DME providers and the use of products would lower significantly and possibly leave Puerto Rico out of the first 10 Metro Areas.

10) As recently as May, 2006, Puerto Rico confronted, for the first time in history, a controversial cease of government operations, for lack of government funding and a disagreement in regards to the fiscal budget. This has brought on severe consequences for the small businesses and 95% of the local DME companies are small businesses.

    Pretending to implement the Competitive Bidding Program as early as 2007, and with our looking forward to a recession, would bring on adverse consequences to small local businesses and it will not give opportunity to this to substitution.

11) The fact that Puerto Rico's status is a "Commonwealth of the United States" has made it more difficult for us to have our voices heard. Whenever there is a

project of law pending, the National Association of Durable Medical Equipment. "AA Homecare" exhorts us to call our local representatives to let them know how a project would affect us. As Puerto Rico does not vote in national elections, we have no representation, nor is there a political interest to listen to us.

Edna Díaz
President
EBJ Orthotics & Medical Equipment, Inc.

Submitter : Mrs. Christa Huddleston **Date:** 06/28/2006

Organization : Market Centre Physical Therapy

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS on a daily basis I have patients come into my clinic with pre-fabricated orthotics that are inappropriate for the diagnosis. They have been given these by other providers, orthotic companies or physician offices. We try to customize these braces by fabricating thermoplastic inserts with the correct angle of wrist support or thumb support. Often, however we have to start over with the correct splint or pre-fabricatee orthotic that is appropriate for the diagnosis. As trained professionals, I am a Certified Hand Therapist as well as an Occupational Therapist, we are skilled in the custom fabrication of all upper extremity orthotics. I make hinged elbow orthosis that my pts love as well as a wide variety of thumb, wrist and digit splints. We need to be able to continue to have the freedom to select and fit both prefabricated orthotics, splints and supports along with fabricating and fitting custom orthotics and splints to best serve our patients. We charge far less for these items than the Medical suppliers and orthotists. I have seen the charges on patients bills from other suppliers, as much as 80 to 90% mark up. We may charge 20 - 25% higher than our cost.
We also make regular changes to custom splints as swelling and healing occurs and the fit of the splint or need of the splint changes.
Please allow us to continue to practice in all our areas of expertise and not come under the DMEPOS bidding process. We are not in the same category of commercial providers, as we are skilled practitioners who must evaluate and specifically prescribe the correct orthotic based on diagnosis, precautions, ergonomics and disease process.
Delay in the ability to meet our patient needs would significantly impact their medical condition. Please oppose the rule for competitive aquisition for Occupational therpists, physical therpists and Certified Hand Therapists.
Thank you for your time and support,
Respectfully,
Christa I Huddleston MSOTR CHT
360-455-8155

Submitter : Dr. Neil Hecht

Date: 06/28/2006

Organization : Dr. Neil Hecht

Category : Physician

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

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.

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

Organization : Tyler Moore

Category : Attorney/Law Firm

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Dear Sir or Madam:

On behalf of long term care providers in the skilled nursing home industry, and the suppliers of enteral products particulary, please reconsider placing enteral products on competitive bidding.

Competitive bidding has not been tested in skilled nursing facilities. And equally important, enteral products were excluded from the testing as not suited for competitive bidding.

Patients in skilled nursing facilities are more vulnerable than in other settings. The issue is one of costs, but more importantly one of quality in a potentially critical environment. Quality of Service as well as choice of product and timing are crucial. Costs can be and are monitored, it is the quality of service that cannot be bidded.

Please do not include enteral products on the competitive bidding process. Thanks for taking the time to listen to the users on behalf of residents who are not able to voice their concerns.

Submitter : Ms. Carolyn Carlson **Date:** 06/28/2006

Organization : Horizon Healthcare Services

Category : Home Health Facility

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

See Attached.

CMS-1270-P-687-Attach-1.DOC

HORIZON HEALTHCARE SERVICES
2106 HARRISBURG PIKE
LANCASTER, PA 17601

June 27, 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:

Horizon Healthcare Services 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.

Horizon Healthcare Services is located in Lancaster Pennsylvania. Our Home Infusion Company services a ten county area and has been in business for twenty- three years. We are a growing company and have approximately 625 patients on service on any given day.

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

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

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

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

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

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

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

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

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

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

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

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 717-544-3594.

Sincerely,

Carolyn J. Carlson, RN
Chief Operating Officer

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

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

Organization : Lowry Drug Company, Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

Background

Background

It is my personal belief from the evidences from Polk County Fla. that competitive bidding will not only be a failure to Medicare recipiants, and to home care providers, but to the American Tax paers as well. Not only will the cost of implimentation be enormous but also the cost from transfering cost from part B to Part A which generally runs 3000 percent more for treatment. I for the life of me can not understand why CMS is pushing to cut back on the area that has the potential to save Medicare the most monies. Would a Super Bowl Coach break the legs of his star quaterback? Competitive bidding will see the "cheapest" supplier providing the services that will result in poorer quality of care resulting in increased hospital stays.

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

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

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

CMS needs to establish an implementation timeline that identifies the critical steps leading-up to competitive bidding. However, given the number of steps that must be commenced and completed, we urge CMS to adopt a realistic timeline and not rush through the process. The remaining steps include:

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

Competitive Bidding Areas

Competitive Bidding Areas

The determination of MSAs are a great concern of mine. As a provider 30 miles North of Charlotte NC, we have a very mixed patient bases. To the South we have housing developments stactked next to each other, to the North we have a very rural and distant population. How will these issues be addresses?

The NPRM is silent on whether CMS will commence competitive bidding in 10 MSAs at the same time, or stagger the initial implementation of competitive bidding in 2007. We recommend that CMS phase-in the first 10 MSAs. This will allow CMS to identify and correct problems as competitive bidding commences before the problems become widespread.

Also it is unclear why CMS proposes a separate competitive bidding program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in competitive bidding during 2007 and 2009, a separate program for them in 2010 would be unnecessary. Further, there is no definition for a mail order supplier under Medicare program rules. Many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes. As a result, we are unsure who would qualify to participate in a national competition for mail order supplies.

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

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

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

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

Establishing the Competitive Bidding Area
CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established in an MSA. CMS must identify the MSAs in which it will commence competitive bidding in 2007 in an interim final rule. CMS should also schedule a meeting of the PAOC after it identifies the MSAs.

Criteria for Item Selection

Criteria for Item Selection

I am concerned that while selecting the greatest expense to CMS (oxygen) CMS must also understand that they are also selecting the greatest potential for increased cost on the part A side. For example, the latest figures show that the average COPD exhaserbation hosptial stay cost $4800.00 per day with an average stay of 4 days which equals $19,200.00 per year. Currently you pay me about $2500.00 per year to prevent this. Do you really think that the "cheapest" bidder will prevent this from happening? Have you ever thought about investigating providers that high a high patient readmentance?

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

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

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

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

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

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

As a small family owned and operated supplier which most in this industry are, we do not have the time nor the resources to cover huge MSAs. It is a proven fact that genrally the smaller the supplier the better the care, the better the care, the fewer unscheduled hospitalizations, and the lower the cost. Small suppliers must be allowed to participate without being shut out because or burdonsome application proceses and or administrative cost.

Payment Basis

Payment Basis

As you know there are direct and indirect cost associated with providing care and this cost are not static the following are some issues that need to be considered.
Payment Basis

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

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

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

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

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

CMS should note that the authority under '1834h(1)(H)(ii) applies only to orthotics as defined under '1847a. Specifically, the