Submitter : Mr. Dean Kremer **Date:** 06/30/2006

Organization : Joint Active Systems, Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

My comments in regards to CMS-1270-P are in a word document attached to this submission.

CMS-1270-P-1054-Attach-1.RTF

#1054

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June 30, 2006

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

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

Dear Dr. McClellan:

We are Joint Active Systems, Inc. (JAS). We are an Illinois corporation and currently employ about 70 workers. In addition, more than 160 individuals in other States work for JAS throughout the country. We manufacture clinically-proven, patented, static progressive stretch devices/orthosis used to treat restricted range of motion in the shoulder, elbow, wrist, forearm pronation/supination, knee, ankle, and finger joints secondary to trauma, surgery, immobilization, burns, or neurologic injury. More importantly, we have enrolled in the Medicare Program for the sole purpose of supplying and billing only the devices that we manufacture. JAS requested and obtained the following Healthcare Common Procedure Coding System (HCPCS) codes for its devices: E1801, E1806, E1811, E1816, E1818, and E1841. We respectfully submit our comments to the proposed rule regarding the Competitive Acquisition for Certain DMEPOS and Other Issues (CMS-1270-P), which was released on May 1, 2006 (71 Fed. Reg. 25654).

1. General Comments

We strongly urge the Centers for Medicare and Medicaid Services (CMS) to delay the implementation of the competitive acquisition program (CAP) for DMEPOS items until the Supplier Quality Standards (Quality Standards) are finalized and released by CMS. CMS must not require suppliers to make a competitive bid on any DMEPOS item without affording them the opportunity to be informed about the additional cost that they must incur in order to comply with the new Quality Standards. The benefits of true competition as Congress intended can only be realized if the suppliers have all of the facts that are necessary to make informed bids.

As you know, even the Program Advisory and Oversight Committee (PAOC) recommended that CMS delay the CAP until the Quality Standards are made available to the suppliers, especially given that, according to CMS, significant revisions have been made to the draft Quality Standards that were introduced on September 26, 2005. Furthermore, CMS has stated that it would release the final version of the Quality Standards in June of 2006. To date, CMS has not done so. Therefore, JAS requests that CMS accept the recommendation of the PAOC.

2. Criteria for Item Selection

If an entity that is the sole manufacturer and supplier of a particular DMEPOS item is unable to bid or participate in CAP, then the Medicare Program has effectively eliminated access to this DMEPOS item by the beneficiaries. This clearly is not the intent of Congress. Therefore, CMS must exempt such manufacturer-suppliers from the proposed requirement that all suppliers bid for all items in a particular product category to be finalized and announced by CMS. Instead, in order to protect each beneficiary's access to such single-source DMEPOS items, manufacturers like JAS that supply only those DMEPOS items that they manufacture should be afforded the same exemption proposed for skilled nursing facilities (SNFs) and physicians. Like SNFs and physicians providing DMEPOS items only to their patients, manufacturer-suppliers are not "commercial suppliers" because they do not supply every DMEPOS item reimbursable by the Medicare Program.

Alternatively, CMS should phase in such single-source DMEPOS items and manufacturer-suppliers after 2009. Delaying the inclusion of such items and suppliers will allow CMS to not only learn about the effects of CAP in general but also address the unique issues of single-source DMEPOS items and m anufacturer-suppliers in particular. L ikewise, CMS m ust designate the product categories narrowly. CMS must permit suppliers to bid for those DMEPOS items that only they can supply. By requiring suppliers to bid for every DMEPOS item in a product category, CMS would hinder true competition and fail to assure the most savings because the one manufacturer-supplier that could provide the lowest bid would actually not be able to bid because it only supplies those DMEPOS items that it manufactures.

In addition, CMS must comply with the Congressional mandate of Section 1847(b)(7) of the Social Security Act and actually "consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals." CMS must seriously consider excluding from CAP those DMEPOS items that are supplied only by the manufacturer. Congress did not intend CAP to prevent Medicare beneficiaries from accessing DMEPOS items that CMS has coded and has been reimbursing prior to either the enactment of the Medicare Modernization Act of 2003, which mandated the CAP, or the implementation of CAP itself.

3. Submission of Bids under the Competitive Bidding Program

CMS must only apply CAP to "commercial suppliers." Just as CMS realized that SNFs and physicians are not "commercial suppliers," CMS must understand and acknowledge that manufacturers that only supply the DMEPOS items that they manufacturer are not "commercial suppliers." While SNFs and physicians supply the full range of DMEPOS items only to their patients, manufacturer-suppliers supply only those DMEPOS items that they manufacture. Therefore, because of the limited type of DMEPOS items that such manufacturer-suppliers provide

to Medicare beneficiaries, they are less of "commercial suppliers" than even the SNFs and physicians supplying every type and quantity of DMEPOS items.

Again, CMS must designate the product categories narrowly. CMS simply must permit suppliers to bid for those DMEPOS items that only they can supply. It is not only logical but also beneficial to the Medicare beneficiaries. For JAS, it would be particularly ironic if it could not bid or participate in CAP. In 2005, JAS met with CMS (Joel Kaiser and a few DME Regional Carrier medical directors) to discuss the pricing of the codes for its devices that JAS has requested and obtained through the HCPCS coding process. CMS has not yet responded to the request to increase the reimbursement rates. Now, JAS is struggling with the painful requirement that all bids must be lower than the current Medicare rates. It would indeed be a slap in the face if CMS were to deny JAS, the sole supplier of the devices that it manufacturers, the opportunity to even bid because CMS defined the product categories broadly. Most importantly, the Medicare beneficiaries would be denied access to these clinically effective and cost efficient devices, which require 3 months of wear-time on average and not the 15 (now 13) months permitted by CMS.

4. Conditions for Awarding Contracts

Again, CMS must delay implementation of the CAP until it has finalized and published the Quality Standards. Alternatively, CMS should phase in single-source DMEPOS items and manufacturer-suppliers after 2009.

5. Opportunity for Participation by Small Suppliers

CMS must consider the small manufacturers like JAS that have enrolled in the Medicare program only to be able to supply the DMEPOS items that they manufacture. These manufacturers have accepted this course, despite the risk of being subject to various additional Medicare restrictions (e.g., Stark self-referral prohibitions), because they have experienced problems merely selling their DMEPOS items to Medicare "commercial suppliers." They want to ensure that their DMEPOS items are properly delivered to, fitted by, and used by the Medicare beneficiaries. CMS must not penalize such manufacturer-suppliers.

Section 1847(b)(6)(D) addresses the "protection" of small suppliers and not just the identification of such suppliers. Therefore, CMS must treat small suppliers differently. Manufacturers that only supply the DMEPOS items that they manufacture are not "commercial suppliers" that supply the full and complete list of DMEPOS items. CMS must actively help small suppliers, including manufacturer-suppliers, so that they may participate in CAP and provide the Medicare beneficiaries access to such single-source DMEPOS items.

6. Opportunity for Networks

CMS must provide sufficient time for suppliers to establish and work collaborative in the networks permitted by CMS under the proposed rule if CMS truly wishes to allow suppliers to form networks in order to bid competitively. CMS must not erroneously believe that the potential for volume is the motivating factor for the suppliers. Instead, CMS must realize and accept the fact that suppliers want to and need to bid and participate in CAP to merely stay in the Medicare program.

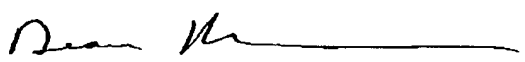
7. Quality Standards and Accreditation

Again, CMS must delay implementation of the CAP until it has finalized and published the Quality Standards. Alternatively, CMS should phase in single-source DMEPOS items and manufacturer-suppliers after 2009.

* * * * *

On behalf of over 230 hard-working families of JAS, we thank you for the opportunity to comment on the proposed CAP for DMEPOS items. We hope that CMS will truly consider each of our comments.

Sincerely,



Dean Kremer
President

cc: Sandra Bastinelli (via e-mail)
Carol Blackford (via e-mail)
Stacy Coggeshall (via e-mail)
Joel Kaiser (via e-mail)
Martha Kuespert (via e-mail)
Herb Kuhn (via e-mail)
Walt Rutemueller (via e-mail)
Linda Smith (via e-mail)

Submitter : **Ms. Twyla Hoskins** **Date: 06/30/2006**

Organization : **Stevens Hospital**

Category : **Occupational Therapist**

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

I am greatly concerned regarding limiting Medicare recipients to predetermined vender pre-fab splints. In my experience as an Occupational Therapist for 18 years, I have frequently treated patients who come to see me with ill-fitting splint or splints that do not provide necessary support. When this occurs, the patient often chooses to discontinue wearing the splint or comes to see me with complications from an ill-fitting splint. Not all pre-fab splints are a problem, of course, but providing a patient with a pre-fab splint and no other options can result in poor compliancy or in further Medicare costs associated with adjusting for a correct fit. As an Occupational Therapist I have the training and expertise to insure a correct fit of whatever splint is indicated for a patient, whether pre-fab or custom-fitted, and to provide proper follow-up. I believe that this is more cost-effective than a one-pre-fab-splint-fits-all approach, and increases healing and return of function. Therefore, I am against the proposed CMS-1270-P as it is written.

Sincerely,
Twyla Hoskins, OTR/L

Submitter : Mr. David Gold **Date:** 06/30/2006

Organization : Bonel Meical Equipment, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

We understand that the overall objective of any form of competitive bidding is to guarantee a volume of work in return for a lower payment rate. Our concern is that the level of service to the patients will be compromised. What happens to the patient's primary right to choose? Our hope is that the smaller community based suppliers will not be entirely excluded from rendering services if the patient chooses them. Is there any provision under the proposal to allow for payment to such a provider at the adjusted rate? Additionally, how is the 'Any Willing Provider' law (enacted in some States) affected?

Submitter : **Ms. Evelyn Herndon** **Date: 06/30/2006**

Organization : **Ellis County Home Medical Equipment**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachement

CMS-1270-P-1057-Attach-1.DOC

#1057

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

Timing Concerns

Supplier Standards and Deficit Reduction Act Implementation

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

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

Opportunity to Comment on the Supplier Standards

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

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

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

Overall Implementation Time-line

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

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

Payment Basis

Inflation Update

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

Grandfathering Medicare Advantage

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

Beneficiary Switch to Contract Suppliers

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

Application of DRA to Oxygen Patients

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

Authority to Adjust Payment in Other Areas

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

Limitation on Beneficiary Liability

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

Competitive Bidding Areas

Staggered Implementation

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

Nationwide or Regional Mail Order Competitive Bidding Program

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

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

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

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

Establishing the Competitive Bidding Area

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

Criteria for Item Selection

Items Included in Competitive Bidding

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

Potential for Savings

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

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

Additional Criteria for Item Selection

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

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

Brand-Specific Requirements

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

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

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

Coding Issues and Item Selection

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

Product Categories for Bidding Purposes

General Issues

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

Requirements to Bid on all Products in a Category

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

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

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

Conditions for Awarding Contracts

Quality Standards and Accreditation

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

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

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

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

Market and Supplier Capacity

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

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

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

Assurance of Savings

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

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

Determining the Single Payment Amount

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

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

Rebate Program

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

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

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

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

Bulletin at 1.

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

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

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

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

Bulletin at 5 (Emphasis supplied).

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

Terms of Contract

Repair or Replacement of Equipment

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

Termination of Contract

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

Judicial and Administrative Remedies

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

Change of Ownership

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

Participation of Small Suppliers

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

Submitter : **Ms. Susanne Higgins** **Date: 06/30/2006**

Organization : **Kleiser Therapy Svcs & Midwestern University**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

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

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

I am Susanne Higgins, and I am an Occupational Therapist specializing in the treatment of upper extremity disorders. I am also a certified hand therapist. I am currently working for a therapist owned outpatient, private practice and frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

I also teach orthotics and related issues to Occupational Therapy students in a graduate program at Midwestern University in Downers Grove IL. The 2, semester long, Orthotics courses are required for all of our students who are working toward a Masters degree in Occupational Therapy. In these, and other courses, I teach the students the disease process, functional and ADL needs, ergonomics, precautions, future orthotic needs, underlying principles about selecting designing, fitting and modifying orthoses. This pertains to custom made and off the shelf devices.

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. Off the shelf orthoses frequently require modification, fitting adjustments and re-adjustments. I provide orthosis 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.

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.

Finally, I receive a very small margin of profit from these prefabricated orthoses. The savings to Medicare from upper extremity orthoses would be minimal. 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.

Sincerely,

Susanne Higgins OTR/L, CHT

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

Organization :

Category : **Health Care Industry**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

if the regions and the equipment categories are not yet available how can providers submit appropriate bids? all suppliers should meet quality standards before any bidding is allowed isn't this country still the land of the free? to have the option to choose who you want to go to? when did this stop?

Submitter : Mr. Mark Leahey **Date:** 06/30/2006

Organization : Medical Device Manufacturers Association

Category : Device Association

Issue Areas/Comments

GENERAL

GENERAL

Please see Attachment.

CMS-1270-P-1060-Attach-1.PDF

#1060

MDMA

MEDICAL DEVICE MANUFACTURERS ASSOCIATION

June 29, 2006

Via Electronic Submission

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8011
Baltimore, MD 21244-1850

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

Dear Dr. McClellan:

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market, I am filing the following comments to the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding the competitive bidding program for certain covered items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), published in the Federal Register on May 1, 2006.[1] MDMA represents hundreds of medical device companies, and our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

MDMA is greatly concerned that the proposed competitive bidding program will harm beneficiary access to advanced medical devices, especially those developed by small manufacturers. CMS notes that the goals of the competitive bidding program include assuring beneficiary access to quality DMEPOS and creating a payment structure that is "more reflective

of a competitive market."[2] Unfortunately, the competitive bidding program, as proposed by CMS, is unlikely to achieve these goals. Instead, by requiring bidders to compete primarily on the basis of price of covered items, and by locking in suppliers for three-year contracts, the proposed program risks introducing anti-competitive elements into the Medicare program. As a result, innovative technologies produced by small manufacturers may be shut out of the program, denying beneficiaries the opportunity to receive the most appropriate care, increasing costs to Medicare in the form of increased hospitalizations and physician visits, and discouraging future innovation. MDMA urges CMS to carefully consider the impact that application of an untested competitive bidding program will have on innovative technologies and revise the proposal accordingly.

The Proposed Program's Emphasis on Prices of Individual Items Fails to Recognize the Value of Innovative Technologies (Determining Single Payment Amounts for Individual Items; Conditions for Awarding Contracts; Opportunity for Participation by Small Suppliers)

Under the proposed program, after determining whether each supplier meets certain quality and financial standards, CMS would select suppliers on the basis of their bid prices and expected capacity.[3] The payment rate for each item would be set using the median of the winning suppliers' bids.[4] CMS proposes to require that the prices for each item submitted by winning bidders be less than the current fee schedule amount for that item.[5] If a supplier's bid price is less than the single payment amount, CMS proposes to allow the supplier to pay a rebate to the beneficiary.[6] Winning bidders would be offered three-year contracts with CMS.[7]

We are concerned that this process for selecting suppliers and setting rates will produce a "race to the bottom," in which suppliers bid on and offer only the lowest-cost devices. By requiring DME suppliers to achieve savings on each item rather than in the aggregate – contrary to the agency's implementation of the Competitive Acquisition Program for drugs and biological

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1 71 Fed. Reg. 25653 (May 1, 2006).
2 Id. at 25657.
3 Id. at 25677.
4 Id. at 25679.
5 Id. at 25678.
6 Id. at 25680.

products – CMS would encourage suppliers to bid on the oldest, lowest-priced product within each Healthcare Common Procedure Coding System (HCPCS) code to ensure that their bids are accepted. The proposal to allow suppliers to pay rebates if their bid prices are lower than the single payment amount also would encourage suppliers to offer lower-cost, less innovative products, particularly from large manufacturers, rather than innovative technologies from small manufacturers. Unlike large manufacturers who can spread the cost of discounts across many products, small manufacturers may have only one or two products on the market and are not able to offer the deep discounts needed to support lower bid prices and rebates. Because the rate for each item is determined using the winning bids, the final payment amounts also are likely to be inadequate to support access to innovative products.

The proposed process also fails to recognize that innovative devices may achieve savings for Medicare through reduced hospitalization or physician visits. Although some innovative devices have higher prices than older products, they offer technological advantages that allow more patients to receive care safely, avoiding complications and costly hospital stays. The overall cost of care to the beneficiary and the Medicare program would be lower if the innovative device is used, yet the proposed program would not recognize this value. **We urge CMS to develop a method of evaluating bids and setting payment rates that fully recognizes the value of innovative technologies and encourages their appropriate use and/or consider a method that achieves cost savings in aggregate rather than on an item by item basis.**

The Proposed Program Would Fail to Establish Appropriate Payment Rates for New Technologies (Gap-Filling)

CMS proposes to set payment rates for new items with new HCPCS codes that are introduced in the middle of a billing cycle using a revised gap-filling process.[8] This process would set the rate for the new item based on the payment amounts for "comparable items." MDMA is concerned that this process will result in inappropriate rates for new technologies for which there are no comparable products. These rates may not be adequate to support beneficiary access to new technologies. Additionally, CMS' use of an unpredictable rate-setting methodology could create

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7 Id. at 25680.

market instability that would discourage future investment in developing advanced treatment options. Instead, **MDMA recommends that payment amounts for each new technology be based on the costs of that technology, not other, potentially different devices. We urge CMS to remove this proposal from the final rule. CMS should initiate a separate rulemaking process to propose and receive comments on a rate-setting methodology that will support innovation and beneficiary access to advanced technologies.**

The Proposed Program Threatens Beneficiary Access to Care from Trusted Suppliers (Opportunity for Participation by Small Suppliers; Opportunity for Networks; Physician Authorization/Treating Practitioner)

Although we appreciate CMS' efforts to ensure that small suppliers can participate in the program[9] and to allow physicians to specify a particular product brand,[10] we are concerned that the proposal does not provide adequate assurance that beneficiaries will be able to obtain appropriate, innovative medical technologies from trusted suppliers. Currently, beneficiaries may obtain DMEPOS from any participating supplier, including small suppliers who specialize in certain types of equipment. This wide choice of suppliers helps to ensure beneficiaries' access to advanced technology. Under the proposed program, beneficiaries would be required to obtain DMEPOS from contracted suppliers. In many respects, such as evaluation of bid prices, consideration of market capacity, and opportunity to offer rebates, the proposed program favors large suppliers. CMS acknowledges that its proposed option to form networks for bidding, intended to "allow suppliers to band together to lower bidding costs, expand service options, or attain more favorable purchasing terms," may be "challenging" for suppliers.[11] Many small suppliers, particularly those who focus on specialized technologies, may not be able to submit winning bids.

We are concerned that the proposed program would limit the Medicare market to a handful of large suppliers in each area. Many beneficiaries would be required to change suppliers, possibly disrupting their current course of therapy. They also could lose access to the devices they

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8 Id. at 25688.
9 Id. at 25682.
10 Id. at 25684.

currently rely on to treat serious conditions. As we have seen with certain group purchasing organizations, suppliers that obtain large shares of the market often seek sole source contracts with large manufacturers. Although these arrangements may result in lower prices for some items, they are fundamentally anticompetitive because they block other manufacturers' entry into the market and discourage the use of new technologies that may be better for patients and that could produce savings in the long run. Under CMS' proposed competitive bidding program, these arrangements also would make it very difficult to implement the proposal to allow physicians to specify a particular product for their patients. This proposal requires suppliers in each area to offer a broad range of products. If an area is served by large suppliers that carry only products from large manufacturers, there would be no assurance that every brand of DMEPOS would be available in every area. **MDMA recommends that CMS refine its proposal to ensure that small suppliers can continue to serve Medicare beneficiaries and to protect beneficiaries' continuous access to innovative technologies by supplying those technologies when physicians specify a product for their patients.**

* * *

We thank CMS for the opportunity to comment on this proposed rule. As always, MDMA looks forward to working with the agency in the future to improve access to the best and innovative technologies that our industry has to offer.

Sincerely,

Mark B. Leahey
Executive Director
Medical Device Manufacturers Association

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[11] Id. at 25683.

Submitter : Mr. James Cohen **Date:** 06/30/2006

Organization : Home Care Delivered, Inc

Category : Health Care Provider/Association

Issue Areas/Comments

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

Rather than use the median of the winning bids to determine the single payment amounts for individual items, Home Care Delivered recommends using the same methodology used for the competitive bidding demonstration projects. Although the calculation of a median bid is a simpler, easier to understand methodology, we believe it is unfair to winning bidders who would be put in a position to have to accept a much lower price than the bid that was originally submitted. This could result in winning bidders electing not to contract with CMS which could have an adverse effect on access. According to the proposed rule, if access becomes a problem, CMS would then go to the existing contracted suppliers to determine if they could met the unmet demand. However, if the other suppliers could not sufficiently absord this unmet demand, CMS would go to the suppliers who were not winners and offer contracts at the single payment amount. The obvious question here is why would a supplier who has submitted a bid price that is higher than the median accept a payment that is considerably below what the supplier has determined to be their minimum acceptable price.

We believe that the methodology used for the competitive bidding demonstration projects is a much fairer method of determining the single payment amount for individual items. First, it does not force a winning bidder to have to choose whether to accept a much lower price or decline becoming a contracted supplier. Second, it ensures that the single payment amount that contracted suppliers receive is at least as much as their bids. We feel this is a key issue in the Competitive Acquisition Program. Based on the concept of competitive bidding, providers would be competing based on the minimum price they could accept and remain a viable business entity. A great deal of time and effort will go into preparing these bids and it would be unfair to then require suppliers to accept a much lower payment. The result as previously mentioned could be winning suppliers leaving the Medicare program creating an access problem for many beneficiaries who cannot affort to be without medical supplies and equipment.

Submitter : **Dr. Barbara Aung** **Date: 06/30/2006**

Organization : **Aung FootHealth Clinics**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1270-P-1062-Attach-1.DOC

CMS-1270-P-1062-Attach-2.DOC

#1062

June 23, 2006

Barbara J. Aung, DPM, CWS
6644 E. Carondelet Drive
Tucson, Arizona 85710

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 in order to supply my patients with the appropriate device that can ensure a positive outcome for the patient.

At this time I would like to take the opportunity to share my fifteen years of experience in the arena of limb preservation and amputation prevention as a medical director of a hospital based wound care center, in private practice, as a consultant to the Centers for Disease Control and the National Institutes of Health National Diabetes Education Program, and as a current consultant and Past Chairmen of the State of Arizona Department of Health Services and Prevention Diabetes Control Program to mention a few of my activities.

I know that there has been and continues to be a somewhat cookie cutter approach with the thought that "anyone" can render care of this nature. No matter how or who has stressed this format of competitive bidding to exclude the podiatric physician are simply incorrect and/or ill advised, and in turn will be adversely effecting patients and their care.

I can cite countless instances where when a patient was under the care of a provider not possessing the necessary knowledge/experience of a podiatric physician for a lower extremity wound(s) or complication, and where these conditions did not respond to their care and/or with additional complications arising that were not favorable to a positive outcome for the patient, not to mention running up an extensive cost of care bill without resolve of the medical condition(s)

That being said this is not the exception but the rule in wound care which adversely affects the patient, costly to the insurance carrier(s), and reduces the quality of life for the patient and their family members. In general, the patient is referred to me and my clinics as a last resort or when all "else" has failed in the provider's mind or their level of knowledge/experience in addressing the patient's needs has been exceeded.

The positive and cost effective side of these circumstances is that once the patient is referred to our (podiatric) clinics (this tend is growing as the MD/DO are exposed through interaction with a podiatric physician and begin to appreciate what our profession offers in care). Upon presentation the patient is properly evaluated, the underlying cause/source of the wound(s) is determined and a plan of care is implemented and the long term cost of care is greatly reduced because we are actually treating the patient utilizing guidelines of evidenced based medicine not just guessing and hoping the care works. (I can provide numerous studies showing such results which have already and continue to be presented to CMS with the March 2005 meeting serving as an example).

One of the essential elements of the care to resolve the wound and prevent further complications such as re-ulceration/wound size increase is the utilization of off-loading the limb/wound site with a prosthetic, brace, AFO, orthotic etc and more importantly the involvement and proactive/active care of the aforementioned devices by a podiatric physician armed with the medical education/knowledge and coupled with the experience one attains by working daily in the "trenches" of this aspect medical care. When these devices/services are "farmed out" to large suppliers the physician-patient relationship/continuity of care is broken and the patient is ill-served. Just asked my patient population (which I would be happy to provide) again of fifteen years, they will tell you the same with incorrect devices being dispense contrary to the physician order, improperly fitted prosthetics/AFO causing little or no resolve of condition(s), or additional complications and again cost of care increases.

I know of no other profession and in particular those of us who have a passion for and do provide this level of care our patient's deserve that can make such a claim. The results that are attained are what and why my MD/DO colleagues refer to me and my podiatric counterparts. They recognize the value of our care and look upon us with respect and as equals. Please note that podiatric physician do and are saving CMS and other insurance carriers cost of care expenses as we implement and utilize the aforementioned evidenced plan of care including durable medical equipment.

This may come as a surprise to you and your staff but a sizeable amount of physicians are aware of the budget limitations and the need to reduce the cost of care so that these dollars be better utilized and "stretched" (physicians and their practices are businesses to and must adhere to the same management principals as a large corporation). We are attempting to work with you and not against you, even thought we continue to have reimbursement for our services reduced over the past decades. Everyone wants their healthcare needs addressed but they certainly do not want to pay for it, yet because of the very reasons/beliefs as to why we have chosen a career as a physician we continue with a goal of bettering the lives and health of the patient populations we serve. We are not the enemy.

The nature of the language contained in this revised/new acquisition program discriminates against a podiatric physician without any documentation to support such discrimination. I believe under title 19 the Medicare Act a podiatric physician is designated as and is acknowledged as a physician just as an MD/DO is and this should be no different in this case. I have testified to this fact before the Arizona legislature and this fact was accepted and acknowledged by this body of government without hesitation.

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.

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

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

Sincerely,

Barbara J. Aung, DPM, CWS

#1062

June 23, 2006

Barbara J. Aung, DPM, CWS
6644 E. Carondelet Drive
Tucson, Arizona 85710

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

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One of the essential elements of the care to resolve the wound and prevent further complications such as re-ulceration/wound size increase is the utilization of off-loading the limb/wound site with a prosthetic, brace, AFO, orthotic etc and more importantly the involvement and proactive/active care of the aforementioned devices by a podiatric physician armed with the medical education/knowledge and coupled with the experience one attains by working daily in the "trenches" of this aspect medical care. When these devices/services are "farmed out" to large suppliers the physician-patient relationship/continuity of care is broken and the patient is ill-served. Just asked my patient population (which I would be happy to provide) again of fifteen years, they will tell you the same with incorrect devices being dispense contrary to the physician order, improperly fitted prosthetics/AFO causing little or no resolve of condition(s), or additional complications and again cost of care increases.

I know of no other profession and in particular those of us who have a passion for and do provide this level of care our patient's deserve that can make such a claim. The results that are attained are what and why my MD/DO colleagues refer to me and my podiatric counterparts. They recognize the value of our care and look upon us with respect and as equals. Please note that podiatric physician do and are saving CMS and other insurance carriers cost of care expenses as we implement and utilize the aforementioned evidenced plan of care including durable medical equipment.

This may come as a surprise to you and your staff but a sizeable amount of physicians are aware of the budget limitations and the need to reduce the cost of care so that these dollars be better utilized and "stretched" (physicians and their practices are businesses to and must adhere to the same management principals as a large corporation). We are attempting to work with you and not against you, even thought we continue to have reimbursement for our services reduced over the past decades. Everyone wants their healthcare needs addressed but they certainly do not want to pay for it, yet because of the very reasons/beliefs as to why we have chosen a career as a physician we continue with a goal of bettering the lives and health of the patient populations we serve. We are not the enemy.

The nature of the language contained in this revised/new acquisition program discriminates against a podiatric physician without any documentation to support such discrimination. I believe under title 19 the Medicare Act a podiatric physician is designated as and is acknowledged as a physician just as an MD/DO is and this should be no different in this case. I have testified to this fact before the Arizona legislature and this fact was accepted and acknowledged by this body of government without hesitation.

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.

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

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

Sincerely,

Barbara J. Aung, DPM, CWS

Submitter : Mrs. SONIA RUBIO-YATES

Date: 06/30/2006

Organization : HAND

Category : Occupational Therapist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I AM IN OCCUPATIONAL THERAPIST THAT HAS BEEN SPECIALIZING IN THE REHABILITATION OF THE HANDS AND UPPER EXTREMITY FOR 14 YEARS. I MAKE CUSTOM SPLINTS FOR MY PATIENTS WITH HAND INJURIES. I CAN MAKE THESE SPLINTS AND CONTINUE TO PROVIDE THERAPY WITHOUT INTERUPTIONS. I CAN ADJUST THE SPLINTS AS NECESSARY TO ENSURE THE PATIENTS ARE MAKING PROGRESS. FABRICATING CUSTOM HAND SPLINTS CAN ONLY BE DONE BY A THERAPIST THAT IS TREATING THE PATIENT ACTIVELY. THESE ADJUSTMENTS SOMETIMES REQUIRE A WEEKLY ADJUSTMENT IN ORDER TO MAKE PROGRESS OR DEPENDING ON WHERE THE PATIENT IS CLINICALLY. THIS IS SOMETHING THAT NEEDS TO BE DONE BY A LICENSED HEALTH CARE PROVIDER THAT UNDERSTANDS THE PATIENT CONDITION AND UNDERSTANDS PRECAUTIONS RELATED TO THE UNDERLYING PATIENT CONDITION. THANK YOU FOR YOUR ATTENTION TO THIS MATTER.

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

Organization : MAC Jurisdiction A Advisory Council

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1064-Attach-1.DOC

CMS-1270-P-1064-Attach-2.DOC

#1064

MAC Jurisdiction A Advisory Council
A United Voice Representing
HME, Respiratory and Oxygen, Infusion, Orthotics /Prosthetics, and Rehabilitative Technology Providers

Via Electronic Transmission

June 29, 2006
Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1270-P
7500 Security Boulevard
Baltimore, MD 21224

Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment

Dear Dr. McClellan:

The MAC Jurisdiction A Advisory Council (MAC A) appreciates the opportunity to submit comments relative to the Competitive Acquisition for Certain Durable Medical Equipment. The Jurisdiction A Advisory Council is an invited group of individual suppliers and state association executive directors who meet regularly with representatives from the Jurisdiction A MAC and the PSC, Tricenturion, who serve to enhance communication and understanding of MAC policies and procedures regarding claims. We also have specific provider representation ("A Teams") that review Medicare policy and provide input into our council dedicated to certain coverage modalities.

Our members provide home medical equipment,oxygen and respiratory products, orthotics and prosthetics, re/hab assistive technology and home infusion therapy products and services to approximately **85%** of the Medicare beneficiaries in the Jurisdiction A MAC.

MAC A Advisory Council is a member of the American Association for Homecare (AAH) and would like to stress the following issues and we would like to state that we fully endorse the comments that have been submitted by AAH. Overall, we feel the NPRM lacks some specificity in areas that are important to our members. Providers need the details of the competitive bid areas, the quality standards, the approved agencies for Accreditation and the product classes/groups now. It is also important not to use subjective wording such as "substantial". The requirements and process should be defined in quantitative terms to allow a complete understanding by the providers.

Timeline

From the operational prospective of our businesses, we need to plan and budget for staff, inventory, vehicles, Information Technology, and communications just to name a few items. In an effort to assure that the transition to Competitive Acquisition (CA) is not wrought with problems, we are suggesting that CMS establish an implementation timeline that identifies the critical steps leading-up to competitive acquisition. We urge CMS to consider the operational aspects of our businesses and adopt realistic timelines. The remaining steps include:

- Publication of the supplier standards
- Selection and announcement of the CBIC including detailed bid scoring criteria
- Selection of the accrediting bodies
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- 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

The proposal states that providers do not have to factor inflation into their bids because the competitive bid price will be updated annually by the CPI-U.

- Providers need assurances in the bid process that the CPI-U will not be overridden by other legislation or regulation.
- If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids.

Medicare Advantage

The NPRM does not address the impact of competitive acquisition on Medicare Advantage (MA) 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 acquisition? Will these patients have the opportunity to continue to use their existing supplier when they reenter the traditional Medicare program?

Recommendation: Patients moving from an MA plan to traditional Medicare should 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 acquisition 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 of the lack of detailed knowledge of the beneficiary's decision.
- Providers would need access to detailed information to assure that they bill properly. Access to the Common Working File would assist in resolving this issue.

Recommendation: There should be a defined time frame within which a patient can transfer to a new provider. All transitioning patients should start a new rental period.

Bid Prices

CMS states that suppliers may not submit bids higher than the current fee schedule amount for an item.

- This establishes an artificial ceiling on the bids and does not allow for appropriate payment considerations for items that are not currently reimbursed at competitive fees.
- This further complicates acquisition considerations for the provider. It may require the provider to bid at a higher rate on other products in the group.

Recommendation: Remove the restrictive language in the final rule. Allow the appropriate pricing to be considered for each product.

DRA implications for Capped Rental to Oxygen Patients

The DRA further complicates the Competitive Acquisition process. Several issue need to be addressed surrounding ownership, grandfathering and repairs.

- Will forced ownership be required for Capped Rentals and Oxygen equipment?
- With the breadth of products available in the market place providers may lack expertise in trouble shooting and repairing the product owned by the patient.
- 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?
- DRA forced ownership provisions on oxygen and capped rental equipment have important ramifications for competitive acquisition. Providers cannot provide meaningful comments on many issues in the NPRM without understanding how CMS will administer the DRA requirements.

Recommendation (s): 1.CMS should publish an interim final rule before it publishes the final rule on competitive acquisition. 2. To ensure quality patient care, CMS should consider the ramifications of forced ownership and the requirement that the winning bidders must service and repair all patient owned equipment.

Authority to Adjust Payment in Other Areas

The NPRM states that CMS has the authority, with respect to items included in a competitive acquisition program, to use the payment information obtained through competitive acquisition to adjust the payment amounts for those items in areas outside the competitive acquisition area.

- The authority for the DME, 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 acquisition 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 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 acquisition. Consequently, the authority to use information derived from a competitive acquisition 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 from competitive acquisition 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.

- It is illogical that CMS would consider utilizing prices from a competitive bid area with some volume expectations to a non competitive bid area that does not have like markets or volume expectations.

Limitation on Beneficiary Liability
We understand that Medicare will not cover DMEPOS items subject to competitive acquisition furnished to a beneficiary in a competitive acquisition 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. Does this restrict the beneficiary's freedom of choice to pay for a product or have repairs done if they chose to pay for the service?
- Other portions of the NPRM specifically state that ABNs will be permitted under a competitive acquisition program, and the MMA requires that CMS continue to allow suppliers to use ABNs.

Recommendation(s): 1.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. 2. Allow providers to use an ABN, thus giving the freedom of choice to the beneficiary.

Competitive Bidding Areas

Staggered Implementation
The NPRM is silent on whether CMS will commence competitive acquisition in 10 MSAs at the same time, or stagger the initial implementation of competitive acquisition beginning in 2007.
Recommendation: We recommend that CMS phase-in the first 10 MSAs. This will allow CMS and its contractors to identify and correct problems as competitive acquisition commences.

Nationwide or Regional Mail Order Competitive Bidding Program
It is unclear why CMS proposes a separate competitive acquisition program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in competitive acquisition during 2007 and 2009, a separate program for them in 2010 would be unnecessary.

When CMS has provided a greater level of detail, we would appropriately comment on the need for this provision.

Competitive Bidding Area
We question CMS's authority to extend competitive acquisition outside an identified 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 acquisition in 2007 in an interim final rule.

Criteria for Item Selection

Items Included in Competitive Bidding

CMS identifies three categories of items that are subject to competitive acquisition 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 acquisition 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 s upplies are not included in competitive acquisition 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 competitive acquisition for a product category? When referencing the allowed charges is this billed or paid dollars?
- Annual growth in expenditures: Is there a threshold growth percentage and does it vary by the dollar size of the category? Is this billed or paid dollars?
- 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? Will these studies cross disciplines? e.g. hospital admissions, Home Health visits, emergency room visits.

Product Categories for Bidding Purposes

Issues for Clarification and Correction

The true meaning and explanation of product categories was not clear in the NPRM. Is it to be by product type or HCPCS code?

- CMS must define products categories narrowly to make sure that they are consistent and representative of the products that a supplier might actually furnish. By example, a broad category for wheelchairs or power wheelchairs will not work.
- Power wheelchair codes are in the process of being revised and have been in that process for several years due to their complexity. It makes them inappropriate for use in a competitive acquisition model.
- Complex Rehab wheelchairs are predominantly custom-configured to the individual. These complex pieces of equipment are inappropriate for use in a competitive acquisition model.
- Manual wheelchairs HCPCS codes will be subjected to a similar recoding process beginning in 2007. Therefore there may be valid codes in place by 2008 in the "wheelchair" product category that do not exist during the bid process.
- The final rule should be changed so that a provider who bids on the category of manual wheelchairs will not be required to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. In addition, they should not be required to bid on all types of accessories including seat and back cushions.
- CMS should ensure that the process accounts for narrow product categories so that providers may submit proposals for products and services that they currently have expertise in providing.

Skilled Nursing Facilities and Physicians

CMS proposes that only skilled nursing facilities (SNFs) and physicians selected as contract suppliers would be eligible to provide DMEPOS in a competitive biding area. Physicians and SNFs can limit their services to their own residents or patients and would not be required to service all beneficiaries in an MSA. In contrast, DMEPOS suppliers awarded contracts, cannot refuse to serve any beneficiary. This means that contract suppliers would be required to accept beneficiaries regardless of the costs the supplier may have to absorb (e.g., assuming a caped rental in the 10th rental month) whereas SNFs and physicians could limit their service costs. Including SNFs and physicians in the same competition with DMEPOS suppliers will distort the bid evaluation and selection of the pivotal bid because SNFs and physicians will have

significantly lower costs to operate under the acquisition program. We recommend that CMS conduct separate competitions for those items that will be furnished by SNFs or physicians such as enteral nutrition, equipment and supplies.

Conditions for Awarding Contracts

Issues for Clarification and Correction

CMS should not proceed with competitive acquisition until it is sure that that all suppliers who want to submit bids have had an opportunity to go through the accreditation process.

CMS should consider the following evidence of supplier's financial stability instead of the items in the NPRM:

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

- CMS needs to identify the criteria it will use to select accrediting bodies before the final rule is published. There is no benefit in waiting. This has been discussed and positive options provide by the PAOC.

- We support an aggressive accreditation campaign to assure that providers in any MSA with a competitive acquisition program who which to participate are able to be accredited before the bid solicitations are published.

- The "pivotal" bid methodology outlined in the NPRM does not include any mechanism to ensure that there are no unreasonably low bids. The proposed methodology will allow and almost encourages suppliers with small individual capacity to submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity.

- CMS must eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. A key term used often at the last PAOC meeting was sustainability. Winning suppliers who can not actually afford to stay in business with a low winning bid ultimately do nothing for the beneficiary.

- Another phrase used often at the last PAOC meeting was the minimalist approach to the number of winning suppliers to provide minimum capacity

requirements in the competitive acquisition area. There are limitless natural-occurring events that could create unanticipated access problems for beneficiaries in the MSA. CMS should consider other variables beyond capacity that may affect the selection of winning bidders.

- Artificially limiting bids by disqualifying bids above the current fee schedule amount for an item is not truly "competitive" based on market prices. Use the methodology proven in the demonstrations that focused on 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.

- As defined in the NPRM, the Single Payment Amount for "winning suppliers" 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 acquisition area due to a higher level of capacity. It does not make any sense that Congress had this expectation in mind when it authorized competitive acquisition under the MMA. CMS should set the payment amount at the pivotal bid level as defined in the NPRM.

- CMS should remove the Rebate Program from the rule. There is a statutory prohibition on beneficiary inducements that 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. As discussed and described at the last PAOC meeting, the rebate program proposed in the NPRM is problematic and it does not fit any of the statutory exceptions.

- Once again, it was clearly and loudly discussed at the last PAOC meeting that CMS should be driving beneficiaries to HIGH QUALITY SUPPLIERS and instead the NPRM seems to be focusing on LOWEST COST SUPPLIERS.

Recommendation: CMS should withdraw the rebate proposal.

Terms of Contract

Issues for Clarification and Correction

We support a recommendation 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 and CMS should solicit bids for the repair of patient owned equipment.

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.

CMS cannot unreasonably withhold its approval of a change of ownership of a winning supplier and should not deny winning supplier status to new owners on the basis that its capacity is not necessary within the competitive acquisition area.

CMS has taken a very narrow view of its obligation to ensure that small suppliers are adequately represented among contract suppliers. CMS should expand this to allow greater participation by small suppliers with a small supplier set asides in at least some MSAs.

CMS' proposal for allowing networks is void of any of the practical details for implementation. If this is to be a viable option, substance needs to be placed around it or else it is of no value.

Physician Authorization/Treating Practitioner

CMS has proposed to allow physicians to prescribe a specific brand or type of equipment. This provision seeks to preserve beneficiary access to equipment. We do not believe this provision should be included in competitive bidding. A physician always has had the freedom to prescribe a particular brand or item and we believe this would continue under competitive bidding. Suppliers are always looking satisfy a physician's request for specific equipment particularly if the equipment requested is clinically superior. We would request that CMS establish a process to reimburse at a higher rate a specific piece of equipment requested by a physician if that physician can demonstrate the medical necessity and clinical superiority of the equipment. We believe that if a specific piece of equipment is requested by a physician, there should be documented medical need and clinical justification for the equipment. Suppliers should also be reimbursed at a higher rate to compensate them for the additional expenses associated with obtaining such an unique item. Further, we are concerned that there could be increased beneficiary risk of injury because supplies will be forced to repair brand specific items for which they are not knowledgeable of or qualified to repair. Finally, we are concerned that manufacturers could promote their expensive brands to physicians which could inappropriately drive up the requests for these types of equipment.

Recommendation: We propose that this provision be removed from the final rule. There is no conclusive evidence that providers are not currently providing brand specific products as prescribed by the physician.

Implementation Contractor
We request CMS define the quantitative, objective measures and evaluation tools that the CBIC(s) will use in evaluating the bids submitted by suppliers.

Providers need to understand the data and information that will be reviewed by the CBIC(s) as well as the actual scoring and evaluation process to be used. Without this guidance, providers have no assurance that bid evaluations will be performed in a fair, objective and quantitative manner and not using qualitative, immeasurable, or judgment related methods.

We would agree that the evaluation process should not be performed by the MACs but would request that the actual scoring mechanism that will be used to evaluate bids be published with sufficient time for a supplier to review prior to the RFB process.

New Gap-Filling Methodology

CMS proposes to implement a new gap-filling methodology that would rely on a technology assessment process to establish fee schedule amounts for new HCPCS codes and for new DMEPOS products. CMS has used gap-filling since 1989 to estimate what the average reasonable charges would be for a new item if the item had been paid for under Medicare during the fee schedule base period. Under the current gap-filling methodology, CMS "deflates" the current manufacturer suggested retail price (MSRP) for an item using the CPI-U to estimate its 1989 MSRP. CMS then trends that price forward using the legislatively mandated covered item update for the item through the current year. Because the gap-filling methodology assumes that the MSRP increases are consistent with increases in the CPI-U, and because the covered item update has been 0% or "frozen" numerous times by Congress since the fee schedules were created, gap-filling can result in Medicare payment amounts that are too high or unrealistically low.

According to the NPRM, CMS has engaged contractors to evaluate technologies for the purpose of making payment and HCPCS coding decisions for new items. CMS states that its purpose in engaging the contractors was to identify technologies that provide demonstrated clinical benefits and recognize those benefits over existing technologies. Although the NPRM does not identify what products CMS assessed, they were assessed in three main areas:

- Functional Assessment – to evaluate the device's operations, safety, and user documentation relative to the Medicare population. Health care providers were asked to determine how and under what circumstances they would prescribe the product for a Medicare beneficiary.
- Price Comparison Analysis – to evaluate the costs of the product compared to similar products on the market or alternative treatment modalities.
- Medical Benefit Assessment – to evaluate the effectiveness of the product. Scientific literature reviews and interviews with health care providers were conducted to determine if the product significantly improved clinical outcomes compared to other products and treatment modalities.

CMS is proposing to use these three types of assessments to help set fee schedule amounts when new HCPCS codes are created for a category of items. CMS would also use the technology assessment to determine whether new HCPCS codes need to be established for new products and to determine the payment amount for new items. CMS intends to use the technology assessment process any time after January 1, 2007 to adjust payment amounts that were previously established using the gap-filling methodology if it determines that those pricing methods resulted in payment amounts that do not reflect the cost of furnishing the item.

We are encouraged to know that CMS recognizes that the current gap-filling methodology can have arbitrary results. We also agree that CMS should depart from the practice of "deflating" current MSRP to arrive at a gap-filled amount and that CMS should use the median current retail price for new items to establish the payment amount. We remain concerned, however, because the proposal for a technology assessment process is vague and lacks any opportunities for stakeholder participation. More importantly, CMS' only authority to adjust payment amounts for an item or a category of items is the IR authority under §1842(b)(8) and (9), and CMS is not authorized to depart from the authority.

Under the IR methodology established by Congress, CMS must make a determination that using the "standard rules for calculating payment" results in a payment amount that is not inherently reasonable. Congress explicitly directed the Secretary to identify the factors that it would use to determine when a payment amount is not "inherently reasonable" because it is either grossly excessive or grossly deficient. CMS must use "valid and reliable data" in making this determination and in establishing a new payment amount.[1] Importantly, IR includes specific procedural safeguards that apply to determinations to adjust a payment amount by more than 15%. For payment adjustments greater than 15%, CMS must consider (among other factors) the "potential impact of such a determination on quality, access, and beneficiary liability, including the likely effect on assignment rates and participation rates."

[1] 42 C. F. R. §405.502 (g).

Under the proposal in the NPRM, CMS could avoid complying with the IR methodology simply by migrating existing products into new HCPCS codes. Congress specifically required notice and comment and the use of valid and reliable data under the methodology to protect beneficiaries and providers from poorly conceived payment reductions that affect access. CMS cannot use a technology assessment to make a payment adjustment based on a determination that a payment amount does not "reflect the cost of furnishing the item" because those factors cannot serve as the basis for a special payment adjustment under §1842b (8) and (9).[2]

We do not disagree that CMS should establish fee schedule amounts for new products using the median retail price for the item. However, to the extent that CMS intends to use a technology
assessment to establish a payment amount or a new HCPCS code for new products, we cannot provide meaningful comments without additional information. At a minimum CMS must identify the factors it would consider in deciding to initiate a technology assessment and establish mechanisms to solicit participation from interested stakeholders. More importantly, this proposal has ramifications beyond the DMEPOS competitive acquisition program and CMS may have limited stakeholder input by including it in this NPRM.

Recommendation: CMS should initiate a separate rulemaking proceeding to address this issue and allow broader stakeholder participation.

Changes in HCPCS Codes During A Bidding Cycle
We disagree with the proposals for paying new HCPCS categories that are established during a competitive acquisition cycle. These items should be re-bid, assuming they are appropriate for acquisition.

Conclusion
Please consider very seriously our comments as well as those submitted by other interested and concerned parties. The Competitive Acquisition rule has sweeping impacts on the industry and more importantly, on the patients we serve. The plan must be logical and implemented in a manner that can be successful.

---

[2] We also note that we do not understand how the technology assessment CMS proposes can be used to arrive at a determination that the payment amount for an item does not reflect the cost of furnishing an item. The criteria proposed for the technology assessment focus on a cost benefit analysis of the technology relative other similar products. This analysis is different from an analysis of provider costs to furnish the product which would include not only the acquisition cost of the product, but also the cost of servicing the beneficiary, the cost of accreditation and other regulatory compliance, as well documentation, billing, and other costs.

Again, we sincerely appreciate the opportunity to submit our comments and concerns on the Competitive Acquisition Program for Durable Medical Equipment. Please do not hesitate to contact us with any questions.

Respectfully submitted,

Laraine Forry

Laraine Forry – 717-938-8719
Jurisdiction A Council Co-Chair

Gary Morse

Gary Morse – 240-912-3838
Jurisdiction A Council Co- Chair

#1064

MAC Jurisdiction A Advisory Council
A United Voice Representing
HME, Respiratory and Oxygen, Infusion, Orthotics /Prosthetics, and Rehabilitative Technology Providers

Via Electronic Transmission

June 29, 2006
Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1270-P
7500 Security Boulevard
Baltimore, MD 21224

Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment

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- Implementation within each MSA

Payment Basis

Inflation Update

The proposal states that providers do not have to factor inflation into their bids because the competitive bid price will be updated annually by the CPI-U.

- Providers need assurances in the bid process that the CPI-U will not be overridden by other legislation or regulation.
- If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids.

Medicare Advantage

The NPRM does not address the impact of competitive acquisition on Medicare Advantage (MA) 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 acquisition? Will these patients have the opportunity to continue to use their existing supplier when they reenter the traditional Medicare program?

Recommendation: Patients moving from an MA plan to traditional Medicare should 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 acquisition 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 of the lack of detailed knowledge of the beneficiary's decision.
- Providers would need access to detailed information to assure that they bill properly. Access to the Common Working File would assist in resolving this issue.

Recommendation: There should be a defined time frame within which a patient can transfer to a new provider. All transitioning patients should start a new rental period.

Bid Prices

CMS states that suppliers may not submit bids higher than the current fee schedule amount for an item.

- This establishes an artificial ceiling on the bids and does not allow for appropriate payment considerations for items that are not currently reimbursed at competitive fees.
- This further complicates acquisition considerations for the provider. It may require the provider to bid at a higher rate on other products in the group.

Recommendation: Remove the restrictive language in the final rule. Allow the appropriate pricing to be considered for each product.

DRA implications for Capped Rental to Oxygen Patients

The DRA further complicates the Competitive Acquisition process. Several issue need to be addressed surrounding ownership, grandfathering and repairs.

- Will forced ownership be required for Capped Rentals and Oxygen equipment?
- With the breadth of products available in the market place providers may lack expertise in trouble shooting and repairing the product owned by the patient.
- 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?
- DRA forced ownership provisions on oxygen and capped rental equipment have important ramifications for competitive acquisition. Providers cannot provide meaningful comments on many issues in the NPRM without understanding how CMS will administer the DRA requirements.

Recommendation (s): 1.CMS should publish an interim final rule before it publishes the final rule on competitive acquisition. 2. To ensure quality patient care, CMS should consider the ramifications of forced ownership and the requirement that the winning bidders must service and repair all patient owned equipment.

Authority to Adjust Payment in Other Areas

The NPRM states that CMS has the authority, with respect to items included in a competitive acquisition program, to use the payment information obtained through competitive acquisition to adjust the payment amounts for those items in areas outside the competitive acquisition area.

- The authority for the DME, 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 acquisition 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 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 acquisition. Consequently, the authority to use information derived from a competitive acquisition 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 from competitive acquisition 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.

- It is illogical that CMS would consider utilizing prices from a competitive bid area with some volume expectations to a non competitive bid area that does not have like markets or volume expectations.

Limitation on Beneficiary Liability
We understand that Medicare will not cover DMEPOS items subject to competitive acquisition furnished to a beneficiary in a competitive acquisition 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. Does this restrict the beneficiary's freedom of choice to pay for a product or have repairs done if they chose to pay for the service?
- Other portions of the NPRM specifically state that ABNs will be permitted under a competitive acquisition program, and the MMA requires that CMS continue to allow suppliers to use ABNs.

Recommendation(s): 1.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. 2. Allow providers to use an ABN, thus giving the freedom of choice to the beneficiary.

Competitive Bidding Areas

Staggered Implementation
The NPRM is silent on whether CMS will commence competitive acquisition in 10 MSAs at the same time, or stagger the initial implementation of competitive acquisition beginning in 2007.
Recommendation: We recommend that CMS phase-in the first 10 MSAs. This will allow CMS and its contractors to identify and correct problems as competitive acquisition commences.

Nationwide or Regional Mail Order Competitive Bidding Program
It is unclear why CMS proposes a separate competitive acquisition program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in competitive acquisition during 2007 and 2009, a separate program for them in 2010 would be unnecessary.

When CMS has provided a greater level of detail, we would appropriately comment on the need for this provision.

Competitive Bidding Area
We question CMS's authority to extend competitive acquisition outside an identified 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 acquisition in 2007 in an interim final rule.

Criteria for Item Selection

Items Included in Competitive Bidding

CMS identifies three categories of items that are subject to competitive acquisition 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 acquisition 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 s upplies are not included in competitive acquisition 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 competitive acquisition for a product category? When referencing the allowed charges is this billed or paid dollars?
- Annual growth in expenditures: Is there a threshold growth percentage and does it vary by the dollar size of the category? Is this billed or paid dollars?
- 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? Will these studies cross disciplines? e.g. hospital admissions, Home Health visits, emergency room visits.

Product Categories for Bidding Purposes

Issues for Clarification and Correction

The true meaning and explanation of product categories was not clear in the NPRM. Is it to be by product type or HCPCS code?

- CMS must define products categories narrowly to make sure that they are consistent and representative of the products that a supplier might actually furnish. By example, a broad category for wheelchairs or power wheelchairs will not work.
- Power wheelchair codes are in the process of being revised and have been in that process for several years due to their complexity. It makes them inappropriate for use in a competitive acquisition model.
- Complex Rehab wheelchairs are predominantly custom-configured to the individual. These complex pieces of equipment are inappropriate for use in a competitive acquisition model.
- Manual wheelchairs HCPCS codes will be subjected to a similar recoding process beginning in 2007. Therefore there may be valid codes in place by 2008 in the "wheelchair" product category that do not exist during the bid process.
- The final rule should be changed so that a provider who bids on the category of manual wheelchairs will not be required to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. In addition, they should not be required to bid on all types of accessories including seat and back cushions.
- CMS should ensure that the process accounts for narrow product categories so that providers may submit proposals for products and services that they currently have expertise in providing.

Skilled Nursing Facilities and Physicians

CMS proposes that only skilled nursing facilities (SNFs) and physicians selected as contract suppliers would be eligible to provide DMEPOS in a competitive biding area. Physicians and SNFs can limit their services to their own residents or patients and would not be required to service all beneficiaries in an MSA. In contrast, DMEPOS suppliers awarded contracts, cannot refuse to serve any beneficiary. This means that contract suppliers would be required to accept beneficiaries regardless of the costs the supplier may have to absorb (e.g., assuming a caped rental in the 10th rental month) whereas SNFs and physicians could limit their service costs. Including SNFs and physicians in the same competition with DMEPOS suppliers will distort the bid evaluation and selection of the pivotal bid because SNFs and physicians will have

significantly lower costs to operate under the acquisition program. We recommend that CMS conduct separate competitions for those items that will be furnished by SNFs or physicians such as enteral nutrition, equipment and supplies.

Conditions for Awarding Contracts

Issues for Clarification and Correction

CMS should not proceed with competitive acquisition until it is sure that that all suppliers who want to submit bids have had an opportunity to go through the accreditation process.

CMS should consider the following evidence of supplier's financial stability instead of the items in the NPRM:

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

- CMS needs to identify the criteria it will use to select accrediting bodies before the final rule is published. There is no benefit in waiting. This has been discussed and positive options provide by the PAOC.

- We support an aggressive accreditation campaign to assure that providers in any MSA with a competitive acquisition program who which to participate are able to be accredited before the bid solicitations are published.

- The "pivotal" bid methodology outlined in the NPRM does not include any mechanism to ensure that there are no unreasonably low bids. The proposed methodology will allow and almost encourages suppliers with small individual capacity to submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity.

- CMS must eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. A key term used often at the last PAOC meeting was sustainability. Winning suppliers who can not actually afford to stay in business with a low winning bid ultimately do nothing for the beneficiary.

- Another phrase used often at the last PAOC meeting was the minimalist approach to the number of winning suppliers to provide minimum capacity

requirements in the competitive acquisition area. There are limitless natural-occurring events that could create unanticipated access problems for beneficiaries in the MSA. CMS should consider other variables beyond capacity that may affect the selection of winning bidders.

- Artificially limiting bids by disqualifying bids above the current fee schedule amount for an item is not truly "competitive" based on market prices. Use the methodology proven in the demonstrations that focused on 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.

- As defined in the NPRM, the Single Payment Amount for "winning suppliers" 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 acquisition area due to a higher level of capacity. It does not make any sense that Congress had this expectation in mind when it authorized competitive acquisition under the MMA. CMS should set the payment amount at the pivotal bid level as defined in the NPRM.

- CMS should remove the Rebate Program from the rule. There is a statutory prohibition on beneficiary inducements that 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. As discussed and described at the last PAOC meeting, the rebate program proposed in the NPRM is problematic and it does not fit any of the statutory exceptions.

- Once again, it was clearly and loudly discussed at the last PAOC meeting that CMS should be driving beneficiaries to HIGH QUALITY SUPPLIERS and instead the NPRM seems to be focusing on LOWEST COST SUPPLIERS.

Recommendation: CMS should withdraw the rebate proposal.

Terms of Contract

Issues for Clarification and Correction

We support a recommendation 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 and CMS should solicit bids for the repair of patient owned equipment.

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.

CMS cannot unreasonably withhold its approval of a change of ownership of a winning supplier and should not deny winning supplier status to new owners on the basis that its capacity is not necessary within the competitive acquisition area.

CMS has taken a very narrow view of its obligation to ensure that small suppliers are adequately represented among contract suppliers. CMS should expand this to allow greater participation by small suppliers with a small supplier set asides in at least some MSAs.

CMS' proposal for allowing networks is void of any of the practical details for implementation. If this is to be a viable option, substance needs to be placed around it or else it is of no value.

Physician Authorization/Treating Practitioner

CMS has proposed to allow physicians to prescribe a specific brand or type of equipment. This provision seeks to preserve beneficiary access to equipment. We do not believe this provision should be included in competitive bidding. A physician always has had the freedom to prescribe a particular brand or item and we believe this would continue under competitive bidding. Suppliers are always looking satisfy a physician's request for specific equipment particularly if the equipment requested is clinically superior. We would request that CMS establish a process to reimburse at a higher rate a specific piece of equipment requested by a physician if that physician can demonstrate the medical necessity and clinical superiority of the equipment. We believe that if a specific piece of equipment is requested by a physician, there should be documented medical need and clinical justification for the equipment. Suppliers should also be reimbursed at a higher rate to compensate them for the additional expenses associated with obtaining such an unique item. Further, we are concerned that there could be increased beneficiary risk of injury because supplies will be forced to repair brand specific items for which they are not knowledgeable of or qualified to repair. Finally, we are concerned that manufacturers could promote their expensive brands to physicians which could inappropriately drive up the requests for these types of equipment.

Recommendation: We propose that this provision be removed from the final rule. There is no conclusive evidence that providers are not currently providing brand specific products as prescribed by the physician.

Implementation Contractor
We request CMS define the quantitative, objective measures and evaluation tools that the CBIC(s) will use in evaluating the bids submitted by suppliers.

Providers need to understand the data and information that will be reviewed by the CBIC(s) as well as the actual scoring and evaluation process to be used. Without this guidance, providers have no assurance that bid evaluations will be performed in a fair, objective and quantitative manner and not using qualitative, immeasurable, or judgment related methods.

We would agree that the evaluation process should not be performed by the MACs but would request that the actual scoring mechanism that will be used to evaluate bids be published with sufficient time for a supplier to review prior to the RFB process.

New Gap-Filling Methodology

CMS proposes to implement a new gap-filling methodology that would rely on a technology assessment process to establish fee schedule amounts for new HCPCS codes and for new DMEPOS products. CMS has used gap-filling since 1989 to estimate what the average reasonable charges would be for a new item if the item had been paid for under Medicare during the fee schedule base period. Under the current gap-filling methodology, CMS "deflates" the current manufacturer suggested retail price (MSRP) for an item using the CPI-U to estimate its 1989 MSRP. CMS then trends that price forward using the legislatively mandated covered item update for the item through the current year. Because the gap-filling methodology assumes that the MSRP increases are consistent with increases in the CPI-U, and because the covered item update has been 0% or "frozen" numerous times by Congress since the fee schedules were created, gap-filling can result in Medicare payment amounts that are too high or unrealistically low.

According to the NPRM, CMS has engaged contractors to evaluate technologies for the purpose of making payment and HCPCS coding decisions for new items. CMS states that its purpose in engaging the contractors was to identify technologies that provide demonstrated clinical benefits and recognize those benefits over existing technologies. Although the NPRM does not identify what products CMS assessed, they were assessed in three main areas:

- Functional Assessment – to evaluate the device's operations, safety, and user documentation relative to the Medicare population. Health care providers were asked to determine how and under what circumstances they would prescribe the product for a Medicare beneficiary.
- Price Comparison Analysis – to evaluate the costs of the product compared to similar products on the market or alternative treatment modalities.
- Medical Benefit Assessment – to evaluate the effectiveness of the product. Scientific literature reviews and interviews with health care providers were conducted to determine if the product significantly improved clinical outcomes compared to other products and treatment modalities.

CMS is proposing to use these three types of assessments to help set fee schedule amounts when new HCPCS codes are created for a category of items. CMS would also use the technology assessment to determine whether new HCPCS codes need to be established for new products and to determine the payment amount for new items. CMS intends to use the technology assessment process any time after January 1, 2007 to adjust payment amounts that were previously established using the gap-filling methodology if it determines that those pricing methods resulted in payment amounts that do not reflect the cost of furnishing the item.

We are encouraged to know that CMS recognizes that the current gap-filling methodology can have arbitrary results. We also agree that CMS should depart from the practice of "deflating" current MSRP to arrive at a gap-filled amount and that CMS should use the median current retail price for new items to establish the payment amount. We remain concerned, however, because the proposal for a technology assessment process is vague and lacks any opportunities for stakeholder participation. More importantly, CMS' only authority to adjust payment amounts for an item or a category of items is the IR authority under §1842(b)(8) and (9), and CMS is not authorized to depart from the authority.

Under the IR methodology established by Congress, CMS must make a determination that using the "standard rules for calculating payment" results in a payment amount that is not inherently reasonable. Congress explicitly directed the Secretary to identify the factors that it would use to determine when a payment amount is not "inherently reasonable" because it is either grossly excessive or grossly deficient. CMS must use "valid and reliable data" in making this determination and in establishing a new payment amount.[1] Importantly, IR includes specific procedural safeguards that apply to determinations to adjust a payment amount by more than 15%. For payment adjustments greater than 15%, CMS must consider (among other factors) the "potential impact of such a determination on quality, access, and beneficiary liability, including the likely effect on assignment rates and participation rates."

[1] 42 C. F. R. §405.502 (g).

Under the proposal in the NPRM, CMS could avoid complying with the IR methodology simply by migrating existing products into new HCPCS codes. Congress specifically required notice and comment and the use of valid and reliable data under the methodology to protect beneficiaries and providers from poorly conceived payment reductions that affect access. CMS cannot use a technology assessment to make a payment adjustment based on a determination that a payment amount does not "reflect the cost of furnishing the item" because those factors cannot serve as the basis for a special payment adjustment under §1842b (8) and (9).[2]

We do not disagree that CMS should establish fee schedule amounts for new products using the median retail price for the item. However, to the extent that CMS intends to use a technology
assessment to establish a payment amount or a new HCPCS code for new products, we cannot provide meaningful comments without additional information. At a minimum CMS must identify the factors it would consider in deciding to initiate a technology assessment and establish mechanisms to solicit participation from interested stakeholders. More importantly, this proposal has ramifications beyond the DMEPOS competitive acquisition program and CMS may have limited stakeholder input by including it in this NPRM.

Recommendation: CMS should initiate a separate rulemaking proceeding to address this issue and allow broader stakeholder participation.

Changes in HCPCS Codes During A Bidding Cycle
We disagree with the proposals for paying new HCPCS categories that are established during a competitive acquisition cycle. These items should be re-bid, assuming they are appropriate for acquisition.

Conclusion
Please consider very seriously our comments as well as those submitted by other interested and concerned parties. The Competitive Acquisition rule has sweeping impacts on the industry and more importantly, on the patients we serve. The plan must be logical and implemented in a manner that can be successful.

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[2] We also note that we do not understand how the technology assessment CMS proposes can be used to arrive at a determination that the payment amount for an item does not reflect the cost of furnishing an item. The criteria proposed for the technology assessment focus on a cost benefit analysis of the technology relative other similar products. This analysis is different from an analysis of provider costs to furnish the product which would include not only the acquisition cost of the product, but also the cost of servicing the beneficiary, the cost of accreditation and other regulatory compliance, as well documentation, billing, and other costs.

Again, we sincerely appreciate the opportunity to submit our comments and concerns on the Competitive Acquisition Program for Durable Medical Equipment. Please do not hesitate to contact us with any questions.

Respectfully submitted,

Laraine Forry

Laraine Forry – 717-938-8719
Jurisdiction A Council Co-Chair

Gary Morse

Gary Morse – 240-912-3838
Jurisdiction A Council Co- Chair

Submitter : **Ms. Paulette Beninate** **Date: 06/30/2006**

Organization : **IV Services**

Category : **Pharmacist**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

IV Services
1581 carol sue ave, suite E
gretna, la 70056

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
CMS

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

Dear Dr. McClellan:

IV 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 supplies as issued in the Federal Register on May 1, 2006.

IV services is a small busiess, Our primary patient population is Medciare/Medicaid. These patients, in our geographical location, are for the most part uneducated. They need constant attention for home infusion to be effective and to save the govt millions by keeping them out of the hospital. I find it odd that the federal govt. touts small business as the backbone of our economy, yet continues to make it more difficult for us to survive.

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 signifimedication 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.

I suggest CMS put all infusion and enteral therapies under PART B.
Part D has created a quagmire.I also plead with CMS not to pull the rug out from small business. It is not fair to "the backbone of the economy" not to be able to participate.

Paulette Beninate, RPH
owner IV Services

Submitter : Mr. Thomas Jeffers

Date: 06/30/2006

Organization : Hill-Rom Company, Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

Attaching general comment letter addressing a number of issue areas outlined above.

CMS-1270-P-1066-Attach-1.DOC

#1066

June 30, 2006

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

RE: Proposed Rule on Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues

Dear Dr. McClellan:

Hill-Rom Company, Inc., on behalf of itself and its affiliates, submits 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).

Hill-Rom, based in Batesville, Indiana, is a recognized leader in the worldwide health care community providing healthcare facilities in the U.S. and abroad with integrated care process and environment solutions that help caregivers deliver effective and efficient care to their patients in acute care, long term care and home care environments.

These comprehensive solutions can include facility assessments, high quality and advanced products including hospital beds, stretchers and furniture. In home care, our portfolio is inclusive of similar quality therapeutic surfaces specifically designed for the home care environment. Regardless of the care setting, we offer professional programs; clinical consultation and technical support that can help improve asset productivity, operational efficiency and patient outcomes. From a product standpoint in home care, we primarily provide group 2 and group 3 therapy support surfaces. Additionally, we also provide the Vest™ system, which facilitates airway clearance therapy at home. Finally, it is important to note that through our subsidiaries, we operate both as a manufacturer and supplier. As a consequence, our comments will largely reflect that perspective.

Overall, we employ over 6,000 associates worldwide, approximately 4,500 of these in the United States.

Exclude Support Surfaces/Criteria for Item Selection

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

Inappropriate code specificity exists when products with a limited set of basic features and benefits are assigned to the same code with related products that have advanced features. One example is E0277 – Powered Air Mattress.

In this code, the advanced products have different technological features that provide greater therapeutic benefits and/or support the special needs of some beneficiaries. Market utilization data from a variety of sources shows that both clinicians and beneficiaries prefer the advanced products because of these improved patient benefits. Within this code, advanced products account for a majority of the Medicare Part B claims.

Because of the additional costs associated with these features, the advanced products are also at the higher end of the price range for this code. Current fee schedules allow for adequate payment of the advanced products. Given the proposed bid methodology, there is a risk that suppliers may choose to provide only the less-advanced, less-costly products classified in the code in order that they may be selected as a contracted supplier. If this occurs, there could be such significant reductions in payment that the advanced products, those preferred and used most often, will no longer be available to beneficiaries. Competitive bidding should not restrict or reduce beneficiary and/or clinician access to the most appropriate, medically necessary products.

Work to address many of the above concerns has been underway for a number of years. Since January of 2002, we have been participating in the Support Surface Standards Initiative ("S3I"), a coalition formed between wound care clinicians, associations, researchers, academia and industry. As you may be aware, CMS has also been involved in this very complex task. Efforts are presently underway to develop and implement uniform terminology, test methods and reporting standards to compare support surface characteristics. Originally a two year project, the extended timeline speaks to the complexity of the issues requiring resolution in order to create a useful model that can be used as a guide for clinicians, manufacturers and most importantly, beneficiaries as they engage in product selection decisions. We believe that completion of this project is a necessity before support surfaces can be appropriately bid. The importance of this initiative would seem to be further underscored by the recent release of

AHRQ data which details increased hospitalizations of patients that also have a pressure ulcer(s) up by 63% during the period 1993-2003.

CMS has the authority to establish separate subcategories for items within a given category if there is differential clinical benefit and or value for specific items within the code. **We recommend that before EO277 or other codes similarly situated, are included in any stage of competitive bidding, CMS should exercise its authority to subdivide the codes and either: a) exclude the advanced products, such as support surfaces, from bidding or, b) require and evaluate separately bids for each subcategory. In order to ensure that codes are appropriately subdivided, we also recommend that CMS seek stakeholder input and publish for comment all proposed subdivisions prior to bidding.**

Finally, manufacturer/suppliers should not be required to bid on each code within a product category. For example, support surfaces are classified into three groups and within two of the three groups, there are numerous codes assigned. It would be difficult for a manufacturer, and most suppliers, to offer every code within the group. Further, it is not necessary. Cognizant of the clinical indications, clinicians and patients make choices based on preferences, ease of use, etc. **Allowing manufacturers and other suppliers to bid on the specific codes that they manufacture or provide, preserves valuable expertise they bring to the program.**

Accreditation

Manufacturers which also function as suppliers, and that are presently accredited, should be extended some consideration in this area. Hopefully, some recognition of their current accreditation will be made. A concern would be that if any adjustment would have to be made (e.g. different accrediting body) that ample time be provided in order to accommodate a manufacturer or other supplier that operated in numerous locations on a national basis.

Financial Information

Financial standards are a significant component in the approval process for bidders. The authorizing legislation states that the Secretary may not award a contract to an entity that does not meet applicable financial standards. The proposed rule invites comments on financial standards, while describing the documents that might be required from bidders. However, proposing data collection instruments is not the same as proposing financial eligibility standards. CMS should first consider the difficult question of which financial standards are appropriate, and then determine the documentation needed to implement those standards.

The establishment of financial standards for Part B providers is an unprecedented task. While financial standards exist for managed care organizations, hospitals and other cost reporting providers, such standards will not easily translate to the diverse DME markets. These financial standards must be flexible enough to regulate remote mail order companies, small local DME dealers, skilled nursing facilities, retail pharmacies and publicly-traded national corporations like Hill-Rom.

We wish to emphasize the unique circumstance of manufacturers and other suppliers like ourselves that are subsidiaries of public companies and urge that you take this situation into account. The operations of public company subsidiaries can be much more complex financially than a typical DME supplier. There are additional complications relative to how they provide and present financial information. Care should be taken to ensure that they are able to reasonably comply with the financial standards implemented by CMS without having to incur undue cost or burden.

The opportunities for serious inadvertent errors should not be underestimated. If financial standards are too restrictive or documentation requirements too narrow, then qualified, financially healthy, suppliers and new companies without a financial history will be eliminated from the Medicare Part B program. On the other hand, if financial standards are too lax, then the actions of suppliers unable to match the challenges of a competitive acquisition market, could have potentially dramatic implications for patients under their care.

Repairs/Service

Manufacturers should not be compelled to service other supplier's products. They may lack the training and expertise to adequately perform needed repairs/maintenance. Additionally, if a manufacturer/supplier is not ultimately a winning bidder, it could prove difficult for winning bidders to service the equipment because they will not have access to parts or may not be appropriately trained to handle repairs. In our circumstance, Hill-Rom is the exclusive source for parts associated with products we manufacture.

Medical Policies

We have very serious concerns regarding the suggestion that products / HCPCS codes from multiple medical policies could be combined together into one competitive bidding product category. Our concerns are based on the following:

Medical policies are created as much to categorize medical conditions and coverage as they are to categorize products and codes. For example, if we look at competitive bidding from the standpoint of managing specific conditions, it would be

unreasonable to consider combining a wound care patient group together with a patient group requiring a hospital bed or a wheelchair. Yet, from a simplistic approach it may seem appropriate to combine the medical policy for "wheelchair seating" with "wheelchairs" and "support surfaces" with "hospital beds" in forming competitive bidding product category. Yet, if we look at the coverage criteria / clinical indicators contained in these medical policies, the clear contrast between them becomes evident. In order to insure quality and access in a competitive bidding environment, we must insure that the best providers have the opportunity to bid. We have largely structured our home care business around addressing wound care. **It cannot be assumed that providers with a wound care expertise and focus are also wheelchair or walker providers.**

The goal of competitive acquisition must be to reasonably reduce system and beneficiary costs while maintaining or enhancing quality and access. Any combination of HCPCS codes from multiple medical policies together into one competitive bidding product category will reduce the number of providers capable of bidding for specific goods and services. Those providers that carry the broadest product offering will benefit to the detriment of the specialty providers. Ultimately, the very providers most adept at providing quality goods and services for a specific medical policy may be prohibited from bidding due to medical policies being combined that extend beyond their expertise and product offering.

Gap Filling

CMS proposes to amend its current gap filling methodology for establishing fee schedule amounts for certain items of new DMEPOS and for readjusting fee schedules for some items of DMEPOS which had been previously established using gap filling. The proposed new procedure would include a technology assessment based on a comparison of three areas: function, price and medical benefit. CMS 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 concur 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 criteria would be used for assessment in each of the three areas?
- When and how would outside contractors be used?
- When and how would outside stakeholder opinions be solicited?

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

Moreover, this new initiative is not required as part of the implementation for competitive bidding and is not mandated by either the MMA or the DRA. **Consequently, we recommend that all references to the technology assessment as a part of gap filling be removed from the final rule and that a separate proposed rule, with specific procedural requirements, be promulgated for comment.**

Determining Single Payment Amounts for Individual Items

We submit that the methodology for determining the single payment amount will have an adverse impact on beneficiary access to needed items, especially if the method of bidding items by current HCPCS codes is not changed. This method is different from the method used in the demonstration projects. There is no assurance that all suppliers who bid at or below the pivotal bid will be able to furnish the involved items at a payment amount equal to the median of the bids equal to or lower than the pivotal bid. In addition, in the proposed rule, the pivotal bid is the bid just sufficient to meet demand. If the supplier bidding the pivotal bid is not able to provide the items at the median in the proposed rule, the demand will not be met and access will be impaired. At the minimum, this method will create tremendous pressure to provide the least expensive items in the code, and to minimize service in order to cut costs. **We therefore propose that the pivotal bid be the payment amount.** This is likely to result in substantial savings to the Medicare program, while avoiding access and quality issues likely to arise from using the lower median amount.

Rebate Program

CMS proposes to allow contract suppliers to provide beneficiaries with rebates. The rebate would occur in instances when the supplier submitted bids for an individual item in an amount below the single payment amount. The rebate would be equal to the difference between the provider's actual bid and the single payment amount.

We do not believe that the rebate provision should be included in competitive bidding. The rebate proposal raises inducement and anti-kickback issues. We do not believe the provisions of the federal health care program anti-kickback statute or the Medicare anti-inducement statute can be repealed by a CMS regulation. The HHS Office of Inspector General has on numerous occasions expressed the view that the provision of

things of value to beneficiaries violate these laws. Assuming, however, that the OIG would approve the rebate proposal as an exception under these laws, we submit that the same policies underlying these laws work against the rebate provision. The policies underlying the laws include that the rebate will have an adverse impact on the quality of care, and the OIG has disapproved proposed beneficiary inducements for just this reason. The rebate provision also violates the single payment amount provision of the Act, by permitting different payment amounts for different contract suppliers. Finally, we submit that suppliers will have more than adequate incentive to bid aggressively in the competitive acquisition program without the rebate provision, and that it therefore should be eliminated.

Implementation

CMS should stagger the bidding in MSAs to allow for an orderly implementation of the program. Such an approach would also allow CMS to identify problems that occur in the competitive bidding areas and correct them before issues become widespread. Consideration also should be given to spreading the products bid between various MSAs to reduce the potential for issues being replicated across the system. Additionally, beginning with products that were part of the pilots might reduce potential risks given the experience CMS has gained from those initial efforts.

Innovation

Given what the industry has endured over the past two years (freeze of fee schedule in '04, FEHBP cuts in '05, Deficit Reduction Act provisions in '06 and now completive bidding in '07), it's difficult to see how this program does not end up as a "race to the bottom" with quality and beneficiary access ultimately being impacted. In this environment, manufacturers will be hard pressed to bring new innovations to such a restrictive market. Consequently, the requirement that bids be less than the current fee schedule amount may not be congruent with maintenance of the level of quality to which the program has become accustomed.

Thank you for your time in considering these comments and suggestions. Hill-Rom appreciates the opportunity to share a manufacturer/supplier perspective as you endeavor to craft a competitive bidding program that retains quality and access for Medicare beneficiaries. Please feel free to contact me directly at the following phone number (812) 934-7958 with any questions that you may have.

Sincerely,

Thomas J. Jeffers
Director, Government Affairs

Submitter : Ms. Kathryn Boogher

Date: 06/30/2006

Organization : Ms. Kathryn Boogher

Category : Individual

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

attachment

GENERAL

GENERAL

Attachment

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

attachment

CMS-1270-P-1067-Attach-1.DOC

CMS-1270-P-1067-Attach-2.DOC

CMS-1270-P-1067-Attach-3.DOC

#1067

Comments on Competitive Bidding

RE: File Code CMS-1270-P

Rushing Implementation

Establish and announce who the MSA's are going to be for 2007 and beyond, in advance of competitive bidding implementation, so providers in that area can ban together or create networks to be successful in the bid process.

Establish and announce what products are going to be apart of competitive bidding to allow providers adequate time to establish what costs are involved in the servicing of a product prior to the bid process.

Accreditation Standards and Quality Standards in Place before Starting

Establish Quality Standards for Suppliers and have them in place before the competitive bidding process is rolled out. This will allow providers the ability to adequately evaluate what their bids can realistically be based on the new quality standards.

Establish who the Accreditation providers are going to be to allow providers the chance to get properly accredited. Need to grandfather all existing accredited companies and allow them time to meet the new requirements when they are up for re-accreditation.

Impact on Small Business

Don't restrict a provider's rights to sell their business just because they won the bid. Many things can happen to a provider, (ex: death, bankruptcy, business closure, etc) so CMS should have guidelines in place to adequately replace the provider in that MSA.

Most providers are independently owned small businesses. This group of providers will probably be put out of business as they cannot sustain the loss the Medicare revenue to their company.

Comments on Competitive Bidding cont.

RE: File Code CMS-1270-P

Patient Choice Eliminated

Patient choice will be eliminated. Beneficiaries will see a change in providers and the service levels they were accustomed to through their local provider. Many beneficiaries will be serviced by providers who only come to town one day a week and do no provide the after hour service they currently have. There will be an increase in patients seeking emergency room services because the out of town winning provider will/can not get to them in a timely manner.

The financial burden that has been placed on DMEPOS providers through a CPI freeze for the past seven years and then a decrease of up to 20% in January 2005 has placed a lot of providers at risk of staying in business. Pricing is based on 1986/1987 reasonable charges and everyone knows that today's prices for equipment and overhead are far higher than twenty years ago. The rush to competitive bidding without consideration to the financial burdens placed on providers by accreditation, capping of equipment and purchase of oxygen systems will put many small providers out of business. This is a group of small business owners who employee real people whose lives will be affected when the provider closes due to financial hardship. This will further decrease access to providers by beneficiaries in many locales throughout the nation.

True Cost of Competitive Bidding and Demon station Project Cost Analysis

The added levels of administration that are being added to review and maintain the competitive bidding process are not cost savings factors that were considered when the demonstration projects were being conducted. The savings being projected to Congress are not realistic numbers.

Make Rules Right First Time to Keep Competitive Bidding Sustainable

CMS has had to backdate and revise several times all policies it has put into place over the past 18 months. This places a burden on the provider to keep up with the guidelines by going back in time and then having to keep up with all the revisions that occur. CMS needs to decide on a policy-GET IT RIGHT THE FIRST TIME and go forward with a future date. Seems like CMS is generating paper to create, maintain or justify their jobs. (ex: backdate capped rental to 1/1/06 eff 5/30/06). Providers are not in compliance with existing supplier standards and beneficiaries were told one thing at the time of delivery of the equipment and now the provider has to spend extra money and time to explain that CMS changed the rule and backdated it six months.

Comments on Competitive Bidding

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CRITICARE
Home Health Services, Inc.
1006 West 6th Street Lawrence, KS 66044

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

Re: Written Comments file code CMS-1270-P

Issue Identifier: *Section F. Deficit Reduction Act of 2005 (Pub. L. 109-171)*

Section 5101(b) of the DRA amending section 1834(a) (5) of the act to limit monthly payments for oxygen equipment to a 36 month period of continuous use with transfer of ownership to the beneficiary should be repealed for the following reasons.

The justification for medical oxygen therapy has been well established. Beneficiary longevity and quality of life are greatly enhanced by the provision of continuous oxygen therapy for those that the medical criteria for coverage have been met. The need for, effects of, and cost effectiveness of home oxygen therapy have been well documented as well. The ownership of oxygen equipment by vulnerable patients needs to be eliminated and the competitive bidding model needs to be seriously modified before implementation, if not eliminated outright as well.

Issue Identifier: *Section E. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173).*

Repeal of Section 5101(b) of the DRA amending section 1834(a)(5) of the act should be repealed for the following reason(s):

Comment(s) regarding the stated objectives of the Medicare DMEPOS Competitive Bidding Program are as follows:

> **Stated Objective:** *"...To limit the financial burden on beneficiaries by reducing their out-of-pocket expenses for DMEPOS they obtain through the program..."*

Beneficiaries will have increased out-of-pocket expenses for beneficiary owned (13 month capped rentals from Jan. 1, 2006 or 36 month rental oxygen) equipment whose ownership has been transferred to the beneficiary

Medicare has for years stated that backup systems are unnecessary. Providers will no longer be able to provide such services to beneficiary owned systems. Service call charges will apply whenever a beneficiary owned system (specifically, oxygen concentrator) fails and the beneficiary will pay out-of-pocket a much larger charge for repairs and maintenance fees.

There will be no financial incentive for providers to provide 24 hour emergency services to beneficiaries with patient owned equipment and such services will be provided on an unassigned basis (more out-of pocket charges) if the beneficiary can even "find" a provider willing to service them.

Current capped rental rules allow for breaks in service – what about breaks in oxygen equipment services? The payment methodology for "capped oxygen" has not been established.

Medicare purchased equipment beneficiaries will have much larger out-of-pocket expenses for DMEPOS obtained through the program due to limited manufacturer and supplier warranties. Beneficiaries will be responsible for charges related to evaluation, pickup and delivery, repair labor and shipping costs for beneficiary owned items under warranty.

Beneficiaries will be responsible for supplier and/or manufacturer's non-warranty service charges for equipment failure and/or maintenance.

Examples: Humidifier changes, Service calls for regulator installation, Access to contracting suppliers will be difficult at best. Non-emergency equipment issues will cause beneficiaries to incur added costs.

"...under new section 1834(a) (5) (F) (II) (bb), maintenance and servicing payments for beneficiary owned oxygen equipment (for parts and labor not covered by the supplier's or manufacturer's warranty) will be made only if they are reasonable and necessary..."

"...In a future rulemaking, we will propose to revise regulations found in part 414, subpart D to incorporate these DRA provisions...."

> A second objective of the Medicare DMEPOS Competitive Bidding Program as stated is: *"To assure beneficiary access to quality DMEPOS as a result of the program".*

What about blind, arthritic and otherwise disabled beneficiaries who require assistance?
The ownership (and resulting responsibility for maintenance and repair) of equipment for this vulnerable patient population is dangerous. Filter changes, analysis of oxygen concentration, beneficiary added costs (Service Calls for patient owned equipment) and after hours calls, will all be passed through to the beneficiaries.

The added costs to contract suppliers for gasoline, mileage, overtime, etc. were previously by providers at no cost under the rental program – once the beneficiary "owns" their equipment, no responsibility of a supplier to continue with services (even if the supplier remains in business) will create an undue burden on this vulnerable patient population. Limited or non-existent access by contract suppliers to CMN, qualifying information for emergency services will likely cause the supplier to provide services unassigned because they are unable to give the beneficiary an informed ABN regarding services and qualification of beneficiaries for patient owned concentrators will be unavailable for after hour's services.

Issue Identifier: *Section C. Payment Basis, Number 2. General Payment rules (Proposed § 414.408 (c-j)).*

> *"...Each item of DME that is paid for under these sections is classified into a payment category, and each category has its own unique payment rules..."*

Beneficiaries will not have access to newer technology for competitively bid products.
The conclusion that "*...Competitive bidding provides a way to harness marketplace dynamics to create incentives for suppliers to provide quality items in an efficient manner and at a reasonable cost...*" is flawed.

The elimination of over half of the suppliers in an area of evaluation is expected, even heralded by the CMS personnel according to a recent teleconference. Participants were told that it is estimated that over half of the providers currently providing services will not be included in the competitive bid program. Where will the beneficiary find a provider to provide services? How will they identify a contract provider? How will the provider provide informed consent for services when the first contact with the beneficiary will be an after hours, emergency telephone call? These are all very serious issues, which will require attention before competitive bidding for services is implemented.

Identification of beneficiary eligibility for DMEPOS either capped or purchased will prove time consuming and for after hours services, impossible. Based upon the 2003 figures for oxygen equipment provided, there are an estimated eleven million oxygen patients currently served by the fee for service system. Putting so large a population of frail, elderly, infirm patients who are dependent upon oxygen services at risk is an example of

government "unconcern" on an unprecedented scale. When disaster strikes, contracting suppliers will not know if a beneficiary "qualifies" for equipment, indeed, the supplier will not even know who the beneficiaries are who own equipment. Serious consideration must be given to providing contract suppliers with qualifying information, patient information and patient addresses for beneficiary owned equipment in order to mitigate emergency services when needed. Remember, this is a vulnerable patient population whose medical necessity for oxygen has been established. The delay between finding a supplier and receiving services will likely cause increased emergency room visits and subsequent hospitalization. Where will the "savings" be with that?

The inability of a contracted, competitive bidder to service "all" manufacturer "types" of equipment will prove problematic at best. Accreditation and the still to be announced "Quality Standards" will likely cause a provider to provide the cheapest, but standard type equipment for beneficiaries serviced. Supplier Accreditation requires following manufacturers recommendations for service interval, filter changes (both internal and external) and maintenance. Some services require internal repair and replacement of items which beneficiaries will be unable to perform. At present, no training of beneficiaries for internal annual bacteria filter changes, is recommended by the manufacturer(s). Patient owned equipment will fail – who will repair or replace it?

Additional equipment service and maintenance intervals will prove problematic. Enteral pump certification, liquid oxygen stationary and portable annual recertification, oxygen cylinder hydro-testing, conserver testing and/or recertification, etc. will all fall by the wayside when beneficiaries own such complicated, maintenance intensive and critical (to their health) equipment.

Some examples of problem areas where "service" is paramount by the supplier are enumerated below. The examples are given to show that this vulnerable patient population require a level of expertise and "service" which is not recognized by a model for the lowest bid – patient's are NOT a commodity, and the medical service provided by a DMEPOS supplier is not simply a piece of equipment that one can purchase.

Note: These patients may suffer great harm, even death if their special equipment and service needs are not met.

- Transtracheal Oxygen patients – these patients require specialized instruction, care and supplies. A contract supplier must be able to provide such services or should not be allowed to accept such patients. A Respiratory Therapist is usually specially trained to address specific patient issues such as catheter care, cleaning and instruction.
- Tracheostomy patients – again, such patients require specialized instruction, care instruction and supplies, usually by a Respiratory Therapist.
- High Oxygen Liter Flow patients – such patients require special attention to their oxygen needs – a "standardized" approach to their care will prove both dangerous and inadequate.
- Blind patients – Many equipment types are not able to be utilized by these patients and with a "standardized", low cost piece of equipment, they will be underserved and/or un-served.
- Arthritic patients – many patients are unable to perform daily living activities without assistance, and the current DMEPOS provider often provides additional services which are not addressed by the competitive bidding model, such as equipment cleaning, maintenance, humidifier changes, etc. which will be unavailable.
- Patients without caregivers/family helpers – DMEPOS providers often assist patients in the home without reimbursement simply because the service interval has been increased for at risk patients. The low bid scenario will eliminate such assistance and these patients will utilize the ambulance, emergency room and hospital services at a much higher cost to the Medicare Trust Fund.
- Deaf patients – special patient populations require added time and instruction, even specialized equipment services. These un-reimbursed "services" will not be available under the competitive bidding model.
- Disabled patients (wheelchair bound) – these patients are often unable to perform routine daily maintenance of equipment due to their disability. Such services are un-recognized by the competitive bidding model and will be unavailable or at an increased cost to the beneficiary.

- Ventilator patients – this high risk patient population must not be forgotten. Numerous factors regarding mobility, emergency services and patient/caregiver instruction will be unavailable in the competitively bid "product". A lack of professional services will place this patient at great risk of injury or death.
- Medicated patients – many patients suffer from confusion and/or medication effect(s), causing them to be unable to perform simple tasks such as filter and humidifier changes, etc. Who will provide these services using the competitive bidding model? These patients are often confused and unable to understand instructions, much less perform complex maintenance on medical equipment.
- Hospice transfers to Medicare – patients who revoke hospice services to enter the Medicare program will not have access to services and/or will be required to change suppliers. Such continuity changes are distressing and often dangerous to this special population of patients. A contract supplier will be required to provide equipment, but will they be able to provide the "service" that these critically ill patients require?
- No transportation patients (no drivers license or vehicle) – public transportation is not everywhere, these patients will likely over-utilize emergency services when their equipment fails as they are likely unable to afford the service charges that will be required of a contract supplier.
- No telephone patients – this patient population will not even be able to "call" a contract supplier for emergency and/or after hour services, even if they are able to identify such a supplier. Who will care for them when a disaster strikes? Who will know that they even need assistance?

SUMMARY:

The effect of the DRA and competitive bidding will prove catastrophic for oxygen patients, in particular. The drive to homogenize and standardize service will prove only to limit beneficiary access to medically necessary therapy. The services provided by oxygen suppliers are not "commodities" to be bought and sold. Perhaps we should distribute the home telephone numbers of the congressmen and women in the districts where oxygen patients reside in order for the beneficiaries to call them when their oxygen concentrators fail (and they will fail) and no supplier will be willing or able to come to the beneficiary's residence to assist them. What will happen to the beneficiary? They will be forced to use the ambulance services to transport them to the hospital for care. The average cost will increase exponentially for "oxygen services"; it will simply be called something else, and be paid for by another part of the same Medicare Trust Fund (same payer, different pocket).

Competition implies a number of factors – including beneficiary access to "service" – the implication that an oxygen concentrator is simply a commodity to be bought and sold is inherently fallacious. It is the "status quo" which provides the beneficiary with the most choices of equipment product(s), services and providers. It is the "status quo" which provides small businesses with the incentive to purchase innovative and "new" technologies to provide an ever increasing "improvement" in the quality of care and services associated with oxygen use. Competition is "alive and well" with the current fee-for-service program and will certainly be eliminated once the initial bidding has been accomplished.

Find an amount you think is fair to pay, and the market will decide if the reimbursement level is sufficient to continue to provide "quality" patient care. Services are already less than they were before due to the annual cuts in reimbursement to providers for equipment services such as oxygen concentrators – portable oxygen is not reimbursed at anyone's definition of "fair" – the arbitrary decision to allow approximately $31.00 per month for unlimited portable oxygen cylinders and/or liquid oxygen fills bears no basis in reality to the true costs of such a service – a single liquid oxygen fill costs more than the monthly reimbursement rate for the same – and many, many beneficiaries need 2 or more fills per month in order to meet their ambulatory level of activities – when liquid oxygen is unavailable to the beneficiaries, and it will not be available under competitive bidding – the quality of life and activity levels of beneficiaries will be greatly curtailed.

Access to new technology will be stifled – travel will be limited to what the beneficiary can afford to pay for privately – and no out of MSA competitive bidding area provider will be willing or able to provide services for the new reimbursement amount, whatever it may be. The intake process alone, considering paperwork burden, compliance with standards of care, etc. will cost the provider more than reimbursement (which, by the way, is

the current situation as well, except they can attempt to at least break even if they provide a concentrator at the current low level of reimbursement).

The lack of providers (over half are expected to close their doors with competitive bidding), standardization and homogenization of equipment (no "new" technologies will be provided – after all, we are just "selling" a product, not services) will occur in order for the few, surviving, large companies to provide the lowest level of equipment services they can. Large companies may well be able to "lowball" the bidding and control the process through size and financial reserves that are unavailable to the average small business owner. It will be only a few years before the surviving companies raise the prices to a sustainable level – it is inevitable that once the monopoly has been established, it will become "apparent" that service is something that both the Medicare program and the beneficiary require.

Who will you ask to provide these services then? All the small companies will have closed their doors, and frankly, having observed the past twenty years of bureaucratic bungling and over-regulation fostered by HHS and CMS, how will you induce them to come back? Large companies have an unfair advantage in the initial stages of a competitive bidding model – and the inability of smaller companies to enter into the recommended "network model" due to antitrust provisions, competitive distrust and lack of financial/legal resources will prove the death of the current home healthcare services.

Small companies will be unable to compete with larger companies based upon price only, the current level of care and service component that allows small companies to "out-compete" the larger companies drives the improvement of services throughout the industry, not just in oxygen services but in all aspects of durable medical equipment services. The provision of better warranties and quality of equipment, personal customer service, commitment to new and "improved" technology will simply not be available under the proposed competitive bidding model. Everyone will get the "same" equipment, and the "same" poor level of service – which I anticipate to greatly impact morbidity and mortality of the beneficiaries under such a system.

The beneficiaries are NOT interested in having the "lowest bidders" minimum level of equipment and services – they expect and deserve the "best" level of service possible for the "least" amount of out-of-pocket expense available – there can not be "shopping around" for a better company when the lowest bid model drives services – what you see will be what you get – and it will be miserable and dangerous for the beneficiaries.

Face it, small companies and large companies are paid the same for equipment – the only reason beneficiaries use small, local companies is that the personal level of service and commitment to quality care that is available to the beneficiary from the smaller companies far outshines that provided under the large, low bid model. Insurers such as HMO's already attempt to provide the lowest bid model of care, and the entry and exit of HMO's into various markets has proven that such a service level is unacceptable to the American Public.

There is likely a "firestorm" of beneficiary protest just now beginning, and the HHS and CMS are going to be directly in the center of it. It is certainly prudent to consider pricing when considering buying an automobile. It does not make sense when purchasing critical, medically necessary equipment AND services for beneficiaries who rely on the home healthcare system to keep them alive.

You might save money by purchasing a used automobile and performing the maintenance and service on it yourself, but do you really think an ill, medicated, and worried, short of breath oxygen patient would choose to do so? The implied lack of understanding (seen in the DRA provisions) of what the current healthcare system provides to beneficiaries is staggering.

It is the "quality" of care at the lowest "price" that we are all trying to achieve. The figures show that homecare saves millions over emergency care and hospitalization. The true "cost" of the services and equipment provided by the DMEPOS provider is a bargain – the DRA makes it a flea market auction. That may be fine for knick-knacks and such, but when it comes to the life and health of the beneficiary, second-hand and/or bargain equipment will prove to be no bargain. It is only the health and well-being of the beneficiary that is being bargained for.

Submitter : Mr. Jack Pivar **Date:** 06/30/2006

Organization : Assistive Technology Group, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1068-Attach-1.DOC

#1068

Comments on the Proposed Rule on Competitive Bidding

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Assistive Technology Group, Inc. is the parent corporation of seven companies that provide custom rehab equipment in nine states. Our subsidiary, Centrad Healthcare, Inc. provides non-custom medical equipment and medical supplies to both home patients and patients in long term care facilities in 25 states. Our rehab companies specialize in custom rehab equipment which is individually designed and assembled to meet the unique needs of persons with myriad of health problems related to severe neurological disorders, traumatic brain and spinal cord injury and progressively debilitating diseases. In these comments we will concentrate on those issues that affect our companies most directly. We incorporate by reference the comments submitted on behalf of our industry by The National Association for the Support of Long Term Care (NASL), the American Association for Homecare (AAH), and the National Coalition for Assistive and Rehabilitative Technology (NCART).

Custom Rehab Equipment should be excluded from competitive bidding.

The proposed rule does not address the issue of items of equipment which are custom made and therefore are not suitable for competitive bidding. It is respectfully suggested that this omission should be corrected and, among others, custom rehab equipment, such as custom wheelchairs, should be among those categories of DME to be excluded. The wheelchairs and mobility products referred to are customized items designed and assembled for the individual needs of specific beneficiaries. Each individual piece of equipment provided by custom rehab suppliers is different to a greater or lesser extent from all other items. The needs of the individual beneficiary are determined through the interchange of a clinical team including the physician, therapists and specially trained personnel from the supplier. The supplier's personnel supplies many hours of labor that are not specifically compensated, while the labor required varies by diagnosis it often exceeds thirty hours. The detailed physician order developed by this team specifies equipment that uniquely meets the needs of the individual beneficiary. It is respectfully suggested that such highly specialized and custom assembled equipment cannot be effectively subjected to a competitive bid. It is significant that custom rehab equipment was not part of either demonstration project. Moreover, the entire coding system for wheelchairs is being revamped as this rule is being commented upon. Sixty-four new codes have been issued and are still being reviewed. The LCD and fee schedules for these codes have not yet been issued. It is unrealistic to suggest that, given the limited experience physicians and therapists have had with these new codes, a supplier could undertake a meaningful bidding process. Lastly, the very

complexity of this equipment would make accurate evaluation of bids difficult. *In short custom rehab equipment is completely unsuitable for competitive bidding.*

The proposed rule fails to acknowledge that certain care settings require special treatment and should be exempted from competitive bidding.

The proposed rule would suggest that any item that is competitively bid within an MSA will only be available through the winning bidders regardless of care setting. This position fails to recognize that certain settings such as Nursing Homes are inappropriate places to apply competitive bidding. In the long term care facility, Part B funded items such as enteral nutrition and off the shelf orthotics are provided to support a specific, physician-ordered therapeutic regimen either by the facility or by independent entities under contract to the facility to provide such therapies. In either case the provision of these therapies requires special expertise in the institutional setting and necessitates close cooperation between the supplier and the facility staff. The management of such therapies as enteral feeding in the institutional setting is complex and affects the most fragile population in the facilities. As written the proposed rule would interfere with the right of a long term care facility to control the quality of care given to its residents. It would force such facilities to accept winning bidders as their supplier of bid products. Such an approach not only affects the facility's ability to meet its responsibilities under statute and regulation but also threatens the smooth provision of these therapies within the facilities. *CMS should exempt from competitive bidding those care settings that are inappropriate for competitive bidding*

The proposed rule does not address the statutory requirement that provision be made for participation by small suppliers adequately.

As written the proposed rule fails to adequately assure participation by small suppliers. The only effort made to assure small supplier participation is the suggestion that such suppliers can form networks to bid §414.418. The rule fails to provide sufficient detail with regard to what will be required to allow a network to bid. Questions regarding structural requirements, bidding format, billing structure, membership limitations, and others remain unanswered. A number of the few specifics given in the proposed rule would undermine the effectiveness of networks and reduce their potential effect on the bidding process. The proposed rule gives the supplier the choice of bidding as part of a network or individually but not both. This rule is unreasonable and unfairly limits the participation of small suppliers in the process. There is any number of reasons that a small supplier might choose to bid individually while participating as a member of a network. The effect of the rule as proposed would be to limit the competitive nature of the bid. A second problematic proposal is the exclusion of all but the smallest suppliers from networks. It is likely that properly constructed networks will result in greater competition in the bidding process. There is no reason for CMS to limit the use of networks other than to require that all network members meet the requirements for bidding.

Lastly, it is respectfully suggested that CMS has misinterpreted the intent of the Congress in its approach to the small supplier issue. We contend that Congress intended that the bidding process be so structured as to assure that small suppliers were included in the winning bid.

Nothing in the proposed rule would create such assurance. *In sum the proposed rule has completely failed to address this statutory requirement and must be rewritten.*

CMS Must Publish An Updated Implementation Timeline.

It is respectfully suggested that CMS 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 the current overly aggressive implementation plan.

Accreditation should be required prior to bidding.

Only accredited providers should be eligible to submit bids. At the present time only a small percentage of suppliers are accredited. Regardless of the decisions made concerning supplier standards, at a minimum, credible accreditation serves to assure CMS that bidding suppliers meet generally recognized industry standards. The initial release of a RFB should not proceed until it can be determined that a sufficient number of suppliers, both large and small, have accreditation credentials from recognized accrediting bodies to meet the needs of the beneficiaries in the area to be bid. The criteria to be used to identify the accrediting bodies should be released immediately. All providers accredited by organizations that meet the criteria CMS identifies should be grandfathered in to the process. The failure to take this action will not only threaten the success of the bid but will make it more difficult to assure the participation of small providers.

The proposed rule fails to provide adequate information concerning the bid process for complete comment.

It is imperative that CMS provide an opportunity for the industry to comment on such issues as:

1.) The screening process that will be used to determine whether a submitted bid will be given any consideration. Issues such as accreditation, financial capacity, and the accuracy of the predicted service capacity provided by the bidder must be taken in to account. Bids lacking credibility should not be considered.

2.) 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. Simply accepting all bids, regardless of whether they are realistic would be unwise. Likewise, rejecting all bids that exceed the existing fee schedule could, unfairly, skew the bids to an unsustainable low price.

3.) How the total needed capacity will be determined. The proposed rule indicates that the number of winning bidders will be limited to the total necessary to meet the needs of the beneficiaries in the bid area. No information is given as to how this determination will be made. For instance, will bidders be asked to describe their present usual service area? If not, in MSAs covering a large geographic area bids could be awarded to suppliers that have the necessary capacity but are not adequately geographically distributed to assure adequate coverage. Likewise, in an MSA having both urban and suburban areas the failure to include adequate suppliers familiar with servicing the urban areas could result in access problems for beneficiaries located within those areas. It is respectfully suggested that the proposal to limit winning bidders to the number necessary to just meet demand is a serious mistake. Capacity should be exceeded by at least 30% in order to account for issues such as those raised here and the real likelihood of attrition among the winning bidders.

4.) The methodology for determining the composite bid is unclear making meaningful comment impossible. As the proposed rule fails to provide sufficient explanation of how product categories will be determined and provides little or no information on how products will be weighted in establishing a composite bid we cannot provide more complete comment with regard to this issue.

These identified deficiencies make the limited comment period unrealistic. Without more specifics the comments are of necessity incomplete.

The proposed restrictions on the sale of winning contractors go too far.

The proposal, contained in Section §414.414(e) 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 requirements, that contracted supplier and its new ownership should retain its contract. *CMS should not interfere excessively in the operation of suppliers.*

All decisions concerning competitive bidding must be based on the best interests of the beneficiaries.

Relying solely on costs and volume for product selection fails to recognize that competitive bidding can have significant impact on the quality of care provided to beneficiaries. CMS must consider issues such as access, the need to meet the specific needs of the beneficiary, and medical propriety of the products supplied in its decision making process. Many HCPCS codes cover a wide range of products with significant variance in cost. While, in some instances these

products are interchangeable, in others they are not. In considering what products to bid CMS should pay careful attention to this issue in order to avoid bidding under a code that is so broad that a low bid could restrict access to a medically necessary, although more expensive product. *Competitive bidding should not be a substitute for appropriate medical policy and cannot be allowed to affect the access to appropriate products.*

The identification of the areas to be bid must be very carefully considered.

It is respectfully suggested that, given the experimental nature of this program, the MSAs chosen for the first round of bidding should be the smallest of the 10 largest and the most defined geographically. Even within any given MSA careful consideration must be given to excluding areas that already experience access problems or present special challenges for the supplier. Moreover, no bid should be extended beyond the boundaries of an MSA. To do so would introduce variables that are, at this time, unknown and could have unpredictable results.

The proposed methodology for determining the "Single Payment Amount" is fatally flawed and ignores the basic economic principles of competitive bidding.

The proposed rule indicates that the single payment amount, that is the amount to be paid to winning bidders, will be set at the mean of the bids arrayed from the lowest accepted bid to the "Pivotal Bid", the highest bid necessary to be included to account for the required supplier capacity. This proposal results in requiring one half of the winning suppliers to agree to accept in payment an amount less than that which they actually bid for the product. In theory, the purpose of competitively bidding a product is to obtain the lowest price at which a bidder can delivery the product. What makes CMS think that the winning suppliers whose bid was above the Single Payment Amount will be willing to provide the product at a price that, presumably, is less than the lowest price at which they can provide that product? *This pricing methodology will result in winning bidders dropping out and, likely access problems for beneficiaries.*

The proposed rebate provision violates the Anti-Kickback statute and is counter to established Medicare policy.

The Anti-Kickback statute and years of OIG opinions and reports have established that providing incentives to anyone, including beneficiaries, to utilize products and/or services paid for by Medicare is bad policy and, indeed, illegal. Even if OIG were willing to overlook enforcement of the Anti-Kickback Statute this would be bad policy that would, eventually, drive smaller suppliers from the market and provide incentives where none are required. *Long standing Medicare policy should not be changed to allow the provision of incentives by suppliers to beneficiaries.*

Allow Traveling Beneficiaries From Competitive Bidding Areas to Be Serviced At Standard Medicare Allowable. (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.*

The deficiencies identified in this Proposed Rule are so extensive that CMS should take the time to consider the submitted comments and rewrite the rule and release it for further comment before taking any action towards implementation of the bid process.

Submitter : **Dr. William Blake** **Date: 06/30/2006**

Organization : **Foot and Ankle Associates, Inc.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

FOOT AND ANKLE ASSOCIATES, INC.
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June 22, 2006

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

Dear Dr. McClellan:

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

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

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

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

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

Sincerely,

William J. Blake, D.P.M.

WJB/md

Submitter : Mr. Jayson Slotnik **Date:** 06/30/2006

Organization : Biotechnology Industry Organization

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#1070

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. Alan Channin **Date:** 06/30/2006

Organization : Mr. Alan Channin

Category : Health Care Professional or Association

Issue Areas/Comments

Issue

Issue

I am an ATS/CRTS who works in the area of providing rehab equipment with consumers that have needs for assistive technology. I believe that competitive bidding would limit the access consumers will have to obtaining the proper equipment that they need. The competitive bidding program will remove the one to one relationship with a certified provider that the consumer now has. This would mean the consumer would not have the ability to have assessments, fitting and delivery of these products which is essential for providing properly fitted equipment. It will also affect the consumer in getting their equipment service or repaired. The impact of this bill will reduce the number of companies that provide this type of equipment which will then reduce the service to these products that the consumer will need. Please make sure that rehab equipment is removed from competitive bidding.

Submitter : Dr. John Coster **Date:** 06/30/2006

Organization : National Association of Chain Drug Stores

Category : Health Care Provider/Association

Issue Areas/Comments

Background

Background

The National Association of Chain Drug Stores (NACDS) is providing our comments on the proposed Medicare competitive bidding program for DME, the establishment of new quality standards for DME suppliers, and the requirement that suppliers be accredited by CMS-approved accrediting organizations in order to obtain and maintain a Medicare DME billing number.

NACDS represents about 200 companies that operate approximately 35,000 community retail pharmacies in the United States. However, there are more than 53,000 community retail pharmacy sites that provide diabetic supplies and services to Medicare beneficiaries of one form or another. Our members are the primary providers of prescription drugs and pharmacy services to Medicare beneficiaries in the United States. They also provide various types of durable medical equipment to Medicare beneficiaries, especially items used by individuals with diabetes that self monitor their blood glucose levels.

General Comments on Competitive Bidding Program

Based on available data, we estimate that over 7 million current Medicare beneficiaries have diabetes, and this number likely will continue to grow. It is important that CMS promote policies that help these beneficiaries better manage their overall condition through lifestyle changes and appropriate monitoring of blood glucose levels. Regular self-monitoring of blood glucose levels and appropriate changes in treatment by individuals and health care providers based on the results can help to improve these levels and lessen the risk of other serious and costly medical complications.

We share the agency s goal that Medicare beneficiaries continue to appropriately and regularly monitor their blood glucose levels. In this regard, we wanted to provide our views on how a competitive bidding program might affect this goal, especially given the potential for subsequent limitations on the scope of supplies available to diabetics and access to these products.

Diabetic Testing Supplies are Widely Available

Medicare beneficiaries primarily purchase diabetic testing supplies through an extensive network of more than 56,000 community retail pharmacies. Thus, unlike other DME products that may be sold through a limited number of specialty suppliers, Medicare beneficiaries currently have broad access to these products in the market and they take advantage of this accessibility. Few, if any, other DME covered items or services are distributed by as many suppliers in the market as are blood glucose monitoring supplies. A competitive bidding program would likely reduce access to these products in the market, as well as limit the opportunity for beneficiaries to receive professional advice in choosing a monitor and proper education to assure its appropriate use.

Competitive Bidding Areas

Competitive Bidding Areas

NACDS opposes the establishment of a national mail order competitive bidding program for diabetic testing supplies after 2009, and the premise under which CMS advocates for the establishment of such program. We strongly oppose any requirement that forces or coerces people with diabetes to obtain their supplies from one particular type of outlet, such as a mail order program.

More than two-thirds of Medicare beneficiaries with diabetes obtain their testing supplies from community retail pharmacies. Asking millions of Medicare beneficiaries to suddenly shift their source of supply of these products could disrupt their testing and their overall quality of care. Beneficiaries traditionally obtain all their diabetic management products from a single pharmacy including their prescription drugs and testing supplies. This integration of care long promoted by Congressional and CMS policymakers will be seriously disrupted if Medicare beneficiaries suddenly have to find the means to locate all the necessary supplies that they used to obtain from one location.

These individuals may want to continue to use a retail pharmacy to obtain their testing supplies, even if their traditional pharmacy has not been selected as a contract supplier, because they do not trust mail order delivery. But, these individuals may therefore have to travel to two different pharmacy locations a pharmacy location for their prescription drugs and a pharmacy supplier location for their testing supplies where before they just went to the one local retail pharmacy to obtain their medications and testing supplies. This is fragmentation of care and is a major inconvenience for the Medicare beneficiary.

At the May 22, 2006 meeting of the PAOC, CMS conceded that face-to-face contact between beneficiaries may be required and that a mail order program may require a tailored approach based on the type of DMEPOS being supplied. For example, the Proposed Rule differentiates between original procurement and replacement of blood glucose monitoring systems and related supplies. CMS gives too little importance to the importance of follow up to diabetes care monitoring, especially in the elderly population, and believes that after an initial visit, that beneficiaries can receive all their replacement diabetic testing supplies through the mail.

Often times, face to face follow up monitoring is as important as the initial education about the product for several reasons. The beneficiary may have additional questions of the health care provider regarding how to use their monitor, or questions about the overall health care status. By limiting interactions with health care providers, especially pharmacists, CMS is creating a program that could result in negative health outcomes and increased spending on medical care services. We recommend that any proposal by CMS to implement a mail order program be subject to a separate rulemaking and that, under any circumstances, this program be voluntary for beneficiaries. Medicare beneficiaries rely on their retail pharmacists for ongoing advice and counseling on management of their diabetes condition.

CMS also assumes that mail order delivery of testing supplies is more cost effective than delivery by retail pharmacies. The cost per unit through mail order may be lower, but it doesn t mean that the beneficiary is testing any more frequently, or the cost per testing strip used is less. Many mail order firms have automatic renewal of testing supplies whether or not the beneficiary needs them. This can result in waste. If the beneficiary is being monitored by the retail pharmacist however, the pharmacist can help promote more frequent testing and make sure the beneficiary is testing appropriately.

Finally, CMS makes no provision for Medicare beneficiaries to obtain diabetic testing supplies from retail-based suppliers in cases that the mail order facility does not deliver products on time or the produ

Conditions for Awarding Contracts

Conditions for Awarding Contracts

Conditions for Awarding Contracts

We agree that Medicare suppliers should meet minimum standards for quality and customer service. However, we believe retail pharmacies that supply items of DME to Medicare should be exempted from additional accreditation requirements because pharmacies are licensed by state boards of pharmacy and already meet high standards for professionalism and customer service.

At a minimum, pharmacies that want to serve as Medicare DME suppliers should be given a grace period that would allow all state boards to incorporate any needed standards into their existing pharmacy practice acts that would allow these boards to act as independent accrediting organizations for pharmacy DME suppliers. We would then urge that any pharmacy that is in good standing with the state board of pharmacy be deemed accredited for the purposes of being able to bid under the CB program or participate as a Medicare DME supplier. Without such a process for retail pharmacies, many may forego participation in the program because of the expense and time in being accredited.

We ask that CMS clarify whether the program will require bidders to bid on specific individual products or groups of products within each product category defined. With respect to the pivotal bid, we ask whether CMS will group bids from similar classes of trade to determine a pivotal bid for that class of trade. For example, will CMS group all the mail order bids for diabetic supplies as well as group all the bids from retail suppliers. Lower class-of-trade pricing may be available to mail order suppliers that may not be available to retail-based providers. CMS risks a shortage of retail-based providers eligible to participate if all the bids from these two supplier classes are grouped together.

CMS would not award a bid to any entity unless the amounts being paid are less than the total amounts that would have been paid under the current fee schedule approach. Does this requirement extend to only the first year of the three year cycle or all three years of the cycle? Also, it is unrealistic to expect a provider to incur the additional costs to meet all the additional accreditation requirements outlined in the regulation, as well as the costs of completing all the paperwork to participate in this program, and still bid below the current fee schedule payment amounts. Moreover, there is no mechanism mentioned for CMS to distinguish among the bids based on the quality of the products being provided.
With respect to multiple contractors, the proposed rule indicates that we will have multiple contract suppliers in each competitive bidding area for each product category if at least two suppliers meet all the requirements for participation& Does this mean that CMS will only award the contract to two suppliers in any area if two suppliers can meet expected demand, or at a minimum will award contracts to at least two suppliers? What if both or all of the suppliers that are at or below the pivotal bid are mail order suppliers, or just large retail suppliers, not small or regional suppliers?

Criteria for Item Selection

Criteria for Item Selection

Criteria for Item Selection

CMS must recognize that specific test strips are used in specific monitors and that these strips may not be used in other monitors. We would agree that, for the sake of beneficiaries health, CMS group items together that would logically be used together, such as grouping a certain test strip with its accompanying monitor. However, CMS should recognize that the diversity of the diabetic testing products that are available on the market reflects the diversity in the testing needs of the Medicare population.

CMS should also consider the number of suppliers that are providing an item as it determines which items to include in the CB program. A market, in which few suppliers have significant high charges for a particular item, is much different than a market in which most or the majority of suppliers have small charges for a particular item. The existence of more suppliers in the market might indicate that a higher degree of competition exists in that market, and that competitive bidding might work for this product given the wide number of suppliers. However, it might indicate that Medicare beneficiaries see convenience as the most important aspect of being able to obtain that product. It should raise concerns for CMS as to whether that product is truly a good candidate given that restrictions will result from competitive bidding.

We acknowledge that diabetic testing supplies is a very high category of spending under the DMEPOS benefit. However, recent increases in charges for these items may not result solely from high prices for these items. They may result from an increase in use. Given the increasing prevalence of diabetes in the Medicare population, the growth in charges for diabetic testing supplies may reflect a growth in use, not necessarily an increase in unit cost or margin.

Because the market for diabetic testing supplies is already highly competitive, CMS may not realize significant if any savings by including these items in the program. In fact, we believe that CMS must consider increased costs due to other medical interventions that will likely be needed as a result of the fragmentation of care and potential reduced blood glucose testing that could occur as a result of the competitive bidding program. Once these additional costs are factored in, the likely result will be increased costs to the Medicare program, not decreased costs.

We are concerned that CMS has developed a bidding system that does not recognize the diversity within the full range of items in each product group, particularly those related to blood glucose monitoring systems. Blood glucose monitoring systems and related supplies are not commodity items there is a significant amount of innovation and differentiation among these systems that is related to quality of care factors and patient need. We urge CMS not to overlook the importance of

encouraging diversity of product availability within a product group.

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

CMS proposes to use a methodology establishing the single payment amount that is not based on past experience (e.g., a demonstration project such as those conducted in Polk County, Florida and in San Antonio, Texas). To set the single payment amount, CMS determines the pivotal bid and then sets the single payment amount as the median of these bids. We are concerned that use of the median bid would be unfair to suppliers that bid higher than the median, but are now required to sell their products at the lower median bid. If a supplier is among the upper half of bidders, and the median price is selected, that supplier will have to supply the product at a price lower than its bid. That process calls into question whether successful bidders will be likely to cooperate and sell product at that lower price. If successful bidders are not willing to supply products at the lower price, then the available supply of a particular item may not reflect the actual point that is supposed to be captured in setting the pivotal bid.

CMS does not indicate how it intends to compensate for the fact that mail order suppliers may receive preferential class of trade pricing, which would potentially allow these suppliers to drive very low bids. Including these mail order price bids along with bids for retail-based suppliers might leave retail suppliers with no choice but not to bid or provide these products at significant losses. CMS should consider creating separate pivotal bids for mail order suppliers and retail suppliers so that more retail suppliers can be included in the competitive bidding program. By separating the two classes of trade, you possibly increase the number of winning bidders as well as increase Medicare beneficiaries access to retail-based DME suppliers.

Education and Outreach

Education and Outreach

Education and Outreach

We agree with CMS that the development of this program will require a significant amount of outreach and education to providers and beneficiaries. As CMS has learned from the launch of Medicare Part D, reaching Medicare beneficiaries can be challenging, especially low-income Medicare beneficiaries. In addition, relying on the internet to inform beneficiaries about changes in Medicare may only reach a small percentage of all Medicare beneficiaries. It is our belief that many beneficiaries will not know about the implications of the CB program until such time as they attempt to obtain a particular item that was included in a CB program in their area. That is, they will go to the pharmacy and may find that the pharmacy is no longer able to supply them the product as they have in the past. It will then be up to the pharmacist to explain the CB program, and help direct them to the place (or method) that is the easiest for the beneficiary to obtain their supplies.

In addition to any theoretical savings that might result from a CB program, beneficiaries should also know that the products that they receive might be different than the ones that they are currently using, and of different quality. There is simply no way for CMS to guarantee that this program will result in contracted suppliers providing the same nature or quality of items that a beneficiary is currently using. The bottom line is that any educational materials should prepare the beneficiary for these important facts, not just the benefits of competitive bidding.

The other fact is that many Medicare beneficiaries are not physically able to come to a pharmacy and pick up their prescription drugs or other supplies. They often send a relative or caregiver, who may expect that they can simply pick up the items. The caregiver or relative may find that they have to take the prescription for the DME item to another supplier who may or may not be close to the beneficiary s traditional supplier creating inconvenience for the caregiver or relative. Given that many Medicare beneficiaries that use DME items are very sick, infirmed, or have cognitive impairments, CMS has a significant challenge in educating beneficiaries and their caregivers both about the program and what they have to do to obtain the item.

Many of these DME items require physician prescriptions, so physicians who may be used to initially calling-in a prescription for these items to a pharmacy supplier and then sending a hard copy may find that they have to contact multiple suppliers until they find one that is under contract in that CB area to provide the item. This creates more administrative work for physicians as well.

Opportunity for Networks

Opportunity for Networks

Opportunity for Networks

NACDS supports the ability of providers to form networks in order to submit bids. This ability will be especially important for smaller suppliers that would gain efficiencies and economies of scale by pooling their purchasing power. We are concerned, however, that no suppliers submitted bids as networks under the demonstration programs. Were CMS requirements to form a network so onerous that they in effect prohibited the formation of these networks? We ask CMS to elaborate further in the final regulation as to why they think smaller suppliers didn t form networks.

When considering the 20 percent rule for networks, it raises an interesting question of whether networks are placed at a competitive disadvantage through a limitation on the percentage of marketshare that the network can have in any CB area. For example, if a large supplier whether located in the CB area, or a mail order provider already has more than 20 percent of the market, how will CMS address whether or how those providers would be allowed to participate in that area? It seems to create an un-level playing field by allowing single entities with more than 20 percent marketshare to compete when there may be no similar restrictions on providers that already have more than such percentage marketshare.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

NACDS represents more than 200 companies that operate 35,000 community retail pharmacies. While some of our members are large chain pharmacies, most of our members are smaller or regional chain operators that currently sell blood glucose monitoring supplies to Medicare beneficiaries. Small businesses have been afforded the opportunity to compete in networks (see section below) under this proposed CB program, however it seems unrealistic that these small suppliers will have the time and resources to establish such networks. We understand that such an opportunity was afforded small suppliers under the competitive bidding demonstrations, but no such networks were formed.

We are concerned that small suppliers may not have the chance to win awards in CB areas for certain frequently-dispensed items from these locations. For example, given that CMS has already indicated an interest in awarding only those number of contracts necessary in a CB region, but no less than two, the ability of small suppliers to potentially win bids is sharply reduced. This is especially the case in the diabetic testing supplies market, where CMS has indicated an interest in significantly expanding the use of mail order as the primary distribution method. If CMS determined that a national or regional mail order contractor, as well as another large retail-based supplier, can meet the requirements of providing adequate access to a particular item, then the chance of small suppliers winning the bids is greatly diminished. Small suppliers may also not have the financial resources to meet all the requirements regarding bid submission or be able to obtain to afford accreditation.

For that reason, we encourage CMS to include a minimum number of small suppliers in each CB region for each CB item included in that region. Clearly, it was Congress intent to help small suppliers participate in the program, and retain or expand their Medicare DME business. At the same time, we urge that CMS establish a technical assistance program to assist small providers to engage in the competitive bidding processes, including providing a forum for the establishment of networks

In addition, in determining whether a small supplier has the capability of serving the whole CB area, CMS should consider that a small supplier is likely to be called on exclusively by beneficiaries that live in the proximity of the supplier. Thus, when considering the capability of a small supplier to meet this standard, it should be in relation to the overall sales of this supplier for the CB product in question relative to total sales for that product in the whole CB area. Smaller suppliers are often perceived by beneficiaries as providing better, more personal service. For the program s success, it behooves CMS to do all it can to include smaller suppliers in the CB program in CB regions, especially retail pharmacies.

Finally, while CMS indicates that it conducted focus groups with small suppliers, we do not know of any of our smaller supplier member companies that were contacted or participated in these focus groups. That is unfortunate, given that smaller pharmacy suppliers are a major source of diabetic testing supplies for the Medicare population.

Payment Basis

Payment Basis

Payment Basis

NACDS strongly urges that any CB program for diabetic testing supplies include a requirement that a minimum number of community-based suppliers be included, and that these suppliers be geographically dispersed within the MSA to provide convenient access for Medicare beneficiaries to diabetic testing supplies. Under Medicare Part D, plans have to meet TRICARE pharmacy access standards, which specify minimum requirements for plans relative to access to retail pharmacies. A similar requirement should be included for this CB program. Many Medicare beneficiaries have limited mobility and cannot travel long distances to obtain their supplies. Many may also not want to obtain their supplies through a mail order vendor.

NACDS strongly opposes the application of bid prices in one competitively-bid area to set payment rates for these items in other areas that were not competitively-bid areas. CMS indicates that it may use this authority after January 1, 2009. Prices bid in one area represent the cost structure of suppliers in that area. These cost structures are reflected in the bids. Suppliers in Kansas are likely to have a much lower cost structure than those in Manhattan. Therefore, applying competitive bid prices in one area based on bids submitted in another area would be inappropriate.

We believe that CMS should allow for public comment on any methodology they might use to apply prices in one area to another area, similar to that which would have been used under the inherent reasonableness regulation.

NACDS is concerned with the requirement that suppliers be accredited by licensed accrediting organizations to obtain and use a Medicare billing number. We feel this would compromise the ability of retail pharmacies to provide Part B drugs to Medicare beneficiaries. Some pharmacies may decide not to participate in the competitive bidding program for DME, but will want to continue to supply Part B drugs. Pharmacies that elect to provide Part B drugs but not DME should not be precluded from doing so because of the accreditation requirements to become a DME supplier.

CMS proposes only to allow CPI updates for the two subsequent years after the three-year competitive bid contract is awarded. CMS should make accommodations for potential changes in the market relative to pricing updates of competitive bidding payment amounts. Market conditions and changes can occur during that time such as industry consolidation which can affect the market prices of these DME items to suppliers. Retail pharmacies have no control over their costs of goods, so CMS needs to permit a process to allow providers to be paid more than the CPI update if there are significant changes in market conditions.

Physician Authorization/Treating Practitioner

Physician Authorization/Treating Practitioner

Physician Authorization/Treating Practitioner

Beneficiaries should have the ability to obtain specific products within HCPCS codes if they are medically necessary as determined by the physician. However, it is not fair that suppliers be required to supply any item within a HCPCS code if their bid was accepted based on a product that they carry in their stock. This is a fundamental problem with the competitive bidding program. Items that may be grouped within a particular code may have a wide variety of functions and features, making it possible that there are a wide range of prices. A supplier may bid based on a price at which he believes he can furnish the product that he stocks. However, if no additional payments would be made for specific, more expensive products that are ordered by physicians, it may result in significant financial losses for the supplier if he is required to supply it at the single bid price.

Not offering an appropriate array of items may create significant, unnecessary barriers to quality care. Presumably, if a physician orders a particular brand, the physician has exercised his or her clinical judgment that the item is the best item for the patient. The Proposed Rule could disrupt physician judgment in the ordering of items of DMEPOS based solely on the availability of that brand from the winning bidder even though the item is nonetheless a covered item under the Medicare HCPCS system today.

For example, certain blood glucose meters may require a large amount of blood to establish an accurate reading. On the other hand, another meter within the same HCPCS code may require only a drop of blood which, for people with diabetes can make a startling difference in patient compliance. If the winning bidder does not supply the meter requiring only a small amount of blood, then it is entirely possible that the patient who is forced to use the first meter will fall out of compliance with adequate blood glucose monitoring practices. The initial decision a health care provider makes based on an individual patient should not be subverted because of the supplies available under the competitive bidding program.

Regulatory Impact Analysis

Regulatory Impact Analysis

The regulatory impact analysis for the competitive bidding program does not include the cost associated with accreditation. The costs of accreditation should be factored into the impact analysis for the competitive bidding program. Although the quality standards and accreditation requirements apply to all DME suppliers regardless of participation in the competitive bidding program, firms located in an MSA where the competitive bidding program is implemented will have to gain accreditation to be able to provide products included in the program. Retail pharmacies and specialized DME suppliers that typically offer a limited range of DME products which are more likely to be subject to competitive bidding such as diabetic supplies & equipment will clearly view accreditation as a cost of participation in the competitive bidding program.

The regulatory impact analysis assumes that the competitive bidding program will provide savings averaging around 20 percent. Although the analysis indicates that adjustments were made to account for subsequent price reductions for some services, assuming 20 percent savings may be optimistic. Firms participating in the competitive bidding demonstration program did not have to meet the extensive quality standards required under the proposed rule or receive accreditation in order to participate. These added costs to suppliers could increase bids, thereby reducing savings.

The analysis assumes no impact on beneficiaries because a sufficient number of quality suppliers will be selected to serve the entire market. The impact analysis assumes that 37 percent of existing suppliers more than 1 out of every 3 will not receive contracts to supply competitively bid items. As CMS acknowledges, beneficiaries will need to change suppliers if their existing supplier does not receive a contract. For some types of supplies notably diabetic supplies and equipment it may be harmful to the patient to disrupt established contacts with suppliers.

Regulatory Impact Analysis

Suppliers that do not receive contracts may also lose sales of non-competitively bid DME items if those same items can be purchased with one transaction from a contracted supplier. Non-contracted suppliers that offer more than just DME supplies, such as retail pharmacies where people may also purchase prescription drugs and other items, may lose additional sales if they do not receive a contract.

Simply ensuring adequate numbers of DME suppliers in a metropolitan area also does not guarantee ready access. For example, in a large metropolitan area, contract suppliers may be concentrated in areas that are difficult to get to for beneficiaries with limited mobility or access to transportation. Whereas an individual may currently travel a short distance to a nearby supplier, they may now be asked to travel much farther to obtain DME items.

The regulatory impact analysis estimates that 90 percent of the businesses affected by the proposed rule will be small businesses. The impact analysis suggests that small business will be helped by separate bidding for products within a DME category, and their chances of winning contracts increase when submitting multiple bids for different products. It is not clear that this proposal would reduce the costs to small business; it could actually increase costs by requiring suppliers to prepare multiple bids. It is also not clear that chances increase with multiple bids, as the odds depend on the number of bidders.
CMS makes unsubstantiated statements in the analysis such as While there may be some decrease in choice of suppliers, there will be a sufficient number of suppliers to assure adequate access. The analysis goes on to say, based on the competitive bidding demonstrations, that ...we assume that there will be no negative impacts on beneficiary access as a sufficient number of quality suppliers will be selected to serve the market. Further, &.we anticipate that the necessity of switching suppliers will be minimal in many product categories because of the existence on grandfather policies&

CMS offers no evidence to suggest that any of these statements will hold true for diabetic testing supplies. The fact is that if access to diabetic testing supplies is sharply reduced or is shifted to mail, then the testing habits and frequency of Medicare beneficiaries with diabetes could significantly change resulting in adverse health consequences. We strongly urge that a separate regulatory impact analysis be done exclusively for diabetic testing supplies within this program. For example, CMS estimates that 50 percent of bidding suppliers will be winners. Even if all the pharmacies in the United States bid, and only half are awarded contracts, then millions of Medicare beneficiaries would have to travel twice the difference then they do now to get their testing supplies.

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

CMS statement that providers that are not awarded contracts must use a contract supplier to furnish these items to the Medicare beneficiaries to whom they provide services is unclear. Does this mean that pharmacies that are not contract suppliers for a particular CB item in a CB region can still supply the item to a beneficiary as long as they obtain the item from a CB supplier?

CMS indicates that it will conduct bidding for items that are grouped into product categories , and that potential bidders must submit bids for items in each product category. We support this concept of product categories bidding, given that in the diabetic testing supply area, there is a need to match glucose monitors and the accompanying strips. We suggest that in this area, CMS detail specific monitors and strips for which competitive bids would be sought. Alternatively, CMS might consider dividing the monitors HCPCS code into monitors that are functionally equivalent so that bidding could be done on items that have similar features. This would assure that physicians and beneficiaries would have a wide range of currently-available monitors from which to choose, but that the bid reflected prices for the different types of monitors that are available.

Although CMS recognizes in the preamble to the proposed regulation, the importance of the relationship between a DMEPOS suppliers and the Medicare beneficiary , it goes on to say that the use of product categories will facilitate the transition for those beneficiaries who have to change suppliers. These are contradictory statements, and could illustrate a lack of understanding by CMS of the relationship between a beneficiary and a pharmacist relating to the provision of diabetes care. Disruption of the source of health care products and services could be very problematic for many Medicare beneficiaries, who are loathe to make changes in suppliers of their diabetic testing supplies. CMS has provided no evidence in the proposed regulation to demonstrate that such changes will not have a negative impact on the quality of care delivered to Medicare beneficiaries with diabetes. In fact,

We urge CMS to determine whether inclusion of diabetic testing items in the CB program would in fact result in savings to the entire Medicare program, not just the DME portion of the Medicare program. It is very likely that the disruption in testing patterns and sources of supply will result in situations where Medicare beneficiaries lose tight control of their blood glucose monitoring and require the use of other Medicare-covered health care services. The use of these services would obviously reduce any potential savings that might be generated from the CB program. We also urge that CB not be conducted for these diabetic testing items until CMS has tested their inclusion on one CB region, and a determination is made as to whether savings result to the Medicare program rather than simply to the competitive bidding portion of the Medicare program.

We also think that because beneficiaries generally obtain all their diabetic management supplies (including prescription medications) from one provider such as retail pharmacies CMS should accept as many bids as possible, not as few bids as possible, in this category. As we have noted, beneficiaries have convenient access to these testing products now. Sharply reducing access to these products will mean that beneficiaries may have to travel long distances or use mail order, neither of which may be the best method for the beneficiary to obtain these products.

Finally, competition requires that a sufficient number of suppliers be available to bid in the marketplace. CMS must be careful that this competitive bidding approach does not result in the elimination of suppliers in the marketplace. This would result in fewer suppliers and less competition, resulting in increased prices over time.

Terms of Contracts

Terms of Contracts

Terms of Contract

The proposed rule is not clear as to whether CMS will be awarding contracts for the supplier to provide a specific item or items within a particular HCPCS code or for the entire code? If it is for the entire code, this could mean that the product being supplied is the lowest cost item in that code. We suggest that bids be submitted for individual products within that code so that the suppliers know exactly which products (or related products) they are bidding for and that the nature of the bid reflects the cost to the supplier of providing that specific item to the Medicare beneficiary.

There are frequent changes in ownership in pharmacy providers due to mergers and acquisitions. For this reason, we encourage CMS to provide sufficient time for acquiring pharmacies that may not have been winning bidders to meet the various standards outlined in this section as well as any final quality standards that are issued. It is possible that a non-accredited participating chain of pharmacies may be acquiring a chain that was a competitive bid supplier in a particular CB region. CMS should allow the acquiring chain to determine whether it wants to continue in the program after the merger and acquisition, and provide sufficient time to meet any final accreditation requirements if the acquiring chain was not accredited at the time of purchase.

The Terms of Contract section requires that the items furnished under a competitive bidding program must be serviced by a contract supplier for that competitive bidding program& CMS must recognize that diabetic testing items furnished by suppliers, including pharmacies, such as glucose monitors, cannot in theory be serviced by a supplier. Pharmacies can help the beneficiary understand how to use the monitor, and help the beneficiary with small issues or problems, but major servicing of the monitor, and manufacturing issues relating to the monitor are the responsibility of the monitor s manufacturer. Pharmacies can help the beneficiary return the monitor to the manufacturer, but cannot be expected to service the item.

Suppliers that bid to supply an item or group of items are required only to supply the item in the HCPCS code that they stock in their stores, and for which they submit a bid. Given the wide range of products that are available, it is not realistic to expect that a beneficiary can request any item within that HCPCS code if the supplier s bid is based on a certain item.

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

Organization : **Michigan Health**

Category : **Other Association**

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

see attachment.

CMS-1270-P-1073-Attach-1.PDF

#1073

MHA

MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Advocating for hospitals and the patients they serve.

June 30, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
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Washington, DC 20201

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

Dear Dr. McClellan:

On behalf of our 144 member hospitals the Michigan Health & Hospital Association appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule concerning competitive bidding for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). This rule is crucial to many Michigan hospitals that efficiently provide DMEPOS services to thousands of patients in a timely manner. Hospital-based DMEPOS providers ensure that patients who are ready to leave the hospital are able to do so without delay, and with the equipment and supplies necessary to keep them safe and to continue recovery or maintain functionality.

Hospitals providing DMEPOS are different from organizations that solely provide DMEPOS. Hospital-based DMEPOS providers are part of the package of medical services, an extension of the hospitals services to patients with all types of needs, including the most complex. Many hospital-based DMEPOS programs are not-for-profit entities, which also influences their emphasis on the patient in a way that does not always apply for large DMEPOS chain suppliers. Hospitals are 24/7 operations, which makes the availability of assistance continual. Patients are not required to wait for deliveries by mail, and face-to-face encounters between the provider and the patient are typical. Hospitals provide DMEPOS to patients in several ways. Some hospitals operate a DMEPOS operation that serves only their patients, others provide DMEPOS for the community-at-large, others rely solely on external DMEPOS vendors, and the remaining hospital-based DMEPOS programs are hybrids.

The proposed rule raises several broad concerns about CMS' plans to phase-in competitive bidding for selected DMEPOS items. First, the proposed rule lacks specificity for many key components of the agency's competitive bidding program, such as an explicit recommendation on the DMEPOS items to be included in Phase I, a targeted list of metropolitan areas to be included in Phase I, specific quality criteria and a concrete description of the price-setting methodology, among other provisions. It is inappropriate to implement these major provisions in

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a final rule without first subjecting them to public comment. Second, CMS' effort to collect direct beneficiary input on DMEPOS priorities and needs, as discussed at the recent DMEPOS Payment Advisory and Oversight Committee meeting, was limited and unrepresentative of the patient population. Finally, the MHA is concerned that CMS treats hospital-based DMEOPS programs the same as commercial suppliers.

The MHA member hospitals have extensive experience with competitively bid DMEPOS and believe that cost savings have not been accomplished through these programs. Instead, there is a cost-shift within the health care continuum. Limited or exclusive provider panels that don't include the hospital-based service increase overall hospital costs. Numerous instances have been documented where administrative costs are increased, patient discharges are delayed, and hospitals provide supplies or equipment without reimbursement, in an effort to provide the right patient care given that the contracted provider is unable to deliver the appropriate equipment without extensive delays in discharge.

CMS should implement the following recommendations:

- Issue an interim final rule to allow CMS to present a more detailed proposal for public comment and to garner further input from stakeholders. The lack of detail in the proposed rule makes it difficult for stakeholders to develop robust comments.

- Proceed cautiously in implementing competitive bidding for DMEPOS providers that also are health care providers since they were not involved in the pilot. In particular, CMS should give consideration to the hospital-specific recommendations made below, which preserve continuity of care for Medicare beneficiaries treated by hospitals and health systems that need DMEPOS. Under the current CMS timeline it appears that small DMEPOS providers will not be able to create networks, ultimately preventing these providers from participating in the program.

- Consider the negative impact to Medicare beneficiaries who may be forced to use multiple DMEPOS suppliers causing confusion and potentially distressing situations.

CMS intends to use its statutory authority to adjust Medicare payments for DMEPOS products in other parts of the country that do not participate in competitive bidding based on the agency's experience with products included in the competitive bidding program. For example, if CMS achieves a 20 percent savings on hospital beds through competitive bidding in participating metropolitan areas, the agency could reduce Medicare payments throughout the country without requiring a competitive bidding process in the new areas. CMS notes that it has "not yet developed a detailed methodology" for using this authority and invites comments on this issue. Without a specific proposal to comment on, the MHA strongly objects to CMS using the final rule to spell out the agency's detailed plan for using this authority. Instead, CMS should develop a detailed methodology and issue a comprehensive description of its proposal for public comment. CMS should also consider the potential negative impact on small and rural hospital providers.

The MHA is especially concerned about preserving high-quality care for medically complex patients needing DMEPOS. For these patients, DMEPOS requiring clinical intervention is often part of the patient's care plan and, therefore, there is greater sensitivity to disruptions in DMEPOS access and quality that could delay discharge from the hospital, or, once home, restrict healing and create clinical complications. These types of DMEPOS products are used by more medically acute patients who should not be subject to the early stages of DMEPOS competitive bidding, which is certain to involve trial-and-error that could negatively impact DMEPOS access and quality for these vulnerable patients. CMS should exclude from the competitive bidding program those DMEPOS products that require clinical interventions. Competitive bidding would be inappropriate for ventilator services for patients with respiratory failure or chronic respiratory disease.

Hospital-based DMEPOS programs should be eligible to participate in the competitive bidding program, if they communicate to CMS that they are not submitting a bid price, but accept the single price determined through the bidding process. Given the broad and complex role hospitals play and the importance of timely DMEPOS for hospital patients, all hospital-based DMEPOS programs should be eligible to provide DMEPOS items for the hospital's patients, including DMEPOS subject to competitive bidding. By supporting the ability of hospital-based DMEPOS programs to continue providing DMEPOS to their patients, CMS will be affirming the need for hospitals to proceed in a timely fashion to execute the care plan developed by Medicare patients' physicians.

Many hospitals with certified DMEPOS programs have acquired external certification from organizations such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) through one of two means: They have either received external certification specifically for the DMEPOS operation or the DMEPOS operation has been included within the hospital's overall certification due to its integrated relationship with other hospital operations. It is important that hospital-based DMEPOS programs that are integrated within the hospital's broader quality accreditation should be allowed to fill this requirement through the hospital's comprehensive accreditation. In addition, hospital-based DMEPOS programs that are not included in the overall hospital quality accreditation, but are certified separately by an external accreditation entity, should not be required to obtain new certification until the current one expires. Through these allowances, CMS would avoid imposing a redundant cost on these hospital-based DMEPOS programs that have already acquired accreditation. We can provide more detailed input regarding the final DMEPOS supplier quality standards after CMS publishes them.

According to the proposed rule, individual products subject to competitive bidding will be identified by HCPCS codes and further described at the time of CMS' request for a bid. Hospitals are concerned that DMEPOS competitive bidding will severely limit beneficiary choice due to new cost pressures on suppliers that could lower quality and lessen variety in DMEPOS inventories. To uphold high quality of care, CMS must require suppliers provide an adequate selection of brands or products within each HCPCS code subject to competitive bidding. It is important to recognize that DMEPOS brands are not always interchangeable. We acknowledge the enormous challenge in addressing this issue, but we urge CMS to minimize the unintended consequence of reduced beneficiary access, choice and quality. This is especially

important for medically complex patients, including patients with one or more chronic diseases. These patients often require a specific brand or product to meet their clinical needs and maximize their quality of life.

CMS expects to set the single payment amount at the median of the bids for each DMEPOS product selected for competitive bidding. We strongly oppose this method because it favors national chain suppliers that deliver a large volume of DMEPOS. It is unreasonable to adopt a methodology that guarantees that half of "winning" bidders, those with bids above the median price, would be paid less than their bid. In addition, since the submitted bids apparently will not be weighted by supplier capacity, the bid from a supplier with very limited capacity would have the same impact on the single payment amount calculation as a supplier with a large capacity. Therefore, we urge CMS to adopt a payment methodology similar to the approach used in the pilot programs, which ensures that most contract suppliers are paid no less than their bid amount. We also are concerned that the median price would be capped at the fee schedule price, which does not account for costs associated with complying with quality standards and acquiring quality accreditation.

Lack of timely DMEPOS access would be harmful for patients who are clinically ready to return to home or the community. Timely DMEPOS access is critical for medically complex patients with very specific DMEPOS needs, such as high-flow oxygen via a tracheotomy tube. Delaying the discharge of Medicare beneficiaries due to restricted and untimely availability of specific DMEPOS would produce serious problems for patients' continuity of care and also for the hospital. CMS' plans to require that certain DMEPOS be provided by mail-order DMEPOS companies would be especially detrimental to timely hospital discharge due to slow access. From the hospital perspective, it is essential for CMS to ensure that DMEPOS be made available on a timely basis and to ensure that hospital-based suppliers who provide necessary products and services be reimbursed for supplying patients leaving the hospital. **Specifically the definition of "contracted supplier" should include a supplier that is owned and operated by a hospital system.**

The MHA appreciates this opportunity to submit comments on CMS' plans to implement competitive bidding for selected DMEPOS. Please address any questions about our comments and recommendations to me or Laura Appel, senior director for legislative policy, at (517) 703-8606 or lappel@mha.org

Sincerely,

Brian Peters
Senior Vice President, Advocacy

Submitter : Dr. Benjie Cox **Date:** 06/30/2006

Organization : Greene County Drug Store

Category : Pharmacist

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

Thank you for the opportunity to comment on the proposed regulation to implement a competive bidding program for DMEPOS. I offer the following comments for consideration as CMS develops the final regulation. I strongly object to CMS' alternative proposal that would require customers to obtain replacement supplies of certain items through designated providers. This restricts their choices. This proposal would severely restrict our customers' access to needed items and supplies and may compromise patient health outcomes. The competitive bidding program should NOT include common DMEPOS supplies such as diabetic testing supplies. This would greatly affect our elderly customers. They need our counseling and direction in obtaining their supplies. The mail order system has failed them on several occasions. Thank you again for allowing me to comment and for considering my view. Benjie Cox

Submitter : Mrs. DEBORAH SMITH **Date:** 06/30/2006

Organization : ADVANCE VISION MEDICAL, INC.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

WITH COMPETITIVE BIDDING, PATIENTS WILL GET LESS HOME CARE. MANY PATIENTS DO NOT REALLY KNOW HOW TO OPPERATE OXYGEN EQUIPMENT. SOMETIMES THEY FORGET WHAT TO DO WHEN THEY HAVE PROPLEMS. MOST PROPLEMS CAN BE HANDLED BY PHONE, BUT OTHERS WE HAVE TO SEE THEM. SOMETIMES WE HAVE TO GIVE THEM ANOTHER CONCENTRATOR. WITH LESS COMPANIES IN BUSSINESS, THERE WILL NOT BE ENOUGH PEOPLE TOO HANDLE THESE PATIENTS. THESE PATIENTS NEED THERE OXYGEN OR THEY WILL DIE.

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

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1076-Attach-1.DOC

#1076

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June 30, 2006

Mark McClellan, M.D., PhD
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Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S. W.
Washington, D.C. 20201

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

Visiting Nurse Service Equipment and Supplies (VNSES) is pleased to submit comments on CMS' Notice of Proposed Rulemaking for Competitive Acquisition for Certain DMEPOS and Other Issues. As a local provider of home medical equipment (HME) that promotes optimal health and independence, VNSES rents and sells HME to patients with a broad array of needs.

VNSES submits the following comments on CMS' Notice of Proposed Rulemaking published May 1, 2006, in the *Federal Register* (71 *Federal Register* 25654), Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues. As CMS requested, our comments are divided into sections with "headers" that correspond to the particular subject in the proposed rule.

1. Procedural Issues

A. Need for Additional Comment Period on Issues with No Proposal in NPRM

There are numerous times in the NPRM that CMS provides no specific proposal but instead asks for public comment on a particular issue. For example, under proposed 42 CFR §414.408(e), "Authority to Adjust Payments in Other Areas," CMS invites comments and recommendations on this issue, without providing any proposed methodology to implement this section of the law. We strongly recommend that once CMS receives comments on this and other issues for which it has no proposal, that CMS issue these proposals in another proposed regulation. If CMS chooses not to do this, there will be no opportunity for comment on any proposal before CMS issues it in final regulation. This would be inconsistent with the Administrative Procedures Act. Therefore, we strongly recommend that CMS provide for an additional comment period particularly on issues for which CMS has no identified proposal in this NPRM.

B. Need to Address Competitive Acquisition in conjunction with Deficit Reduction Act (DRA) Issues

CMS' implementation of the DRA provisions on capped rental equipment and the "rent to purchase" of oxygen equipment will have a significant impact on the bid process and bid amounts. These new reimbursement provisions impact winning and losing bidders and beneficiaries. CMS should allow stakeholders to address these issues together when it publishes the DRA NPRM later this year.

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 DRA of 2005 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 Professional Advisory Oversight Committee (PAOC) before an interim final rule is published. This will permit CMS to obtain industry input one more time before publishing a final rule and initiating program implementation.

C. Need for Public Comment on Final Quality Standards

VNSES applauds CMS for its apparent intent to ensure that all suppliers providing items and services under the competitive acquisition programs meet defined Quality Standards. At the time of this writing, however, CMS has not issued the final DMEPOS Supplier Quality Standards. We believe that these Quality Standards must be analyzed in the context of this proposed regulation, and therefore recommend that CMS either extend the comment deadline for this NPRM to 60 days after CMS issues the final Quality Standards, or allow for a formal comment period on the Quality Standards, for a period of at least 60 days once CMS issues the final Quality Standards. In addition, CMS should respond to public comments on the Quality Standards as part of its response to comments it receives on this NPRM.

2. Implementation Contractor

The proposed rule states that CMS will contract with a new entity, the Competitive Bidding Implementation Contractor (CBIC), whose primary functions will be to provide oversight and decision making, operation design functions, bidding and evaluation, access and quality monitoring. There is no further information regarding how CMS plans to choose the CBIC; but VNSES

recommends that CMS ensure that any CBIC entity avoids any potential conflict of interest. For example, a conflict of interest would exist if a CBIC were also a private payor that negotiates directly with DME/HME providers in a managed care context.

3. Payment Basis

Payment for Supplies/Accessories for Items Subject to Grandfathering.

VNSES supports CMS' proposal that accessories and supplies used in conjunction with an item furnished under the proposed grandfathering process can also be furnished by the grandfathered suppliers.

Payment Adjustment to Account for Inflation (proposed 414.408(b)).

CMS states that suppliers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U. Suppliers 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 in all fairness instruct bidders to include an inflation adjustment in their bids.

Authority to Adjust Payments In Other Areas (proposed 414.408(e)).

Effective for items furnished on or after January 1, 2009, CMS has the authority to use payment information from the competitive bidding program to adjust payment amounts to items in an area not in a competitive bid area. CMS is proposing to use this authority, but has not proposed any specific methodology for doing so. Instead, CMS invites comments and recommendations regarding a methodology CMS should use to implement this authority. VNSES recommends that CMS issue a separate NPRM addressing this issue to allow for comments on specific proposals.

Grandfathering Medicare Advantage Beneficiaries

The NPRM does not address the impact of competitive bidding on Medicare Advantage (MA) 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 an 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 capped rental period if a beneficiary decides to switch from a grandfathered supplier to a contract supplier.

4. Competitive Bidding Areas

VNSES recommends that CMS identify the initial ten MSAs in the final regulation implementing competitive bidding. The geographic location of the initial ten MSAs is the most critical information that must be made public as soon as possible, to allow suppliers sufficient time to become accredited and be able to prepare to submit bids.

CMS should stagger the implementation of competitive bidding in the initial ten MSAs to allow for a more orderly roll out of the program. This would also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread or occur in all ten initial MSAs at once.

Establishing the CBAs for 2007 and 2009 (proposed §414.410(b))

CMS is proposing to establish competitive bidding areas (CBAs) in ten of the largest MSAs in 2007, and 80 MSAs in 2009. However, CMS does not believe it is confined to areas within an MSA, and proposes specific criteria for when to include areas outside an MSA. It appears from reading the statute that CMS does not have the authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA states that the competitive acquisition areas will be established "***in***" an MSA. Therefore we strongly oppose any criteria CMS proposes to use to annex areas next to an MSA; and, we urge CMS to reject its proposal to have the discretion to define a CBA to be larger than an MSA.

5. Nationwide or Regional Mail Order (proposed §414.410(d)(2))

CMS is proposing to establish a nationwide or regional competitive bidding program, effective January 1, 2010, for the purposes of awarding contracts to suppliers to furnish these items across the nation or a region to beneficiaries who elect to obtain them through the mail order outlet.

It is unclear why CMS anticipates having a separate Competitive Bidding (CB) program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in Competitive Acquisition (CA) in MSAs during 2007 and 2009, a separate program for them in 2010 should be unnecessary. In addition, many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes. A cleaner definition of "mail order supplies" should be established.

6. 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 §1834(a)(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 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?

Regarding CMS' proposed criteria for selecting items to include in competitive bidding, VNSES recommends that CMS add a critical step as it determines which products will be included in competitive bidding. Specifically, CMS should first identify the savings it believes may be attained by including the particular product category, and should compare those costs with the administrative costs related to implementing competitive bidding for that product category. It doesn't appear that the costs associated with implementing the program would, in many product category cases, make the approach cost effective. Specifically, CMS estimates that its aggregate savings in 2008 will be $110 million. Using CMS' tables for the top ten eligible DME policy group allowed charges, with the allowed charges of $7.4 billion, savings of $110 million indicates a savings of 1.4% in 2008. That could be a waste of both time and resources, with the creation of a new bureaucracy including new Medicare contractors, and other related financial costs. We understand CMS is under a Congressional mandate, however, it would likely be more logical for CMS to focus on product categories that will ensure savings that more than balance associated administrative costs. Thus, VNSES recommends that CMS first identify the savings it believes may be attained by including the particular product category, and should compare those costs with the administrative costs related to implementing competitive bidding for that product category.

Definition of "Product Categories"

The proposed regulation should have included a definition of the product categories that CMS would potentially include in the initial ten MSAs, and we recommend that CMS identify in the final rule the definition of product categories that might be selected for the initial ten MSA. Further, we strongly recommend that CMS define product categories only as subsets of the current policy groups; CMS should not combine products from more than one policy group. For example, CMS should not include items from oxygen and hospital beds in any definition of "product categories." This will benefit smaller suppliers, and simplify the administration of competitive bidding for suppliers as well as for CMS.

CMS Should Exclude High End Custom Manual Wheelchairs

Manual wheelchairs HCPCS codes will soon be the subject of a significant recoding process beginning in 2007. Due to its greater breadth as a category, manual wheelchairs will probably cost more to bid categorically. Complex Rehab Technology

patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the NPRM proposal, a supplier who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standards, ultra lightweight, bariatric or manual tilt-in-space. In many cases, complex Rehab manual wheelchairs require multiple components to achieve appropriate fit and function for the individual. Therefore, due to the complexity of certain manual wheelchair configurations and the new code process for these items, manual wheelchairs will not be suitable for competitive bidding in 2007, and we recommend that CMS exclude these items.

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

Product Categories for Bidding Purposes

Under the proposed rule, each product category would also include all of the ancillary related supplies. Suppliers would be required to submit bids to reflect all items within the product category. We support this approach as it should allow Medicare beneficiaries a "one stop shopping" opportunity to receive all the necessary products and accessories from one contract supplier. Likewise, we support the proposal that would permit a supplier to bid for only the products and accessories they are seeking to furnish under competitive bidding as it permits suppliers to specialize if they so choose.

- CMS should be more specific about the information it will give bidders so that they can determine an appropriate bid in light of the requirement that they must accept any beneficiary in the MSA regardless of the number of rental months remaining on capped rental or oxygen equipment.
- Data suppliers will need to have to determine "worst case" scenario – how many beneficiaries using oxygen and capped rental items – that winners may be forced to take on.

8. Conditions for Awarding Contracts (proposed §414.414)

Quality Standards and Accreditation (proposed §414.414(c))

CMS is proposing to phase-in the accreditation requirement. VNSES strongly recommends that CMS explicitly require all suppliers submitting bids to demonstrate, as part of the bid submission, that they have already received accreditation status through an accreditation organization that has received "deemed status" or the equivalent from CMS. A "phase-in" approach is really inappropriate because it leaves open the possibility that bids from suppliers who may not be successful in receiving accreditation status will be included in the single payment amount calculation, and would therefore taint the bid calculation and contract supplier selection processes.

Instead, once CMS announces the initial ten specific MSA geographic locations, CMS should allow sufficient time for all interested bidders to complete the accreditation process (receive notice from the approved accreditation organization that the organization has either met the Quality Standards or not). This would ensure that all suppliers submitting bids have become accredited, and would create a "level playing field" among all submitting bidders in that they have incurred the significant costs that accreditation requires.

Therefore, VNSES disagrees with CMS' proposal in the NPRM where CMS states that it will allow a "grace period" during which unaccredited providers can participate in the bidding process. VNSES strongly recommends that CMS not allow unaccredited providers to complete accreditation during an unspecified grace period. If CMS allows unaccredited suppliers to submit bids,

then bid information from bidders who do not become accredited during the grace period will be woven into the various calculations – including supplier capacity, pivotal bids and single payment amounts calculations, fundamentally tainting the validity of those calculations. CMS cannot eliminate this deficiency by simply later eliminating those bidders who do not become accredited. Instead of going through the administratively burdensome process of recalculating supplier capacity, pivotal bids, and single payment amounts, it will be more efficient to allow a defined time period (consult accreditation organizations for what would be the appropriate period of time) to allow suppliers interested in submitting bids to go through the accreditation process.

CMS should allow additional time for suppliers to analyze the CMS final quality standards in conjunction with the NPRM. The quality standards will affect the cost of servicing beneficiaries and as such are an integral part of the bid process.

If CMS chooses to reject this recommendation and allow suppliers a grace period to meet the Quality Standards and obtain accreditation after bid submission, then if one of these suppliers subject to the grace period ends up not becoming accredited, CMS must re-calculate the single payment amount if any supplier is suspended or terminated from the program using the bid amount of the next supplier or suppliers needed to replace the stated capacity of the suspended/terminated supplier.

Finally, CMS should grandfather all providers accredited by organizations that meet the criteria CMS identifies.

Financial Standards (proposed §414.414(d))

CMS should consider the following evidence of a supplier's financial stability:

- Insurance certificates
- Trade references
- Income/Balance sheets
- Letters of credit

Evaluation of Bids (proposed §414.414(e))

Overall, the bid evaluation and the selection of winning bidders processes should be designed to result in pricing that is rational and sustainable. CMS has not identified any process in its proposed evaluation of bids procedures that will enable CMS to determine that the submitted bids are rational. Once it receives bids, after CMS arrays suppliers' composite bids from low to high, CMS must conduct an analysis of the composite bids and discard any that are unreasonably low.

Logical Consideration of Criteria

The evaluation of the supplier's financial stability, accreditation status, and compliance with all requirements must take place before the bid prices are arrayed and the pivotal bid is selected. Bids from disqualified suppliers should not be considered in selecting the winning bid point or setting the payment amount.

a. Market Demand and Supplier Capacity (proposed §414.424(e))

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 not unreasonably low bids. Although competitive bidding is premised on the theory that suppliers will submit their "best bid," in fact there will undoubtedly 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 strongly recommend that the bid solicitation and evaluation process include safeguards against this type of bidding strategy. 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 for a variety of reasons.

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 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 easily address these types of access problems quickly enough to avoid potentially serious disruption to patient care. Additionally, CMS should consider other variables beyond capacity that may affect the selection of winning bidders. For example, beneficiary convenience and proximity to contract suppliers would diminish under a scenario where CMS selects only two or three contract suppliers.

b. Determine the Pivotal Bid

CMS states that "During the demonstration, evaluating quality and financial standards was time-consuming for the bid evaluation panel...". This statement implies that CMS does not plan to evaluate the quality and financial standards of all suppliers that submit bids at the outset of the bid evaluation process. Further, it is unclear in the proposed regulation at what point CMS plans to evaluate whether bidders do in fact meet all the requirements, including quality standards (accreditation), financial standards, Medicare supplier standards, etc. It is imperative that CMS conduct this evaluation process at the outset before the bid evaluation process begins to ensure that bid information from a bidder that does not meet one or more of the requirements is not included in any part of the evaluation process. Otherwise, the entire bid calculation (including pivotal and single payment amount calculations) and contract supplier selection process will be tainted with information from non-qualifying bidders.

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

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 can still meet the "assurance of savings" requirement through alternative means. If bids received are higher than the current allowable, CMS should choose not to include that particular item or product category in the competitive bid program, because that is a strong indicator that savings are unlikely. Requiring that the bid be equal to or less than the fee schedule as a requirement of the RFB artificially restricts bidding.

Determining Single Payment Amounts for Individual Items (proposed §414.416

CMS proposes to determine the single payment amounts for individual items by using the median of the supplier bids that are at or below the pivotal bid for each individual item within each product category. A necessary prerequisite is that CMS must first eliminate from all calculations information from bidding suppliers who don't meet all the quality and financial standards, and other

requirements. Next, CMS should apply a test of reasonableness to all bids, and eliminate unreasonably high or low bids. Therefore, the single payment amount calculation should be based upon a review of all "reasonable" bids. This should provide a better representation of what the market price actually should be, rather than the median of the lowest bids.

9. Proposed Rebate Program

In the NPRM, CMS proposes to allow contract suppliers who submitted bids for an individual item below the single payment amount to provide the beneficiary with a rebate. The rebate would be equal to the difference between their actual bid amount and the single payment amount. CMS proposes that the rebate be voluntary but that the contract suppliers cannot implement on a case-by-case basis. Contract suppliers would also be prohibited from directly or indirectly advertising these rebates to beneficiaries, referral sources, or prescribing health care professionals.

VNSES has serious concerns with this proposal and recommends that CMS eliminate it. This proposal appears to be in conflict with the Medicare and Medicaid Anti-Kickback and Beneficiary Inducements laws.

Section 1128A(a)(5) of the Social Security Act 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 thus should 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 appear to 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 needs. The rebate offered by contract suppliers under the CMS program would not fit into this exception.

10. Terms of Contract (proposed §414.422)

CMS states that the length of the contracts may be different for different product categories. VNSES strongly urges CMS to have the same length contract for all products in a particular competitive bid area to minimize confusion among beneficiaries, referring physicians and suppliers. As it is, there are numerous variables that these stakeholders will have to understand (which products are part of the competitive bids, the boundaries of the competitive bid, etc.), it will simply add more confusion if there are different lengths of contracts for different product categories in the same geographic area.

Repairs and Replacements of Patient Owned Items Subject to Competitive Bidding

CMS proposes to require that repairs or replacement of patient-owned items subject to competitive bidding must be furnished only by a contract supplier. Given the new Deficit Reduction Act provisions that will result in beneficiaries owning significantly more items of DME than currently, VNSES strongly recommends that CMS develop detailed repair and replacement codes that would be part of the bid process. This has not been necessary when many items of DME had been rental items. With increased beneficiary ownership, specific codes for repair of specific items will be necessary to submit bids for repairs, as well as to facilitate claims processing.

Change in Ownership (proposed §414.422(d))

It is certainly reasonable for CMS to review a change of ownership to determine whether the buyer meets the standards before granting the new company contract supplier status. However, CMS cannot unreasonably withhold its approval of a change of

ownership and should not deny winning supplier status to a new owner on the basis that its capacity is not necessary within the competitive bidding area. CMS should approve a change of ownership If the new entity will meet applicable quality standards and confirm to other requirements of competitive bidding. CMS approval should not be withheld based on a determination that the supplier's capacity was not necessary.

The proposal to restrict the acquisition of a winning supplier unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the supplier'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.

Termination of Contract

CMS must include procedural safeguards for contract suppliers prior to terminating their contract. Minimum requirements for the process would be 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.

11. Administrative or Judicial Review (proposed §414.424)

We recommend that CMS ensure that procedures are in place for bidders to ensure that calculations related to its bids are reviewed for accuracy, and that there are appropriate procedures in place for suppliers to redress issues such as simple calculation errors. Further, 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.

12. Opportunity for Networks

CMS is proposing to allow suppliers the option to form networks for bidding purposes, with several criteria that would have to be met to be a recognized and valid network. VNSES has a number of concerns regarding this proposal; primarily that the proposal is complex and will be very difficult for small suppliers to be able to have time to form a network and comply with all the requirements, given the aggressive implementation timeline CMS has indicated. We note that it might reasonably take close to a year for a small group of suppliers to form a network. As a result, CMS' network proposal is not a practical option for small suppliers who want to participate in competitive bidding, unless CMS provides significantly more time between its announcement of the initial ten selected MSAs and the date by which suppliers will have to submit bids.

13. Physician Authorization/Treating Practitioners and Consideration of Clinical

CMS proposes to allow physicians and other treating practitioners to request a specific item, brand, or mode of delivery. When this occurs, contract suppliers would be required to furnish that item or mode of delivery, assist the beneficiary in finding another contract supplier in the CBA that can provide that item, or consult with the physician or treating practitioner to find a suitable alternative product or mode of delivery for the beneficiary. While we understand this requirement is based in the Medicare Modernization Act, CMS should consider that this requirement is likely to increase suppliers' costs, as often the physician might be requiring the supplier to provide an item that is more costly than what the supplier may typically maintain in its inventory.

VNS EQUIPMENT & SUPPLIES
An Affiliate of VISITING NURSE SERVICE

14. Gap Filling

VNSES applauds CMS' recognition of the inadequacies of CMS' current gap-filling methodology used to determine fees when new HCPCS codes are created. The gap filling formula has become less and less relevant, as the market prices for many home medical products have simply not kept pace with inflation in other economic sectors. We agree with CMS, "there is an inherent responsibility to pay enough for beneficial new technologies to ensure beneficiary access to care, while also being a prudent payer".

Procedural Issues

VNSES strongly recommends that CMS separate its proposal for changing its current gap fill methodology from its proposed regulation on competitive acquisition for certain DMEPOS items. The gap-fill methodology and its replacement pertains to all new codes that are created outside of CMS' implementation of competitive acquisition and deserves appropriate separate consideration, public comment and related procedures.

Regarding a proposed replacement to the current gap fill methodology, VNSES recommends that CMS follow defined procedural rules when exercising this authority, similar to the process CMS has developed for its National Coverage Determination process. For example, CMS should ensure that the public is informed at the time CMS initiates the process, there is a formal opportunity for public input and a formal opportunity for CMS to respond to public comment; and that all of these processes occur during a defined time period. Importantly, CMS needs to establish meaningful appeal rights for affected parties. Finally, the process for determining fees for new codes needs to be transparent (e.g., CMS must disclose all sources of data it relies upon in its determination), and CMS must be reasonably accountable to affected parties. In addition, the process should include a process to "lookback" and determine whether CMS pricing decisions have in fact impacted beneficiary access.

Thank you for the opportunity to provide comments on this very important proposed regulation. VNSES is available to discuss these matters in further detail. Please contact Karen Talbott or James Newbrough by telephone at (330) 745-1601 or via electronic mail at ktalbott@vnsa.com or jnewbrough@vnsa.com.

Sincerely,

Karen L. Talbott

Karen L. Talbott
President

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

Organization : **Restore Management Co., LLC**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

RESTORE MANAGEMENT COMPANY, LLC.
245 Cahaba Valley Parkway, Suite 200
Pelham, Alabama 35124
Telephone (205)942-6820 Fax (205)942-5627

June 30, 2006

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

RE: Proposed rule 42CFR Parts 411, 414 and 424, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Dear Mr. McClellan,

We are a company that provides therapy services to Medicare beneficiaries in Skilled Nursing Facilities as well as in out patient settings. We are concerned about some of the content in the above-mentioned proposed rule.

Criteria for Item Selection Under Off-The-Shelf Orthotics
The proposed rule states that off-the-shelf orthotics would require mean adjustments that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform without the assistance of a certified orthotist.
The proposed rule further states that it considers any adjustments that can only be made by a certified orthotist to be adjustments that require an expertise in trimming, bending, molding, assembling, or customizing to fit the individual.

Concerns with this reasoning are:
" Off-the-shelf orthotics are viewed as one size fits all and minor adjustments are seen as having a negligible effect on the patient. Medicare beneficiaries in a long-term care setting usually have multiple risk factors for skin breakdown and multiple diagnoses that place them at risk for contracture development and pain syndromes. It does take the skills of a qualified physical or occupational therapist to provide adjustments because of the multitude of factors effecting the fit and wear of the orthotic. Adjustments made by unskilled persons, who have no training in human anatomy, physiology or orthotic management, may easily result in harm to the patient s skin, joints and other soft tissue structures. This is especially true when that patient cannot express their discomfort or have impaired sensation, as is often the case in long-term care facility residents. Serious damage may have occurred by the time the improper fit is detected.

" In Section 220 of the Medicare Benefit Policy Manual, Section 427 of the Benefits Improvement and Protection Act and Section 302 of the Medicare Modernization Act, CMS recognizes that occupational and physical therapists have the skills to assess for, design, fabricate, fit and adjust orthotics to meet the patient s specific needs. They also have in depth knowledge of disease processes that can affect fit, skin integrity, pain level, and functional activity levels and can use orthotics to address these issues. Occupational and physical therapists provide in house training for multiple shifts of staff on individualized wear protocols over several days or weeks as needed to ensure the best fit with the least harm to the patient and can quickly reassess and adjust an orthotic when caregivers report a problem. While orthotists and prosthetists are highly skilled individuals who have special skills in custom design and molding of high temperature thermoplastic orthotics and prosthetics, they cannot always provide what best suits our patients needs. In our rural setting it may be days before an orthotist may be able to visit the facility. The patient would either have to go without their orthotic and be at risk of pain and injury or continue to wear the ill-fitting orthotic and be at risk of pain, skin breakdown or suffer joint damage while waiting on an orthotist to adjust their splint. Occupational and physical therapists are on site and are qualified to provide this service as they have done for years.

Please include occupational and physical therapists in providing this valuable service to our patients. We have education and training specifically in geriatrics and can provide

Submitter : Mr. Corey Carroll **Date:** 06/30/2006

Organization : Parkway Pharmacy and Medical Supply

Category : Health Care Professional or Association

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I have been in the industry for about 13 years. The company I work for a has been a DME provider for 22 years. Competitive bidding is a sore subject for alot of DME providers. Capped rental time on oxgyen is another. I'm pretty sure that we will see oxygen in your local yard sales come Jan. 2009. I wounder if anyone checked with the FDA on this one..... I'm sure not. Now back to the other great subject, competitive bidding. Does CMS think about the people that will be affected with this. Yes, the DME provider, hospitals, home health/hospice, Dr's offices and ect. We all understand that we will be affected with this matter, but what about the most important person.... the customer. We all know that we are not the most important to all of you , but the customer should be to you and I. The service that they will receive will not be up to par and everyone knows it. Customers having their own choice is what makes everyone fight so hard for the customer. We will not need to worry about that any longer. We will like to make a bid for Dme and supplies, even if we do not agree it is the best way to handle the problems. Please understand the problem that will come from this. Please feel free to call me anytime. I would love to talk to you about these subjects. Thanks for including us in these process and your time.
Corey Carroll
Parkway Pharmacy and Medical Supply.
This letter is our comments from Parkway Pharmacy and Medical Supply.

Submitter : Mr. James Bond **Date:** 06/30/2006

Organization : Alicks HME

Category : Other Health Care Professional

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I am against the whole competive bidding. I feel the customer is going to suffer with lower cost people are going to have to decrease customer service.

Submitter : Ms. Kathryn Boogher **Date:** 06/30/2006

Organization : Ms. Kathryn Boogher

Category : Individual

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Attachment

GENERAL

GENERAL

Attachment

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

Attachment

CMS-1270-P-1080-Attach-1.DOC

CMS-1270-P-1080-Attach-2.DOC

CMS-1270-P-1080-Attach-3.DOC

#1060

Comments on Competitive Bidding

RE: File Code CMS-1270-P

Rushing Implementation

Establish and announce who the MSA's are going to be for 2007 and beyond, in advance of competitive bidding implementation, so providers in that area can ban together or create networks to be successful in the bid process.

Establish and announce what products are going to be apart of competitive bidding to allow providers adequate time to establish what costs are involved in the servicing of a product prior to the bid process.

Accreditation Standards and Quality Standards in Place before Starting

Establish Quality Standards for Suppliers and have them in place before the competitive bidding process is rolled out. This will allow providers the ability to adequately evaluate what their bids can realistically be based on the new quality standards.

Establish who the Accreditation providers are going to be to allow providers the chance to get properly accredited. Need to grandfather all existing accredited companies and allow them time to meet the new requirements when they are up for re-accreditation.

Impact on Small Business

Don't restrict a provider's rights to sell their business just because they won the bid. Many things can happen to a provider, (ex: death, bankruptcy, business closure, etc) so CMS should have guidelines in place to adequately replace the provider in that MSA.

Most providers are independently owned small businesses. This group of providers will probably be put out of business as they cannot sustain the loss the Medicare revenue to their company.

Comments on Competitive Bidding cont.

RE: File Code CMS-1270-P

Patient Choice Eliminated

Patient choice will be eliminated. Beneficiaries will see a change in providers and the service levels they were accustomed to through their local provider. Many beneficiaries will be serviced by providers who only come to town one day a week and do no provide the after hour service they currently have. There will be an increase in patients seeking emergency room services because the out of town winning provider will/can not get to them in a timely manner.

The financial burden that has been placed on DMEPOS providers through a CPI freeze for the past seven years and then a decrease of up to 20% in January 2005 has placed a lot of providers at risk of staying in business. Pricing is based on 1986/1987 reasonable charges and everyone knows that today's prices for equipment and overhead are far higher than twenty years ago. The rush to competitive bidding without consideration to the financial burdens placed on providers by accreditation, capping of equipment and purchase of oxygen systems will put many small providers out of business. This is a group of small business owners who employee real people whose lives will be affected when the provider closes due to financial hardship. This will further decrease access to providers by beneficiaries in many locales throughout the nation.

True Cost of Competitive Bidding and Demon station Project Cost Analysis

The added levels of administration that are being added to review and maintain the competitive bidding process are not cost savings factors that were considered when the demonstration projects were being conducted. The savings being projected to Congress are not realistic numbers.

Make Rules Right First Time to Keep Competitive Bidding Sustainable

CMS has had to backdate and revise several times all policies it has put into place over the past 18 months. This places a burden on the provider to keep up with the guidelines by going back in time and then having to keep up with all the revisions that occur. CMS needs to decide on a policy-GET IT RIGHT THE FIRST TIME and go forward with a future date. Seems like CMS is generating paper to create, maintain or justify their jobs. (ex: backdate capped rental to 1/1/06 eff 5/30/06). Providers are not in compliance with existing supplier standards and beneficiaries were told one thing at the time of delivery of the equipment and now the provider has to spend extra money and time to explain that CMS changed the rule and backdated it six months.

Comments on Competitive Bidding

RE: File Code CMS-1270-P

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Comments on Competitive Bidding cont.

RE: File Code CMS-1270-P

Patient Choice Eliminated

Patient choice will be eliminated. Beneficiaries will see a change in providers and the service levels they were accustomed to through their local provider. Many beneficiaries will be serviced by providers who only come to town one day a week and do no provide the after hour service they currently have. There will be an increase in patients seeking emergency room services because the out of town winning provider will/can not get to them in a timely manner.

The financial burden that has been placed on DMEPOS providers through a CPI freeze for the past seven years and then a decrease of up to 20% in January 2005 has placed a lot of providers at risk of staying in business. Pricing is based on 1986/1987 reasonable charges and everyone knows that today's prices for equipment and overhead are far higher than twenty years ago. The rush to competitive bidding without consideration to the financial burdens placed on providers by accreditation, capping of equipment and purchase of oxygen systems will put many small providers out of business. This is a group of small business owners who employee real people whose lives will be affected when the provider closes due to financial hardship. This will further decrease access to providers by beneficiaries in many locales throughout the nation.

True Cost of Competitive Bidding and Demon station Project Cost Analysis

The added levels of administration that are being added to review and maintain the competitive bidding process are not cost savings factors that were considered when the demonstration projects were being conducted. The savings being projected to Congress are not realistic numbers.

Make Rules Right First Time to Keep Competitive Bidding Sustainable

CMS has had to backdate and revise several times all policies it has put into place over the past 18 months. This places a burden on the provider to keep up with the guidelines by going back in time and then having to keep up with all the revisions that occur. CMS needs to decide on a policy-GET IT RIGHT THE FIRST TIME and go forward with a future date. Seems like CMS is generating paper to create, maintain or justify their jobs. (ex: backdate capped rental to 1/1/06 eff 5/30/06). Providers are not in compliance with existing supplier standards and beneficiaries were told one thing at the time of delivery of the equipment and now the provider has to spend extra money and time to explain that CMS changed the rule and backdated it six months.

#1080

CHS CRITICARE
Home Health Services, Inc.
1006 West 6th Street Lawrence, KS 66044

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

Re: Written Comments file code CMS-1270-P

Issue Identifier: *Section F. Deficit Reduction Act of 2005 (Pub. L. 109-171)*

Section 5101(b) of the DRA amending section 1834(a) (5) of the act to limit monthly payments for oxygen equipment to a 36 month period of continuous use with transfer of ownership to the beneficiary should be repealed for the following reasons.

The justification for medical oxygen therapy has been well established. Beneficiary longevity and quality of life are greatly enhanced by the provision of continuous oxygen therapy for those that the medical criteria for coverage have been met. The need for, effects of, and cost effectiveness of home oxygen therapy have been well documented as well. The ownership of oxygen equipment by vulnerable patients needs to be eliminated and the competitive bidding model needs to be seriously modified before implementation, if not eliminated outright as well.

Issue Identifier: *Section E. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173).*

Repeal of Section 5101(b) of the DRA amending section 1834(a)(5) of the act should be repealed for the following reason(s):

Comment(s) regarding the stated objectives of the Medicare DMEPOS Competitive Bidding Program are as follows:

> **Stated Objective:** *"...To limit the financial burden on beneficiaries by reducing their out-of-pocket expenses for DMEPOS they obtain through the program..."*

Beneficiaries will have increased out-of-pocket expenses for beneficiary owned (13 month capped rentals from Jan. 1, 2006 or 36 month rental oxygen) equipment whose ownership has been transferred to the beneficiary

Medicare has for years stated that backup systems are unnecessary. Providers will no longer be able to provide such services to beneficiary owned systems. Service call charges will apply whenever a beneficiary owned system (specifically, oxygen concentrator) fails and the beneficiary will pay out-of-pocket a much larger charge for repairs and maintenance fees.

There will be no financial incentive for providers to provide 24 hour emergency services to beneficiaries with patient owned equipment and such services will be provided on an unassigned basis (more out-of pocket charges) if the beneficiary can even "find" a provider willing to service them.

Current capped rental rules allow for breaks in service – what about breaks in oxygen equipment services? The payment methodology for "capped oxygen" has not been established.

Medicare purchased equipment beneficiaries will have much larger out-of-pocket expenses for DMEPOS obtained through the program due to limited manufacturer and supplier warranties. Beneficiaries will be responsible for charges related to evaluation, pickup and delivery, repair labor and shipping costs for beneficiary owned items under warranty.

Beneficiaries will be responsible for supplier and/or manufacturer's non-warranty service charges for equipment failure and/or maintenance.

Examples: Humidifier changes, Service calls for regulator installation, Access to contracting suppliers will be difficult at best. Non-emergency equipment issues will cause beneficiaries to incur added costs.

"...under new section 1834(a) (5) (F) (II) (bb), maintenance and servicing payments for beneficiary owned oxygen equipment (for parts and labor not covered by the supplier's or manufacturer's warranty) will be made only if they are reasonable and necessary..."

"...In a future rulemaking, we will propose to revise regulations found in part 414, subpart D to incorporate these DRA provisions...."

> A second objective of the Medicare DMEPOS Competitive Bidding Program as stated is: *"To assure beneficiary access to quality DMEPOS as a result of the program".*

What about blind, arthritic and otherwise disabled beneficiaries who require assistance?
The ownership (and resulting responsibility for maintenance and repair) of equipment for this vulnerable patient population is dangerous. Filter changes, analysis of oxygen concentration, beneficiary added costs (Service Calls for patient owned equipment) and after hours calls, will all be passed through to the beneficiaries.

The added costs to contract suppliers for gasoline, mileage, overtime, etc. were previously by providers at no cost under the rental program – once the beneficiary "owns" their equipment, no responsibility of a supplier to continue with services (even if the supplier remains in business) will create an undue burden on this vulnerable patient population. Limited or non-existent access by contract suppliers to CMN, qualifying information for emergency services will likely cause the supplier to provide services unassigned because they are unable to give the beneficiary an informed ABN regarding services and qualification of beneficiaries for patient owned concentrators will be unavailable for after hour's services.

Issue Identifier: *Section C. Payment Basis, Number 2. General Payment rules (Proposed § 414.408 (c-j)).*

> *"...Each item of DME that is paid for under these sections is classified into a payment category, and each category has its own unique payment rules..."*

Beneficiaries will not have access to newer technology for competitively bid products.
The conclusion that "*...Competitive bidding provides a way to harness marketplace dynamics to create incentives for suppliers to provide quality items in an efficient manner and at a reasonable cost...*" is flawed.

The elimination of over half of the suppliers in an area of evaluation is expected, even heralded by the CMS personnel according to a recent teleconference. Participants were told that it is estimated that over half of the providers currently providing services will not be included in the competitive bid program. Where will the beneficiary find a provider to provide services? How will they identify a contract provider? How will the provider provide informed consent for services when the first contact with the beneficiary will be an after hours, emergency telephone call? These are all very serious issues, which will require attention before competitive bidding for services is implemented.

Identification of beneficiary eligibility for DMEPOS either capped or purchased will prove time consuming and for after hours services, impossible. Based upon the 2003 figures for oxygen equipment provided, there are an estimated eleven million oxygen patients currently served by the fee for service system. Putting so large a population of frail, elderly, infirm patients who are dependent upon oxygen services at risk is an example of

government "unconcern" on an unprecedented scale. When disaster strikes, contracting suppliers will not know if a beneficiary "qualifies" for equipment, indeed, the supplier will not even know who the beneficiaries are who own equipment. Serious consideration must be given to providing contract suppliers with qualifying information, patient information and patient addresses for beneficiary owned equipment in order to mitigate emergency services when needed. Remember, this is a vulnerable patient population whose medical necessity for oxygen has been established. The delay between finding a supplier and receiving services will likely cause increased emergency room visits and subsequent hospitalization. Where will the "savings" be with that?

The inability of a contracted, competitive bidder to service "all" manufacturer "types" of equipment will prove problematic at best. Accreditation and the still to be announced "Quality Standards" will likely cause a provider to provide the cheapest, but standard type equipment for beneficiaries serviced. Supplier Accreditation requires following manufacturers recommendations for service interval, filter changes (both internal and external) and maintenance. Some services require internal repair and replacement of items which beneficiaries will be unable to perform. At present, no training of beneficiaries for internal annual bacteria filter changes, is recommended by the manufacturer(s). Patient owned equipment will fail – who will repair or replace it?

Additional equipment service and maintenance intervals will prove problematic. Enteral pump certification, liquid oxygen stationary and portable annual recertification, oxygen cylinder hydro-testing, conserver testing and/or recertification, etc. will all fall by the wayside when beneficiaries own such complicated, maintenance intensive and critical (to their health) equipment.

Some examples of problem areas where "service" is paramount by the supplier are enumerated below. The examples are given to show that this vulnerable patient population require a level of expertise and "service" which is not recognized by a model for the lowest bid – patient's are NOT a commodity, and the medical service provided by a DMEPOS supplier is not simply a piece of equipment that one can purchase.

Note: These patients may suffer great harm, even death if their special equipment and service needs are not met.

- Transtracheal Oxygen patients – these patients require specialized instruction, care and supplies. A contract supplier must be able to provide such services or should not be allowed to accept such patients. A Respiratory Therapist is usually specially trained to address specific patient issues such as catheter care, cleaning and instruction.
- Tracheostomy patients – again, such patients require specialized instruction, care instruction and supplies, usually by a Respiratory Therapist.
- High Oxygen Liter Flow patients – such patients require special attention to their oxygen needs – a "standardized" approach to their care will prove both dangerous and inadequate.
- Blind patients – Many equipment types are not able to be utilized by these patients and with a "standardized", low cost piece of equipment, they will be underserved and/or un-served.
- Arthritic patients – many patients are unable to perform daily living activities without assistance, and the current DMEPOS provider often provides additional services which are not addressed by the competitive bidding model, such as equipment cleaning, maintenance, humidifier changes, etc. which will be unavailable.
- Patients without caregivers/family helpers – DMEPOS providers often assist patients in the home without reimbursement simply because the service interval has been increased for at risk patients. The low bid scenario will eliminate such assistance and these patients will utilize the ambulance, emergency room and hospital services at a much higher cost to the Medicare Trust Fund.
- Deaf patients – special patient populations require added time and instruction, even specialized equipment services. These un-reimbursed "services" will not be available under the competitive bidding model.
- Disabled patients (wheelchair bound) – these patients are often unable to perform routine daily maintenance of equipment due to their disability. Such services are un-recognized by the competitive bidding model and will be unavailable or at an increased cost to the beneficiary.

- Ventilator patients – this high risk patient population must not be forgotten. Numerous factors regarding mobility, emergency services and patient/caregiver instruction will be unavailable in the competitively bid "product". A lack of professional services will place this patient at great risk of injury or death.
- Medicated patients – many patients suffer from confusion and/or medication effect(s), causing them to be unable to perform simple tasks such as filter and humidifier changes, etc. Who will provide these services using the competitive bidding model? These patients are often confused and unable to understand instructions, much less perform complex maintenance on medical equipment.
- Hospice transfers to Medicare – patients who revoke hospice services to enter the Medicare program will not have access to services and/or will be required to change suppliers. Such continuity changes are distressing and often dangerous to this special population of patients. A contract supplier will be required to provide equipment, but will they be able to provide the "service" that these critically ill patients require?
- No transportation patients (no drivers license or vehicle) – public transportation is not everywhere, these patients will likely over-utilize emergency services when their equipment fails as they are likely unable to afford the service charges that will be required of a contract supplier.
- No telephone patients – this patient population will not even be able to "call" a contract supplier for emergency and/or after hour services, even if they are able to identify such a supplier. Who will care for them when a disaster strikes? Who will know that they even need assistance?

SUMMARY:

The effect of the DRA and competitive bidding will prove catastrophic for oxygen patients, in particular. The drive to homogenize and standardize service will prove only to limit beneficiary access to medically necessary therapy. The services provided by oxygen suppliers are not "commodities" to be bought and sold. Perhaps we should distribute the home telephone numbers of the congressmen and women in the districts where oxygen patients reside in order for the beneficiaries to call them when their oxygen concentrators fail (and they will fail) and no supplier will be willing or able to come to the beneficiary's residence to assist them. What will happen to the beneficiary? They will be forced to use the ambulance services to transport them to the hospital for care. The average cost will increase exponentially for "oxygen services"; it will simply be called something else, and be paid for by another part of the same Medicare Trust Fund (same payer, different pocket).

Competition implies a number of factors – including beneficiary access to "service" – the implication that an oxygen concentrator is simply a commodity to be bought and sold is inherently fallacious. It is the "status quo" which provides the beneficiary with the most choices of equipment product(s), services and providers. It is the "status quo" which provides small businesses with the incentive to purchase innovative and "new" technologies to provide an ever increasing "improvement" in the quality of care and services associated with oxygen use. Competition is "alive and well" with the current fee-for-service program and will certainly be eliminated once the initial bidding has been accomplished.

Find an amount you think is fair to pay, and the market will decide if the reimbursement level is sufficient to continue to provide "quality" patient care. Services are already less than they were before due to the annual cuts in reimbursement to providers for equipment services such as oxygen concentrators – portable oxygen is not reimbursed at anyone's definition of "fair" – the arbitrary decision to allow approximately $31.00 per month for unlimited portable oxygen cylinders and/or liquid oxygen fills bears no basis in reality to the true costs of such a service – a single liquid oxygen fill costs more than the monthly reimbursement rate for the same – and many, many beneficiaries need 2 or more fills per month in order to meet their ambulatory level of activities – when liquid oxygen is unavailable to the beneficiaries, and it will not be available under competitive bidding – the quality of life and activity levels of beneficiaries will be greatly curtailed.

Access to new technology will be stifled – travel will be limited to what the beneficiary can afford to pay for privately – and no out of MSA competitive bidding area provider will be willing or able to provide services for the new reimbursement amount, whatever it may be. The intake process alone, considering paperwork burden, compliance with standards of care, etc. will cost the provider more than reimbursement (which, by the way, is

the current situation as well, except they can attempt to at least break even if they provide a concentrator at the current low level of reimbursement).

The lack of providers (over half are expected to close their doors with competitive bidding), standardization and homogenization of equipment (no "new" technologies will be provided – after all, we are just "selling" a product, not services) will occur in order for the few, surviving, large companies to provide the lowest level of equipment services they can. Large companies may well be able to "lowball" the bidding and control the process through size and financial reserves that are unavailable to the average small business owner. It will be only a few years before the surviving companies raise the prices to a sustainable level – it is inevitable that once the monopoly has been established, it will become "apparent" that service is something that both the Medicare program and the beneficiary require.

Who will you ask to provide these services then? All the small companies will have closed their doors, and frankly, having observed the past twenty years of bureaucratic bungling and over-regulation fostered by HHS and CMS, how will you induce them to come back? Large companies have an unfair advantage in the initial stages of a competitive bidding model – and the inability of smaller companies to enter into the recommended "network model" due to antitrust provisions, competitive distrust and lack of financial/legal resources will prove the death of the current home healthcare services.

Small companies will be unable to compete with larger companies based upon price only, the current level of care and service component that allows small companies to "out-compete" the larger companies drives the improvement of services throughout the industry, not just in oxygen services but in all aspects of durable medical equipment services. The provision of better warranties and quality of equipment, personal customer service, commitment to new and "improved" technology will simply not be available under the proposed competitive bidding model. Everyone will get the "same" equipment, and the "same" poor level of service – which I anticipate to greatly impact morbidity and mortality of the beneficiaries under such a system.

The beneficiaries are NOT interested in having the "lowest bidders" minimum level of equipment and services – they expect and deserve the "best" level of service possible for the "least" amount of out-of-pocket expense available – there can not be "shopping around" for a better company when the lowest bid model drives services – what you see will be what you get – and it will be miserable and dangerous for the beneficiaries.

Face it, small companies and large companies are paid the same for equipment – the only reason beneficiaries use small, local companies is that the personal level of service and commitment to quality care that is available to the beneficiary from the smaller companies far outshines that provided under the large, low bid model. Insurers such as HMO's already attempt to provide the lowest bid model of care, and the entry and exit of HMO's into various markets has proven that such a service level is unacceptable to the American Public.

There is likely a "firestorm" of beneficiary protest just now beginning, and the HHS and CMS are going to be directly in the center of it. It is certainly prudent to consider pricing when considering buying an automobile. It does not make sense when purchasing critical, medically necessary equipment AND services for beneficiaries who rely on the home healthcare system to keep them alive.

You might save money by purchasing a used automobile and performing the maintenance and service on it yourself, but do you really think an ill, medicated, and worried, short of breath oxygen patient would choose to do so? The implied lack of understanding (seen in the DRA provisions) of what the current healthcare system provides to beneficiaries is staggering.

It is the "quality" of care at the lowest "price" that we are all trying to achieve. The figures show that homecare saves millions over emergency care and hospitalization. The true "cost" of the services and equipment provided by the DMEPOS provider is a bargain – the DRA makes it a flea market auction. That may be fine for knick-knacks and such, but when it comes to the life and health of the beneficiary, second-hand and/or bargain equipment will prove to be no bargain. It is only the health and well-being of the beneficiary that is being bargained for.

Submitter : Mr. RANDALL KEENE **Date:** 06/30/2006

Organization : DOCTORS PHARMACY

Category : Other Health Care Provider

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

I AM A SMALL BUSINESS MAN IN RURAL GEORGIA (OGLETHORPE, GA). A GOOD PERCENTAGE OF OUR CUSTOMERS ARE OF LOWER SOCIOECONOMIC ,MEANS. THEY DEPEND ON ME TO SUPPLY THEIR DIABETIC TESTING SUPPLIES, "BREATHING" MEDICINES, AND VARIOUS OTHER DME SUPPLIES (HOSPITAL BEDS, WHEEL CHAIRS, WALKERS, ETC.). MY CONCERN IS THAT A LARGE PORTION OF THOSE CUSTOMERS WILL BE UNABLE TO GET THEIR SUPPLIES IF I AM UNABLE TO SUPPLY THEM. A PORTION OF THEM HAVE NO PHONES, NO COMPUTER ACCESS, AND ARE UNABLE TO READ OR WRITE. I WILL CONTINUE TO SERVE THEM TO THE BEST OF MY ABILITY, BUT AT THE SAME TIME I WANT TO BE SURE THAT I WILL BE REIMBURSED. THANK YOU FOR ALLOWING ME TO COMMENT ON THIS IMPORTANT LEGISLATION.

Submitter : **Ms. Carolyn Musfeldt** **Date: 06/30/2006**

Organization : **Tennessee Orthopaedic Alliance**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

As a practicing Physical Therapist for 29 years and a specialist in Hand and Upper Extremity Rehabilitation for 22 years, and as a Certified Hand Therapist for 15 years I wish to comment on the Medicare Proposed Rule on Competitive Bidding System for Certain Durable Medical Equipment including Prefabricated Orthoses.

I am currently working in Nashville, Tennessee and frequently treat Medicare patients who require custom and/or prefabricated/off the shelf orthoses. The need for splints and orthoses is evaluated as part of an overall assessment of each patient's individual needs. Each splint is utilized as part of an overall treatment plan and not infrequently must be adjusted or custom fitted to correctly achieve the goal of treatment. An incorrectly applied or ill-fitting splint will often cause problems instead of solving them. Therapists differ from other suppliers of DMEPOS in that they supply orthoses as part of an overall treatment plan and are in a unique position to understand the exact needs and specific problems of each patient.

I am extremely concerned about losing the ability to insure that my patients are correctly fitted with the appropriate splint in a timely manner. Moreover, there being no guarantee that an "approved" provider would even stock and be able to supply the most beneficial orthosis for my patient's specific problem could very well adversely affect my ability to insure the best possible therapeutic outcome for my patient. There are also situations in which a patient could be put at risk for additional injury or worsening of their condition if not immediately protected and stabilized by an appropriate orthosis or splint, as when a cast or post-operative dressing is removed and protective splinting must be applied immediately.

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 for the opportunity to comment on this proposed regulation.

Sincerely,

Carolyn K. Musfeldt, PT, CHT

Submitter : **Ms. Andrea Hankins** **Date: 06/30/2006**

Organization : **North Valley Orthopaedic & Hand Surgery**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

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

I am requesting 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.

My name is Andrea Hankins, and I am an exercise physiologist specializing in the treatment of upper extremity disorders. I have worked with occupationsal and certified hand therapists specializing in the treatment of hands and upper extremities for 18 years. I am currently working in Yuba City, California, and frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

Therapists are unique from other suppliers of DMEPOS. They work as both a provider and a supplier, and it is difficult to divide the two aspects of the profession. 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.

We typically treat very acute patients including post-operative patients that the surgeon sends over to us the day they get their cast off, 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. We 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 we 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.

Please 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 your time.

Sincerely, Andrea Hankins, CES

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

Organization : Missouri Pharmacy Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

Submitter : **Miss. Andrea Silvia** **Date: 06/30/2006**

Organization : **University Orthopedics**

Category : **Occupational Therapist**

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

My name is Andrea Silvia, I am an Occupational Therapist/CHT practicing in an outpatient private practice. As a Certified Hand Therapist, I have been required to practice at least 4000 hours of upper extremity patient care and have over 5 years experience as an Occupational Therapist treating upper extremity disorders. This experience enabled me to sit for a national certification exam which I passed to acquire my CHT title. During this time, and since then I have frequently treated Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthosis.

Therapists are unique providers as we not only treat, but are well qualified to provide DME supplies to our patients. When providing these orthoses, we not only look at the supply, but how the supply will benefit the patient. This is a vital part of our treatment plans, because if they are not properly provided with a supply this may hinder progress of the patient in reaching their functional goals. If the proposed competitive bidding system takes place, it will seriously threaten my ability to effectively treat my patients. A patient's needs are thouroughly evaluated to determine the appropriate orthosis for beneficary use. Should this bill be passed, I will not be able to provide a vital service to help our patients.

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 for the opportunity to comment on this proposed regulation.

Sincerely,

Andrea Silvia OTR/L CHT

Submitter : Ms. Kay Zehms **Date:** 06/30/2006

Organization : Board for Orthotist/Prosthetist Certification (BOC

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1270-P-1086-Attach-1.PDF

#1086

Board for Orthotist/Prosthetist Certification
THE ADVANTAGE IS EXPERIENCE™

Board for Orthotist/Prosthetist Certification
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June 30, 2006

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

RE: Comments on Proposed Rule CMS-1270-P

Dear Dr. McClellan:

We are writing on behalf of the Board for Orthotist/Prosthetist Certification (BOC) in order to expand upon and clarify the points made by Donald O. Fedder in his letter to you dated June 13, 2006, regarding the proposed Competitive Bidding Rule. We appreciate this ongoing opportunity to dialogue with CMS and to provide comment regarding the proposed rule.

Off-the-Shelf (OTS) Orthoses

In Dr. Fedder's letter, he discussed the provision of certain off-the-shelf (OTS) devices in relation to the services of Certified Orthotic Fitters (COF) and Certified Mastectomy Fitters (CMF). While the BOC generally stands by the points outlined within the letter, we would like to clarify certain terms and issues addressed by Dr. Fedder.

In keeping with the language in the proposed rule, the term off-the-shelf (OTS) should be used to describe only those items that are ready-made and may be provided to a patient with minimal or no adjustment or customization for appropriate use. Such items may be literally taken from the box and provided to the patient "as is", and require no expertise for fitting or dispensing. While all OTS orthoses are "prefabricated", not all prefabricated orthoses are OTS. The proposed terms "Fitted High" and "Fitted Low" do not apply to OTS orthoses; rather, these terms refer to prefabricated orthoses that require the expertise of a trained, credentialed practitioner in order to properly fit and dispense. Prefabricated orthoses are not *custom made* for a specific patient, they are *customized* and intimately fit based on an individual patient's measurements. Custom fitted (high and low) prefabricated orthoses require varying degrees of customization and are appropriate only when properly customized by a trained and credentialed individual.

The Certified Orthotic Fitter (COF) credentialed practitioner is qualified to provide professional service to patients in need of custom fitted prefabricated devices. Secondarily, the BOC's Certified Orthotic Fitters (COFs) have been determined by National Commission for Certifying Agencies (NCCA) standards to be independent practitioners specializing in the dispensing of prefabricated custom fitted devices. Custom Fitted orthotic services require the COF to assess the patient's condition, determine the appropriateness of the prescription and custom fit prefabricated device.

The BOC has an overriding belief that OTS orthoses should be exempt from the competitive bidding program completely. The minimal savings that might be gained cannot offset the administrative burdens associated with the inclusion of OTS orthoses in the competitive bidding program.

The Medicare Modernization Act of 2003 (MMA), granted CMS the authority to exempt certain items from a Medicare competitive bidding program that were not likely to result in significant savings. We urge CMS to categorically exempt all OTS orthotics from the Medicare competitive bidding program on the basis that inclusion of OTS orthotics in a competitive bidding program will not produce significant savings to the Medicare program.

Actual data from the competitive bidding demonstration related to certain orthotics provides support for this position. For the 23-month period during which competitive bidding for certain orthotics was tested in San Antonio, TX, the Medicare program saved a total of $89,462, or less than $45,000 per year. CMS determined through its proposed scoring methodology that San Antonio is one of the ten largest MSAs with the highest potential for DMEPOS savings. We believe that other MSAs would likely yield even less savings than the original San Antonio demonstration. Statistics such as these lend little support to the use of competitive bidding in the provision of OTS orthotics.

Additionally, Section 1847(a)(1)(B)(ii) of the Social Security Act gives CMS the authority to phase-in competitive bidding "first among the highest cost and highest volume of items or those items that the Secretary determines have the largest savings potential." OTS orthoses are not high-cost or high-volume items nor do OTS orthoses have the largest potential for savings based on what was learned in the San Antonio demonstration.

The BOC does, however, support the use of quality standards and accreditation as a requirement for the provision of all DMEPOS. We maintain it is only through these avenues that CMS can ensure that Medicare beneficiaries receive the best possible care from highly qualified suppliers, while at the same time protect the Program by limiting unnecessary expenditures for OTS orthoses. To that end, we believe that CMS' focus should be aimed at designing, implementing and enforcing effective quality standards and mandatory accreditation requirements.

Privileging

In Dr. Fedder's letter, he expresses strong opposition to the proposed process for privileging non-credentialed or non-licensed professional staff. While we acknowledge the basis for Dr. Fedder's concerns, the BOC understands that allowing qualified, credentialed suppliers the authority to "privilege" or authorize an employee to perform certain functions is critical to ensuring cost-effective access to quality prosthetic and orthotic care. The process of privileging

entails documenting the qualifications of an individual to perform certain functions while under the supervision of an orthotist, and is an accepted documentation methodology in the majority of healthcare accreditation programs. The practice of granting privileges to healthcare paraprofessionals to allow for them to perform certain services under the supervision of a credentialed professional is a common practice in healthcare delivery, and is an avenue that the BOC supports in the provision of orthotics and prosthetics care.

Again, we appreciate this opportunity to expand upon and clarify the issues Dr. Fedder previously addressed. If we can provider any further information, please do not hesitate to contact us at (512) 965-8968 or the BOC office at the number listed above.

Respectfully Submitted,

Kay L. Zehms, BOCO, LO
Chairman of the Board
Board for Orthotist/Prosthetist Certification (BOC)

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June 30, 2006

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

RE: Comments on Proposed Rule CMS-1270-P

Dear Dr. McClellan:

We are writing on behalf of the Board for Orthotist/Prosthetist Certification (BOC) in order to expand upon and clarify the points made by Donald O. Fedder in his letter to you dated June 13, 2006, regarding the proposed Competitive Bidding Rule. We appreciate this ongoing opportunity to dialogue with CMS and to provide comment regarding the proposed rule.

Off-the-Shelf (OTS) Orthoses

In Dr. Fedder's letter, he discussed the provision of certain off-the-shelf (OTS) devices in relation to the services of Certified Orthotic Fitters (COF) and Certified Mastectomy Fitters (CMF). While the BOC generally stands by the points outlined within the letter, we would like to clarify certain terms and issues addressed by Dr. Fedder.

In keeping with the language in the proposed rule, the term off-the-shelf (OTS) should be used to describe only those items that are ready-made and may be provided to a patient with minimal or no adjustment or customization for appropriate use. Such items may be literally taken from the box and provided to the patient "as is", and require no expertise for fitting or dispensing. While all OTS orthoses are "prefabricated", not all prefabricated orthoses are OTS. The proposed terms "Fitted High" and "Fitted Low" do not apply to OTS orthoses; rather, these terms refer to prefabricated orthoses that require the expertise of a trained, credentialed practitioner in order to properly fit and dispense. Prefabricated orthoses are not *custom made* for a specific patient, they are *customized* and intimately fit based on an individual patient's measurements. Custom fitted (high and low) prefabricated orthoses require varying degrees of customization and are appropriate only when properly customized by a trained and credentialed individual.

The Certified Orthotic Fitter (COF) credentialed practitioner is qualified to provide professional service to patients in need of custom fitted prefabricated devices. Secondarily, the BOC's Certified Orthotic Fitters (COFs) have been determined by National Commission for Certifying Agencies (NCCA) standards to be independent practitioners specializing in the dispensing of prefabricated custom fitted devices. Custom Fitted orthotic services require the COF to assess the patient's condition, determine the appropriateness of the prescription and custom fit prefabricated device.

The BOC has an overriding belief that OTS orthoses should be exempt from the competitive bidding program completely. The minimal savings that might be gained cannot offset the administrative burdens associated with the inclusion of OTS orthoses in the competitive bidding program.

The Medicare Modernization Act of 2003 (MMA), granted CMS the authority to exempt certain items from a Medicare competitive bidding program that were not likely to result in significant savings. We urge CMS to categorically exempt all OTS orthotics from the Medicare competitive bidding program on the basis that inclusion of OTS orthotics in a competitive bidding program will not produce significant savings to the Medicare program.

Actual data from the competitive bidding demonstration related to certain orthotics provides support for this position. For the 23-month period during which competitive bidding for certain orthotics was tested in San Antonio, TX, the Medicare program saved a total of $89,462, or less than $45,000 per year. CMS determined through its proposed scoring methodology that San Antonio is one of the ten largest MSAs with the highest potential for DMEPOS savings. We believe that other MSAs would likely yield even less savings than the original San Antonio demonstration. Statistics such as these lend little support to the use of competitive bidding in the provision of OTS orthotics.

Additionally, Section 1847(a)(1)(B)(ii) of the Social Security Act gives CMS the authority to phase-in competitive bidding "first among the highest cost and highest volume of items or those items that the Secretary determines have the largest savings potential." OTS orthoses are not high-cost or high-volume items nor do OTS orthoses have the largest potential for savings based on what was learned in the San Antonio demonstration.

The BOC does, however, support the use of quality standards and accreditation as a requirement for the provision of all DMEPOS. We maintain it is only through these avenues that CMS can ensure that Medicare beneficiaries receive the best possible care from highly qualified suppliers, while at the same time protect the Program by limiting unnecessary expenditures for OTS orthoses. To that end, we believe that CMS' focus should be aimed at designing, implementing and enforcing effective quality standards and mandatory accreditation requirements.

Privileging

In Dr. Fedder's letter, he expresses strong opposition to the proposed process for privileging non-credentialed or non-licensed professional staff. While we acknowledge the basis for Dr. Fedder's concerns, the BOC understands that allowing qualified, credentialed suppliers the authority to "privilege" or authorize an employee to perform certain functions is critical to ensuring cost-effective access to quality prosthetic and orthotic care. The process of privileging

entails documenting the qualifications of an individual to perform certain functions while under the supervision of an orthotist, and is an accepted documentation methodology in the majority of healthcare accreditation programs. The practice of granting privileges to healthcare paraprofessionals to allow for them to perform certain services under the supervision of a credentialed professional is a common practice in healthcare delivery, and is an avenue that the BOC supports in the provision of orthotics and prosthetics care.

Again, we appreciate this opportunity to expand upon and clarify the issues Dr. Fedder previously addressed. If we can provider any further information, please do not hesitate to contact us at (512) 965-8968 or the BOC office at the number listed above.

Respectfully Submitted,

Kay L. Zehms, BOCO, LO
Chairman of the Board
Board for Orthotist/Prosthetist Certification (BOC)

Submitter : **Dr. John Coster** **Date: 06/30/2006**

Organization : **National Association of Chain Drug Stores**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-1087-Attach-1.DOC

CMS-1270-P-1087-Attach-2.PDF

#1087

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

June 30, 2006

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

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

To Whom It May Concern:

The National Association of Chain Drug Stores (NACDS) is providing our comments on the proposed Medicare competitive bidding program for DME, the establishment of new quality standards for DME suppliers, and the requirement that suppliers be accredited by CMS-approved accrediting organizations in order to obtain and maintain a Medicare DME billing number.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

NACDS represents about 200 companies that operate approximately 35,000 community retail pharmacies in the United States. However, there are more than 53,000 community retail pharmacy sites that provide diabetic supplies and services to Medicare beneficiaries of one form or another. Our members are the primary providers of prescription drugs and pharmacy services to Medicare beneficiaries in the United States. They also provide various types of durable medical equipment to Medicare beneficiaries, especially items used by individuals with diabetes that self monitor their blood glucose levels.

General Comments on Competitive Bidding Program

Based on available data, we estimate that over 7 million current Medicare beneficiaries have diabetes, and this number likely will continue to grow. It is important that CMS promote policies that help these beneficiaries better manage their overall condition through lifestyle changes and appropriate monitoring of blood glucose levels. Regular self-monitoring of blood glucose levels and appropriate changes in treatment by individuals and health care providers based on the results can help to improve these levels and lessen the risk of other serious and costly medical complications.

We share the agency's goal that Medicare beneficiaries continue to appropriately and regularly monitor their blood glucose levels. In this regard, we wanted to provide our views on how a competitive bidding program might affect this goal, especially given the potential for subsequent limitations on the scope of supplies available to diabetics and access to these products.

(703) 549-3001
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www.nacds.org

Diabetic Testing Supplies are Widely Available

Medicare beneficiaries primarily purchase diabetic testing supplies through an extensive network of more than 56,000 community retail pharmacies. Thus, unlike other DME products that may be sold through a limited number of specialty suppliers, Medicare beneficiaries currently have broad access to these products in the market and they take advantage of this accessibility. Few, if any, other DME covered items or services are distributed by as many suppliers in the market as are blood glucose monitoring supplies. A competitive bidding program would likely reduce access to these products in the market, as well as limit the opportunity for beneficiaries to receive professional advice in choosing a monitor and proper education to assure its appropriate use.

CMS Has Limited Competitive Bidding (CB) Experience with Diabetic Testing Supplies

As you know, CMS' prior DME competitive bidding demonstrations did not include diabetic testing supplies. CMS has acknowledged that diabetic supplies were excluded from previous demonstrations because of concerns about how to maintain appropriate patient access to specific brands of test strips. Due to the lack of competitive bidding experience with these items, CMS does not have qualitative or quantitative evidence to indicate whether these products can be provided through such a system without a negative impact on quality of care or creating other risks for Medicare beneficiaries with diabetes.

Medicare Beneficiaries Should Have Access to a Full Range of Diabetic Testing Products

Each Medicare beneficiary is different in terms of his/her ability to use equipment and supplies to monitor blood glucose levels. As a result, Medicare beneficiaries need to have access to a full range of diabetic testing products (i.e., monitors and strips) to assure that they can get a meter that meets their individual needs. For example, newer meters often have features that make them easier to use than older models. Some meters allow users to get blood from places other than their fingertips (Alternative Site Testing). Some have automatic timing, error codes and signals, or barcode readers to help with calibration. Some have a large display screen or spoken instructions for people with visual impairments. Some save readings that can be downloaded to computers in physicians' offices, pharmacies or at home to assist in observation of results.

Retail pharmacies typically stock a wide range of monitors and assist in the selection of the most appropriate monitor for each individual. The least expensive monitor might be right for some beneficiaries, but others may require more advanced technology. A monitor's particular features may be an extremely important distinguishing factor in successful glucose monitoring, encouraging greater compliance and allowing Medicare beneficiaries to manage their diabetes as effectively as possible.

Medicare Beneficiaries Rely on Pharmacists and Pharmacies

The relationships that Medicare beneficiaries have with pharmacists and pharmacies are an important source of information, education and monitoring for Medicare beneficiaries with diabetes. Disruption of these relationships, especially for individuals who are generally resistant to or slow to accept change, could result in less frequent or less effective monitoring. In our experience, patients with diabetes often rely on a particular pharmacy to obtain a wide range of products and services such as prescription items;

OTC items, such as sugar free cough and cold preparations; diabetic testing supplies; insulin and syringes; and other health care related products. Diabetics generally take more prescriptions than individuals with other chronic conditions, and usually have more co-morbidities. Simply put, community pharmacies are typically a central point of contact for patients with diabetes because these pharmacies carry the full range of products and services that diabetics need. If a particular pharmacy was not included in the CB program, this could create confusion for the Medicare beneficiary, as well as a disruption in continuity of care.

CB Could Disrupt Current "Points of Care"

Given that the majority of diabetic test strips are currently sold through retail pharmacies, a competitive bidding model that relies primarily on mail order would create disruption for Medicare beneficiaries that rely on their local pharmacy to obtain their items and services. As noted above, most Medicare beneficiaries use retail pharmacies as their point of care to obtain diabetic testing supplies. Evidence suggests that given a fair choice of obtaining their drugs from a local pharmacy or a mail order pharmacy, beneficiaries will almost always choose their local pharmacy as their source of medications. The same is likely to be true for diabetic testing supplies. Moreover, some concern has been raised that some mail order suppliers either automatically send additional strips to patients or initiate contact with beneficiaries on a regular basis to secure verbal authorization to send additional strips. This practice raises concerns that beneficiaries are oversupplied with test strips by mail order, which can result in higher costs and waste.

CB Creates Disconnect with Medicare's New Part D Prescription Drug Benefit

Medicare Part D covers prescription medications to treat diabetes, as well as insulin, syringes, and supplies relating to the injection of insulin. Medicare Part B will continue to cover diabetic testing supplies. Eventually, Medicare may decide to cover all diabetes testing and treatment items in one part of the program. Until that time, the fact that beneficiaries will have to navigate the different deductible and cost sharing structures of Part D and Part B will be difficult enough. If they also have to use different pharmacies to obtain all these items, that will add to the confusion and inconvenience.

Under Part D, PDPs and MA-PDs can designate that certain pharmacies in their networks are "preferred" while others are "non-preferred". Preferred pharmacies are able to offer lower cost sharing than non-preferred pharmacies. This distinction, combined with a competitive bidding program for diabetic supplies, could create significant confusion for beneficiaries. For example, if a beneficiary's regular pharmacy turns out to be a preferred pharmacy under the Part D PDP plan that he selected, but the same preferred pharmacy is not a winning bidder under the Part B CB program, the beneficiary has to use a different pharmacy to obtain testing supplies.

The beneficiary may be willing to use the pharmacy that is the CB winner or his Part D prescription coverage, except that it may be a non-preferred Part D pharmacy, and the beneficiary will have to pay a higher cost sharing for his prescriptions. Thus, he is forced to use two pharmacies. In another scenario, the pharmacy that the beneficiary is currently using may neither be a preferred pharmacy under the Part D PDP plan chosen by the beneficiary, nor a competitive bidding winner. In this case, the beneficiary could be forced to use two different pharmacies than the one currently being used. CMS should consider the implications of the new Part D program on the competitive bidding program.

We are also concerned that CB will reduce the effectiveness of medication therapy management (MTM) programs that Part D plans are required to offer to Medicare beneficiaries that have certain chronic conditions, such as diabetes. We understand that many Part D plans are focusing their MTM programs on diabetes management, given its prevalence among the Medicare population as well as its overall treatment costs to the Medicare program. Part D plans and their network pharmacies will be in the best position to make MTM programs work for Medicare beneficiaries if a single pharmacy provider is able to provide a wide range of products and services required by the beneficiary – including prescription drugs, insulin, diabetic testing supplies, and OTCs – while also monitoring the care and its outcomes.

CB Savings Are Questionable

Although a significant expenditure item for Medicare Part B, it is unclear what level of potential Medicare savings is possible through competitive acquisition of glucose monitors and related supplies. If Medicare is unlikely to achieve savings for glucose monitors and supplies, CMS has the discretion to delay or exclude application of competitive acquisition to this area. There is also a potential administrative burden for CMS in implementing competitive acquisition for glucose monitors and supplies in light of significant differences between this area and other DME products. Moreover, the fact that CMS can apply CB prices from one area of the country to another area of the country could be problematic, given that retail prices often times reflect the costs of doing business in a particular local area. Prices determined in one area of the country may not reflect the costs of doing business in another area of the country.

Chain Pharmacy Studying Issues Relating to CB for Diabetic Testing Supplies

NACDS asked Health Policy R&D[1] to conduct an examination of potential issues relating to the competitive acquisition of diabetic products and associated services under Medicare Part B. HPR&D examined Medicare policies, federal studies and clinical literature and also conducted a series of initial interviews with pharmacists, diabetes educators and other professionals from the pharmacy and manufacturing sectors. We have included a copy of that final study with this report, and ask that it be included in the official record of this rulemaking.

Comments on Specific Sections of the Proposed Rule

Payment Basis

NACDS strongly urges that any CB program for diabetic testing supplies include a requirement that a minimum number of community-based suppliers be included, and that these suppliers be geographically dispersed within the MSA to provide convenient access for Medicare beneficiaries to diabetic testing supplies. Under Medicare Part D, plans have to meet TRICARE pharmacy access standards, which specify minimum requirements for plans relative to access to retail pharmacies. A similar requirement should be included for this CB program. Many Medicare beneficiaries have limited mobility and cannot travel long distances to obtain their supplies. Many may also not want to obtain their supplies through a mail order vendor.

[1] A policy research firm in Washington, D.C. affiliated with the law firm Powell Goldstein LLP.

NACDS strongly opposes the application of bid prices in one competitively-bid area to set payment rates for these items in other areas that were not competitively-bid areas. CMS indicates that it may use this authority after January 1, 2009. Prices bid in one area represent the cost structure of suppliers in that area. These cost structures are reflected in the bids. Suppliers in Kansas are likely to have a much lower cost structure than those in Manhattan. Therefore, applying competitive bid prices in one area based on bids submitted in another area would be inappropriate.

We believe that CMS should allow for public comment on any methodology they might use to apply prices in one area to another area, similar to that which would have been used under the "inherent reasonableness" regulation.

NACDS is concerned with the requirement that suppliers be accredited by licensed accrediting organizations to obtain and use a Medicare billing number. We feel this would compromise the ability of retail pharmacies to provide Part B drugs to Medicare beneficiaries. Some pharmacies may decide not to participate in the competitive bidding program for DME, but will want to continue to supply Part B drugs. Pharmacies that elect to provide Part B drugs but not DME should not be precluded from doing so because of the accreditation requirements to become a DME supplier.

CMS proposes only to allow CPI updates for the two subsequent years after the three-year competitive bid contract is awarded. CMS should make accommodations for potential changes in the market relative to pricing updates of competitive bidding payment amounts. Market conditions and changes can occur during that time – such as industry consolidation – which can affect the market prices of these DME items to suppliers. Retail pharmacies have no control over their costs of goods, so CMS needs to permit a process to allow providers to be paid more than the CPI update if there are significant changes in market conditions.

Competitive Bidding Areas

NACDS supports the exclusion of diabetic testing supplies from the CB program. These items were not tested by CMS in the demonstration programs. Thus, little evidence is available to guide CMS on knowing how Medicare beneficiaries will react to a program that limits their range of product choices and provider choices for a range of products that are currently widely available.

Moreover, it makes little sense from a patient care perspective to include these items in a CB program in 10 of the largest MSAs when CMS has no credible information to determine the impact of such a program in even a small number of beneficiaries. At most, CB should be tested for these diabetic supplies in only one CB area to reduce the potential negative health impact on Medicare beneficiaries of the disruption of their traditional supply of these items. CMS should study the impact of CB in one region on "customary care access routes" used by beneficiaries, as well as whether there is any increase in hospital or nursing home admissions, or emergency room visits, as a result of potential loss of diabetic control among Medicare beneficiaries. CMS has the authority to phase in implementation of products under the program, and we suggest that this course be taken with regard to diabetic testing supplies.

NACDS opposes the establishment of a national mail order competitive bidding program for diabetic testing supplies after 2009, and the premise under which CMS advocates for the establishment of such

program. We strongly oppose any requirement that forces or coerces people with diabetes to obtain their supplies from one particular type of outlet, such as a mail order program.

More than two-thirds of Medicare beneficiaries with diabetes obtain their testing supplies from community retail pharmacies. Asking millions of Medicare beneficiaries to suddenly shift their source of supply of these products could disrupt their testing and their overall quality of care. Beneficiaries traditionally obtain all their diabetic management products from a single pharmacy – including their prescription drugs and testing supplies. This "integration of care" – long promoted by Congressional and CMS policymakers – will be seriously disrupted if Medicare beneficiaries suddenly have to find the means to locate all the necessary supplies that they used to obtain from one location.

These individuals may want to continue to use a retail pharmacy to obtain their testing supplies, even if their traditional pharmacy has not been selected as a contract supplier, because they do not trust mail order delivery. But, these individuals may therefore have to travel to two different pharmacy locations – a pharmacy location for their prescription drugs and a pharmacy supplier location for their testing supplies – where before they just went to the one local retail pharmacy to obtain their medications and testing supplies. This is fragmentation of care and is a major inconvenience for the Medicare beneficiary.

At the May 22, 2006 meeting of the PAOC, CMS conceded that face-to-face contact between beneficiaries may be required and that a mail order program may require a tailored approach based on the type of DMEPOS being supplied. For example, the Proposed Rule differentiates between original procurement and replacement of blood glucose monitoring systems and related supplies. CMS gives too little importance to the importance of follow up to diabetes care monitoring, especially in the elderly population, and believes that after an initial visit, that beneficiaries can receive all their replacement diabetic testing supplies through the mail.

Often times, face to face follow up monitoring is as important as the initial education about the product for several reasons. The beneficiary may have additional questions of the health care provider regarding how to use their monitor, or questions about the overall health care status. By limiting interactions with health care providers, especially pharmacists, CMS is creating a program that could result in negative health outcomes and increased spending on medical care services. We recommend that any proposal by CMS to implement a mail order program be subject to a separate rulemaking and that, under any circumstances, this program be voluntary for beneficiaries. Medicare beneficiaries rely on their retail pharmacists for ongoing advice and counseling on management of their diabetes condition.

CMS also assumes that mail order delivery of testing supplies is more cost effective than delivery by retail pharmacies. The cost per unit through mail order may be lower, but it doesn't mean that the beneficiary is testing any more frequently, or the cost per testing strip used is less. Many mail order firms have automatic renewal of testing supplies whether or not the beneficiary needs them. This can result in waste. If the beneficiary is being monitored by the retail pharmacist however, the pharmacist can help promote more frequent testing and make sure the beneficiary is testing appropriately.

Finally, CMS makes no provision for Medicare beneficiaries to obtain diabetic testing supplies from retail-based suppliers in cases that the mail order facility does not deliver products on time or the products arrive damaged in the mail. Many Medicare beneficiaries may also be uncomfortable

obtaining their supplies from a mail order entity, leaving them with little or no choice of supplier if a minimum number of retail outlets are not included in the program.

We also believe that a national competitive bidding program for diabetic testing supplies is not only inconsistent but contrary to the work being done on Part D by CMS to improve quality of care for beneficiaries with diabetes and other chronic illnesses under the Medicare Part D medication therapy management programs. It is inconsistent policy to promote integrated care in Part D but on the other hand force beneficiaries to use mail order in Part B. It is inconsistent to launch a "Pharmacy Quality Alliance" in Part D, and develop quality measures for pharmacies and pharmacists, but limit the ability of pharmacists to interact with beneficiaries that have diabetes by reducing the frequency with which they visit pharmacies. We urge the CMS staff that are developing this competitive bidding rule to discuss the impact of their proposed program with the staff that operate the Part D program at CMS.

We also ask CMS to provide justification that they have the statutory authority to establish national competitive bidding areas. We believe it was Congressional intent to establish these areas by specific MSAs. We believe that CMS could overstep its authority by creating national competitive bidding regions and potentially requiring that all diabetic testing supplies be obtained through mail order.

Criteria for Item Selection

CMS must recognize that specific test strips are used in specific monitors and that these strips may not be used in other monitors. We would agree that, for the sake of beneficiaries' health, CMS group items together that would logically be used together, such as grouping a certain test strip with its accompanying monitor. However, CMS should recognize that the diversity of the diabetic testing products that are available on the market reflects the diversity in the testing needs of the Medicare population.

CMS should also consider the number of suppliers that are providing an item as it determines which items to include in the CB program. A market, in which few suppliers have significant high charges for a particular item, is much different than a market in which most or the majority of suppliers have small charges for a particular item. The existence of more suppliers in the market might indicate that a higher degree of competition exists in that market, and that competitive bidding might work for this product given the wide number of suppliers. However, it might indicate that Medicare beneficiaries see "convenience" as the most important aspect of being able to obtain that product. It should raise concerns for CMS as to whether that product is truly a good candidate given that restrictions will result from competitive bidding.

We acknowledge that diabetic testing supplies is a very high category of spending under the DMEPOS benefit. However, recent increases in charges for these items may not result solely from high prices for these items. They may result from an increase in use. Given the increasing prevalence of diabetes in the Medicare population, the growth in charges for diabetic testing supplies may reflect a growth in use, not necessarily an increase in unit cost or margin.

Because the market for diabetic testing supplies is already highly competitive, CMS may not realize significant if any savings by including these items in the program. In fact, we believe that CMS must consider increased costs due to other medical interventions that will likely be needed as a result of the

fragmentation of care and potential reduced blood glucose testing that could occur as a result of the competitive bidding program. Once these additional costs are factored in, the likely result will be increased costs to the Medicare program, not decreased costs.

We are concerned that CMS has developed a bidding system that does not recognize the diversity within the full range of items in each product group, particularly those related to blood glucose monitoring systems. Blood glucose monitoring systems and related supplies are not commodity items – there is a significant amount of innovation and differentiation among these systems that is related to quality of care factors and patient need. We urge CMS not to overlook the importance of encouraging diversity of product availability within a product group.

Submission of Bids under Competitive Bidding Program

CMS' statement that "providers that are not awarded contracts must use a contract supplier to furnish these items to the Medicare beneficiaries to whom they provide services" is unclear. Does this mean that pharmacies that are not contract suppliers for a particular CB item in a CB region can still supply the item to a beneficiary as long as they obtain the item from a CB supplier?

CMS indicates that it will conduct bidding for items that are grouped into "product categories", and that potential bidders must submit bids for items in each product category. We support this concept of "product categories" bidding, given that in the diabetic testing supply area, there is a need to match glucose monitors and the accompanying strips. We suggest that in this area, CMS detail specific monitors and strips for which competitive bids would be sought. Alternatively, CMS might consider dividing the monitors' HCPCS code into monitors that are "functionally equivalent" so that bidding could be done on items that have similar features. This would assure that physicians and beneficiaries would have a wide range of currently-available monitors from which to choose, but that the bid reflected prices for the different types of monitors that are available.

Although CMS recognizes in the preamble to the proposed regulation, "the importance of the relationship between a DMEPOS suppliers and the Medicare beneficiary", it goes on to say that "the use of product categories will facilitate the transition for those beneficiaries who have to change suppliers." These are contradictory statements, and could illustrate a lack of understanding by CMS of the relationship between a beneficiary and a pharmacist relating to the provision of diabetes care. Disruption of the source of health care products and services could be very problematic for many Medicare beneficiaries, who are loathe to make changes in suppliers of their diabetic testing supplies. CMS has provided no evidence in the proposed regulation to demonstrate that such changes will not have a negative impact on the quality of care delivered to Medicare beneficiaries with diabetes. In fact,

We urge CMS to determine whether inclusion of diabetic testing items in the CB program would in fact result in savings to the entire Medicare program, not just the DME portion of the Medicare program. It is very likely that the disruption in testing patterns and sources of supply will result in situations where Medicare beneficiaries lose tight control of their blood glucose monitoring and require the use of other Medicare-covered health care services. The use of these services would obviously reduce any potential savings that might be generated from the CB program. We also urge that CB not be conducted for these diabetic testing items until CMS has tested their inclusion on one CB region, and a determination is

made as to whether savings result to the Medicare program rather than simply to the competitive bidding portion of the Medicare program.

We also think that because beneficiaries generally obtain all their diabetic management supplies (including prescription medications) from one provider – such as retail pharmacies – CMS should accept as many bids as possible, not as few bids as possible, in this category. As we have noted, beneficiaries have convenient access to these testing products now. Sharply reducing access to these products will mean that beneficiaries may have to travel long distances or use mail order, neither of which may be the best method for the beneficiary to obtain these products.

Finally, competition requires that a sufficient number of suppliers be available to bid in the marketplace. CMS must be careful that this competitive bidding approach does not result in the elimination of suppliers in the marketplace. This would result in fewer suppliers and less competition, resulting in increased prices over time.

Conditions for Awarding Contracts

We agree that Medicare suppliers should meet minimum standards for quality and customer service. However, we believe retail pharmacies that supply items of DME to Medicare should be exempted from additional accreditation requirements because pharmacies are licensed by state boards of pharmacy and already meet high standards for professionalism and customer service.

At a minimum, pharmacies that want to serve as Medicare DME suppliers should be given a grace period that would allow all state boards to incorporate any needed standards into their existing pharmacy practice acts that would allow these boards to act as independent accrediting organizations for pharmacy DME suppliers. We would then urge that any pharmacy that is in good standing with the state board of pharmacy be deemed accredited for the purposes of being able to bid under the CB program or participate as a Medicare DME supplier. Without such a process for retail pharmacies, many may forego participation in the program because of the expense and time in being accredited.

We ask that CMS clarify whether the program will require bidders to bid on specific individual products or groups of products within each product category defined. With respect to the pivotal bid, we ask whether CMS will group bids from similar classes of trade to determine a pivotal bid for that class of trade. For example, will CMS group all the mail order bids for diabetic supplies as well as group all the bids from retail suppliers. Lower class-of-trade pricing may be available to mail order suppliers that may not be available to retail-based providers. CMS risks a shortage of retail-based providers eligible to participate if all the bids from these two supplier classes are grouped together.

CMS would not award a bid to any entity unless the amounts being paid are less than the total amounts that would have been paid under the current fee schedule approach. Does this requirement extend to only the first year of the three year cycle or all three years of the cycle? Also, it is unrealistic to expect a provider to incur the additional costs to meet all the additional accreditation requirements outlined in the regulation, as well as the costs of completing all the paperwork to participate in this program, and still bid below the current fee schedule payment amounts. Moreover, there is no mechanism mentioned for CMS to distinguish among the bids based on the quality of the products being provided.

With respect to multiple contractors, the proposed rule indicates that "we will have multiple contract suppliers in each competitive bidding area for each product category if at least two suppliers meet all the requirements for participation..." Does this mean that CMS will only award the contract to two suppliers in any area if two suppliers can meet expected demand, or at a minimum will award contracts to at least two suppliers? What if both or all of the suppliers that are at or below the pivotal bid are mail order suppliers, or just large retail suppliers, not small or regional suppliers?

Determining Single Payment Amounts for Individual Items

CMS proposes to use a methodology – establishing the single payment amount – that is not based on past experience (e.g., a demonstration project such as those conducted in Polk County, Florida and in San Antonio, Texas). To set the single payment amount, CMS determines the "pivotal bid" and then sets the single payment amount as the "median" of these bids. We are concerned that use of the median bid would be unfair to suppliers that bid higher than the median, but are now required to sell their products at the lower median bid. If a supplier is among the upper half of bidders, and the median price is selected, that supplier will have to supply the product at a price lower than its bid. That process calls into question whether "successful" bidders will be likely to cooperate and sell product at that lower price. If "successful" bidders are not willing to supply products at the lower price, then the available supply of a particular item may not reflect the actual point that is supposed to be captured in setting the pivotal bid.

CMS does not indicate how it intends to compensate for the fact that mail order suppliers may receive preferential "class of trade" pricing, which would potentially allow these suppliers to drive very low bids. Including these mail order price bids along with bids for retail-based suppliers might leave retail suppliers with no choice but not to bid or provide these products at significant losses. CMS should consider creating separate "pivotal bids" for mail order suppliers and retail suppliers so that more retail suppliers can be included in the competitive bidding program. By separating the two classes of trade, you possibly increase the number of winning bidders as well as increase Medicare beneficiaries' access to retail-based DME suppliers.

Terms of Contract

The proposed rule is not clear as to whether CMS will be awarding contracts for the supplier to provide a specific item or items within a particular HCPCS code or for the entire code? If it is for the entire code, this could mean that the product being supplied is the lowest cost item in that code. We suggest that bids be submitted for individual products within that code so that the suppliers know exactly which products (or related products) they are bidding for and that the nature of the bid reflects the cost to the supplier of providing that specific item to the Medicare beneficiary.

There are frequent changes in ownership in pharmacy providers due to mergers and acquisitions. For this reason, we encourage CMS to provide sufficient time for acquiring pharmacies that may not have been winning bidders to meet the various standards outlined in this section as well as any final quality standards that are issued. It is possible that a non-accredited participating chain of pharmacies may be acquiring a chain that was a competitive bid supplier in a particular CB region. CMS should allow the acquiring chain to determine whether it wants to continue in the program after the merger and

acquisition, and provide sufficient time to meet any final accreditation requirements if the acquiring chain was not accredited at the time of purchase.

The *Terms of Contract* section requires that the "items furnished under a competitive bidding program must be serviced by a contract supplier for that competitive bidding program..." CMS must recognize that diabetic testing items furnished by suppliers, including pharmacies, such as glucose monitors, cannot in theory be "serviced" by a supplier. Pharmacies can help the beneficiary understand how to use the monitor, and help the beneficiary with small issues or problems, but major servicing of the monitor, and manufacturing issues relating to the monitor are the responsibility of the monitor's manufacturer. Pharmacies can help the beneficiary return the monitor to the manufacturer, but cannot be expected to "service" the item.

Suppliers that bid to supply an item or group of items are required only to supply the item in the HCPCS code that they stock in their stores, and for which they submit a bid. Given the wide range of products that are available, it is not realistic to expect that a beneficiary can request any item within that HCPCS code if the supplier's bid is based on a certain item.

Opportunity for Participation by Small Suppliers

NACDS represents more than 200 companies that operate 35,000 community retail pharmacies. While some of our members are large chain pharmacies, most of our members are smaller or regional chain operators that currently sell blood glucose monitoring supplies to Medicare beneficiaries. Small businesses have been afforded the opportunity to compete in networks (see section below) under this proposed CB program, however it seems unrealistic that these small suppliers will have the time and resources to establish such networks. We understand that such an opportunity was afforded small suppliers under the competitive bidding demonstrations, but no such networks were formed.

We are concerned that small suppliers may not have the chance to win awards in CB areas for certain frequently-dispensed items from these locations. For example, given that CMS has already indicated an interest in awarding only those number of contracts necessary in a CB region, but no less than two, the ability of small suppliers to potentially win bids is sharply reduced. This is especially the case in the diabetic testing supplies market, where CMS has indicated an interest in significantly expanding the use of mail order as the primary distribution method. If CMS determined that a national or regional mail order contractor, as well as another large retail-based supplier, can meet the requirements of providing adequate a ccess to a particular item, then the chance of small suppliers winning the bids is greatly diminished. Small suppliers may also not have the financial resources to meet all the requirements regarding bid submission or be able to obtain to afford accreditation.

For that reason, we encourage CMS to include a minimum number of small suppliers in each CB region for e ach C B it em inc luded in t hat r egion. C learly, it w as C ongress' int ent t o he lp s mall s uppliers participate in the program, and retain or expand their Medicare DME business. At the same time, we urge that CMS establish a technical assistance program to assist small providers to engage in the competitive bidding processes, including providing a forum for the establishment of networks

In addition, in determining whether a "small supplier" has the capability of serving the whole CB area, CMS should consider that a small supplier is likely to be called on exclusively by beneficiaries that live

in the proximity of the supplier. Thus, when considering the capability of a small supplier to meet this standard, it should be in relation to the overall sales of this supplier for the CB product in question relative to total sales for that product in the whole CB area. Smaller suppliers are often perceived by beneficiaries as providing better, more personal service. For the program's success, it behooves CMS to do all it can to include smaller suppliers in the CB program in CB regions, especially retail pharmacies.

Finally, while CMS indicates that it conducted "focus groups" with small suppliers, we do not know of any of our smaller supplier member companies that were contacted or participated in these focus groups. That is unfortunate, given that smaller pharmacy suppliers are a major source of diabetic testing supplies for the Medicare population.

Opportunity for Networks

NACDS supports the ability of providers to form networks in order to submit bids. This ability will be especially important for smaller suppliers that would gain efficiencies and economies of scale by pooling their purchasing power. We are concerned, however, that no suppliers submitted bids as networks under the demonstration programs. Were CMS' requirements to form a network so onerous that they in effect prohibited the formation of these networks? We ask CMS to elaborate further in the final regulation as to why they think smaller suppliers didn't form networks.

When considering the 20 percent rule for networks, it raises an interesting question of whether networks are placed at a competitive disadvantage through a limitation on the percentage of marketshare that the network can have in any CB area. For example, if a large supplier – whether located in the CB area, or a mail order provider – already has more than 20 percent of the market, how will CMS address whether or how those providers would be allowed to participate in that area? It seems to create an "un-level" playing field by allowing single entities with more than 20 percent marketshare to compete when there may be no similar restrictions on providers that already have more than such percentage marketshare.

Education and Outreach

We agree with CMS that the development of this program will require a significant amount of outreach and education to providers and beneficiaries. As CMS has learned from the launch of Medicare Part D, reaching Medicare beneficiaries can be challenging, especially low-income Medicare beneficiaries. In addition, relying on the internet to inform beneficiaries about changes in Medicare may only reach a small percentage of all Medicare beneficiaries. It is our belief that many beneficiaries will not know about the implications of the CB program until such time as they attempt to obtain a particular item that was included in a CB program in their area. That is, they will go to the pharmacy and may find that the pharmacy is no longer able to supply them the product as they have in the past. It will then be up to the pharmacist to explain the CB program, and help direct them to the place (or method) that is the easiest for the beneficiary to obtain their supplies.

In addition to any theoretical savings that might result from a CB program, beneficiaries should also know that the products that they receive might be different than the ones that they are currently using, and of different quality. There is simply no way for CMS to guarantee that this program will result in contracted suppliers providing the same nature or quality of items that a beneficiary is currently using.

The bottom line is that any educational materials should prepare the beneficiary for these important facts, not just the "benefits" of competitive bidding.

The other fact is that many Medicare beneficiaries are not physically able to come to a pharmacy and pick up their prescription drugs or other supplies. They often send a relative or caregiver, who may expect that they can simply pick up the items. The caregiver or relative may find that they have to take the prescription for the DME item to another supplier – who may or may not be close to the beneficiary's traditional supplier – creating inconvenience for the caregiver or relative. Given that many Medicare beneficiaries that use DME items are very sick, infirmed, or have cognitive impairments, CMS has a significant challenge in educating beneficiaries and their caregivers both about the program and what they have to do to obtain the item.

Many of these DME items require physician prescriptions, so physicians – who may be used to initially calling-in a prescription for these items to a pharmacy supplier and then sending a hard copy – may find that they have to contact multiple suppliers until they find one that is under contract in that CB area to provide the item. This creates more administrative work for physicians as well.

Physician Authorization/Treating Practitioner

Beneficiaries should have the ability to obtain specific products within HCPCS codes if they are medically necessary as determined by the physician. However, it is not fair that suppliers be required to supply any item within a HCPCS code if their bid was accepted based on a product that they carry in their stock. This is a fundamental problem with the competitive bidding program. Items that may be grouped within a particular code may have a wide variety of functions and features, making it possible that there are a wide range of prices. A supplier may bid based on a price at which he believes he can furnish the product that he stocks. However, if no additional payments would be made for specific, more expensive products that are ordered by physicians, it may result in significant financial losses for the supplier if he is required to supply it at the single bid price.

Not offering an appropriate array of items may create significant, unnecessary barriers to quality care. Presumably, if a physician orders a particular brand, the physician has exercised his or her clinical judgment that the item is the best item for the patient. The Proposed Rule could disrupt physician judgment in the ordering of items of DMEPOS based solely on the availability of that brand from the winning bidder – even though the item is nonetheless a covered item under the Medicare HCPCS system today.

For example, certain blood glucose meters may require a large amount of blood to establish an accurate reading. On the other hand, another meter within the same HCPCS code may require only a drop of blood which, for people with diabetes can make a startling difference in patient compliance. If the winning bidder does not supply the meter requiring only a small amount of blood, then it is entirely possible that the patient who is forced to use the first meter will fall out of compliance with adequate blood glucose monitoring practices. The initial decision a health care provider makes based on an individual patient should not be subverted because of the supplies available under the competitive bidding program.

Quality Standards and Accreditation for Suppliers of DMEPOS

We appreciate the opportunity to provide comments to CMS on the quality standards and accreditation relative to licensed retail pharmacies providing these products. In view of the comprehensive state pharmacy laws and licensure requirements applicable to both pharmacies and pharmacists, we believe that application of the quality standards and accreditation for licensed retail community pharmacy suppliers is not appropriate, nor necessary as a condition of competitive bidding awards to licensed retail community pharmacies. Because community retail pharmacies and pharmacists already comply with comprehensive state pharmacy laws and regulations including inspection in providing services to their patients. Pharmacists are highly educated and must complete professional training programs, pass licensure examinations, and meet continuing education requirements as a condition of practicing as pharmacists.

We ask that the Secretary deem licensed pharmacies carved out of the quality standards and accreditation processes in view of their extensive licensure requirements under state pharmacy practice regulations. However, if that is not feasible, we ask for the following as an alternative: that state Boards of Pharmacy be deemed CMS approved accreditation organizations if the state pharmacy licensure standards incorporate quality standards applicable to licensed pharmacies providing DMEPOS items and services, and that pharmacies licensed in such states be deemed accredited DMEPOS providers. In this regard, as all states pharmacy regulations may not currently include quality standards related to DMEPOS, we further ask that CMS grant licensed pharmacies a grace period sufficient to allow each state's pharmacy regulations to be modified to incorporate standards for DMEPOS.

Licensed community retail pharmacies and pharmacists play a unique and important role in providing health care for Medicare beneficiaries. This includes providing DMEPOS items such as diabetic supplies and other items and services to complement the dispensing of prescription drugs to Medicare beneficiaries. Community pharmacists are the most accessible health care provider for Medicare beneficiaries and many beneficiaries rely on their community pharmacist for health care advice and information. We believe that it is critical for Medicare beneficiaries to continue to have access to their local community pharmacy and pharmacist for their DMEPOS products and services. This is particularly important with implementation of the Part D prescription drug benefit. Medicare beneficiaries receive their prescription drugs from their community pharmacies and receiving their DMEPOS items and services from their community pharmacy provides for access, continuity of care and enhanced patient compliance with their treatment regimen. We are concerned about the potential for disruption and discordance in beneficiaries' care and treatment if they cannot access both prescription drugs and DMEPOS in the same community pharmacy of their choice.

In consideration of these factors, the existing comprehensive laws and regulations with which pharmacies have to comply, the state licensure of pharmacies and pharmacists, and pharmacists' extensive educational training, community pharmacies should not be faced with the same quality standards and accreditation requirements as DME suppliers that are not licensed health care professionals or those that provide more specialized DME products.

We believe that the Secretary has authority under Section 1834(a)(20) of the Social Security Act (Act) to determine appropriate applicability of the quality standards to suppliers of DMEPOS items. Accordingly, we believe that the Secretary has authority to deem items and services provided by state

licensed pharmacies as meeting the quality and accreditation requirements. Section 1834(a)(20)(A) provides that the Secretary shall establish and implement quality standards for suppliers of items and services described in subparagraph (D) as applied by recognized independent accreditation organizations. Further, Section 1834(a)(20)(D) provides that the items and services are "as the Secretary determines appropriate."

Comprehensive State Pharmacy Laws and Regulatory Oversight

Pharmacies and pharmacists in every state and U.S. territory are subject to stringent state laws and regulations that control the scope of pharmacy practice, required licensure and compliance standards. Accordingly, pharmacies and pharmacists providing DME products and services to their patients already meet different comprehensive standards than other non-licensed health care provider suppliers of DMEPOS items.

Pharmacy laws and regulations thoroughly and comprehensively regulate every aspect of the standards of pharmacy practice and the licensure of pharmacists and pharmacies. Before any pharmacy is permitted to operate and provide drugs, devices, services or supplies to patients, the pharmacy must meet rigorous standards of state licensure, including inspections and compliance with standards for pharmacy practice. As such, State Boards of Pharmacy regulate both the provision of products and the providing of professional services by pharmacies and pharmacists.

State laws set the scope of pharmacy practice for pharmacists. Pharmacies and pharmacists are subject to stringent professional practice standards that obviate the need for these additional quality standards. While the language of each state may differ, all states have laws that establish the scope of pharmacy practice including pharmacists' selection of drugs and devices, provision of patient counseling, professional responsibilities and other acts necessary to provide pharmacy patient care services such as consultation with prescribers about a patient's care and treatment.

Pharmacists Education and Training

State pharmacy laws and regulations establish the qualifications, training and experience requirements for pharmacists and pharmacy technicians including licensure, educational degrees, training, experience and continuing education for pharmacists for these individuals to be permitted to provide professional pharmacy services.

Pharmacists are trained to provide patients with counseling on proper use of drugs and medical devices and to provide counseling services. Pharmacists must graduate from an accredited pharmacy school and be licensed in the states where they practice pharmacy. All pharmacists are now required to graduate from a Doctor of Pharmacy degree program consisting of a minimum of 6 years of education with 2 years pre-pharmacy school and 4 years of pharmacy school. The pharmacists' educational program is extensive and includes clinical training directly with patients for advice on their care and training. After graduation from pharmacy school, pharmacists in all states must pass the National Association of Boards of Pharmacy Pharmacist Licensure Exam ("NAPLEX"). In addition, after graduation and passing the national exam, most graduates enter 1 or 2 year residency programs. In total, this represents at least six years of education and training and, in most instances, closer to eight years. All states

require pharmacists to complete continuing education to maintain licensure, and usually this is 30 hours every two years.

Accordingly, today's pharmacist is uniquely qualified to serve as the medication and medical device use expert for advising and counseling Medicare patients and providing advice to other health care providers on the use of these health care products. Pharmacists are ideally situated to provide Medicare patients using non-service items such as diabetic supplies and other cash and carry items with counseling and important information on the proper use of these items. In addition, with the implementation of the Part D drug benefit, the majority of these patients will obtain their prescription drugs for diabetes and other health conditions from their community pharmacy. Such qualifications, education and training clearly differentiate pharmacists from general unlicensed retailers providing DME products, and should supplant application of the additional quality standards and accreditation to community pharmacies providing DME items and services.

Expecting national, regional or small chains – some large chains have 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 may 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.

State Laws Require Pharmacies to Have a Designated Pharmacist for Compliance

State pharmacy laws mandate that each pharmacy have a designated pharmacist who is responsible and accountable for the management and operation of that pharmacy and compliance with the laws and regulations. The state pharmacy laws, depending on the state, identify this pharmacist as the *pharmacist-in-charge (PIC)* or the *pharmacist manager* (hereafter referred to as the PIC). The PIC is responsible for pharmacies and pharmacists maintaining and providing proof of licensure in their pharmacies, and the pharmacy licensure requires a specific address and other information such as telephone number which would be available for beneficiary access.

State Pharmacy Laws Require Pharmacies to Have a Pharmacist on Duty

For Medicare beneficiaries, purchase of DME items in a community retail pharmacy provides the benefit of having a highly trained professional health care provider, the pharmacist, available to assist them. State pharmacy laws require pharmacies to have a pharmacist on duty when they are open for business and pharmacies must post their hours of operation. Community pharmacies are open early in the morning into the late evening and in many areas there is a 24 hour pharmacy available. When beneficiaries purchase their "over-the-counter" diabetic supplies and other cash and carry non-service items, the delivery occurs in the pharmacy with the pharmacist and the other pharmacy staff available to assist the beneficiary and answer any questions. Should any concerns or problems arise with the supplies, the beneficiaries are able to return them to the pharmacy. We believe that the most optimal

service to Medicare beneficiaries with diabetes and other chronic disease conditions occurs as a result of regular interaction with the pharmacist in the local community pharmacy setting.

State Pharmacy Laws Establish Professional Conduct and Services for Pharmacists and Pharmacy Technicians

State pharmacy laws on professional conduct provide oversight for pharmacists' services. Community retail pharmacies provide beneficiaries with an additional benefit of having a licensed pharmacist available to provide services to the beneficiary as needed and the oversight of the pharmacist-in-charge (PIC).

Community pharmacies are required by state pharmacy laws to maintain adequate operating hours. Moreover, an increasing number of community pharmacies are providing 24-hour services and a significant number remain open until the early evening hours. As a result, community pharmacies are very accessible to beneficiaries.

State pharmacy laws and regulations establish the qualifications, education and training, and examination requirements for pharmacy technicians to be permitted to work in a pharmacy. In most states, pharmacy technicians must be licensed or registered.

Pharmacists and pharmacy technicians are supervised by a pharmacist-in-charge or pharmacist manager who will require the pharmacy staff to adhere to applicable laws and regulations and pharmacy policies and procedures. This would include maintaining any required licensure or registration, competence and following policies and procedures.

Pharmacies are required by pharmacy laws and regulations to maintain complete records in computerized or hard copy for all prescriptions that are filled and refilled. The pharmacy records for prescription DME would be included in these requirements. Pharmacy laws and regulations also require pharmacies to keep hard copy records of new prescriptions and inventory records and invoices.

State Pharmacy Laws Require Pharmacists to Comply with All Laws and Regulations

State laws and regulations require pharmacists to comply with all applicable laws and regulations including federal laws and regulations, to comply with the prescriber's instructions for filling prescriptions, and to consult with the prescriber for approval of any prescription changes. Pharmacists are required to document their communications and instructions from physicians and other health care providers for any clarifications or changes to prescription orders. State pharmacy laws and regulations would subject pharmacies and pharmacists to discipline for misrepresentations about their services. Pharmacists are not permitted to provide recalled products to patients. State pharmacy laws give the state boards of pharmacy authority to discipline pharmacists and pharmacies for improperly providing professional services to patients.

State laws and regulations require pharmacists to review and fully comply with the prescriber's instructions for filling all prescriptions including for any DME and to consult with the prescriber for approval of any prescription changes. Pharmacists are required to document their communications and instructions from physicians and other health care providers for any clarifications or changes to

prescription orders. Pharmacists, as licensed health care professionals, must comply with professional conduct standards that would require them to provide follow-up and referrals for their patients if they determined that was necessary for the patient's care and treatment.

Pharmacists are required to provide their patients with counseling on new prescriptions if requested by the patient. For diabetic supplies and other non-service items, pharmacists would assist patients with training on how to use their diabetic testing supplies and other items upon request. In many states pharmacists engage in collaborative practice with physicians for certain patients, and in these instances additional patient education and training could be required pursuant to the protocol agreed upon between the physician and the pharmacy.

State pharmacy laws and regulations establish stringent requirements for pharmacy computer systems including maintenance of the information. These laws and regulations also establish requirements for maintenance of pharmacy records. Pharmacies' compliance with federal laws and regulations for Medicare patients would include maintaining records for the time periods set under Medicare.

Pharmacies, pharmacists and other pharmacy staff are required to comply with HIPAA and the applicable state laws and regulations to maintain patient privacy and confidentiality of patient records.

Pharmacies and Pharmacists are Subject to Disciplinary Actions by Boards of Pharmacy

The pharmacy and pharmacist licensure laws establish the requirements for pharmacies and pharmacists including the disciplinary authority of the state boards of pharmacy. Pharmacies and pharmacists are subject to board of pharmacy disciplinary actions against their licenses for violations of laws and regulations.

Beneficiaries with comments about pharmacy services and pharmacist providers have the right to contact the state board of pharmacy. The state boards of pharmacy as consumer protection agencies are available to provide this service for patients. This consumer protection option does not exist with other non-licensed DME businesses. Should problems with the monitors or other diabetic supplies arise they can be brought to the attention of the pharmacist. As appropriate depending on the non-service item such as diabetic supplies or other items, the pharmacist could bring this to the manufacturers' attention or assist the beneficiary in how to contact the manufacturer.

Pharmacists are Specifically Educated and Regulated to Work with Physicians in the Delivery of Care to Patients

State pharmacy laws establish the scope of pharmacy practice, and require pharmacists to follow the instructions of the patient's physician including any treatment plan involving a prescription that comes within the pharmacist's scope of practice. Pharmacists' professional responsibilities would include providing the patient with products that follow the prescriber's prescription and have been provided by FDA approved manufacturers. This would include providing the patient with any needed information and pharmacist consultation on the use of the equipment and any needed supplies.

We further believe that the statute gives CMS considerable leeway in determining whether or not to apply these new standards to community pharmacies through accrediting organizations. For example,

CMS has stated that it will be grandfathering in suppliers that have already been accredited by recognized accrediting organizations. Thus, CMS' consideration of "grandfathering" in certain entities indicates that it believes it can substitute CMS' criteria for these other standards. There is nothing in the statute or legislative history that would prevent CMS from adopting by reference another source of standards such as the state pharmacy laws and regulations.

Furthermore, there is nothing in the statute to prevent CMS from determining that the state pharmacy laws and regulations and licensure of community pharmacies and pharmacists will satisfy the quality standards for licensed community pharmacy DME suppliers.

For these reasons, we respectfully ask that the Secretary determine pursuant to the statutory grant of authority under Section 1834(a) (20) that the quality standards and accreditation are not appropriate to licensed community pharmacies nor required as a condition of a competitive bidding award. Accordingly, we ask for the following amendment to the proposed regulation.

(c) Application certification standards.
(22) All suppliers of DMEPOS and other items and services ***unless deemed inappropriate by the Secretary*** must be accredited by a CMS approved accreditation organization before receiving a supplier billing number.

Quality Standards Revision, Accreditation and Suppliers of Part B Drugs

We understand from the Program Advisory and Oversight Committee meeting held in May 2006, that the quality standards are being revised and will subsequently be published. We have questions and concerns about the timing for and application of the quality standards and accreditation to DMEPOS suppliers that are not part of the competitive bidding.

We are concerned about the equity of applying quality standards or accreditation to licensed pharmacy DMEPOS suppliers that are not involved in the competitive bidding as they are already meeting high standards. Moreover, all suppliers will likely encounter difficulties in finding an accreditation organization as they will be concentrating their services on suppliers in the selected competitive bidding areas. We do not believe that the quality standards or accreditation should apply to licensed pharmacies for the reasons discussed above. We further believe that there should be a phased in application for suppliers as the bidding areas are initiated.

Although we strongly believe that licensed pharmacies should be deemed to meet the quality standards and accreditation, we have questions about the accreditation process. For example, we ask for clarification from CMS on how suppliers will know which organizations are CMS approved. Also, we ask for clarification as to whether CMS would consider a pending application for accreditation as meeting the status for a competitive bidding award. Thus if accreditation is a prerequisite for being awarded a competitive bid, we have questions about the equal opportunity and knowledge of approved accreditation organizations for all suppliers and how a pending approval would be viewed. We also request information on how suppliers will be notified of approved accreditation organizations.

We also have questions about the granting of accreditation status for a pharmacy chain. In particular, at the PAOC meeting it was mentioned that one accreditation could apply to a pharmacy chain. We

believe that this is appropriate as all of the pharmacies within the pharmacy chain would be operated the same. We ask CMS for clarification on this matter.

We have questions about the quality standards and accreditation requirements in relation to pharmacies supplying Part B drugs. Many pharmacies provide Part B drugs to Medicare beneficiaries and have a supplier number. We ask for clarification from CMS that the quality standards and accreditation requirements do not have any affect on a pharmacy provider's supplier number for billing for Part B drugs. Our question arises out of the commentary in the proposed rule, which provides that suppliers must comply with the quality standards to receive and retain a provider or supplier billing number used to submit claims for reimbursement. We ask for clarification from CMS that these proposed rules would not prevent a pharmacy from receiving and retaining a supplier number to submit claims for Part B drugs.

Regulatory Impact Analysis

The regulatory impact analysis for the competitive bidding program does not include the cost associated with accreditation. The costs of accreditation should be factored into the impact analysis for the competitive bidding program. Although the quality standards and accreditation requirements apply to all DME suppliers regardless of participation in the competitive bidding program, firms located in an MSA where the competitive bidding program is implemented will have to gain accreditation to be able to provide products included in the program. Retail pharmacies and specialized DME suppliers that typically offer a limited range of DME products which are more likely to be subject to competitive bidding – such as diabetic supplies & equipment – will clearly view accreditation as a cost of participation in the competitive bidding program.

The regulatory impact analysis assumes that the competitive bidding program will provide savings averaging around 20 percent. Although the analysis indicates that adjustments were made to account for subsequent price reductions for some services, assuming 20 percent savings may be optimistic. Firms participating in the competitive bidding demonstration program did not have to meet the extensive quality standards required under the proposed rule or receive accreditation in order to participate. These added costs to suppliers could increase bids, thereby reducing savings.

The analysis assumes no impact on beneficiaries because "a sufficient number of quality suppliers will be selected to serve the entire market." The impact analysis assumes that 37 percent of existing suppliers – more than 1 out of every 3 – will not receive contracts to supply competitively bid items. As CMS acknowledges, beneficiaries will need to change suppliers if their existing supplier does not receive a contract. For some types of supplies – notably diabetic supplies and equipment – it may be harmful to the patient to disrupt established contacts with suppliers.

Suppliers that do not receive contracts may also lose sales of non-competitively bid DME items if those same items can be purchased with one transaction from a contracted supplier. Non-contracted suppliers that offer more than just DME supplies, such as retail pharmacies where people may also purchase prescription drugs and other items, may lose additional sales if they do not receive a contract.

Simply ensuring adequate numbers of DME suppliers in a metropolitan area also does not guarantee ready access. For example, in a large metropolitan area, contract suppliers may be concentrated in areas

that are difficult to get to for beneficiaries with limited mobility or access to transportation. Whereas an individual may currently travel a short distance to a nearby supplier, they may now be asked to travel much farther to obtain DME items.

The regulatory impact analysis estimates that 90 percent of the businesses affected by the proposed rule will be small businesses. The impact analysis suggests that small business will be helped by separate bidding for products within a DME category, and their chances of winning contracts increase when submitting multiple bids for different products. It is not clear that this proposal would reduce the costs to small business; it could actually increase costs by requiring suppliers to prepare multiple bids. It is also not clear that chances increase with multiple bids, as the odds depend on the number of bidders. CMS makes unsubstantiated statements in the analysis such as "While there may be some decrease in choice of suppliers, there will be a sufficient number of suppliers to assure adequate access." The analysis goes on to say, based on the competitive bidding demonstrations, that "...we assume that there will be no negative impacts on beneficiary access as a sufficient number of quality suppliers will be selected to serve the market." Further, "....we anticipate that the necessity of switching suppliers will be minimal in many product categories because of the existence on grandfather policies..."

CMS offers no evidence to suggest that any of these statements will hold true for diabetic testing supplies. The fact is that if access to diabetic testing supplies is sharply reduced or is shifted to mail, then the testing habits and frequency of Medicare beneficiaries with diabetes could significantly change resulting in adverse health consequences. We strongly urge that a separate regulatory impact analysis be done exclusively for diabetic testing supplies within this program. For example, CMS estimates that 50 percent of bidding suppliers will be winners. Even if all the pharmacies in the United States bid, and only half are awarded contracts, then millions of Medicare beneficiaries would have to travel twice the difference then they do now to get their testing supplies.

NACDS appreciates the opportunity to provide these comments and asks that you contact us if you have any questions. Thank you.

Sincerely,

John M. Coster

John M. Coster, Ph.D., R.Ph.
Vice President, Policy and Programs

Attachment: HPRD study

#1087

MEDICARE'S NEW COMPETITIVE ACQUISITION PROGRAM FOR DURABLE MEDICAL EQUIPMENT:

POLICY CONSIDERATIONS INVOLVING BENEFICIARIES WITH DIABETES, COMMUNITY-BASED RETAIL PHARMACIES AND BLOOD GLUCOSE MONITORING

On Behalf of the
National Association of Chain Drug Stores

HealthPolicy R&D
Washington, D.C.
January 2006

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CHAPTER ONE: INTRODUCTION

Medicare provides beneficiaries with access to glucose monitors and test strips that are necessary for the self-monitoring of blood glucose under Medicare Part B.[1,2] Self-monitoring of blood glucose levels with glucose monitors and test strips is an integral component of the pharmacologic therapies used for the chronic management of patients with both type 1 and type 2 diabetes.

In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). This legislation directs the Centers for Medicare and Medicaid Services (CMS) to change the Medicare program in several ways that are significant for patients treated with insulin or other prescription drug therapies used to control blood glucose levels. Specifically:

- The MMA establishes a new prescription drug benefit under Medicare Part D that became effective on January 1, 2006. This benefit provides Medicare coverage for the first time for the chronic use of subcutaneous insulin and oral prescription drugs used to control blood glucose levels in persons with diabetes. In addition, certain high-cost beneficiaries with diabetes and other chronic illnesses will receive medication therapy management services under Part D to optimize their drug regimens and to improve adherence to their medication therapies.

- The MMA also directs CMS to establish a competitive acquisition program for durable medical equipment (DME), related supplies and certain other items under Medicare Part B.[3] CMS must begin implementation of this program in 2007. At this point, it is unclear whether, when and how CMS might apply the new competitive acquisition program to glucose monitors and test strips.

This Report arises from concerns regarding how Medicare's new prescription drug benefit and other recent efforts to improve care for Medicare beneficiaries with diabetes may be adversely altered if glucose monitors, test strips and related services are subject to the DME competitive acquisition program. Medicare's prior DME competitive bidding demonstration program did not include glucose monitors or supplies, and there is no experience to indicate whether these products can be purchased in this manner without undue risk to beneficiaries.[4]

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[1] Centers for Medicare and Medicaid Services (CMS). Medicare National Coverage Determinations Manual. CMS Pub. 100-3. Accessed September 18, 2005 at http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp.
[2] Palmetto GBA. Local Coverage Determinations (LCD) for Glucose Monitors (L11520). Accessed on CMS's Medicare Coverage Database August 8, 2005 at http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=11520&lcd_version9&show=all.
[3] Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), Pub. L. 108-173, § 302(b), (2003), *amending* Social Security Act (SSA) § 1847.
[4] Government Accountability Office (GAO). Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies. September 2004. GAO-04-765. [GAO 2004]

A. Report Objectives

The National Association of Chain Drug Stores (NACDS) commissioned *HealthPolicy R&D*[5] to examine potential considerations for policymakers involving Medicare beneficiaries with diabetes who must use blood glucose monitors as part of the pharmaceutical management of their blood glucose levels. This Report examines Medicare's new DME competitive acquisition program and the potential impacts for beneficiaries with diabetes.

In this Report, *HealthPolicy R&D* examines the following issues:

- The chronic management of blood glucose levels in patients with diabetes — including the use of blood glucose monitors and test strips — and the clinical, technical and patient access issues that policymakers should understand in the context of Medicare's new competitive acquisition program for DME.

- Initiatives by employers and the private sector to develop and implement community pharmacy-based interventions to help manage the care of patients with diabetes.

- Medicare's policies and initiatives that have direct impacts on beneficiaries with diabetes, such as the new prescription drug benefit under Medicare Part D, the coverage policies for blood glucose monitors and supplies under Medicare Part B and the new competitive acquisition program for DME under Medicare Part B. This analysis includes the possible effects of these policies and initiatives on the provision of diabetic care for Medicare beneficiaries.

B. Report Methodology

In preparing this Report, *HealthPolicy R&D* used the following methodology:

- **Literature Review:** *HealthPolicy R&D* conducted a review of the existing literature to identify important themes and trends relating to diabetes disease management, self-monitoring of blood glucose, pharmacy services for diabetes patients and CMS's competitive acquisition program for DME. This literature review included medical and peer-reviewed journals, government-sponsored publications, databases maintained by the U.S. Food and Drug Administration (FDA) and news media sources.

- **Statutory and Regulatory Review:** *HealthPolicy R&D* conducted an analysis of current federal statutory provisions governing the implementation of Medicare's competitive acquisition program for DME. *HealthPolicy R&D* attended the meetings of the Program Advisory and Oversight Committee (PAOC), which Congress and CMS established to provide a public forum to discuss the implementation of the DME competitive acquisition program. Additionally, *HealthPolicy R&D* examined federal laws and regulations

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governing Medicare programs and benefits affecting beneficiaries with diabetes, including: the coverage policies governing glucose monitors and supplies; the new prescription drug benefit and medication therapy management services provided under Part D; and the ongoing demonstration and pilot programs that target beneficiaries with chronic illnesses, including diabetes.

- **Interviews with Thought Leaders:** *HealthPolicy R&D* conducted telephone interviews with a range of stakeholders with expertise in the care, training and education of patients with diabetes, including physicians, pharmacists, diabetes educators, researchers and other professionals from the pharmacy and manufacturing sectors. A list of interviewees and *HealthPolicy R&D's* interview guide are provided at Appendices A and B.

- **Analysis of the Marketplace for Blood Glucose Monitors and Supplies:** *HealthPolicy R&D* collaborated with IMS Health, Inc. to conduct an analysis of industry data involving sales of blood glucose test strips in retail and mail order channels, including an analysis of purchasing patterns by age and type of health care coverage. Data were from the second quarter of 2005 and were obtained from two databases: IMS National Sales Perspective and IMS Xponent Plan Trak. Data for the IMS National Sales Perspective database reflect retail pharmacies (independent/chain pharmacies, mass merchandisers, proprietary stores and food stores with pharmacies) and non-retail pharmacies (federal and non-federal hospitals, clinics, health maintenance organizations, long-term care facilities, home health agencies and other entities). The IMS Xponent Plan Trak data are based on prescriptions filled and are obtained from more than half of all retail pharmacies in the United States, approximately one-quarter of all long-term care facilities and over 70 percent of all mail order outlets.

C. Summary of Findings

A number of findings are discussed in greater detail in this Report, including the following:

- **The Current Role of Community-Based Retail Pharmacies:** Most Medicare beneficiaries currently obtain medically necessary glucose monitors and related supplies from community-based retail pharmacies rather than from home care suppliers or mail order companies.

- **Limitation on Access:** Competitive acquisition programs generally limit the number of entities that may participate in such programs. If glucose monitors and supplies were subject to the competitive acquisition program, then some or all of the community pharmacies in a region could lose the bidding process and be unable to supply these items under Medicare. As a result, a competitive acquisition program that includes glucose monitors and supplies could create a confusing and perhaps contradictory situation. Medicare beneficiaries with diabetes could find it impossible or difficult to obtain medically necessary medications to control their glucose levels (under Medicare Part D) and glucose monitors and supplies (under Medicare Part B) from the same pharmacy.

- **Fragmentation of Care:** Such fragmentation in the provision of the full spectrum of diabetic medications, supplies and equipment is inconsistent with virtually all other policies and initiatives (both public and private) with respect to the care of persons with diabetes.

- **Diversity of Products and Patient Needs:** There are many different types of glucose monitors and supplies grouped together under the same billing codes. A competitive acquisition program may easily create incentives for winning bidders to promote lower cost items rather than matching the patients' needs with the most appropriate equipment and supplies.

- **The Costs of Failing to Control Glucose Levels in Patients with Diabetes:** Mismanaged care for diabetes patients and the failure to achieve control of patients' glucose levels could result in sizable healthcare expenditures that are borne by the Medicare program and other health insurance plans.

- **The Educational Role Played by Pharmacists:** Mounting evidence shows that pharmacist-based programs can result in clinically significant improvements in health outcomes for patients with diabetes. Given the growing interest in these initiatives as part of disease management programs in both the private and public sectors, it may be ill-advised to risk disrupting these patient-pharmacy relationships at the same time that further experience is being gained in the use of community-based pharmacies to promote adherence to blood glucose treatment and monitoring regimens.

CHAPTER TWO: COMPETITIVE ACQUISITION – A WORK IN PROGRESS

Under the Balanced Budget Act of 1997, Congress authorized CMS to test competitive bidding as a method for Medicare to establish prices and to reimburse for some categories of DME covered under Medicare's outpatient (Part B) benefit.[6] Under this demonstration program, CMS opted to exclude glucose monitors and test strips due to concerns that competitive bidding could interfere with beneficiary access to the full range of necessary supplies.[7] As a result, Medicare has never applied competitive bidding or competitive acquisition principles to glucose monitors or test strips.[8]

In 2003, Congress directed CMS to establish a competitive acquisition program for certain categories of DME and other items under Medicare Part B beginning in 2007.[9] Under this competitive acquisition program, CMS can limit the number of suppliers selected to participate based on CMS's assessment of the needs of the Medicare beneficiaries in a particular area. As a result, Medicare beneficiaries will be unable to obtain Medicare coverage for DME items and services from suppliers that are not selected by CMS in the bidding process.

It remains unclear whether or when glucose monitors and supplies will be included under the DME competitive acquisition program. Under the MMA, CMS has the authority to exclude items and services that are unlikely to result in significant savings. CMS also has the authority to phase-in first those items that CMS deems to be the highest cost or highest volume items, as well as those deemed to have the greatest potential to achieve savings for Medicare under competitive acquisition.[10]

A. Medicare's Competitive Bidding Demonstration for DME

CMS conducted the competitive bidding demonstration program in Polk County, Florida and San Antonio, Texas between 1999 and 2002.[11] Items included in the demonstration were identified by Healthcare Common Procedure Coding System (HCPCS) codes.

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[6] Balanced Budget Act of 1997. Pub. L. No. 105-33, § 4319(a), 111 Stat. 251, 392 (1997).
[7] GAO 2004.
[8] Congress and CMS has used the term "competitive bidding" to refer to the demonstration project authorized under the Balanced Budget Act of 1997 and the term "competitive acquisition" to refer to the program for DME established under the MMA. The competitive bidding demonstration was a precursor to the new competitive acquisition program, and many people use the terms "competitive bidding" and "competitive acquisition" interchangeably. The terminology is complicated further by the "competitive acquisition program" for Medicare Part B prescription drugs that Congress also established under the MMA. The program for prescription drugs, often referred to as "the CAP," is structured differently from the DME competitive acquisition and is a separate program.
[9] MMA, § 302(b), (2003), *amending* Social Security Act (SSA) § 1847.
[10] *Id.*
[11] The Polk County demonstration prices were in effect from October 1999 through September 2002. Demonstration prices in the San Antonio area were in effect from February 2001 through December 2002.

CMS's decision to exclude glucose monitors and test strips from the demonstration was based in part on the large range of glucose monitors that fall within the existing HCPCS code (E0601) and the corresponding large range of products that fall within the existing HCPCS code for glucose monitor test strips (A4253).[12] The potential application of competitive acquisition to these products is complicated because most commercially-available monitors have unique test strips that each type of monitor must use. The range of unique monitors and the lack of interchangeability of the test strips render this product area readily distinguishable from many other types of DME (see additional discussion in Chapter Three).

Of the eight categories of products included in the demonstration, CMS included two product areas (oxygen and related products and hospital beds and accessories) in both demonstration sites. In addition to these two products, the Polk County demonstration site initially included the following three categories of products: enteral nutrition formulas, equipment and supplies; urological supplies; and surgical dressings. In San Antonio,[13] the categories of products selected for the demonstration in addition to oxygen and hospital beds were: manual wheelchairs and accessories; nebulizer inhalation drugs; and non-customized general orthotics.

After the demonstration's initial year in Polk County, CMS decided to remove enteral nutrition formulas because the common setting of care for enteral formulas differed significantly from most other items subject to competitive bidding. Specifically, although most products included within the competitive bidding demonstration are provided by traditional DME suppliers in the home of the beneficiary, the majority of beneficiaries receiving enteral nutrition under Medicare Part B are residents of nursing homes.[14]

Generally, CMS concluded that the demonstration program resulted in lower prices without substantial negative impacts on beneficiaries' access to products or the quality of the goods and services provided. However, concerns were raised about product substitution and inadequate service for some items. In the final evaluation of the demonstration program, the evaluators concluded that urological supplies were a poor candidate for future competitive bidding programs.[15]

For urological supplies, concerns were raised in the final evaluation of the demonstration about at least two factors: suppliers did not always provide the most functionally-appropriate catheter because of variation of products within the HCPCS code; and there was a significant increase in the percentage of beneficiaries who reported receiving no training when obtaining their urological equipment and supplies.[16]

CMS concluded that these issues may have resulted from the relative inexperience of some

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[12] GAO 2004.
[13] There was no second bidding cycle in San Antonio.
[14] University of Wisconsin-Madison, Center for Health Systems Research and Analysis—RTI International, Division of Health Economics Research. Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS. November 2003. Accessed July 18, 2005 at http://www.cms.hhs.gov/healthplans/research/dmebid.asp.
[15] *Id.*
[16] *Id.*

suppliers with urologicals, cost pressures related to underbidding or an increase in mail delivery of urological supplies. CMS determined that there could be a deleterious effect on product selection if suppliers offering a choice of urological products left the market and only suppliers that limited their offerings to a single brand remained.[17]

Given the very significant range of products and functional characteristics among commercially-available glucose monitors and test strips that fall within the same HCPCS codes, similar concerns should exist for glucose monitors and test strips (see discussion in Chapter Three).

B. Medicare's New Competitive Acquisition Program for DME

CMS must implement the new DME competitive acquisition program in ten of the largest metropolitan statistical areas (MSAs) by 2007, 80 of the largest MSAs by 2009 and other areas after 2009. Congress instructed CMS to phase-in first those items and services that are among the highest cost and highest volume items and services, as well as those deemed by CMS to have the greatest potential to achieve Medicare savings.

To date, CMS has not published any proposed or final decisions regarding the items, services, MSAs or terms applicable to DME competitive acquisition. Congress and CMS created the PAOC to provide technical guidance on the establishment and implementation of the competitive acquisition program. The PAOC has held periodic public meetings to explore issues related to competitive acquisition of DME, including payment issues, data collection and quality standards.[18]

There are several components of the DME competitive acquisition program that are particularly relevant to this analysis. For example, the MMA required CMS to develop and implement quality standards for DME, prosthetic devices, orthotics and prosthetics, and parenteral and enteral nutrition.[19] Once developed by CMS, the standards must be applied by independent accrediting organizations.[20] Suppliers must comply with the standards to maintain or receive a supplier number, which is necessary to bill the Medicare program for covered items and services.

On September 23, 2005, CMS posted draft quality standards on its website and requested public comments.[21] The comment period ended on November 28, 2005. These draft quality standards are divided into two parts — general requirements (mostly financial and organizational requirements) that apply to all Part B suppliers, and product-specific requirements that apply

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[17] *Id.*

[18] Information regarding the PAOC and the substance of its meetings is available on the CMS website at (accessed November 22, 2005) http://www.cms.hhs.gov/suppliers/dmepos/compbid/paoc.asp.

[19] See generally, Section 302 of the MMA, creating § 1834(a)(20) of the Social Security Act (SSA) (42 U.S.C. § 1395m(a)(2)).

[20] *Id.*

[21] CMS. Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Items and Services: Draft of Proposed Recommendations. Sept. 26, 2005. Accessed at http://www.cms.hhs.gov/suppliers/dmepos/compbid/default.asp.

only to suppliers of particular products and services. The draft quality standards include standards for diabetic equipment and supplies.[22]

Congress directed CMS to develop the quality standards on a parallel track with the competitive acquisition program. Congress intended that the quality standards would play an important role in the competitive acquisition program, helping to ensure that Medicare beneficiaries receive quality care. The strength of the standards in a particular area, as well as the degree to which the standards ensure patient access to a range of products, will have important impacts on whether a product area is a good candidate for inclusion in the competitive acquisition program.

There are a number of other aspects of the competitive acquisition program that warrant examination, including the following:

- CMS must select more than one supplier for each competitive acquisition area for each product category chosen for the program, but CMS can limit the number of suppliers chosen to the amount deemed by CMS sufficient to meet beneficiaries' demand in the area.

- CMS must ensure consideration of small businesses in selecting suppliers to participate in the program, but CMS is not required to establish a small business carve-out to ensure that a particular percentage of Medicare beneficiaries are treated by small businesses.

- Based on the bids submitted, CMS will establish a single payment amount for each item or service in each competitive acquisition area.

- Competitive acquisition contracts must be re-competed at least every three years.

- CMS's selection of suppliers and pricing decisions are not subject to administrative or judicial review.[23]

[22] *Id.*
[23] Section 302(b) amending SSA § 1847 (42 U.S.C. § 1395w-3).

CHAPTER THREE: FINDINGS

Providing effective treatment and chronic management of diabetes is an important objective for the Medicare program. Diabetes is responsible for significant morbidity and mortality. Nearly one-fifth (18 percent) of all Medicare beneficiaries have diabetes, and beneficiaries with diabetes account for approximately one-third of all Medicare spending.[24] Controlling blood glucose levels in individuals with type 1 or type 2 diabetes improves health outcomes, slows the progression of disease and prevents complications of diabetes.[25,26,27]

For example, the importance of glucose control and the daily use of home glucose monitors is demonstrated in a recent study funded by the National Institutes of Health. The investigators found that intensive efforts to control blood glucose levels in patients with type 1 diabetes — including self-monitoring of blood glucose levels by patients at least four times per day — resulted in significant reductions in cardiovascular complications (such as heart attacks and strokes) over long-term follow-up. Patients with less intensive efforts to control blood glucose levels without daily monitoring of blood glucose levels experienced a greater incidence of adverse cardiovascular events during long-term follow-up.[28]

The findings of this Report focus on issues of importance to policymakers when considering whether or how to subject glucose monitors and test strips to the new competitive acquisition program for DME under Medicare Part B. Among other issues, these findings examine the following questions:

- How do glucose monitors and testing supplies differ, if at all, from other items that are potentially subject to Medicare's DME competitive acquisition program?
- What roles do community-based retail pharmacies play in providing Medicare beneficiaries with access to glucose monitors and test strips?
- What are some of the potential concerns that exist in applying competitive acquisition to glucose monitors and test strips?

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[24] CMS. Medicare Health Support to Improve Care of Beneficiaries with Chronic Illnesses. Medicare Fact Sheet. Accessed September 8, 2005 at http://www.cms.hhs.gov/medicarereform/ccip/.

[25] McCulloch D. Managing diabetes for improved health and economic outcomes. *The American Journal of Managed Care*. 2000;6(21):S1089-S1095.

[26] Diabetes Control and Complications Trial (DCCT) Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New England Journal of Medicine*. 1993;329(14):977-986.

[27] UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet*. 1998;352(9131):837-853.

[28] The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study Research Group. Intensive Diabetes Treatment and Cardiovascular Disease in Patients with Type 1 Diabetes. *New England Journal of Medicine*. 2005; 353(25):2643-53.

These issues are discussed in greater detail below.

A. The Use of Glucose Monitors is an Integral Component of the Pharmacologic Interventions Used in the Chronic Management of Diabetes

The use of glucose monitors is a recommended and integral component of the pharmacologic regimens that are used to manage both type 1 and type 2 diabetes. The roles that glucose monitors play in these pharmacologic regimens are reflected in longstanding Medicare policy. For example, the policies of Medicare's durable medical equipment regional carriers (DMERCs) allow coverage of glucose monitors for beneficiaries with diabetes regardless of whether they use insulin. The volume of testing supplies for which the patient is eligible varies (those using insulin are expected to self-monitor their glucose levels more frequently).[29]

Under current policies, Medicare beneficiaries may secure their glucose monitors and supplies from any pharmacy that participates in the Medicare program as a supplier of DME. In practice, this means that Medicare beneficiaries can obtain all of their covered equipment, supplies and prescription drugs for managing their diabetes from a single source — their community-based retail pharmacy.

The total financial costs of diabetes and its complications are staggering. Controlling blood glucose levels can reduce the occurrence of costly complications from diabetes.[30] In fact, the majority of the health care expenses for diabetes are spent on the complications arising from diabetes.

- For patients of all ages, only about 25 percent of health care expenses for diabetes are due to uncomplicated diabetes and diabetes-related supplies and the majority of costs arise from the treatment of diabetes-related conditions and complications.[31]

- The direct medical cost of treating elderly patients with diabetes in 2002 was estimated to be $48 billion.[32]

- Medicare beneficiaries with diabetes account for a disproportionate share of Medicare expenditures. The estimated 18 percent of Medicare beneficiaries with diabetes account

[29] Palmetto GBA. Local Coverage Determinations (LCD) for Glucose Monitors (L11520). Accessed on CMS's Medicare Coverage Database August 8, 2005 at http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=11520&lcd_version9&show=all.

[30] Centers for Disease Control and Prevention (CDC). National Diabetes Fact Sheet, United States, 2003. Accessed November 23, 2005 at http://www.cdc.gov/diabetes/pubs/factsheet.htm.

[31] Hogan P, Dall T, Nikolov P. Economic costs of diabetes in the U.S. in 2002. *Diabetes Care*. 2003;26(3):917-932.

[32] *Id.* This estimate reflects the amount of health care expenditures attributable to providing services to diabetes above the costs they would have incurred if the patients did not have diabetes. This estimate includes expenditures for the treatment of medical conditions directly related to diabetes and for conditions that are complications of the disease.

for 32 percent of total Medicare spending.[33]

- The most costly 10 percent of beneficiaries with diabetes have annual health care expenditures in excess of $25,000 per patient.[34]

B. The Leading Source of Glucose Monitors and Supplies for the Elderly is the Community-Based Retail Pharmacy Setting, and This is in Contrast to Most Items Potentially Subject to the DME Competitive Acquisition Program

Elderly persons with diabetes purchase more than half (62 percent) of their blood glucose test strips from one of the more than 55,000 community-based retail pharmacies currently in operation.[35,36] These community pharmacies include chain drug stores, independent pharmacies and pharmacies located in other stores, including supermarkets or mass merchandisers such as Wal-Mart. Patients with diabetes are reported to visit their pharmacies at least once each month to purchase diabetes medications and supplies.[37] In contrast, the predominant source of most other items of DME is the traditional DME supplier — not community-based retail pharmacies.

The purchase patterns of patients buying blood glucose monitors and supplies raises some concern regarding the inclusion of these supplies in a competitive bidding program. Patients currently are using a variety of monitors for self-testing their blood glucose levels whether they are paying out-of-pocket for the device (cash) or have health insurance that covers the cost.[38] This distribution suggests that there may be differences in monitor functional characteristics and design that are important for some individuals.

Most glucose monitors fall within a single HCPCS code. If there are important clinical or performance differences associated with the costs of monitors categorized within the same HCPCS code, a competitive bidding regimen could result in many beneficiaries having to switch monitors. Competitive bidding creates an incentive for suppliers to provide lower-cost monitors to beneficiaries. This competitive pressure may result in suppliers limiting the choice of monitors readily available to patients or forcing substitution to lower-cost brands of monitors or supplies. This type of forced change could be disruptive for beneficiaries with diabetes, especially for patients with strong preferences or whose conditions and circumstances make the use of a certain device more appropriate.

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[33] CMS. Medicare Fact Sheet: Medicare Health Support to Improve Care of Beneficiaries with Chronic Illnesses. Accessed November 23, 2005 at http://www.cms.hhs.gov/medicarereform/ccip/factsheet1105.pdf.

[34] Krop JS, Powe NR, Weller WE, Shaffer TJ, Saudek CD, Anderson GF. Patterns of expenditures and use of services among older adults with diabetes: implications for the transition to capitated managed care. *Diabetes Care.* 1998;21(5):747-752.

[35] IMS Health, Inc. Data were from first quarter 2005 from IMS National Sales Perspective and IMS Xponent Plan Trak databases. [IMS Data] (See additional discussion in Chapter One of this Report.)

[36] Knapp K, Ray M, Okamoto M, Chang P. The Role of Community Pharmacies in Diabetes Care: Eight Case Studies. *California HealthCare Foundation.* July 2005. [Knapp et al. 2005]

[37] *Id.*

[38] IMS Data.

C. DME Competitive Acquisition may Interact with Part D to Create Unnecessary Fragmentation of the Provision of Medications, Equipment and Supplies for the Control of Glucose Levels in Patients with Diabetes

Under DME competitive acquisition, CMS would limit the number of pharmacies and other suppliers that may provide glucose monitors and supplies to Medicare beneficiaries. This initiative could interfere with the ability of beneficiaries to obtain their glucose medications, glucose monitoring products and related professional guidance from a single source.

Such an outcome would be in direct conflict with basic principles and safeguards for access to pharmacies that Congress established under the new Medicare Part D prescription drug benefit. Under Medicare Part D, Congress ensured that beneficiaries would have access to retail pharmacies of their choosing within close proximity to their homes.

Section 1860D-4(b)(1) of the Social Security Act requires Part D plans to permit any pharmacy that is willing to accept the plans' terms and conditions to participate in the plan pharmacy network.[39] This requirement is intended to ensure adequate participation by community-based retail pharmacies as well as to support beneficiaries' access to prescription drugs.[40]

In its interpretation of these provisions, CMS acknowledges that Part D plans may develop different sets of standard terms and conditions, one set for "preferred" retail pharmacies, another set of standard terms and conditions for "non-preferred" retail pharmacies, and additional sets for mail-order, infusion and long-term care pharmacies. Nonetheless, plans must accept into their pharmacy networks any pharmacy that is willing to contract with the plan based on the standard terms and conditions for that type of pharmacy.[41]

CMS also established retail pharmacy network standards that are similar to the Department of Defense's TRICARE program to ensure that plans satisfy the statutory requirement for providing "convenient access" to beneficiaries. The retail pharmacy network standards require that plans ensure the following:

- Ninety percent of Medicare beneficiaries in urban areas served by the plan live within two miles of a network pharmacy.
- Ninety percent of Medicare beneficiaries in suburban areas served by the plan must live within five miles of a network pharmacy.
- Seventy percent of enrollees in rural areas served by the plan must live within 15 miles of

[39] SSA § 1860D-4(b).
[40] Committee on Ways and Means, U.S. House of Representatives, Joint Explanatory Statement H.R. 1, 108th Cong. 146 (2003). Accessed at http://waysandmeans.house.gov/Special.asp?section=43.
[41] Medicare Program; Medicare Prescription Drug Benefit; Final Rule, 70 Fed. Reg. 4193. 4254 (Jan. 25, 2005) (codified at 42 C.F.R. pts. 400, 403, 411, 417 and 423).

a network pharmacy.[42]

Mail-order pharmacies may supplement a plan's retail pharmacy network, but mail-order pharmacies are not counted toward meeting the Part D pharmacy network standards. Plan networks also may include pharmacies outside of the plan's service area, although these pharmacies also do not count toward meeting the access requirements.[43]

As discussed below, the predominant model in place for Medicare beneficiaries and other patients in the United States is one in which patients can access their glucose medications, glucose monitors and monitor supplies all from a single source — the local retail pharmacy. At the same time that many policymakers are recognizing the problems associated with the fragmented nature of our health care system, it may well be problematic to implement a system that would appear to interfere with the ability of beneficiaries to obtain their glucose management products — and related professional assistance — from a single source.

Given the well-established role that glucose monitors play in the pharmacologic management of diabetes, it appears inconsistent for Medicare to limit access to pharmacies for blood glucose equipment and supplies at the same time CMS is implementing multiple safeguards to ensure wide access to pharmacies providing prescription drugs for blood glucose management under Medicare Part D. This initiative could be disruptive to care as well as frustrating and confusing for Medicare beneficiaries.

D. CMS Does Not Have Experience with DME Competitive Bidding or Acquisition of Glucose Monitors and Supplies in the Retail Pharmacy Setting

Blood glucose monitors and supplies were excluded from Medicare's DME competitive bidding demonstrations conducted in Polk County, Florida, and San Antonio, Texas. This exclusion was due, in part, to concerns by CMS regarding the complexity of matching glucose monitors with the appropriate testing supplies in the context of such a program.[44] In general, most types of monitors are designed to work only with a specific type of test strip.

One issue that arose within CMS's competitive bidding demonstration provides a cautionary tale for including diabetes supplies in the competitive acquisition program. In the demonstration's final evaluation, it was noted that suppliers did not always provide preferred brands for urological supplies. One supplier consolidated its product line to one brand to obtain lower prices from the wholesaler and remain competitive under the demonstration — requiring beneficiaries to use this brand or go to another supplier if they preferred a different brand.

Evaluators of the demonstration noted that this type of response by suppliers could result in a deleterious effect on product selection, especially if suppliers offering a choice of urological

[42] 42 C.F.R. § 423.410(a) (2005).
[43] *Id.*; 70 Fed. Reg. at 4249.
[44] GAO 2004.

products left the market and only suppliers that limited their offerings to a single brand remained. In addition, there was a significant increase in the percentage of beneficiaries who reported receiving no training when receiving their urological equipment and supplies.

These issues, which in part arose due to the diversity of functional characteristics among urological supplies, raise concerns about the potential adverse impacts of competitive acquisition for glucose monitors. As discussed below, there is significant diversity among the various functional characteristics available in glucose monitors.

E. The Diversity of Functional Characteristics among Glucose Monitors for Patients with Differing Needs Provides a Significant Complicating Factor for the Application of DME Competitive Acquisition to Glucose Monitors

There is a wide array of blood glucose monitors for home use that have different functional characteristics. These functional capabilities, which a number of interviewees described as being important to enhance patient adherence rates to blood glucose testing regimens, include the ability to draw blood from alternate sites, the ability to use smaller quantities of blood for each reading and the ability to store multiple readings.

An analysis of the IMS databases revealed that the majority of monitor and monitor supply purchases are for full feature, brand name items that are in the higher cost range of the monitors available on the commercial market.[45] The DME competitive acquisition program could require elderly patients to substitute their current monitors with lower-cost monitors. A number of interviewees stated that monitors should be selected on a patient-by-patient basis to match patient's clinical needs and circumstances. Interviewees also noted that monitor selection may be especially important for the elderly.

Interviewees from the pharmacy community highlighted that pharmacists can assist beneficiaries in selecting an appropriate monitor, and that retail pharmacies typically stock a range of monitors. In total, the IMS Data indicates that more than 50 types of diabetes test strips are purchased by elderly patients from retail pharmacies.[46] Interviewees reported that retail pharmacies typically can order and obtain the appropriate supplies for virtually any type of monitor that a beneficiary may be using.

Currently available monitors offer an array of functional characteristics, and interviewees noted that matching monitors to patients' needs and preferences was important to achieve improved adherence with self-monitoring activities. Patients can choose monitors that provide audible word prompts or larger displays, require less blood or produce results more quickly, to name a few of the ways in which monitor functional characteristics differ. A few monitors also

[45] IMS Data.
[46] *Id.*

minimize the effect of environmental factors or agents, such as humidity, which is known to affect the accuracy of results. The test strips used with the monitors differ as well. For example, some test strips are designed to handle easily or work with monitors that automatically draw the amount of blood required (See Table 1).[47]

Table 1:
Summary of Select Monitor Functional Characteristics[48]

Functional Characteristic	Number of Monitors with Functional Characteristic	Percent of Monitors with Functional Characteristic
Requires few steps (2 or fewer) to operate	11	33%
Monitor calibrates automatically for new test strips	5	15%
Test strip designed for improved ease of handling	19	58%
Testing can be done at alternate sites (e.g., palm, arm)	14	42%
Requires smaller amount of blood	19	58%
Notifies patient if blood sample is too small	7	21%
Offers warning or minimizes effects of blood-related or environmental factors that can effect accuracy (e.g., automatically corrects testing for variations in hematocrit levels and temperature)	2	6%
Provides test results in 10 seconds or less	12	36%
Display screen designed for improved ease of reading (e.g., larger size, backlighting provided)	11	33%
Stores 100 or more test results in memory	20	61%
Averages test results over time	14	42%
Results can be downloaded to a computer for analysis	21	64%
Total number of monitors reviewed	**33**	**100%**

Manufacturers continue to improve the functional characteristics of blood glucose monitors. According to the FDA, newer monitors have functions that make them easier to use than older meters, such as automatic timing, error messages or barcode readers to help patients calibrate

[47] American Diabetes Association. Resource Guide 2005. *Diabetes Forecast.* January 2005.
[48] *Id.*

their monitors.[49] In a recent eighteen month period, the FDA approved twenty-one applications for over-the-counter blood glucose test systems that were either new or offered improved testing capabilities or functional characteristics, such as accuracy at a wider range of glucose levels.[50]

The range of currently available monitor functional characteristics allows patients to find a self-testing system with which they are comfortable and, in some cases, one that provides more accurate results given their individual circumstances. Interviewees and the literature identified the need to match patients with a specific monitor: no single monitor is optimal for everyone. The interviewees highlighted that monitors are not clinical substitutes for one another.

For example, monitor selection may have a direct impact on accuracy for patients with certain physical and cognitive conditions or for patients who reside in certain geographic areas. For example:

- Patients with diseases that affect hemoglobin in the blood (such as anemia) need a glucose monitor that can accommodate a wider-than-normal range of hematocrit levels or their blood-glucose results could be inaccurate.[51,52]

- Patients who have memory problems, such as those in the early stages of Alzheimer's disease, may benefit from monitors that can provide audible, step-by-step directions for testing.

- Certain geographic factors, such as high altitude, temperature or humidity produce unpredictable results in some devices and should be considered when selecting a monitor.[53,54]

- Patients in rural locations may benefit from monitors that allow data to be transmitted electronically to the doctor's office for review.[55]

Older patients also may have different age-related needs and preferences for monitors, which could be adversely affected by limits that competitive bidding may place on the variety of blood glucose monitors available for purchase. Several age-related changes in perception, cognition and movement control can affect the ability of older diabetes patients to self-test.[56,57,58] For

[49] FDA. Glucose Meters & Diabetes Management. Updated 2005. Accessed July 2005 at www.fda.gov/diabetes/glucose.html. [FDA 2005]
[50] FDA. Review of FDA's CHRH 5109(k) Premarket Notification Database. Search of database conducted September 6, 2005 for product codes NBW (Device: System, Test, Blood Glucose, Over The Counter).
[51] Foster SA, Goode JV, Small RE. Home blood glucose monitoring. *The Annals of Pharmacotherapy*. 1999;33(3):355-363. [Foster et al. 1999]
[52] FDA 2005.
[53] FDA 2005.
[54] Kirk and Rheney 1998.
[55] Foster et al. 1999.
[56] McLaughlin AC, Rogers WA, Fisk AD. Age-related glucomonitor design and selection: tools and principles for optimal solutions. *Diabetes Technology & Therapeutics*. 2004;6(3):319-325. [McLaughlin et al. 2004]

example, older adults may find color-coding on screens and flashing indicators difficult to detect or find using small buttons or touch screen icons difficult to use.[59,60,61,62,63]

The incentives inherent in competitive bidding could drive suppliers to offer lower-cost monitors and supplies and may limit the choice of monitors available to patients. These factors could make it difficult to effectively match monitors with patients' needs and circumstances. The American Diabetes Association has stated in a recent publication that any type of controls to manage costs, such as the use of competitive bidding, should ensure that diabetes patients have access to "all classes of equipment and supplies for use with such equipment without undue controls" in order to help them achieve glycemic goals and reduce the risk of complications.[64]

As noted above, an array of monitors are available for sale in the commercial market, most of which fall under the same HCPCS code. One interviewee described the application of a competitive acquisition program to diabetes self-monitoring supplies as "a step back" in time away from the many advances in diabetes medication and supplies that provide patients with an "arsenal" of tools to combat their disease.

Reducing the selection of monitors currently available also could reduce the ability of health care professionals and patients to select a monitor that best meets the needs of the patient and could result in decreased adherence with self-monitoring activities. The experts interviewed by *HealthPolicy R&D* felt strongly that the selection of a monitor involves "a lot of judgment" and is a decision that should be made by a healthcare professional who can assess and evaluate the patient rather than the result of best price or supplier competition.

F. The DME Competitive Acquisition Program Could Operate Contrary to Medicare's Current and Future Initiatives that are Designed to Promote Adherence to Blood Glucose Regimens and Reduce Overall Costs

In both the public and private sectors, payers are placing increasing emphasis on better management of the care of patients with diabetes. This dynamic is not only in response to the

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[57] Skelly AH, Arcury TA, Snively BM, Bell RA, Smith SL, Wetmore LK, Quandt SA. Self-monitoring of blood glucose in a multiethnic population of rural older adults with diabetes. *The Diabetes Educator*. 2005;31(1):84-90.
[58] Mayes M. Management of the older person with diabetes in the community. *British Journal of Community Nursing*. 2000;5(9):448-453.
[59] Briggs AL and Cornell C. Self-monitoring blood glucose (SMBG): now and the future. *Journal of Pharmacy Practice*. 2004;17(1):29-38.
[60] McLaughlin et al. 2004.
[61] Bernbaum M, Albert SG, McGinnis J, Brusca S, Mooradian AD. The reliability of self blood glucose monitoring in elderly diabetic patients. *Journal of the American Geriatrics Society*. 1994;42(7):779-781.
[62] Tu KS, McDaniel G, Gay JT. Diabetes self-care knowledge, behaviors, and metabolic control of older adults—the effect of a post educational follow-up program. *The Diabetes Educator*. 1993;19(1):25-30.
[63] Funnell MM and Merritt JH. The challenges of diabetes and older adults. *Nursing Clinics of North America*. 1993;28(1):45-60.
[64] American Diabetes Association. Standards of medical care in diabetes. *Diabetes Care*. 2005;28:S4-S36.

significant adverse impacts this disease has on patient health, but also to the significant costs arising from patients with diabetes.

For example, Medicare is instituting programs to reduce costs, improve the coordination of care and improve the effectiveness of medication therapies for beneficiaries with diabetes. Since the early 1990s, the Medicare program has expanded its coverage of diabetes-related services and supplies and instituted demonstration and pilot programs to test ways to provide better care to patients with diabetes and other chronic illnesses.

The current Medicare initiatives that are designed to improve the coordination of care and produce cost savings for beneficiaries with diabetes are summarized below.

A. *Medicare Disease Management Demonstration.* This three-year demonstration tests whether providing disease management services and a comprehensive prescription drug benefit to beneficiaries in traditional fee-for-service Medicare who have advanced stage congestive heart failure, diabetes or coronary artery disease will lead to improved health outcomes and lower total expenditures for Medicare. As part of the demonstration, beneficiaries receive disease management services and coverage of most prescription drugs (even those not related to the targeted conditions), although beneficiaries may be subject to some cost sharing for the prescription drugs.[65]

B. *Medicare Health Support Pilot Program.* The first phase of this two-phase pilot program tests whether providing increased support to beneficiaries in traditional fee-for-service Medicare who have congestive heart failure and diabetes will lead to improved clinical outcomes, increased patient satisfaction and reduced Medicare spending.[66] Nine sponsors have been selected to implement phase one of the pilot program, and each will offer self-care guidance and support to beneficiaries to manage their health as well as other strategies such as prescription drug counseling.[67] In the second phase of the program, CMS may expand successful programs or program components on a regional or national basis.[68]

   These pilot programs can include pharmacy services. For example, community pharmacists in Tennessee at CVS pharmacies will provide in-person medication counseling services to beneficiaries referred by XLHealth's nurse coach as part of the Medicare Health Support pilot program. These services will include a review of the patient's prescription and over-the-counter medications, as well as an assessment of existing and potential medication adherence issues.

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[65] CMS. Help for Chronically Ill Beneficiaries: The Medicare Disease Management Demonstration. Medicare Fact Sheet. December 2, 2003. Accessed at: http://www.cms.hhs.gov/researchers/demos/BIPAFctShtDec2003.pdf.
[66] CMS. Medicare Health Support to Improve Care of Beneficiaries with Chronic Illnesses. Medicare Fact Sheet. Accessed September 8, 2005 at http://www.cms.hhs.gov/medicarereform/ccip/factsheet1105.pdf.
[67] CMS. HHS Announces Awards for Programs to Improve Quality of Care for Medicare Beneficiaries with Chronic Illnesses. Medicare News Release. December 8, 2004.
[68] CMS. Medicare Health Support: Highlights of the Program. Accessed September 8, 2005 at http://www.cms.hhs.gov/medicarereform/ccip/highlights.asp.

C. *Medicare Part D Prescription Drug Plan Medication Therapy Management Services.* As part of the new Part D prescription drug benefit, plan sponsors will provide Medication Therapy Management (MTM) program services to certain patients who have high-cost chronic illness, such as diabetes. The services are intended to help optimize therapeutic outcomes by improving medication use and reducing the risk of adverse events for these beneficiaries.[69] Congress did not set minimum requirements for the content of MTM program services, but the MMA requires that plan sponsors develop these services in cooperation with licensed and practicing pharmacists and physicians.[70] CMS has provided guidance on the types of MTM program services that plans could offer, including: patient health assessments; development of drug treatment plans; evaluation and monitoring of patient response to drug therapy; education and training; and coordination of medication therapy with other care management services.[71]

The assistance pharmacists provide beneficiaries with their medications and diabetes self-management regimens could diminish if CMS establishes a competitive acquisition program that results in patients being unable to purchase both their medications and blood glucose monitoring supplies from their community-based retail pharmacies. In this way, competitive bidding of blood glucose monitoring supplies could reduce the effectiveness of Medicare's coordination of care, as well as limit the natural opportunity that exists for patients to speak with and obtain professional services from their pharmacists. The cost savings Medicare is seeking in these programs may also be diminished if patients' adherence with self-care activities declines as a result of barriers to access or less effective equipment is used as a result of the competitive acquisition program.

The cost savings achieved through a competitive acquisition program could very well be less than the increased costs for adverse health outcomes, such as hospitalizations due to declines in patient self-management of their illness, which could result if competitive bidding leads suppliers to limit the range of monitors available to patients. Based on the estimated additional costs that arise when patients' blood glucose levels are not controlled, if the competitive acquisition program interfered or disrupted the glucose testing regimens of just one out of every 20 Medicare beneficiaries with diabetes, the additional costs of treating these patients could exceed $100 to $350 million per year.[72,73]

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[69] All sponsors of Part D benefit plans are required to provide MTM services to patients who have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia and congestive heart failure); are taking multiple covered part D drugs; and are identified as likely to incur annual costs for covered part D drugs that exceed a level specified by CMS.

[70] SSA, Section 1860D-4(c)(2).

[71] 42 CFR Parts 4000, 403, 411, 417, and 423 Medicare Program; Medicare Prescription Drug Benefit; Final Rule. *Federal Register.* January 28, 2005; 70 (18).

[72] Gilmer TP, Manning WG, O'Connor PJ, Rush WA. The cost to health plans of poor glycemic control. *Diabetes Care.* 1997;20(12):1847-1853.

[73] Saaddine JB, Engelfau MM, Beckles GL, Gregg EW, Thompson TJ and N KMV. The diabetes report card for the United States: quality of care in the 1990s. *Annals of Internal Medicine.* 2002;136(8):565-574.

G. Community-Based Pharmacy Programs are Improving Blood Glucose Management and Health Outcomes for Patients with Diabetes and Attracting Interest from Employer-Based and Other Private Sector Efforts to Improve Diabetes Care

Evidence exists that pharmacist-based programs can result in clinically significant improvements in health outcomes for patients with diabetes. Intensive pharmacy-centric interventions can result in positive and clinically significant improvements for patients with diabetes, and employers are contracting with pharmacies to provide these services to their workers. The clinical literature demonstrates that diabetes patients participating in pharmacy-centered interventions have lowered their A1c levels[74,75] by as much as 2 percentage points.[76,77,78,79] Each percentage point decrease in A1c levels is associated with a clinically significant, 40 percent decrease in the risk of diabetes-related microvascular complications such as eye or kidney damage or nerve disease.[80]

Pharmacists provide a variety of services for diabetes patients as part of these interventions. Pharmacy-based interventions reported in the literature typically involve patients meeting with pharmacists every few weeks or months on an ongoing basis, and usually during scheduled appointments. Services provided in these interventions include:

- Reviewing the appropriateness of the patient's drug therapy.
- Consulting with the patient or physician and recommending changes in drug therapy to

[74] The amount of A1c in the blood reflects how well the blood glucose has been controlled, on average, for the past 2 to 3 months. A1c levels generally are tested in the physician office's at least twice a year and do not replace daily self-testing of blood glucose levels at home, which are necessary for adjusting medications and ensuring day-to-day control. American Diabetes Association. All About Diabetes. Accessed December 23, 2005. Available at: http://www.diabetes.org/type-1-diabetes/a1c-test.jsp

[75] Cranor CW, Bunting BA, Christensen DB. The Asheville project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. *Journal of the American Pharmaceutical Association.* 2003;43(2):173-184. [Cranor, Bunting, Christensen 2003]

[76] Jaber LA, Halapy H, Fernet M, Tummalapalli S, Diwakaran H. Evaluation of a pharmaceutical care model on diabetes management. *The Annals of Pharmacotherapy.* 1996;30(3):238-243. [Jaber et al. 1996]

[77] Rothman RL, Malone R, Bryant B, Shintani AK, Crigler B, Dewalt DA, Dittus RS, Weinberger M, Pignone MP. A randomized trial of a primary care-based disease management program to improve cardiovascular risk factors and glycated hemoglobin levels in patients with diabetes. *The American Journal of Medicine.* 2005;118(3):276-284. [Rothman et al. 2005]

[78] Coast-Senior EA. Management of patients with type 2 diabetes by pharmacists in primary care clinics. *The Annals of Pharmacotherapy.* 1998; 32(6):636-641. [Coast-Senior 1998]

[79] Choe HM, Mitrovich S, Dubay D, Hayward RA, Krein SL, Vijan S. Proactive case management of high-risk patients with type 2 diabetes mellitus by a clinical pharmacist: a randomized controlled trial. *The American Journal of Managed Care.* 2005;11(4):253-260. [Choe et al. 2005]

[80] CDC, National Center for Chronic Disease Prevention and Health Promotion, Division of Diabetes Translation. Diabetes Fact Sheet. Corrected 2005. Accessed August 2005 at http://www.cdc.gov/diabetes/pubs/general.htm#prevention.

physicians.

- Providing patient education and consultation regarding disease, its management and drug therapy.
- Obtaining patients' medical histories.
- Performing physical assessments of patients (e.g., monitoring of proper foot care for diabetes patients).
- Monitoring patients for desired and undesired health outcomes and compliance.
- Prescribing medications and ordering and evaluating laboratory tests.[81,82]

Employers are contracting with pharmacies to provide diabetes-related care as part of the health benefits they provide their workers. A recent California HealthCare Foundation report highlighted independent and chain community pharmacies that provide health assessments and education and track health outcome measures, including changes in blood glucose levels, for employees of self-insured employers.[83]

Many of these interventions are modeled after the successful "Asheville Project," a long-running pharmacist-based program established in 1997 by the city of Asheville, North Carolina, to promote adherence to glucose control and monitoring regimens among its employees suffering from diabetes. A large health plan in the area, Mission-St. Joseph's Health System, joined the city in offering the program to its employees in 1999. These local employers offer this pharmacy-led intervention to their employees as a benefit under their health plans. Incentives are provided to encourage employee participation, including the waiving of pharmaceutical co-payments and the provision of blood glucose monitors and education programs. Pharmacists are reimbursed for providing cognitive services to employees with diabetes, including patient education and training, and reviewing patients' self-monitoring of blood glucose data.[84]

Although based on a limited number of patients, the Asheville Project has demonstrated improved patient adherence to glucose control and monitoring regimens, improved patient health and patient satisfaction and decreased overall medical costs. Patients also showed improvements in blood glucose levels and self-monitoring of their blood glucose levels. Overall, the mean direct medical costs decreased at the end of five years by $1,200 per patient per year. Most of the reduction in costs was due to shifts in services: there was a decrease in insurance claims for

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[81] Beney J, Bero LA, Bond C. Expanding the roles of outpatient pharmacists: effects on health services utilization, costs, and patient outcomes (review). *The Cochrane Database System Review Library*. 2000;(3):CD000336.
[82] Singhal P, Raisch DW, Gupchup GV. The impact of pharmaceutical services in community and ambulatory care settings: evidence and recommendations for future research. *The Annals of Pharmacotherapy*. 1999;33(12):1336-1355.
[83] Knapp et al. 2005.
[84] Cranor CW, Christensen DB. The Asheville Project: Short-Term Outcomes of a Community Pharmacy Diabetes Care Program. *JAMA*. 2003; 43(2): 149-59.

emergency department care, inpatient care and physician office visits although costs increased for prescription drugs.[85,86,87]

Pharmacists participating in these employer-sponsored pharmacy interventions report that a competitive acquisition program that removes access to self-monitoring supplies from the pharmacy could provide them with less opportunity and ability to assist beneficiaries with the use of their monitor or to trouble-shoot problems, especially if they are unfamiliar with the patient's brand of blood glucose monitor. Beneficiaries also may be more reticent about seeking assistance from pharmacists for monitors that they purchase elsewhere.

The authors of a recent California HealthCare Foundation study suggest that community pharmacies could be an ideal place to provide professional services to individuals with chronic illnesses such as diabetes because of their prevalence, locations and long hours of operation.[88]

The success of the Asheville Project has led employers in several different states to contract with pharmacies to provide diabetes care services to their workers. These employers typically offer these pharmacy-led benefits to employees and dependents as part of the self-insured health benefits they offer their workers. For example:

- Employers in North Carolina contract with the Piedmont Pharmacy Care Network (PPCN), a coalition of independent pharmacies, to provide diabetes care to workers and their dependents. For the past three years, these PPCN pharmacists have screened, educated and monitored diabetes patients on-site at their place of employment.[89]

- Seven self-insured employers in Wisconsin contract with a network of eight pharmacies to provide diabetes and other health care services to their workers. (This pharmacy network includes chain and independent pharmacies as well as a pharmacy that is part of a health system.) These pharmacists follow protocols to provide workers with diabetes screening, education and monitoring services. For example, the pharmacists assess patients' needs every month for the first six months of the program, and patients who need additional education are referred to a formal diabetes education center. As an incentive, diabetes supplies are provided to patients for free, and co-pays for diabetes-related medications are waived for workers who participate in the program.[90]

- A West Virginia employer contracts with pharmacists to provide in-person diabetes disease management care to its employees.[91]

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[85] Garrett DG, Martin LA. The Asheville Project: Participants' Perceptions of Factors Contributing to the Success of a Patient Self-Management Diabetes Program. *JAMA*. 2003; 43(2): 185-90.
[86] Cranor CW, Buntin BA, Christensen DB. The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program. *JAMA*. 2003; 43(2): 173-84.
[87] Cranor CW, Christensen DB. The Asheville Project: Factors Associated With Outcomes of a Community Pharmacy Diabetes Care Program. *JAMA*. 2003; 43(2): 160-72.
[88] Knapp et al. 2005.
[89] *Id.*
[90] *Id.*
[91] Eckel F (ed.). Beyond Asheville. *Pharmacy Times*. June 2005.

- Clinical pharmacists at the University of Kentucky developed a pharmacy-based program for diabetes patients that is based on the Asheville model and have contracted with the University to provide these services to its employees. [92]

- Employers in Georgia and Ohio also are contracting with pharmacists to provide diabetes care services to their employees. [93]

This trend highlights the potential opportunities that exist now and in the future for community-based pharmacists to provide the interactions and clinical competence to promote adherence within the diabetes community. Given the growing penetration of these initiatives within the retail pharmacy setting, it may be ill-advised to risk disrupting these patient-pharmacy relationships at the same time that further experience and evidence is being gathered that supports the use of community-based pharmacies to promote adherence to blood glucose treatment and monitoring regimens.

[92] *Id.*
[93] *Id.*

CHAPTER FOUR: CONCLUSIONS

CMS does not have experience with competitively bidding blood glucose monitors and supplies. This lack of experience raises two primary concerns regarding the impacts that a competitive acquisition program could have on Medicare beneficiaries with diabetes:

- Nearly two-thirds of blood glucose test strips used by elderly individuals with diabetes are purchased in community-based retail pharmacies. The assistance pharmacists provide beneficiaries with managing their diabetes may diminish if CMS establishes a competitive acquisition program in which diabetes supplies are provided through a limited number of suppliers and mail-order pharmacies. At a time when Medicare has been trying to move away from the provision of fragmented care, competitive acquisition could interfere with patient access and may adversely effect patients' management of their diabetes. For example, beneficiaries may be unable to obtain their glucose monitoring supplies and professional support under a Part B competitive acquisition program from the same in-network pharmacy under Part D that provides their medications and related professional support for controlling blood glucose levels.

- Competitive acquisition may potentially restrict the choice of monitors available to elderly persons who have diabetes. Given the important differences associated with the costs of monitors categorized within the same HCPCS code, competitive bidding could create an incentive for suppliers to provide lower-cost monitors to beneficiaries when higher-cost monitors may possess important functional characteristics for certain patients.

For some patients, pharmacists may be the most accessible healthcare professionals in the community and therefore may be able to play a unique role in caring for patients with diabetes.[94] Estimates vary, but historically diabetes patients are reported to visit the community pharmacy as much as three to eight times more per year than other patients.[95]

Mounting evidence shows that pharmacist-based programs can result in clinically significant improvements in health outcomes for patients with diabetes. Given the growing interest in these initiatives as part of disease management programs in both the private and public sectors, it may be ill-advised to risk disrupting these patient-pharmacy relationships at the same time that further experience is being gained in the use of community-based pharmacies to promote adherence to blood glucose treatment and monitoring regimens.

Taken together — the positive health outcomes for patients receiving interventions involving pharmacists and the possible frequency with which patients come into contact with community pharmacists — it is reasonable to anticipate that health plans and policymakers will embrace

[94] Younis WS, Campbell S, Slack MK. Pharmacists' attitudes toward diabetes and their involvement in diabetes education. *The Annals of Pharmacotherapy.* 2001;35(7-8):841-845.
[95] Van Veldhuizen-Scott MK, Widmer LB, Stacey SA, Popovich NG. Developing and implementing a pharmaceutical care model in an ambulatory care setting for patients with diabetes. *The Diabetes Educator.* 1995;21(2):117-123.

increased reliance on the professional services that can be provided to patients with diabetes in the community pharmacy setting in the future.[96]

The research involved in preparing this Report highlights that significant difficulties exist in attempting to estimate the magnitude of potential savings to the Medicare program of placing glucose monitors and test strips within the DME competitive acquisition program. It is well-accepted that the complications arising from poorly-controlled diabetes are extremely costly for our health care system and for the Medicare program in particular. Based on the reasonable concerns that competitive acquisition may disrupt access to blood glucose monitoring equipment and supplies, competitive acquisition could inadvertently lead to adverse outcomes for some Medicare beneficiaries and increased costs for the Medicare program arising from these adverse patient outcomes.

[96] Jaber et al. 1996.

APPENDIX A. LIST OF STAKEHOLDER INTERVIEWEES

Peggy Bourgeois, APRN, MN, CNS, CDE
Clinical Diabetes, Education, Research & Reimbursement Consultant
Peggy B. Bourgeois Associates, LLC

Benjamin M. Bluml, BPharm
Vice President for Research
American Pharmacists Association Foundation

Frank Burton, BS, RPh
Pharmacist
Burton's Valu-rite Pharmacy
Greensboro, NC

Keith Campbell, PharmD, MBA, FASHP, CDE
Associate Dean and Professor of Pharmacotherapy
College of Pharmacy
Washington State University

Dale B. Christensen, PhD
UNC School of Pharmacy
Pharmaceutical Policy and Evaluative Science
University of North Carolina at Chapel Hill

Ann Constance, MA, RD, CDE
Project Director, Upper Peninsula Diabetes Outreach Network
Michigan Department of Community Health

Samuel C. Durso, MD, AGSF
Associate Professor of Medicine and Clinical Director of Education
Division of Geriatric Medicine & Gerontology
Johns Hopkins Medical Institutions

Lawrence Fisher, PhD
Professor in Residence – Family and Community Medicine
University of California, San Francisco

Dan G. Garrett, MS, FASHP
Senior Director, Medication Adherence Programs
American Pharmacists Association Foundation

Mark Gregory, RPh
Vice President of Pharmacy and Government Relations
Kerr Drugs

Jeff Gross
Director, Patient Care Programs
CVS

Ginger Kanzer-Lewis, RNC, EdM, CDE
President
GKL Associates

Carole' Mensing, RN, MA, CDE
Coordinator
Diabetes Education Program
University of Connecticut

JoAnne Reifsnyder, PhD, RN, AOCN
Consultant
excelleRx Institute

Bruce T. Taylor
Director, Government Marketing
Roche Diagnostics

Jane Wicklund
Senior Manager, Health Policy & Reimbursement
LifeScan, Inc.

APPENDIX B. INTERVIEW GUIDE

On behalf of the National Association of Chain Drug Stores, *Health Policy R&D* is studying a number of issues related to the self-monitoring of blood glucose (SMBG), including an examination of the professional services and other clinical issues that are important to individuals with diabetes. This study is being undertaken in the context of changes that could occur should Medicare include glucose monitors and test strips in the competitive acquisition program that it must begin implementing in 2007 for items classified as durable medical equipment.

As part of this work, we are interested in gathering information and advice from experts in the field of diabetes on the following issues:

- The professional services related to SMBG that are important to individuals with diabetes, especially for elderly persons, and
- Clinical issues related to patients' adherence to SMBG activities.

I. Background

1. Name and contact information of individual being interviewed.
2. Please describe your current position and responsibilities, specifically as they relate to diabetes care and research.

II. Professional services

3. Please describe the typical roles and responsibilities of the various health care professionals involved in caring for a patient with diabetes.
4. What professional services, such as training and disease management, are provided to patients who self-test?
5. Are certain professional services particularly important for Medicare beneficiaries who self-test?
6. What are the benefits and drawbacks of pharmacy-based diabetes management services?
7. What role can retail pharmacists play in diabetes disease management and patient education?

III. Self-testing products

8. Provide an overview of the key characteristics of diabetes self-testing equipment, how prices vary, and the rate of innovation.

9. Where are most self-testing devices and supplies purchased and what factors influence this purchasing decision?

10. What technical advancements and enhancements in monitors/strips/lancets are needed or currently under development?

IV. Selection of a self-testing device

11. What factors are most important in the selection of a blood glucose monitor?

12. Who is involved in the selection of a self-testing device?

13. Are there protocols or guidelines for professions that outline recommended clinical practice for helping patients in the selection of a monitor?

14. How often and why do patients change monitors?

V. Patient compliance and health outcomes

15. To what extent and in what ways might a limit on the array of glucose monitors available to Medicare beneficiaries affect patient compliance or health outcomes?

16. Is there evidence of enhanced compliance or health outcomes with certain patient-education and disease management services?

17. Does the location from which self-testing supplies are purchased (e.g. drug store, mail order) have an impact on patient education or self-testing compliance or competency?

VI. Other

18. Is there evidence from private health plans, employer health benefit programs, or other research to suggest how competitive bidding or limiting the array of glucose monitors available may affect patient outcomes?

19. Who do you recommend we talk with as part of this study?

20. What data, evidence, or other topics should we include in our research?

21. Other comments.

Submitter : Dr. Scott OConnor

Date: 06/30/2006

Organization : Central Illinois Foot & Ankle

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 30, 2006

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

Dear Dr. McClellan:

I wanted to express my belief that the Centers for Medicare & Medicaid Services (CMS) needs 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. The current physician definition needs to be adjusted to the more inclusion (DMEPOS) 1861(r) from 1861(r)(1).

In my practice, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. My patients rely on me, their Podiatric Physician 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 the office, I feel it is necessary to treat my patients in the time of need. If a patient comes in with a bone fracture or severe sprain, the last thing they need to do is to have to go to another location to obtain this device. Further injury may occur as well as interfering in the proper care for the patient. In more rural communities, this may be all the more difficult as well as for the less privileged patients without transportation.

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 O Connor, DPM

Submitter : Mrs. Jane McClellan

Date: 06/30/2006

Organization : Medicap Pharmacy

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I respectfully request that diabetes testing supplies be exempted from the Competitive DME Bidding process. It is critical, especially in our rural area, that our patients continue to receive the current level of service we are able to provide. If this bidding process becomes a reality, we will see a large, negative impact on our patient's health. With restricted access to supplies, those diabetics currently well-maintained will not be testing as frequently as necessary and will not be able to monitor their disease. Retail pharmacists supply critical services to these patients, such as: drug education and diet implications in diabetic care, training on new blood glucose meters, and immediate access to a health care professional that can facilitate treatment plans in conjunction with the patient's physician. Diabetes is one of the most costly diseases in this country and we are just hitting the tip of the iceberg as far as new diagnoses are concerned. With restricted access to supplies, we are certain to see a huge increase in healthcare dollars that are spent to deal with the repercussions of undertreated or untreated diabetes. Please let us continue to do the jobs that we know best and are trained to do, that is patient care.

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

Organization : Metrika, Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

We believe it is important that CMS has the discretion to consider and weigh the value of management enhancement tools that are likely to improve health outcomes for CMS beneficiaries who have the disease for which the DME item is being supplied.

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

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1270-P-1091-Attach-1.DOC

June 30, 2006

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

To whom it may concern:

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

I am a Registered Nurse and Licensed Nursing Home Administrator serving as the Director of Medicare and Rehabilitation for NHS Management LLC, a skilled nursing facility company.

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

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

At the skilled nursing facilities owned and operated by NHS Management we have numerous residents whose care could be interrupted as a result of this implementation thereby 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,

Martha B. Pettit, BSRN
Director of Medicare and Rehabilitation
NHS Management LLC

Submitter : Mr. brian pickel **Date:** 06/30/2006

Organization : Criticare Home Health Services

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-1092-Attach-1.DOC

CRITICARE
Home Health Services, Inc.
1006 West 6th Street Lawrence, KS 66044

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

Re: Written Comments file code CMS-1270-P

Issue Identifier: *Section F. Deficit Reduction Act of 2005 (Pub. L. 109-171)*

Section 5101(b) of the DRA amending section 1834(a) (5) of the act to limit monthly payments for oxygen equipment to a 36 month period of continuous use with transfer of ownership to the beneficiary should be repealed for the following reasons.

The justification for medical oxygen therapy has been well established. Beneficiary longevity and quality of life are greatly enhanced by the provision of continuous oxygen therapy for those that the medical criteria for coverage have been met. The need for, effects of, and cost effectiveness of home oxygen therapy have been well documented as well. The ownership of oxygen equipment by vulnerable patients needs to be eliminated and the competitive bidding model needs to be seriously modified before implementation, if not eliminated outright as well.

Issue Identifier: *Section E. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173).*

Repeal of Section 5101(b) of the DRA amending section 1834(a)(5) of the act should be repealed for the following reason(s):

Comment(s) regarding the stated objectives of the Medicare DMEPOS Competitive Bidding Program are as follows:

> **Stated Objective:** *"...To limit the financial burden on beneficiaries by reducing their out-of-pocket expenses for DMEPOS they obtain through the program..."*

Beneficiaries will have increased out-of-pocket expenses for beneficiary owned (13 month capped rentals from Jan. 1, 2006 or 36 month rental oxygen) equipment whose ownership has been transferred to the beneficiary

Medicare has for years stated that backup systems are unnecessary. Providers will no longer be able to provide such services to beneficiary owned systems. Service call charges will apply whenever a beneficiary owned system (specifically, oxygen concentrator) fails and the beneficiary will pay out-of-pocket a much larger charge for repairs and maintenance fees.

There will be no financial incentive for providers to provide 24 hour emergency services to beneficiaries with patient owned equipment and such services will be provided on an unassigned basis (more out-of pocket charges) if the beneficiary can even "find" a provider willing to service them.

Current capped rental rules allow for breaks in service – what about breaks in oxygen equipment services? The payment methodology for "capped oxygen" has not been established.

Medicare purchased equipment beneficiaries will have much larger out-of-pocket expenses for DMEPOS obtained through the program due to limited manufacturer and supplier warranties. Beneficiaries will be responsible for charges related to evaluation, pickup and delivery, repair labor and shipping costs for beneficiary owned items under warranty.

Beneficiaries will be responsible for supplier and/or manufacturer's non-warranty service charges for equipment failure and/or maintenance.

Examples: Humidifier changes, Service calls for regulator installation, Access to contracting suppliers will be difficult at best. Non-emergency equipment issues will cause beneficiaries to incur added costs.

"...under new section 1834(a) (5) (F) (II) (bb), maintenance and servicing payments for beneficiary owned oxygen equipment (for parts and labor not covered by the supplier's or manufacturer's warranty) will be made only if they are reasonable and necessary..."

"...In a future rulemaking, we will propose to revise regulations found in part 414, subpart D to incorporate these DRA provisions...."

> A second objective of the Medicare DMEPOS Competitive Bidding Program as stated is: *"To assure beneficiary access to quality DMEPOS as a result of the program".*

What about blind, arthritic and otherwise disabled beneficiaries who require assistance?
The ownership (and resulting responsibility for maintenance and repair) of equipment for this vulnerable patient population is dangerous. Filter changes, analysis of oxygen concentration, beneficiary added costs (Service Calls for patient owned equipment) and after hours calls, will all be passed through to the beneficiaries.

The added costs to contract suppliers for gasoline, mileage, overtime, etc. were previously by providers at no cost under the rental program – once the beneficiary "owns" their equipment, no responsibility of a supplier to continue with services (even if the supplier remains in business) will create an undue burden on this vulnerable patient population. Limited or non-existent access by contract suppliers to CMN, qualifying information for emergency services will likely cause the supplier to provide services unassigned because they are unable to give the beneficiary an informed ABN regarding services and qualification of beneficiaries for patient owned concentrators will be unavailable for after hour's services.

Issue Identifier: *Section C. Payment Basis, Number 2. General Payment rules (Proposed § 414.408 (c-j)).*

> *"...Each item of DME that is paid for under these sections is classified into a payment category, and each category has its own unique payment rules..."*

Beneficiaries will not have access to newer technology for competitively bid products.
The conclusion that "*...Competitive bidding provides a way to harness marketplace dynamics to create incentives for suppliers to provide quality items in an efficient manner and at a reasonable cost...*" is flawed.

The elimination of over half of the suppliers in an area of evaluation is expected, even heralded by the CMS personnel according to a recent teleconference. Participants were told that it is estimated that over half of the providers currently providing services will not be included in the competitive bid program. Where will the beneficiary find a provider to provide services? How will they identify a contract provider? How will the provider provide informed consent for services when the first contact with the beneficiary will be an after hours, emergency telephone call? These are all very serious issues, which will require attention before competitive bidding for services is implemented.

Identification of beneficiary eligibility for DMEPOS either capped or purchased will prove time consuming and for after hours services, impossible. Based upon the 2003 figures for oxygen equipment provided, there are an estimated eleven million oxygen patients currently served by the fee for service system. Putting so large a population of frail, elderly, infirm patients who are dependent upon oxygen services at risk is an example of

government "unconcern" on an unprecedented scale. When disaster strikes, [illegible]
if a beneficiary "qualifies" for equipment, indeed, the supplier will not even know who the beneficiaries are who own equipment. Serious consideration must be given to providing contract suppliers with qualifying information, patient information and patient addresses for beneficiary owned equipment in order to mitigate emergency services when needed. Remember, this is a vulnerable patient population whose medical necessity for oxygen has been established. The delay between finding a supplier and receiving services will likely cause increased emergency room visits and subsequent hospitalization. Where will the "savings" be with that?

The inability of a contracted, competitive bidder to service "all" manufacturer "types" of equipment will prove problematic at best. Accreditation and the still to be announced "Quality Standards" will likely cause a provider to provide the cheapest, but standard type equipment for beneficiaries serviced. Supplier Accreditation requires following manufacturers recommendations for service interval, filter changes (both internal and external) and maintenance. Some services require internal repair and replacement of items which beneficiaries will be unable to perform. At present, no training of beneficiaries for internal annual bacteria filter changes, is recommended by the manufacturer(s). Patient owned equipment will fail – who will repair or replace it?

Additional equipment service and maintenance intervals will prove problematic. Enteral pump certification, liquid oxygen stationary and portable annual recertification, oxygen cylinder hydro-testing, conserver testing and/or recertification, etc. will all fall by the wayside when beneficiaries own such complicated, maintenance intensive and critical (to their health) equipment.

Some examples of problem areas where "service" is paramount by the supplier are enumerated below. The examples are given to show that this vulnerable patient population require a level of expertise and "service" which is not recognized by a model for the lowest bid – patient's are NOT a commodity, and the medical service provided by a DMEPOS supplier is not simply a piece of equipment that one can purchase.

Note: These patients may suffer great harm, even death if their special equipment and service needs are not met.

- Transtracheal Oxygen patients – these patients require specialized instruction, care and supplies. A contract supplier must be able to provide such services or should not be allowed to accept such patients. A Respiratory Therapist is usually specially trained to address specific patient issues such as catheter care, cleaning and instruction.
- Tracheostomy patients – again, such patients require specialized instruction, care instruction and supplies, usually by a Respiratory Therapist.
- High Oxygen Liter Flow patients – such patients require special attention to their oxygen needs – a "standardized" approach to their care will prove both dangerous and inadequate.
- Blind patients – Many equipment types are not able to be utilized by these patients and with a "standardized", low cost piece of equipment, they will be underserved and/or un-served.
- Arthritic patients – many patients are unable to perform daily living activities without assistance, and the current DMEPOS provider often provides additional services which are not addressed by the competitive bidding model, such as equipment cleaning, maintenance, humidifier changes, etc. which will be unavailable.
- Patients without caregivers/family helpers – DMEPOS providers often assist patients in the home without reimbursement simply because the service interval has been increased for at risk patients. The low bid scenario will eliminate such assistance and these patients will utilize the ambulance, emergency room and hospital services at a much higher cost to the Medicare Trust Fund.
- Deaf patients – special patient populations require added time and instruction, even specialized equipment services. These un-reimbursed "services" will not be available under the competitive bidding model.
- Disabled patients (wheelchair bound) – these patients are often unable to perform routine daily maintenance of equipment due to their disability. Such services are un-recognized by the competitive bidding model and will be unavailable or at an increased cost to the beneficiary.

- Ventilator patients – this high risk patient population must [illegible] mobility, emergency services and patient/caregiver instruction will be unavailable in the competitively bid "product". A lack of professional services will place this patient at great risk of injury or death.
- Medicated patients – many patients suffer from confusion and/or medication effect(s), causing them to be unable to perform simple tasks such as filter and humidifier changes, etc. Who will provide these services using the competitive bidding model? These patients are often confused and unable to understand instructions, much less perform complex maintenance on medical equipment.
- Hospice transfers to Medicare – patients who revoke hospice services to enter the Medicare program will not have access to services and/or will be required to change suppliers. Such continuity changes are distressing and often dangerous to this special population of patients. A contract supplier will be required to provide equipment, but will they be able to provide the "service" that these critically ill patients require?
- No transportation patients (no drivers license or vehicle) – public transportation is not everywhere, these patients will likely over-utilize emergency services when their equipment fails as they are likely unable to afford the service charges that will be required of a contract supplier.
- No telephone patients – this patient population will not even be able to "call" a contract supplier for emergency and/or after hour services, even if they are able to identify such a supplier. Who will care for them when a disaster strikes? Who will know that they even need assistance?

SUMMARY:

The effect of the DRA and competitive bidding will prove catastrophic for oxygen patients, in particular. The drive to homogenize and standardize service will prove only to limit beneficiary access to medically necessary therapy. The services provided by oxygen suppliers are not "commodities" to be bought and sold. Perhaps we should distribute the home telephone numbers of the congressmen and women in the districts where oxygen patients reside in order for the beneficiaries to call them when their oxygen concentrators fail (and they will fail) and no supplier will be willing or able to come to the beneficiary's residence to assist them. What will happen to the beneficiary? They will be forced to use the ambulance services to transport them to the hospital for care. The average cost will increase exponentially for "oxygen services"; it will simply be called something else, and be paid for by another part of the same Medicare Trust Fund (same payer, different pocket).

Competition implies a number of factors – including beneficiary access to "service" – the implication that an oxygen concentrator is simply a commodity to be bought and sold is inherently fallacious. It is the "status quo" which provides the beneficiary with the most choices of equipment product(s), services and providers. It is the "status quo" which provides small businesses with the incentive to purchase innovative and "new" technologies to provide an ever increasing "improvement" in the quality of care and services associated with oxygen use. Competition is "alive and well" with the current fee-for-service program and will certainly be eliminated once the initial bidding has been accomplished.

Find an amount you think is fair to pay, and the market will decide if the reimbursement level is sufficient to continue to provide "quality" patient care. Services are already less than they were before due to the annual cuts in reimbursement to providers for equipment services such as oxygen concentrators – portable oxygen is not reimbursed at anyone's definition of "fair" – the arbitrary decision to allow approximately $31.00 per month for unlimited portable oxygen cylinders and/or liquid oxygen fills bears no basis in reality to the true costs of such a service – a single liquid oxygen fill costs more than the monthly reimbursement rate for the same – and many, many beneficiaries need 2 or more fills per month in order to meet their ambulatory level of activities – when liquid oxygen is unavailable to the beneficiaries, and it will not be available under competitive bidding – the quality of life and activity levels of beneficiaries will be greatly curtailed.

Access to new technology will be stifled – travel will be limited to what the beneficiary can afford to pay for privately – and no out of MSA competitive bidding area provider will be willing or able to provide services for the new reimbursement amount, whatever it may be. The intake process alone, considering paperwork burden, compliance with standards of care, etc. will cost the provider more than reimbursement (which, by the way, is

the current situation as well, except they can attempt to at least break even if they provide a [illegible] current low level of reimbursement).

The lack of providers (over half are expected to close their doors with competitive bidding), standardization and homogenization of equipment (no "new" technologies will be provided – after all, we are just "selling" a product, not services) will occur in order for the few, surviving, large companies to provide the lowest level of equipment services they can. Large companies may well be able to "lowball" the bidding and control the process through size and financial reserves that are unavailable to the average small business owner. It will be only a few years before the surviving companies raise the prices to a sustainable level – it is inevitable that once the monopoly has been established, it will become "apparent" that service is something that both the Medicare program and the beneficiary require.

Who will you ask to provide these services then? All the small companies will have closed their doors, and frankly, having observed the past twenty years of bureaucratic bungling and over-regulation fostered by HHS and CMS, how will you induce them to come back? Large companies have an unfair advantage in the initial stages of a competitive bidding model – and the inability of smaller companies to enter into the recommended "network model" due to antitrust provisions, competitive distrust and lack of financial/legal resources will prove the death of the current home healthcare services.

Small companies will be unable to compete with larger companies based upon price only, the current level of care and service component that allows small companies to "out-compete" the larger companies drives the improvement of services throughout the industry, not just in oxygen services but in all aspects of durable medical equipment services. The provision of better warranties and quality of equipment, personal customer service, commitment to new and "improved" technology will simply not be available under the proposed competitive bidding model. Everyone will get the "same" equipment, and the "same" poor level of service – which I anticipate to greatly impact morbidity and mortality of the beneficiaries under such a system.

The beneficiaries are NOT interested in having the "lowest bidders" minimum level of equipment and services – they expect and deserve the "best" level of service possible for the "least" amount of out-of-pocket expense available – there can not be "shopping around" for a better company when the lowest bid model drives services – what you see will be what you get – and it will be miserable and dangerous for the beneficiaries.

Face it, small companies and large companies are paid the same for equipment – the only reason beneficiaries use small, local companies is that the personal level of service and commitment to quality care that is available to the beneficiary from the smaller companies far outshines that provided under the large, low bid model. Insurers such as HMO's already attempt to provide the lowest bid model of care, and the entry and exit of HMO's into various markets has proven that such a service level is unacceptable to the American Public.

There is likely a "firestorm" of beneficiary protest just now beginning, and the HHS and CMS are going to be directly in the center of it. It is certainly prudent to consider pricing when considering buying an automobile. It does not make sense when purchasing critical, medically necessary equipment AND services for beneficiaries who rely on the home healthcare system to keep them alive.

You might save money by purchasing a used automobile and performing the maintenance and service on it yourself, but do you really think an ill, medicated, and worried, short of breath oxygen patient would choose to do so? The implied lack of understanding (seen in the DRA provisions) of what the current healthcare system provides to beneficiaries is staggering.

It is the "quality" of care at the lowest "price" that we are all trying to achieve. The figures show that homecare saves millions over emergency care and hospitalization. The true "cost" of the services and equipment provided by the DMEPOS provider is a bargain – the DRA makes it a flea market auction. That may be fine for knick-knacks and such, but when it comes to the life and health of the beneficiary, second-hand and/or bargain equipment will prove to be no bargain. It is only the health and well-being of the beneficiary that is being bargained for.

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

Organization : **Home Solutions Infusion Therapy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1093-Attach-1.DOC

#1093

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June 28, 2006

Honorable Mark B. McClellan, M.D., Ph.D.

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:

Home Solutions Infusion Therapy 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.

Home Solutions Infusion Therapy is a large multi-state provider of home infusion therapies. I established the company in 1996 and currently we have in excess of 1000 patients on census. We have 3 separate pharmacy locations; 2 in New Jersey and the other in Pennsylvania. We have been accredited by the Joint Commission on Healthcare Accreditation since our inception. Advances in health care technology make it possible to shorten the hospital stay or even eliminate the need for hospitalization of many patients in need infusion services. We have disease state specific programs that are comprehensive, flexible and cost effective. These programs are supported by specialty trained professionals at every level. Our clinicians are available 24 hours a day 7 days a week to assure complete and continuous care coordination.

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:

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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

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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 609-926-6577 x136.

Sincerely,

Todd D. Timbrook, RPh
President

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

Submitter : Ms. Martha Holley **Date:** 06/30/2006

Organization : Holley Hand Therapy, Inc.

Category : Occupational Therapist

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

As a Certified Hand Therapist, Occupational Therpaist with over 19 years of experience, I am writing to express my opposition to the proposed bidding for Pre-Fabriacted splints/orthotics. Our education and specialty makes us uniquely able to evaluate and determine proper orthotic needs. In addition, other factors such as diagnosis, mental capacities and complicating factors are essential in the supply of pre-fabricated equipment to the patient. Ultimately, the patient will be harmed and not have access to the professional and skilled treatment that they deserve. Therefore, I must strongly object to this proposal of a 'Bid for Service.' Thank you.
Martha A. Holley, OTR/L, CHT.

Submitter : Mr. Mark Smith

Date: 06/30/2006

Organization : Med-Ox Home Medical

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

As a small business owner of a DME company with five locations in the state of Ohio, I am gravely concerned of this proposed competitive bidding process. We employ 54 people serving over 1500 home care patients and we take great pride in our ability to compete in the open market on service. Home care patients know they have options and the freedom to choose their home care providers locally. If service is lacking they can change providers when they feel the need to do so. CMS, in my opinion is making the home medical industry less competitive by eliminating as few as 34% of the providers and in our own industry predictions, it could be as high as 60%. This is staggering to not only our industry but to the patients currently being served by small business providers like us. This is my livelihood and all I have known for the last 24 years of my business career.

All that competitive bidding is to save can be achieved by rate adjustments established by CMS and at the same time could preserve small businesses like ours. I am assured that once competitive bidding puts many of us out of business, there would be fewer companies available to bid the next go around, therby creating an Oligopoly that would eventually rule the industry where CMS will have achieved an anti-competitive environment.

Finally, I know that home care patients will ultimately suffer for lack of service and freedom of choice. I also believe that costs will dramatically increase in more institutional settings as the trend will move away from homecare which I beliveve is the answer to the high cost of healthcare in general. Someday, I predict that a politician will stand up and take a stand to promote Home Care to reduce healthcare costs but that will be too late for some of us who will have been eliminated by a bureaucracy capable of eliminating competition and creating a "selective contracting" environment that makes government bigger and stifles free-enterprise.

Thank You,
Mark Smith
Partner
Med-Ox Home Medical

Submitter : Mr. Michael Gresavage **Date:** 06/30/2006

Organization : Hollister Incorporated

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1096-Attach-1.PDF

#1096

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June 27, 2006

Hon. Mark B. McClellan, M.D., PhD.
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Mail Stop C4-26-05
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Baltimore, MD 21244
www.cms.hhs.gov/eRulemaking

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

Dear Dr. McClellan:

Hollister would like to begin by thanking CMS for the opportunity to comment on the Proposed Rule for the Medicare DMEPOS Competitive Bidding Program. We understand the enormity of CMS's task in implementing competitive bidding, and we can appreciate that CMS staff are fully dedicated to the task.

It is Hollister's opinion that there are a number of key issues to be addressed before competitive bidding can be implemented. A key component of the Proposed Rule calls for the implementation of supplier quality standards and contains requirements for CMS approved accreditation organizations that will be applying quality standards for all DMEPOS suppliers, including DMEPOS suppliers participating in competitive bidding. However, CMS has not finalized the quality standards to date. Additionally, per CMS's admission, the draft standards that were released on September 23, 2005 received over 5,000 comments and therefore the final standards will likely look very different from the draft. Hollister was honored to assist in the process of drafting certain product-specific quality standards; however, we remain very concerned that this second round of product-specific quality standards may be finalized without any public scrutiny or public comment period.

The proposed quality standards may include performance management requirements to ensure development, implementation, monitoring, and evaluation of policies, procedures, and products to enable suppliers to maintain compliance with regulatory requirements and CMS policy instructions. The accreditation organization(s) have not been chosen and the cost for accreditation cannot be

determined at this time. The link between Quality Standards and this Proposed Rule make meaningful comments inconceivable at a time when there are so many pieces still missing from this puzzle. We encourage CMS to take this process more slowly, recognizing that there are *sequential* steps to follow - some of those steps cannot, and should not, be completed at the same time.

Payment Basis

Authority to Adjust Payment in Other Areas (§414.408(e))

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. We believe 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.

Concerning those items on which CMS does have the authority to exercise this process, it could have devastating effects on small suppliers serving areas in which the economics of serving beneficiaries is greatly different from the Competitive Bidding area (CBA). The proposed rule gives no indication of what methodology will be used to adjust payments, and a substantive proposal with the opportunity to comment is needed. 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.

Competitive Bidding Areas (CBAs)

Nationwide or Regional Mail Order Competitive Bidding Program (§414.410(d)(2))

Implementing a national or regional mail order DMEPOS competitive bidding program—or the proposed mail order alternative requiring Medicare beneficiaries to obtain certain DMEPOS items via mail order suppliers—would manipulate the market, rather than promote competition. Mail order suppliers are already included under the proposed provisions. There is no need to create a distinct or separate DMEPOS competitive bidding program for mail order.

Additionally, rather than a mandatory requirement for provision DMEPOS items via mail order, CMS should continue to allow Medicare beneficiaries to obtain their DMEPOS products via their preferred access channel. While some Medicare beneficiaries may choose to obtain certain

DMEPOS items via mail order, many Medicare beneficiaries prefer to obtain necessary DMEPOS items from local community suppliers. A case in point is a patient who has just undergone ostomy surgery and has yet to determine what products are most suitable for their long-term use, and needs to go through an iterative process to do so because of differences in body contours and skin type and condition. Many of these beneficiaries prefer to conduct this business personally with a local supplier who may be better positioned to understand their specific challenges or needs. These local suppliers can see the fitting issues that the beneficiary is experiencing and offer immediate solutions to those issues whereas a mail order supplier would send another sample to *hopefully* remedy the situation. The delay due to mail delivery causes the beneficiary to continue to deal with a fitting/leaking problem longer than necessary, which may put their skin at risk. Hollister believes that beneficiary choice must be maintained to ensure that beneficiary adherence to prescribed treatment regimens are not jeopardized.

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 a 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.

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).

Medicare covers ostomy supplies under the Prosthetic Device benefit. Although they are reimbursed under the same methodology as DME in accordance with section 1834a(2)(B) & (C), they are not a 'covered item' as the term is defined under 1834a(13). It has therefore been our understanding, especially as it was supported by information presented at the December 2004 PAOC meeting, that supplies unrelated to DME (such as ostomy, tracheostomy and urological supplies) were not within the scope of competitive bidding. Additionally, the Proposed Rule states that surgical dressings are ineligible for inclusion.

The proposed rule concentrates almost exclusively on item selection based on the potential for savings. We believe that quality of service to beneficiaries should also be a significant factor. In particular, product groups that require a significant degree of personal service are inappropriate for inclusion in competitive bidding.. Ostomy supplies, especially their provision to beneficiaries who have recently undergone surgery, should not be included. Additionally past surveys have shown that, due to low fee levels, only around 16% of Participating Providers choose to supply ostomy products and the proposed rule includes a requirement that bids must be below existing fee levels; this will reduce participation even more.

Ostomy supplies were not included in the Demonstration Projects and their inclusion in competitive bidding would lead to much enforced supplier switching and reduced access to the most medically appropriate products.

CMS should confirm that ostomy products and supplies and urological supplies are not included in competitive bidding under §1847(a)(2). Further, CMS should include in the Final Rule a definitive list of those product categories that are eligible for inclusion.

Conditions for Awarding Contracts

Quality Standards and Accreditation (§414.414(c))

The NPRM states that CMS will allow a "grace period" during which unaccredited providers can participate in the bidding process. Unaccredited providers who are winning bidders may complete accreditation during 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 be accredited.

Assurance of Savings (§414.414(f))

CMS should recognize that the fee schedule for certain HCPCS codes are insufficient for quality product. Because of that, CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for a HCPCS code. 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.

Assurance of Multiple Contractors (§414.414(g))

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.

Determining Single Payment Amounts for Individual Items

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

CMS' preferred methodology of basing the payment amounts on the median of the selected supplier's bids has the disadvantage that some supplies would inevitably have to accept a fee for some products that is below what they bid. This could be the case 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 significantly different from the method used in Demonstration Projects. CMS should set the payment amount at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category.

Rebate Program (proposed§414.416(c))

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 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. 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), we feel CMS should withdraw the rebate proposal.

Physician Authorization/ Treating Practitioner

The Proposed Rule would keep intact the provision that permits a physician to prescribe a particular brand or mode of delivery of an item within a particular HCPCS code if the physician determines

that use of the particular item would avoid an adverse medical outcome on the individual (section §414.440). The Proposed Rule would expand this provision by permitting certain treating practitioners, including physician assistants, nurse practitioners, and clinical nurse specialists to act as physicians for purposes of prescribing a particular brand or mode of delivery if the practitioner determines that the use of the item would avoid an adverse medical outcome to the patient.

As CMS correctly notes in the Proposed Rule, suppliers under competitive bidding may only offer certain brands within a HCPCS code. Hollister commends CMS for permitting a variety of qualified practitioners, in addition to physicians, to prescribe particular brands or modes of delivery where appropriate. We believe this will help to ensure that patients have access to the most appropriate treatments and technologies, leading to enhanced quality of care.

This is particularly true for products such as Ostomy, which are self-administered and often selected by the beneficiary him/herself (choosing the one that is especially suitable for their specific skin type/skin condition, body contours and other factors). These prosthetic devices are very personal to the beneficiary. This situation again displays a strong argument for why products such as ostomy supplies should not be included in competitive bidding. If CMS does include items like Ostomy and urological supplies in competitive bidding, we feel it is imperative that the supplier provide the exact product that the beneficiary needs (or assists the beneficiary in finding an approved supplier in their competitive bidding area that can provide the product) unless the beneficiary expressly agrees to try something else.

Gap-Filling (Proposed § 414.210(g))

Establishing payment amounts for new DMEPOS items is an extremely important process that is unrelated to the implementation of the DMEPOS competitive bidding program. Because of this, Hollister believes that it is inappropriate to include this provision within the DMEPOS competitive bidding Proposed Rule and requests that any proposals related to payment for new DMEPOS items be made under a separate rulemaking process. Doing so will ensure that all appropriate stakeholders have an opportunity to properly evaluate and provide comment on the proposed provisions.

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 that 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 with coordinating communication between coverage, coding and payment, the administration and review of a comparative technology assessment is a comprehensive effort that

raises many important procedural questions. As such, CMS has left far too many questions without an ability to evaluate a methodology or any details related to this proposal.

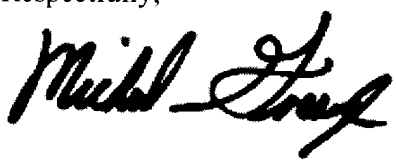
Because of the complexity, comprehensive nature and serious implication for this type of initiative, the use of a comparative technology assessment should be held to at least the same level of procedural predictability and transparency as the process for development of a National Coverage Determination. Moreover, this new initiative is not required as part of the implementation for competitive bidding and is not mandated by the MMA.

Hollister therefore recommends that CMS deal with the technology assessment issues in a separately published proposed rule containing specific procedural criteria and detailed methodology. We also recommend that all references to the technology assessment as a part of gap filling be removed from the Final Rule.

In summary, we are concerned about how the proposed rule will affect the quality of life for the Medicare beneficiaries who use our products. Ostomy and urological supplies are very personal in nature and some of the proposed changes could cause disruption of service and access issues for a population that depends on a brand of product that uniquely works for them. Medicare needs to remember that they service a varied population with varied complications and varied needs to ensure a proper fit to a prosthetic device like an ostomy pouch.

Hollister feels there is much in the Proposed Rule that is not yet well defined and that there will inevitably be a great number of comments. The quality standards have not been released, the MSAs have not been chosen, and the product categories have not been established. In short, there are many pieces missing in this puzzle. Hollister strongly suggests that Medicare carefully consider the comments received and that a much more developed Interim Final Rule is published, allowing public comment on a document that is closer to a Final Rule with quality standards, accreditation organizations named and products and locations outlined.

Respectfully,



Michael Gresavage
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

dce

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

Organization : **Tropical Palms Hand Therapy, Inc.**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am very concerned about the impact of a competitive billing process for Medicare DME on small businesses such as mine. I am an Occupational Therapist and a Certified Hand Therapist with 26 years of experience. This means that I have a high degree of specialized knowledge about the rehabilitation of orthopedic arm and hand injuries and that a portion of my training and services includes the ability to issue and fabricate splints (orthotics) for the upper extremity.

My primary concern is that I will not be able to be competitive anough to provide the necessary DME orthotics for my medicare patients because I am a small business and I only supply Certified Hand Therapy. Hand Therapy already has a very slim profit margin because the staff costs are so great and the medicare reimbursement does does change whether the service is delivered by an entry level Occupational therapist assistant (about $12/hour) or one with years of experience and board certifications (about $40+/hour). Our profit is often made by our experience and training in making and fitting orthotics.

My second area of concern is that I will have to accept professional responsibility and liability for a patient referred to me but the splint (or orthotic) may have to be fabricated by someone with much less knowledge or experience than I have. The orthotic is most times the crux of the treatment and it can definitely affect a patient outcome if it is not managed properly.

Please consider keeping the system the way it is and allowing us, the specialists, to determine the type of orthotics a medicare patient needs to make a full recovery.

Sincerely,

Pam Tutten, OT, CHT
owner

Submitter : Ms. mary ellen spradlin **Date:** 06/30/2006

Organization : health care reimbursement solutions, inc

Category : Health Care Industry

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Please see attached letter

CMS-1270-P-1098-Attach-1.DOC

#1098

June 30, 2006

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

Re: Centers for Medicare & Medicaid Services (CMS)
42 CFR Parts 411, 414 and 424
(CMS-1270-P) RIN 0938-AN14
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

VIA: **www.cms.hhs.gov/eRulemaking**

Dear Colleagues:

As a Billing Service for Home Medical Equipment Suppliers, we welcome the opportunity to comment on this proposed rule which would implement competitive bidding programs for certain items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) throughout the United States in accordance with sections 1847(a) and (b) of the Social Security Act.

As a Billing Service, we represent the home care industry in 5 states, for stand alone and hospital based providers of home medical equipment. The following comments reflect the our collective years of experience and our assessment of the impact the above rule would have upon beneficiaries of the Medicare/Medicaid program, in addition to the impact on the providers of home medical equipment, their employees and our employees.

COMMENTS/ISSUES/QUESTIONS:

It is our view that the term "Competitive Bidding" is a misnomer for a flawed system which might more aptly be described as "Selective Acquisition." It is also our belief that the two pilot projects have demonstrated significant negative consequences for beneficiaries by effectively eliminating the normal, healthy competition that currently exists between the DMEPOS provider community to provide beneficiaries with fast, efficient, and effective products and services. Along with this comes the fact that the majority of beneficiaries are supplied by small businesses. These small businesses are our clients. Due to their size, which diminishes their ability for affording accreditation, their minimal service locations and size of delivery area many of them will be excluded from the bidding process. This exclusion will in the end result in the closing of many providers r esulting in the increase in Unemployment throughout the United States. It is important to mention at this point that the United States was founded on freedom and entrepreneurship. This basically eliminates the freedom from the Medicare Beneficiary. This eliminates the entrepreneurship from the American Public as small business involvement in the Home Medical Equipment industry will be virtually eliminated.

Reasonable and significant cost-savings from providers can and should ultimately be achieved without eliminating normal competition in the marketplace and without eliminating virtually the entire, existing DMEPOS provider panel. The bottom line, we believe, that creation of a "limited provider panel" through the proposed national competitive bidding (NCB) program is bad policy for

beneficiaries and providers alike. While this NCB option may, in some instances, result in product price reduction, it will at the same time severely reduce overall patient access, choice and service, ultimately shifting increased care costs to other areas of the hospital system and health care continuum; e.g., increased length of stay in inpatient/acute settings and/or increased patient re-admission frequency or disease severity, etc. from moving to a "low price" model being encouraged by NCB..

On this point, we ask that CMS concur in the general understanding that any potential product cost savings gained through National Competitive Bidding for DMEPOS---including oxygen, wheelchairs, beds, respiratory equipment, wound care, diabetic supplies etc.---will ultimately be offset by increased costs in both the tertiary inpatient and outpatient care settings.

As the experience of DMEPOS providers demonstrates, these costs are recognized through increased administrative, oversight and program management expense, and often prevent patients from getting the most efficient and optimal health care available.

RECOMMENDATIONS: We recommend that CMS should stagger the bidding in MSAs in 2007 to allow for an orderly rollout of the program. This will actually allow CMS to identify problems that occur in the competitive bid areas and to work with providers and patients alike to help correct them before the problems become even more widespread. In addition to this staggering, CMS should move back implementation of the 2007 date, due to the questions remaining about the program, e.g. accrediting bodies and MSA's involved.

The initial MSA's and products selected should be clearly and distinctly identified in the final rule. Unfortunately however, under the current proposed CMS timeline, it appears that small DMEPOS providers will not have enough time to create legitimate and functional networks, which will ultimately eliminate, as mentioned above, "small" DMEPOS providers that want to participate, regardless of their industry knowledge, experience, and/or specialized expertise

CMS' process to determine the number of suppliers to meet projected demand in an MSA, along with its defined methodology to estimate supplier capacity, appears to heavily favor the large, high volume regional suppliers, rather than the smaller, independent DMEPOS providers, again as stated earlier, eliminating the small business and entrepreneurship of the American Public.

CMS' assertion that the NPRM provides an "equal" opportunity for small suppliers to participate is questionable, and there appears to be no guarantee that any of the winning bidders might be a small business, or even a network of small business providers.

We would urge that CMS consider the significant and potential negative impact that the NPRM may/will ultimately have on small DME businesses and upon the actual, "true" competitiveness of the second and third rounds of the competitive bidding process.

CMS should consult with the Small Business Administration to better assess the impact the NPRM will have on small businesses as both tax-paying members and constituents of the communities that they serve. Again, as mentioned above, the impact on Unemployment in those areas should be considered as well.

CMS should further explain and clarify the specific methodology that will be used to determine whether an MSA is "competitive" during the 2008 - 2009 bid expansion process.

CMS Bid scoring still needs to be improved, and more clearly defined. Suppliers need to know exactly what factors are/will be utilized and what weights will be given to these factors, especially if/when providers are attempting to bid subsets of a major product category.

CMS should explain and clarify what specific measures will be used to decide and how much an item's potential savings could be as a result of competitive bidding.

QUESTIONS: Annual Medicare DMEPOS allowed charges - Is there a specific volume/quantity, or simply a dollar threshold expenditure level that will trigger "competitive acquisition" for a particular product and/or product category? Alternatively, is there a specific threshold growth percentage in a product category that will determine whether it will be subject to competitive acquisition and/or will it vary by the overall dollar expenditures within the product category?

How will CMS determine the appropriate number of suppliers for a product category in each MSA? What specific supplier capacity thresholds will be used to determine this and how will those "capacity" thresholds be specifically determined?

How will potential "cost savings" through Competitive Acquisition be statistically determined and/or validated by actual data for the vast majority of products and categories that were not included in the two initial Demonstration Projects in FL and TX? What reports and/or types of data will be reviewed and considered when evaluating potential cost-savings? Who (either within or outside of CMS) will review the studies and determine their actual statistical validity and applicability for modeling potential future Medicare program savings? Anticipating roll out of the bid price to all areas, not just the MSA's, has CMS considered that the rural provider has significantly higher costs due to the distances traveled to deliver product to the Medicare Beneficiary?

Lack of Established Quality Standards and/or qualified "Accrediting Bodies"

The NPRM clearly states that providers must meet "quality standards," yet the proposed "final" versions of the DMEPOS provider quality standards have not yet been released. It is, therefore, difficult at best, if not impossible, to fully articulate and provides clear comments on these proposed rules for competitive biding when these rules refer to quality standards that have not been fully defined and released.

Ultimately, in the interest of establishing and providing some type of a baseline "provider standard," only accredited providers should be eligible to submit and be awarded "winning bids". In addition, accreditation MUST be affordable for the small provider. Current accrediting bodies' standards are significantly higher than those expected from CMS and their cost reflects that. CMS should not proceed with competitive bidding until it is certain that all of this is possible. CMS needs to clearly identify and establish both the objective and subjective criteria that it will use to identify and deem the accrediting bodies now, before proceeding with trying to implement the actual competitive acquisition processes.

We agree that Accreditation is and should be required, yet affordable, for any provider to service patients under the proposed rules, but again, no final, specific accreditation standards and criteria and/or approved accrediting bodies have yet been clearly identified. The proposed rule appears to still allow non-accredited organizations to bid and be awarded a bid prior to being accredited.

It remains unknown if any of the accreditation bodies will even be interested and/or have the functional accrediting capacity to undertake the standards and criteria which are yet to be specifically defined and established by this proposed rule. Therefore, accreditation organizations, as well as the associated standards, should be in place prior to any further movement towards any competitive bid. Only providers that have attained accreditation should be allowed to bid or be awarded any bid, without these organizations being named, the time constraint to meet this is clearly faulty. Patient safety and care dictates that providers should not be awarded a bid and be able to provide equipment and supplies without first demonstrating competency and proficiency in this area.

CMS should however, grandfather any/all providers that are already accredited by organizations that meet the new criteria that CMS identifies. However, CMS should then allow additional time for providers to analyze the quality standards in conjunction with the overall NPRM rule. The quality standards and cost of accreditation will ultimately affect the overall cost of servicing beneficiaries and are an integral part of the bid process. Therefore, CMS should consider further extending the NPRM comment period and any subsequent implementation plan(s), at least until those "definitive" quality standards are available and have completed the actual rule making process.

It is unrealistic to classify this process as a competitive bid when bidders are ultimately being encouraged, and essentially being forced to bid below a pre-determined price level. The result of this rule could result in bid awards that are established at unrealistic and unsustainable pricing levels. To maintain the integrity of the bidding process, CMS should have some way to objectively evaluate bids for statistical validity, sustainability and overall economic reasonableness. A mechanism for unreasonable bids needs to be incorporated in the final rule to weed out and eliminate purely "lowball" bids.

The prohibition on entities' ability to change ownership during specific periods of the bid award seems overly intrusive and an infringement on an entity's basic business rights.

FUNDAMENTAL ISSUES: The proposed rule appears to primarily utilize cost and volume for product selection. Unfortunately, the potential negative impacts in terms of overall patient access and inclusion and continuity with established care plans and protocols does not appear to be addressed. Consideration to overall medical appropriateness needs to be considered, as well as overall patient access to care and services.

Potential cost considerations that will affect many other areas of the overall health care continuum do not appear to be adequately considered or addressed. There appears to have been no examination of negative cost implications for physicians, home health nursing care providers, hospice, inpatient and outpatient hospitals, integrated healthcare delivery systems and owned-providers, as well as multiple and various other healthcare providers. It is obviously critical that protections and minimization of overall cost impacts throughout the health care service and cost continuum are clearly identified, discussed, and fairly addressed in the final rules. Pushing "costs" out of products alone will most certainly result in detrimental cost-shifting and even cost-increases in other areas of the continuum.

<u>REBATE COMMENTS/ISSUES:</u>

The NPRM mentions a rebate option that contracted providers may choose to underbid and utilize based upon the idea of increasing patient volume...We believe that the potential use of "rebates" to beneficiaries in health care delivery is ultimately an unwise and potentially fraud-encouraging concept

that is without clear or reasonable legal precedent. The provision of rebates to beneficiaries is actually contradictory to other laws and regulations applicable to the Medicare program, including the Anti-Kickback Statute and the beneficiary inducement statute.

We therefore strongly encourage the elimination of this proposed "rebate" provision. Rebates could and would potentially encourage an increase in over utilization and could result in beneficiaries placing pressure on their healthcare providers to order unnecessary products and services. It is fairly certain that Congress did not intend competitive biding to include cash rebates to consumers with the potential of increasing unnecessary product utilization. We question as to whether this feature is consistent with the law.

RECOMMENDATION: The actual items that will be put up for bid should be identified now to solicit and allow further provider-based discussions and comments. We have great concern that products will be grouped-based on product categories. This approach doesn't address the individual medical policy groupings that do not always follow product groupings. Even in the best grouping situations, patients and providers, along with inpatient and outpatient referring entities could feasibly be placed at a significant disadvantage, since they would have to deal with multiple providers of different products for the same patient. Multiple providers of DMEPOS in a home are not only dangerous from a patient safety perspective, but extremely inefficient for the provider and physician who are supervising and coordinating the patient's overall care.

The bid process needs to allow for economically realistic and sustainable bids, rather than simply encouraging "lower priced" bids. In the demonstration projects, some items were bid higher than the current Medicare allowable at that time. Mandating that all "winning" bids below the current Medicare level is ultimately short-sighted and unrealistic in that it effectively could negate reasonable and sustainable pricing levels which are based upon actual activity-based operational costs.

A statistically valid and accurate screening mechanism needs to be developed to completely remove and eliminate unreasonably low and ultimately unsustainable bids. The proposed rule appears to have a loophole where bidders can "low ball" their bid to grantee inclusion, yet not have to honor that "low ball" bid as their actual price paid. The use of statistical models to prevent this situation should be clearly established, defined and implemented prior to the actual biding process.

The determination of supplier's potential service capacity also needs to be better defined. It is still somewhat unclear exactly how CMS will determine a supplier's potential capacity. The proposed rule appears to discriminate and favor the large, regional providers, while the small and medium providers will effectively be shut out of the bidding process as it is currently proposed.

The process for the establishment of networks needs better definition. It is unclear as to the required corporate structure, the responsibilities of the network providers to the network administrator, the patient and CMS. The accreditation requirements for potential established or new provider networks are also still very unclear.

The two initial Competitive Acquisition demonstration projects in TX and FL ultimately neglected to look at the overall impact and costs that NCB will place on other areas of the healthcare continuum.

What economic provider relief is being considered for other areas of the healthcare continuum that will ultimately be exposed to increased costs and administrative burdens posed by NCB? Since none of these impacts were apparently evaluated or studied during the demonstration projects, there is certainly

additional potential negative care and cost implications that will likely be the result of the implementation of widespread NCB.

The NPRM in effect will result in an unfunded federal mandate for other associated members of the healthcare continuum as they seek to move and transition patients to the most clinically appropriate and cost-effective setting of care, not to mention decreased Tax Revenue due to decreased providers and employees and increased Unemployment. To rapidly facilitate acute-care inpatient and/or outpatient facility discharges, the implementation of an NCB mandate has the potential to disadvantage patients within physicians networks, hospitals, integrated healthcare delivery systems, home health, hospice, outpatient and long term care settings who will simply have to employ detrimental cost-shifting.

This concludes our comments. We value our partnership with CMS in our common mission to provide quality health care services and products for Medicare beneficiaries.

Sincerely,

Mary Ellen Spradlin
President
Heath Care Reimbursement Solutions, Inc.
365 Mill Street, P O Box 865
Ortonville, MI 48462
(248) 627-5416

June 30, 2006

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

Re: Centers for Medicare & Medicaid Services (CMS)
42 CFR Parts 411, 414 and 424
(CMS-1270-P) RIN 0938-AN14
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

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RECOMMENDATIONS: We recommend that CMS should stagger the bidding in MSAs in 2007 to allow for an orderly rollout of the program. This will actually allow CMS to identify problems that occur in the competitive bid areas and to work with providers and patients alike to help correct them before the problems become even more widespread. In addition to this staggering, CMS should move back implementation of the 2007 date, due to the questions remaining about the program, e.g. accrediting bodies and MSA's involved.

The initial MSA's and products selected should be clearly and distinctly identified in the final rule. Unfortunately however, under the current proposed CMS timeline, it appears that small DMEPOS providers will not have enough time to create legitimate and functional networks, which will ultimately eliminate, as mentioned above, "small" DMEPOS providers that want to participate, regardless of their industry knowledge, experience, and/or specialized expertise

CMS' process to determine the number of suppliers to meet projected demand in an MSA, along with its defined methodology to estimate supplier capacity, appears to heavily favor the large, high volume regional suppliers, rather than the smaller, independent DMEPOS providers, again as stated earlier, eliminating the small business and entrepreneurship of the American Public.

CMS' assertion that the NPRM provides an "equal" opportunity for small suppliers to participate is questionable, and there appears to be no guarantee that any of the winning bidders might be a small business, or even a network of small business providers.

We would urge that CMS consider the significant and potential negative impact that the NPRM may/will ultimately have on small DME businesses and upon the actual, "true" competitiveness of the second and third rounds of the competitive bidding process.

CMS should consult with the Small Business Administration to better assess the impact the NPRM will have on small businesses as both tax-paying members and constituents of the communities that they serve. Again, as mentioned above, the impact on Unemployment in those areas should be considered as well.

CMS should further explain and clarify the specific methodology that will be used to determine whether an MSA is "competitive" during the 2008 - 2009 bid expansion process.

CMS Bid scoring still needs to be improved, and more clearly defined. Suppliers need to know exactly what factors are/will be utilized and what weights will be given to these factors, especially if/when providers are attempting to bid subsets of a major product category.

CMS should explain and clarify what specific measures will be used to decide and how much an item's potential savings could be as a result of competitive bidding.

QUESTIONS: Annual Medicare DMEPOS allowed charges - Is there a specific volume/quantity, or simply a dollar threshold expenditure level that will trigger "competitive acquisition" for a particular product and/or product category? Alternatively, is there a specific threshold growth percentage in a product category that will determine whether it will be subject to competitive acquisition and/or will it vary by the overall dollar expenditures within the product category?

How will CMS determine the appropriate number of suppliers for a product category in each MSA? What specific supplier capacity thresholds will be used to determine this and how will those "capacity" thresholds be specifically determined?

How will potential "cost savings" through Competitive Acquisition be statistically determined and/or validated by actual data for the vast majority of products and categories that were not included in the two initial Demonstration Projects in FL and TX? What reports and/or types of data will be reviewed and considered when evaluating potential cost-savings? Who (either within or outside of CMS) will review the studies and determine their actual statistical validity and applicability for modeling potential future Medicare program savings? Anticipating roll out of the bid price to all areas, not just the MSA's, has CMS considered that the rural provider has significantly higher costs due to the distances traveled to deliver product to the Medicare Beneficiary?

Lack of Established Quality Standards and/or qualified "Accrediting Bodies"

The NPRM clearly states that providers must meet "quality standards," yet the proposed "final" versions of the DMEPOS provider quality standards have not yet been released. It is, therefore, difficult at best, if not impossible, to fully articulate and provides clear comments on these proposed rules for competitive biding when these rules refer to quality standards that have not been fully defined and released.

Ultimately, in the interest of establishing and providing some type of a baseline "provider standard," only accredited providers should be eligible to submit and be awarded "winning bids". In addition, accreditation MUST be affordable for the small provider. Current accrediting bodies' standards are significantly higher than those expected from CMS and their cost reflects that. CMS should not proceed with competitive bidding until it is certain that all of this is possible. CMS needs to clearly identify and establish both the objective and subjective criteria that it will use to identify and deem the accrediting bodies now, before proceeding with trying to implement the actual competitive acquisition processes.

We agree that Accreditation is and should be required, yet affordable, for any provider to service patients under the proposed rules, but again, no final, specific accreditation standards and criteria and/or approved accrediting bodies have yet been clearly identified. The proposed rule appears to still allow non-accredited organizations to bid and be awarded a bid prior to being accredited.

It remains unknown if any of the accreditation bodies will even be interested and/or have the functional accrediting capacity to undertake the standards and criteria which are yet to be specifically defined and established by this proposed rule. Therefore, accreditation organizations, as well as the associated standards, should be in place prior to any further movement towards any competitive bid. Only providers that have attained accreditation should be allowed to bid or be awarded any bid, without these organizations being named, the time constraint to meet this is clearly faulty. Patient safety and care dictates that providers should not be awarded a bid and be able to provide equipment and supplies without first demonstrating competency and proficiency in this area.

CMS should however, grandfather any/all providers that are already accredited by organizations that meet the new criteria that CMS identifies. However, CMS should then allow additional time for providers to analyze the quality standards in conjunction with the overall NPRM rule. The quality standards and cost of accreditation will ultimately affect the overall cost of servicing beneficiaries and are an integral part of the bid process. Therefore, CMS should consider further extending the NPRM comment period and any subsequent implementation plan(s), at least until those "definitive" quality standards are available and have completed the actual rule making process.

It is unrealistic to classify this process as a competitive bid when bidders are ultimately being encouraged, and essentially being forced to bid below a pre-determined price level. The result of this rule could result in bid awards that are established at unrealistic and unsustainable pricing levels. To maintain the integrity of the bidding process, CMS should have some way to objectively evaluate bids for statistical validity, sustainability and overall economic reasonableness. A mechanism for unreasonable bids needs to be incorporated in the final rule to weed out and eliminate purely "lowball" bids.

The prohibition on entities' ability to change ownership during specific periods of the bid award seems overly intrusive and an infringement on an entity's basic business rights.

FUNDAMENTAL ISSUES: The proposed rule appears to primarily utilize cost and volume for product selection. Unfortunately, the potential negative impacts in terms of overall patient access and inclusion and continuity with established care plans and protocols does not appear to be addressed. Consideration to overall medical appropriateness needs to be considered, as well as overall patient access to care and services.

Potential cost considerations that will affect many other areas of the overall health care continuum do not appear to be adequately considered or addressed. There appears to have been no examination of negative cost implications for physicians, home health nursing care providers, hospice, inpatient and outpatient hospitals, integrated healthcare delivery systems and owned-providers, as well as multiple and various other healthcare providers. It is obviously critical that protections and minimization of overall cost impacts throughout the health care service and cost continuum are clearly identified, discussed, and fairly addressed in the final rules. Pushing "costs" out of products alone will most certainly result in detrimental cost-shifting and even cost-increases in other areas of the continuum.

REBATE COMMENTS/ISSUES:

The NPRM mentions a rebate option that contracted providers may choose to underbid and utilize based upon the idea of increasing patient volume...We believe that the potential use of "rebates" to beneficiaries in health care delivery is ultimately an unwise and potentially fraud-encouraging concept

that is without clear or reasonable legal precedent. The provision of rebates to beneficiaries is actually contradictory to other laws and regulations applicable to the Medicare program, including the Anti-Kickback Statute and the beneficiary inducement statute.

We therefore strongly encourage the elimination of this proposed "rebate" provision. Rebates could and would potentially encourage an increase in over utilization and could result in beneficiaries placing pressure on their healthcare providers to order unnecessary products and services. It is fairly certain that Congress did not intend competitive biding to include cash rebates to consumers with the potential of increasing unnecessary product utilization. We question as to whether this feature is consistent with the law.

RECOMMENDATION: The actual items that will be put up for bid should be identified now to solicit and allow further provider-based discussions and comments. We have great concern that products will be grouped-based on product categories. This approach doesn't address the individual medical policy groupings that do not always follow product groupings. Even in the best grouping situations, patients and providers, along with inpatient and outpatient referring entities could feasibly be placed at a significant disadvantage, since they would have to deal with multiple providers of different products for the same patient. Multiple providers of DMEPOS in a home are not only dangerous from a patient safety perspective, but extremely inefficient for the provider and physician who are supervising and coordinating the patient's overall care.

The bid process needs to allow for economically realistic and sustainable bids, rather than simply encouraging "lower priced" bids. In the demonstration projects, some items were bid higher than the current Medicare allowable at that time. Mandating that all "winning" bids below the current Medicare level is ultimately short-sighted and unrealistic in that it effectively could negate reasonable and sustainable pricing levels which are based upon actual activity-based operational costs.

A statistically valid and accurate screening mechanism needs to be developed to completely remove and eliminate unreasonably low and ultimately unsustainable bids. The proposed rule appears to have a loophole where bidders can "low ball" their bid to grantee inclusion, yet not have to honor that "low ball" bid as their actual price paid. The use of statistical models to prevent this situation should be clearly established, defined and implemented prior to the actual biding process.

The determination of supplier's potential service capacity also needs to be better defined. It is still somewhat unclear exactly how CMS will determine a supplier's potential capacity. The proposed rule appears to discriminate and favor the large, regional providers, while the small and medium providers will effectively be shut out of the bidding process as it is currently proposed.

The process for the establishment of networks needs better definition. It is unclear as to the required corporate structure, the responsibilities of the network providers to the network administrator, the patient and CMS. The accreditation requirements for potential established or new provider networks are also still very unclear.

The two initial Competitive Acquisition demonstration projects in TX and FL ultimately neglected to look at the overall impact and costs that NCB will place on other areas of the healthcare continuum.

What economic provider relief is being considered for other areas of the healthcare continuum that will ultimately be exposed to increased costs and administrative burdens posed by NCB? Since none of these impacts were apparently evaluated or studied during the demonstration projects, there is certainly

additional potential negative care and cost implications that will likely be the result of the implementation of widespread NCB.

The NPRM in effect will result in an unfunded federal mandate for other associated members of the healthcare continuum as they seek to move and transition patients to the most clinically appropriate and cost-effective setting of care, not to mention decreased Tax Revenue due to decreased providers and employees and increased Unemployment. To rapidly facilitate acute-care inpatient and/or outpatient facility discharges, the implementation of an NCB mandate has the potential to disadvantage patients within physicians networks, hospitals, integrated healthcare delivery systems, home health, hospice, outpatient and long term care settings who will simply have to employ detrimental cost-shifting.

This concludes our comments. We value our partnership with CMS in our common mission to provide quality health care services and products for Medicare beneficiaries.

Sincerely,

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Submitter : Mr. Jeffrey Bush **Date:** 06/30/2006

Organization : Becton, Dickinson and Company (BD)

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1099-Attach-1.DOC

#1099

Helping all people
live healthy lives

June 30, 2006

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Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
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Washington, D.C. 20201

Re: ***File Code CMS-1270-P: Comments Related to the Proposed Rule for Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues***

Dear Doctor McClellan:

Becton, Dickinson and Company (BD), a medical technology company that serves healthcare institutions, life science researchers, clinical laboratories, industry and the general public, through the manufacture and sale of medical supplies, devices, laboratory equipment and diagnostic products, submits the following comments to the Centers for Medicare and Medicaid Services (CMS) regarding the proposed rule for Medicare's competitive acquisition for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and other issues (CMS-1270-P).

General Comments

BD would like to convey the following six overarching themes in its comments to CMS on the DMEPOS competitive bidding proposed rule:

I. Assurance of high quality, cost beneficial healthcare for Medicare beneficiaries

II. Alignment between Congress' goals in MMA and the Medicare program to encourage cost beneficial care delivery with minimal waste, fraud, and/or abuse

III. Concern that the proposed rule could have discouraging effects on the development and/or utilization of beneficial and long-term cost-effective new technologies

IV. Concern regarding the potential implementation of competitive bidding for diabetes testing supplies without first studying the effects on beneficiaries with diabetes

V. Concern that existing HCPCS codes for diabetes testing supplies do not sufficiently differentiate related innovations in the context of competitive bidding, that this coding system was not designed with competitive bidding in view, and that these factors are likely to have a negative effect on new technology introduction and utilization

VI. Patient self-testing is a rare Medicare benefit that demands special consideration in terms of patient preference and convenience to ensure adequate testing compliance

VII. Specific comments related to details in the proposed rule

I. Assurance of high quality, cost beneficial healthcare for Medicare beneficiaries

First, and most important, BD is committed to sustaining and improving the health of all Medicare beneficiaries through the appropriate and efficient utilization of medical technologies. In this, we share CMS' goal of providing the highest quality, most effective healthcare for the most efficient cost possible. We believe that many new technologies, if properly incentivized and implemented, will provide the means by which the Medicare program will reduce overall expenditures over the long-term.

More specifically, related to diabetes testing supplies that are a potential target of competitive bidding, BD has a long history of experience and innovation in the broad field of diabetes care. BD built the first-ever manufacturing facility in the U.S. to produce syringes and needles in 1906 and has been the leading innovator in insulin injection devices ever since. More recently, BD has applied its knowledge of diabetes care to the field of blood glucose monitoring. As a recent entrant to an already competitive field, BD combined its injection and blood sampling technologies with innovative communications features to improve diabetes care for thousands of patients and their caregivers. The BD Logic® Blood Glucose System offers the fastest testing time with the smallest blood sample size. It is also the first monitor available for wireless communication (using RF technology) with an insulin pump. As a result, BD's system has gained broad acceptance among insulin-dependent patients who utilize it to more effectively integrate their blood glucose testing values with insulin dosing volumes.

II. Alignment between Congress' goals in MMA and the Medicare program to encourage cost beneficial care delivery with minimal waste, fraud, and/or abuse

As you know, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) contained policy implications far beyond the addition of a prescription drug benefit for Medicare beneficiaries. BD supports many of the cost and quality objectives embodied throughout the MMA from the perspective of promoting high quality and cost beneficial healthcare. In particular, BD sees Section 302 of the MMA as an historic opportunity for CMS to protect beneficiary access to quality DMEPOS while also reducing the amount that the Medicare program and beneficiaries pay for such items.

As we are certain you are also aware, the actual cost that Medicare bears for any DME item is a function not just of price, but also of the fraud, waste, and abuse associated with providing the item. Under the proposed rule, suppliers whose bids are based on innovative products and/or business practices capable of reducing fraud, abuse, and waste may not be properly evaluated. While a simple, low-price bid may be appropriate in some circumstances, we believe that it is in CMS' interest to reserve some discretion to consider and weigh other non-price variables that have the potential to help the agency meet a wider range of MMA objectives and deliver even greater real cost-savings

than a no-frills low price bid. However, we also recognize that creating such mechanisms within the context of competitive bidding could further complicate an already complex competitive bidding process. Therefore, we urge CMS to provide specific, additional pathways, both within, and potentially outside of competitive bidding, for the introduction of new technologies and processes that can generate additional savings to the program through the reduction of fraud, abuse, and/or waste or that create other beneficial program efficiencies.

III. Concern that the proposed rule could have discouraging effects on the development and/or utilization of beneficial and long-term cost-effective new technologies

The fundamental assumption inherent to the structure and function of any competitively bid procurement is that the items within a particular classification that are being bid upon are either interchangeable, or the purchaser has some mechanism or method to differentiate the value to him/her of various options within a classification. The proposed method of differentiation in the competitive bidding program is the HCPCS coding set. The history of innovation in diabetes care has been one of incremental improvement that has created a wide range of products of varying capabilities and features that are all encompassed under few existing codes.

We are specifically concerned that new innovations in diabetes care, for example, that could lead to a reduction in program costs through the elimination of waste, fraud and/or abuse, further improved patient self-management through blood glucose results combined and/or coordinated with specific outcomes measurements, or the integration of other policy objectives of CMS, HHS and Congress, such as technology that facilitates entry of patient results directly into the electronic medical record, will not be recognized as differentiated products under the current scheme and precedents. We again implore CMS to consider these needs that are in the long-term best interests of the program and provide specific pathways that will ensure cost effective and beneficial innovation occurs within the competitive bidding program.

IV. Concern regarding the potential implementation of competitive bidding for diabetes testing supplies without first studying the effects on beneficiaries with diabetes

Competitive bidding for diabetes testing supplies was not evaluated in any of the DME competitive bidding demonstration projects. Despite its high ranking in overall program expenditures, this category was not chosen for study, presumably due to the complexity it would have added to the demonstrations and the clearly different nature of the diabetes testing supplies market by comparison to other categories of DME.

BD believes that competitive bidding for diabetes testing supplies should not be implemented without an extensive study of the effects that competitive bidding is likely to have on beneficiaries' frequency and adequacy of testing, perhaps through an area specific demonstration. To this effect, if CMS plans to include competitive bidding for diabetes testing supplies, we urge the agency to use its stated authority in "Criteria for Item Selection" to limit bidding for diabetes testing supplies to a single competitive bidding area in order to test and learn about the suitability of competitive bidding for these critical supplies and to minimize the potential disruption to patient care.

We would also urge the agency to very carefully follow any group of patients with diabetes who might be put at risk related to the continuing self-management of their disease. Again, the cost to the Medicare program for treating diabetes is much greater than the simple acquisition cost of these

supplies. It is imperative that CMS consider the longer-term outcomes and complications that could arise if patients cease self-management of their diabetes as a result of consequences related to a competitive bidding program. Thus, clearly, CMS must weigh the potential savings available through competitive bidding for diabetes testing supplies with the implications on potential increased costs in other areas of the Medicare program, including Part A and Part D costs.

V. Concern that existing HCPCS codes for diabetes testing supplies do not sufficiently differentiate related innovations in the context of competitive bidding, that this coding system was not designed with competitive bidding in view, and that these factors are likely to have a negative effect on new technology introduction and utilization

As noted in point III, the HCPCS coding set is the proposed system for product differentiation in the competitive bidding program. While we agree with CMS that this system has generally worked adequately over time, we must point out that it was not designed for, nor has it been used extensively for the purpose of a competitive bidding program. There may be product categories within the various DMEPOS products that are not well differentiated and can be identified under a single code; however, as we have pointed out both in meetings with the agency and in these comments, diabetes testing supplies are highly differentiated in clinically relevant areas with respect to patient self-testing. For this reason, we recommend that CMS provide additional differentiation within existing HCPCS codes if it plans to implement competitive bidding for diabetes testing supplies.

Examples of potential coding structures would include addition of temporary HCPCS codes, applicable for competitive bidding only, that would identify specific features of testing materials and devices that are important to Medicare beneficiaries, such as wireless communications between blood glucose meters and insulin pumps, strip size, readability of results, sample size, memory storage capability, etc. Many of the more advanced meters may contain several of these important features, but less advanced meters that would currently fall under the same HCPCS code do not. Thus, it is conceivable, in certain cases, to capture multiple features under the same code, but it is particularly important to provide enough differentiation in coding to ensure that beneficiaries have access to products with features that will assist them in remaining compliant with their testing and management regimens.

For example, we would propose one code for meters that communicate wirelessly with insulin pumps. The interaction between the meter and the pump allows the insulin dependent beneficiary to better control her diabetes through consistent testing and dosing. Other features can also be important factors leading to Medicare beneficiaries' consistent disease management. Therefore, additional code separation that identifies commonly available, important functional features may also be needed.

VI. Patient self-testing is a rare Medicare benefit that demands special consideration in terms of patient preference and convenience to ensure adequate testing compliance

Generally, within the context of the Medicare program, medical professionals expeditiously provide medical care to Medicare beneficiaries. Beneficiaries typically have access to the training and expertise of some of the best physicians, nurses and other allied health professionals in the world. However, the sheer magnitude, burden and corresponding cost of tightly managing diabetes through

direct, continuous contact with a beneficiary's medical professional means that, given the state of technology today, it is impractical for Medicare to pay for constant professional management of beneficiaries who are afflicted with diabetes.

Yet, several studies have clearly demonstrated that blood glucose levels must, in fact, be tightly managed in order for patients to avoid many of the serious and life threatening complications that will otherwise occur due to diabetes if patient vigilance is low. For example, the landmark Diabetes Control and Complications Trial (DCCT) published in the *New England Journal of Medicine,* 329(14), September 30, 1993, demonstrated significant reductions in eye, kidney, and nerve complications for diabetics who carefully controlled their blood glucose levels versus those who did not. Additionally, numerous reports from the UK Prospective Diabetes Study (UKPDS) have found that intensive glucose control decreases the risk of diabetic complications.

Clearly, avoidance of complications associated with diabetes is likewise critical for Medicare to minimize significant associated program costs. In fact, the UKPDS-generated article, "Cost Effectiveness of an Intensive Blood Glucose Control Policy in Patients with Type 2 Diabetes" (BMJ, Vol. 320, May 20, 2000, 1373-78.) indicated that while treatment costs increased significantly with intensive testing, the cost of complications decreased substantially. Patient self-testing was devised as an efficient method to capitalize on the opportunity to minimize diabetes complications, and technology was developed that has enabled patients to treat their own disease, with assistance from many medical professionals on a periodic basis. This approach has minimized the healthcare system burden of effectively treating patients with diabetes, but it is important for CMS to understand and acknowledge that technology in this area has added benefits and continues to evolve. We would argue that more beneficiaries with diabetes have better managed their disease as a result of technology advancement, and that this has led to fewer long-term complications related to diabetes with consequently lower overall program expenditures.

Many HHS initiatives related to diabetes management indicate that there is relatively broad governmental concurrence on the benefits of tight management of blood glucose levels for patients with diabetes. Yet, the proposed rule makes no clear effort to ensure that patient choice is a component of the bidding process. This may be appropriate for many products, but becomes problematic for products that require an already challenging patient burden. Competitive bidding is likely to cause some beneficiaries to unwillingly switch from one mode of diabetes management to another method with which they are not as familiar or comfortable.

We are therefore concerned that forced switching may lead to alienation of the patient with regard to the management process and subsequent non-compliance with testing and glycemic control. It is conceivable that beneficiaries may find that they are completely unable to personally manage their diabetes with the competitively bid products offered in their area for a variety of reasons, including visual acuity issues, dexterity challenges, etc. The data from the DCCT and UKPDS support that these scenarios are likely to lead to higher overall treatment costs than may be saved through competitive bidding. On the other hand, while there are no published data that document patient compliance when they switch from familiar to unfamiliar products, it is logical that this could be a significant issue, depending on the winning suppliers and the range of products they choose to offer. We submit that CMS and the beneficiaries who depend on Medicare for their diabetes management cannot afford to risk the potential negative outcomes that could potentially occur, and we urge the agency to very carefully consider and provide for the mitigation of any such contingencies.

VII. Specific comments related to details in the proposed rule

"Implementation Contractor" §414.406

As CMS intends to utilize the services of competitive bidding implementation contractors (CBICs) for the implementation of the Medicare competitive bidding program, and, as these costs will represent incremental costs that would not otherwise have occurred in the absence of a competitive bidding program, it is our view that the agency must ensure that these costs do not exceed program savings from competitive bidding. Further, as the agency intends to interpret section 1847(b)(2)(A)(iii) of the Social Security Act (the Act) to apply to single payment amounts for each individual product bid, and not the overall bid or the bidding program in aggregate, it must allocate CBIC costs to each individual product code bid by a customary means of cost accounting and should not implement competitive bidding for any products for which these allocated costs will exceed program savings for the individual product code under the competitively determined single payment amount.

"Payment Basis" §414.408(a)

We agree that beneficiaries should have the freedom to choose items, at their own discretion, for which the Medicare program will not make payment, through the proper use of Advanced Beneficiary Notices (ABNs). This should include, but not be limited to, the beneficiary's decision to purchase competitively bid items from non-contract suppliers or items from contract suppliers that were competitively bid, but for which items the contract supplier in question was not a winning bidder.

"Payment Basis" §414.408(b)

We applaud the agency for acknowledging the need to ensure that bidders are protected from inflation, and we believe that the proposed methodology utilizing the CPI-U as an annual update factor will appropriately meet this objective.

"Payment Basis" §414.408(e)

We agree that the MMA provides authority to CMS to adjust payment amounts in non-competitively bid areas based on single payment amounts established in competitive bidding areas (CBAs); however, we urge the agency to exercise extreme caution in using this authority. We are very concerned that this practice could significantly undermine access to products in non-competitively bid areas that are economically dissimilar from the CBAs wherein the reference single payment amount was established.

We commend the agency for its intention to establish specific criteria with regard to its utilization of this authority. With respect to threshold level, any proposed percentage difference criterion is likely to be arbitrary; however, we believe the difference should be significant, and other program regulations and/or instructions establish percentage payment differences that may be used as a guideline to inform CMS' judgment related to this criterion. We encourage the agency to determine a percentage payment difference and propose it for public comment to further inform its decision-making on this issue. We also believe that the statute allows for both positive and negative changes

related to this provision. While positive changes may be assumed to be rare, we propose that the criterion reflect CMS' authority to use competitively bid single payment amounts to increase or decrease those payment amounts that are below or above the single payment amount, respectively, by at least the established percentage difference in an economically similar area that is not part of a CBA.

With regard to the scope of adjustments for areas outside of CBAs, we propose that adjustments should only be considered for areas that are demonstrated to be significantly similar in nature. Similarity evaluation should include comparison of metrics such as price indices, wage indices, cost of living factors, and other such cost differences that are functional components of doing business in different areas of the country. As such, we believe that prices should only be adjusted on a local basis wherein evaluation of a locality reasonably concludes that it is economically similar to an existing CBA.

"Competitive Bidding Areas"

Given the agency's experience in implementing the competitive bidding demonstrations in relatively confined areas, by comparison to some of the largest MSAs, we agree that it is wise to implement the program in some of the smaller MSAs first to gain experience and data for eventual implementation in the largest MSAs in later years.

We also agree that the statute provides authority to implement competitive bidding in areas smaller than an entire MSA, as appropriate, but we do not believe it is the intent of Congress to expand competitive bidding to areas larger than an MSA. Additionally, given the definition of an MSA, expanding a competitive bidding program outside of the borders of the MSA raises questions and concerns related to the similarity in economic structure and function of otherwise unrelated areas. Rather, we would recommend that CMS exercise its stated authority to apply competitively bid pricing from a CBA to an area outside the MSA after it had established economic similarity between them, and the other criteria of **§414.408(e)** (yet to be established) have been met (such as pricing disparity, etc.).

Regarding the selection method for the ten MSAs that are to be bid in the initial round of competitive bidding, we generally agree that the dual focused method proposed will identify the largest concentrations of Medicare expenditures per beneficiary, and it is likely that areas with higher concentrations of suppliers per beneficiary are likely to produce more bidders, although we are uncertain whether this particular metric is truly an indication of greater potential savings. In any event, we do not believe the suppliers per beneficiary metric is useful for application during the initial round of bidding because many of these areas will nevertheless be included in the additional seventy MSAs that are added for 2009.

Therefore, we suggest that CMS identify the top eighty MSAs for competitive bidding using the methodology as proposed. However, for the initial competitive bidding programs, we propose that the agency use only the allowed DMEPOS charges per beneficiary metric when selecting the ten MSAs from the set of eighty. This will provide CMS with a range of valuable data from areas that have many suppliers per beneficiary and areas with fewer suppliers per beneficiary. These data will further provide CMS with information regarding the actual savings drivers by comparing metrics for

the various areas against the actual savings gained in those areas. Choosing MSAs based on expected optimal savings is short-sighted and will produce savings estimates for subsequent years that are less likely to meet projections, if CMS is correct in its assumptions. Thus, we recommend a more balanced initial approach, given that within two years of initial implementation, all of these areas will be included in the program.

"Competitive Bidding Areas" §414.410(d)(2)

We agree that many beneficiaries obtain their diabetes testing supplies via mail order services, but we also know that many beneficiaries obtain their supplies through local pharmacies as well. Often, the beneficiary develops a relationship with the pharmacist and seeks advice regarding medications and other treatment regimens, including their diabetes control program. It is important that CMS protect and foster these interactions in any regional or national mail order competitive bidding program, as they are likely to further encourage the beneficiary's compliance. To this effect, we urge the agency to allow beneficiaries to move from either a competitively bid area or a non-competitively bid area to a competitively bid mail order program and back again at their discretion without penalty.

In addition, due to the concerns we have raised with competitive bidding and its potential effects on Medicare beneficiaries with diabetes in general, we further urge the agency not to implement a mail order competitive bidding program for diabetes testing supplies until the effects of such a program on beneficiaries with diabetes have been carefully studied, perhaps through a pilot program. In any event, we would expect that the agency would not force beneficiaries to use a mail order only program, but rather, CMS may eventually establish a mail order competitive bidding program as an additional option that could provide increased access to products for beneficiaries at their discretion.

"Criteria for Item Selection"

Related to the assertion in the preamble that CMS has the authority to phase in individual product categories, we agree that CMS does indeed possess this authority. Moreover, we strongly urge the agency to invoke this authority with respect to any eventual plans to implement competitive bidding for diabetes testing supplies, as these products have not been previously tested in competitive bidding, and their suitability for competitive bidding has not been established.

"Criteria for Item Selection"

With respect to the selection of product categories for competitive bidding, we understand that the agency was not prepared to identify categories that were to be initially bid within this proposed rule; however, we believe CMS could have proposed the actual components of all potential categories for competitive bidding so that stakeholders and the public at large could provide comments on the relative applicability of the components in a given category. This is particularly important to ensure clinical consistency across a product category, and so that CMS may learn whether there are established product offerings among DMEPOS suppliers that may be unnecessarily disrupted by the competitive bidding program. For example, if CMS creates a category that requires products that are deemed by suppliers to be unrelated to other products within the category, and that they, for efficiency reasons, do not carry, they may be unable to participate in the bidding. Frankly, it may be too late to address such issues upon issuance of the RFBs.

Since CMS did not propose to use the DMERC-established categories, but rather intends to create categories that are specifically designed for competitive bidding, the agency should seek public input on whether the components of categories that it may choose to include in competitive bidding are acceptable to a consensus of clinical and existing business practices to ensure a fully optimal bidding process in a given competitive bidding area. As CMS has not yet chosen the specific categories that will be bid, it should propose the category components, by HCPCS code, for all categories that it is considering to potentially include in any competitive bidding area.

"Submission of Bids Under the Competitive Bidding Program" §414.412(d)

We would agree that requiring bidding suppliers to provide all products within a category would be a more convenient approach for Medicare beneficiaries who require only one category of DMEPOS products, but the many beneficiaries who suffer from co-morbidities may find that they must go to several different suppliers for their DMEPOS products. For example, a beneficiary who must purchase two categories of DMEPOS products could go to one contract supplier who was a winning bidder for one of the categories, but a losing bidder for the other. Even though this supplier might have the other products on its shelves, it would not be able to sell the products to the beneficiary (except through an ABN); rather, they would have to direct the beneficiary to a winning supplier for the other products. We find this to be problematic for beneficiaries and suppliers, and while no simple solution may exist, we recommend that CMS very carefully and thoughtfully consider alternatives to mitigating this sort of challenging scenario.

"Conditions for Awarding Contracts" §414.414

As CMS notes, a supplier, following any applicable grace period, that did not attain accreditation, would have its contract suspended or terminated. Given that such suspension or termination under the proposed capacity bid selection method could mean that remaining suppliers may not meet capacity in the competitive bidding area for the product category, we assume that CMS would then move to the next supplier(s) that would provide for satisfaction of the calculated capacity in the CBA. We further assume that CMS would void the bid of the non-compliant bidder and re-calculate the single payment amount based on actual, viable bids. We believe this process for re-calculation of the single payment amount in the event of non-viable bids should be detailed in the proposed rule. It is important to re-calculate the single payment amounts in order to retain the integrity of the bidding process when these scenarios arise. Failure to address this issue invites the potential for unfair bidding and/or foul play.

"Conditions for Awarding Contracts" §414.414(e)

With respect to market demand and supplier capacity, our read of section 1847(b)(4)(A) is that the Secretary ***may*** (not must) select the number of suppliers necessary to furnish items to meet the projected demand in the geographic area. However, the statute also clearly requires CMS to award multiple contracts. Thus, even though one supplier may be able to meet the capacity of the area, CMS acknowledges that it must select at least two suppliers (**§** 414.414 (g)). We believe a reasonable interpretation of the intent of Congress, given these components of the statute is that this language was intended as a minimum requirement, not a limitation. Therefore, we believe CMS has discretion to include suppliers above the calculated capacity for a CBA. Exercising this discretion would

provide the agency with a contingency "safety net" for supply in the event of issues with one or several suppliers.

"Conditions for Awarding Contracts" §414.414(e)

Upon several reads of the process for determining pivotal bids, we are concerned that it is unclear which product or products within a category will be the driving force behind the selection for the cumulative capacity in a CBA. It is conceivable that a supplier may be able to meet the capacity for the one item in the category chosen as the pivotal cumulative capacity and not have similar capacity for other items in the same category. In any event, we recommend that CMS more clearly state how it will determine the item or items that are to be chosen for capacity determinations.

"Conditions for Awarding Contracts" §414.414(h)

As we noted in a previous comment, we believe that CMS should re-calculate the single payment amount when winning suppliers do not meet the accreditation standards established in order for a supplier to be a qualified bidder. We also believe this would be proper more generally when a supplier, for any reason, exited the competitive bidding program. Rather than require bidders, who may be selected as suppliers subsequent to a bidding process in which they participated but were not winners initially, to accept a single payment amount determined without the input of their valid bid, or re-bidding in order to add capacity, we propose that the agency simply recalculate the single payment amount, taking into account the bid of the actual suppliers who are providing capacity. Section 1847(b)(5)(A) of the Social Security Act indicates that the Secretary shall determine the single payment amount based on bids submitted and accepted for the related items and services. Thus, we believe the statute supports this approach, and that the single payment amounts should reflect the bids of suppliers actually engaged in the competitive bidding program at any given point in time.

"Determining Single Payment Amounts for Individual Items" §414.416(b)

Given the statute indicates that single payment amounts are to be determined by bids submitted and accepted for an item, and that CMS proposes to consider all bids submitted by a qualified supplier meeting applicable quality standards and which submits a bid for an item that is lower than the applicable fee schedule amount for that item, we believe it is a reasonable interpretation of the statute to deem that any such bids that meet these criteria are, in fact, accepted. This interpretation would also mitigate the issue of recalculating the single payment amount when a supplier exits the program, as detailed above.

In any event, we support the use of a median calculation as a statistically valid method for determining the single payment amount. We suggest that the agency determine the single payment amount based on the median of all submitted bids by qualified suppliers whose bids are below the applicable fee schedule amount for the given item.

"Determining Single Payment Amounts for Individual Items" §414.416(c)

We are concerned that allowing suppliers who bid below the single payment amount to offer rebates to patients would normally cause suppliers to run afoul of inducement and anti-kickback laws. CMS

does not set forth in the rule what safe harbors protect suppliers in this instance, and we believe the agency should minimally provide this information. While we understand the intent is to provide incentive for suppliers to bid aggressively, thereby providing beneficiaries with additional savings, we believe it would also provide suppliers with further incentive to offer lower quality products and fewer patient choices. We recommend that CMS not implement this provision of the proposal.

"Terms of Contract" §414.422

As section 1847(b)(3)(B) requires the Secretary to re-compete contracts no less often than every three years, there is clearly discretion to re-compete more frequently than the proposal currently indicates. We suggest that the agency consider re-competition more frequently in the early stages of the competitive bidding program in order to capitalize on initial learning and experience.

"Terms of Contract" §414.422

With respect to information collected from the supplier, we recommend that under training and qualifications, suppliers be required to reflect whether they, or another entity, will provide required training, service, and ongoing support for a competitively bid item. If it is a party other than the supplier, we recommend that the party be specifically identified.

"Opportunity for Participation by Small Suppliers"

We would agree that choosing multiple suppliers in a CBA provides additional opportunity for small suppliers; however, in cases where very few suppliers are selected (for example, two or three), this additional opportunity is likely marginal. We would argue that evidence that small suppliers had equal opportunity to participate in the process would include the winning of contracts by some small suppliers in each CBA. By way of example, CMS could ensure that small suppliers won contracts by using its discretion to expand the capacity calculation within a CBA to be some percent above the minimum capacity need and requiring this incremental capacity be awarded to suppliers that meet the small supplier definition put forward in the rule.

"Physician Authorization/Treating Practitioner" §414.420

We understand that it is impractical to expect a contract supplier to provide every brand of products included in a HCPCS code. In many cases, product differentiation of various brands may be minimal; in other cases, such as diabetes testing supplies, there is significant differentiation under few HCPCS codes. Herein lies the challenge of utilizing the existing HCPCS coding system. While we would agree with the spirit of the CMS comment that the HCPCS process has worked adequately in the past, we must disagree with the presumption that it adequately separates items by function for a competitive bidding program in all cases. As you are aware, HCPCS was not designed for use in a competitive bidding program.

Given the potential impact to patient care and outcomes that we outlined in our general comments related to the lack of functional differentiation for important components of diabetes testing supplies within existing HCPCS codes, we strongly recommend that CMS utilize its stated authority pursuant to section 1847(b)(7) of the Act to establish separate categories within HCPCS codes for

diabetes testing supplies and potentially other products for use solely within competitive bidding programs.

The example we advanced in our general comments was for one specialized feature important to insulin dependent beneficiaries with diabetes who use infusion pumps (wireless communication between blood glucose monitor and infusion pump to optimize the testing/dosing continuum and subsequently maintain optimal glucose control), but we are aware that there are other important differentiated features among available products and urge the agency to carefully consider creating several separate categories within the diabetes testing supplies HCPCS codes. To be clear, we are not advocating for separation by brand, but rather by functional differentiation.

With respect to new innovations, the HCPCS process will continue to operate independently from the competitive bidding program. We believe there are many incremental innovations to come that will continue to improve Medicare beneficiary care within the category of diabetes testing supplies. Given the history of differentiation within HCPCS for this category, we strongly urge the agency to retain and use its authority to create categories within HCPCS codes for innovations that improve beneficiary care and/or reduce program costs.

"Gap-filling" §414.210(g)

We agree with other commenters that the gap-filling component proposed in the competitive bidding rule should be removed and addressed in a separate rule with far more procedural detail if the agency intends to move it to a regulation (it has only been described in program instructions and manuals in the past). While payment amounts for new DMEPOS items must be established in conjunction with competitive bidding, we believe that the gap-filling issue deserves far more scrutiny and review than it is likely to be given in this broader context of the competitive bidding rule.

With respect to the existing processes for gap-filling, we agree that payment inaccuracies often result, although our experience is that they tend to be skewed to the lower end of the spectrum. We also disagree with the implied assertion that manufacturers, as a standard practice, establish retail prices based primarily on how Medicare sets new payment amounts. While the eventual reimbursement rate cannot be separated from a new product's success, it is certainly not the practice at BD to attempt to "game" the system in the simplistic way described in the proposed rule preamble; rather, through various data collection, we typically try to estimate the value that a new product will deliver to the healthcare system when setting pricing. Thus, we must consider potential patient outcomes, pricing for any predicate products already on the market, and existing or expected competitive pressures, among other factors. We know that many of our competitors implement similar internal processes. Nevertheless, we agree that the system can be improved and support efforts to create a more rational process. This is especially important for the introduction of, and assurance of beneficiary access to, beneficial new technologies, as the agency properly notes in this section.

Furthermore, in reflecting upon CMS' proposal for new item assessment, we recognize that the agency may need to collect different information than is provided through the FDA process; however, it would appear that some of the proposed assessments are duplicative of FDA processes. Specifically, the description of "Functional Assessment," wherein the device operation, safety, and user documentation is evaluated, is particularly curious. We believe the FDA process establishes these parameters effectively for the Medicare population.

Related to the "Medical Benefit Assessment", we agree that such an assessment, when conducted properly, objectively, and comprehensively, can provide important information regarding the value of a new product. However, any such technical assessment must be conducted through a transparent process. Further, detailed criteria that a product must meet in order to gain this coding differentiation should be proposed and should reflect public comment. If a product demonstrates constructive adherence to these criteria through appropriate evidence, differentiated coding should be granted. Finally, the timing of the process from application to decision should be clearly established and should not incorporate any undue delay. CMS should also acknowledge that many new technologies do not have a vast array of evidence supporting their claims when they are first introduced to the market. Rather than dismiss such technologies through an inconclusive technology assessment process, the agency should make every effort to not impair the evidence development process by restricting coding and subsequent payment amounts that do not reflect the costs of providing potentially promising new technologies.

We thank you for the opportunity to provide these comments, and we look forward to following up with the agency to discuss specific details in areas where we believe we can provide value to the agency and assist it in its mission to continuously improve beneficiary health and minimize overall program expenditures by focusing on the long-term, most cost beneficial and effective diagnostics and treatments.

Sincerely,

Jeffrey P. Bush
Director, Corporate Reimbursement
BD
1250 H. Street NW, Suite 1102, Washington, DC 20005

Submitter : Dr. Jeffrey Frederick **Date:** 06/30/2006

Organization : APMA

Category : Physician

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

It is very clear that my patient outcomes would suffer from removal of DME items from my office by the competetive bidding process. I am a foot/surgeon specialist that is the most qualified to determine the need of my patient. With an aging population as my primary database of patients, I am the most qualified and should not be excluded from providing care to my patients. I am outraged that my patients could suffer from an oversight not allowing qualified doctors to provide DME items for their patients. Wound Care dressings and bracing are helping thousands of patients with the quality of their lives and is preventing morbity and loss of limb. Removing DME items from my office would be a backwards step in health care.

CMS-1270-P-1100-Attach-1.DOC

Dr. Jeffrey Frederick, DPM, FACFAS

17333 W. Ten Mile
Southfield, MI 48075
248-443-0400

Board Certified, American Board of Podiatric Surgery
Fellow, American College of Foot Surgeons

June 28, 2006

Competitive Bidding process DME items

It is very clear that my patient outcomes would suffer from removal of DME items from my office by the competitive bidding process. I am a foot/surgeon specialist that is the most qualified to determine the need of my patient. With an aging population as my primary database of patients, I am the most qualified and should not be excluded from providing care to my patients.

I am outraged that my patients could suffer from an oversight not allowing qualified doctors to provide DME items for their patients. Wound Care dressings and bracing are helping thousands of patients with the quality of their lives and is preventing morbity and loss of limb. Removing DME items from my office would be a backwards step in health care causing unnecessary suffering for patients. As a physician and provider of health care, do not tie my hands and remove the tools to help my patients. Many patients do not have access to medical supply companies that can provide these items, just by physical distance from where they live.

I understand the need to examine the DME process and the need for competitive bidding, but <u>all</u> qualified physicians should be exempt. Discrimination against specialists is not good for patient care.

Sincerely,

Jeffrey Frederick DPM, FACFAS

Submitter : **Mrs. Theodora Haara** **Date: 06/30/2006**

Organization : **Medassure Inc.**

Category : **Other Health Care Provider**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

am an active registered nurse, seeing patients regularly, and one of the owners of Medassure Inc. I shudder and fear the direction of the health care you are planning. Your plan affects me both as a supplier and a person of Medicare age.

As a supplier of oxygen for over ten years, we know people equate oxygen with life. Concentrators do not deliver adequate oxygen indefinitely. They need checks, maintenance and replacement. This care done properly is expensive, and is a responsibility not to be taken lightly. We could not afford to service and accept patients without adequate reimbursement. We would not survive. When people are gasping for breath you shouldn t cut off their oxygen. This could be the result.

CONSUMER REBATES!

Being honest in business is the easiest and hardest way to conduct business. Build in consumer rebates and you open the door for problems. Make this honest. Please don t put an incentive for fraud in your plan.

BIDDING PROCESS

Unqualified bidders should not be used in calculating single payment amounts . Many businesses or people will promise everything and deliver nothing . Providing a service or piece of equipment involves experienced personnel from the telephone, purchasing, warehouse, delivery, and the person who is responsible for providing the resources for payment even when Medicare is playing games. This process must be honest, really honest.

If you do not provide location, specifics and time to develop an accurate, workable and attainable plan and bid, the outcome will be a disaster. Your work will have been wasted and cause great harm.

I know your desire is not to cause harm to the people of America, but I fear that will the outcome.

Theodora Darlene Haara, RN, Owner

Medassure Inc.

5246 S 40th Street

Phoenix, AZ 85040

Phone (602) 470-9700

Submitter : **Mr. Donald Clayback** **Date: 06/30/2006**

Organization : **The MED Group**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1270-P-1102-Attach-1.DOC

#1102

THE MEDGROUP

June 30, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Hand Delivered and Via Electronic Mail: http://www.cms.hhs.gov/eRulemaking

Re: (File Code CMS-1270-P) Notice of Proposed Rule Making entitled "Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues"

Dear Dr. McClellan:

I am writing on behalf of The MED Group (MED), a nationwide network of independently owned home medical equipment and rehab technology companies. We have approximately 250 member companies with over 800 operating locations across the country. Our member companies provide products and services to hundreds of thousands of Medicare beneficiaries within their local communities. Please visit www.medgroup.com for more information on our organization and membership.

We also are members of and serve on the Board of Directors of the American Association for Homecare (AAH) and the National Coalition for Assistive and Rehab Technology (NCART).

To begin, we want echo the concerns expressed by the American Association for Homecare that the information in the NPRM is inadequate to serve as a basis for public comments on several important issues. A rule making procedure must provide notice of a proposed agency action with reasonable specificity to solicit informed public comments. The NPRM falls short of this standard with respect to how §5101 of the Deficit Reduction Act of 2005 (DRA) and the final quality standards that will apply under competitive bidding. As you know, §5101 forces Medicare beneficiaries to own their capped rental or oxygen equipment at the end of a statutory period of continuous use. Without establishing the scope of this new requirement and how it will dovetail with competitive bidding, the NPRM is incomplete and vague, limiting our ability to comment.

We are aware that CMS will publish regulations to implement the DRA in the near future. However we need an opportunity to assess and comment on how the new rules will apply under the framework for competitive bidding. We suggest that CMS issue an interim final rule to allow additional comments on this issue prior to publishing a final rule implementing competitive bidding. In addition, because the NPRM fails to identify the Metropolitan Statistical Areas (MSAs) and the DMEPOS items that will be subject to competitive bidding, we request that CMS also schedule a meeting of the Provider Advisory and Oversight Committee (PAOC) before it begins to implement the program.

Although we understand CMS's concerns about meeting the deadlines in the MMA, it is imperative that CMS allow stakeholders an opportunity to comment on the quality standards before they become final. Allowing time for additional comments is unlikely to significantly delay the program. It is also appropriate inasmuch as CMS by-passed the procedural protections of the APA and the oversight of the Office of Management and Budget that would otherwise be part of a rulemaking procedure applicable to the standards. In any event, as we stated above, competitive bidding is a radical departure from the traditional DMEPOS benefit, and CMS has no experience with this program on a wide scale. Consequently, CMS should tolerate delays and not rush the quality standards or any other aspect of competitive bidding.

MED appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' Notice of Proposed Rule Making entitled "Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues". As requested, we have indicated the "issue identifier" at the beginning of each comment. The following are our comments and recommendations:

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. The aggressive implementation plans particularly hurt small providers. Small providers will not have time to create networks, which eliminates them as a practical option for small businesses that want to participate.

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 Must Be Included 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 subsequent 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 Congress in establishing the PAOC in the first place.

4.) "General"- **Beneficiaries With Medicare As Secondary Insurance Should Be Excluded From Competitive Bidding.** CMS should exclude those Medicare beneficiaries that have Medicare as a secondary payor from inclusion in the competitive bidding program. These beneficiaries' claims should be processed and paid under the standard fee schedule.

5.) "Payment Basis"- **Medicare Advantage Beneficiaries Should Be Included Under The Grandfathering Provision.** 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.

6.) "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 based on the beneficiary's permanent residence for up to five months.

7.) "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. However, no information is provided on how CMS intends to do this. It is critical for CMS to make every effort to understand any regional cost differences (i.e. labor costs, delivery costs etc.) to ensure that the savings would be comparable if a competitive bidding program was established in that MSA. Moreover, CMS must complete this analysis to ensure that any

reduction in payment would not negatively impact appropriate access to medically necessary equipment. CMS needs to issue a separate NPRM addressing this issue to allow for substantive comments on specific proposals.

8.) "Competitive Bidding Areas"- **Do Not Extend Competitive Bidding Beyond Defined MSA Boundaries.** (proposed §414.410) 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 Made With Beneficiary Welfare In Mind.** CMS must be sensitive to and implement provisions to prevent the many problems competitive bidding may create for beneficiaries. These include an individual beneficiary having to deal with multiple suppliers. The inappropriateness of including items that are custom and service oriented in nature must also be recognized. CMS cannot rely solely on costs and volume for product selection. Issues such as supplier access and medical necessity of beneficiaries who use the items must be addressed. Competitive bidding should not be a substitute for appropriate medical policy.

10.) "Criteria for Item Selection"- **The Methodology For Calculating The Potential For Savings Must Be Specified.** CMS should explain and clarify what specific measures will be used to decide an item's potential savings as a result of competitive bidding. Specifically, CMS should address the following: (A.) *Annual Medicare DMEPOS allowed charges*: Is there a threshold expenditure level that will trigger inclusion in a product category? (B.) *Annual growth in expenditures*: Is there a threshold growth percentage and does it vary by the dollar size of the category? (C.) *Savings in DMEPOS demonstrations*: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects? (D.) *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? (E.) *Allowed Charges*: Does this mean paid claims?

11.) "Criteria for Item Selection"- **Complex Rehab And Assistive Technology Items Must Be Excluded From Competitive Bidding.** We are concerned that the only reason identified for products to be excluded from the competitive bidding program is purely based on calculated potential savings. MED believes that Congress certainly intended that consideration be given to the clinical outcomes for Medicare beneficiaries. MED recommends that CMS accept the recommendations of PAOC members and presenters during the February 2006 PAOC meeting that complex rehab and assistive technology devices be exempted from competitive bidding. We do not believe that products that are evaluated, fitted, configured, adjusted or programmed to meet the specific and unique needs of an individual with a primary diagnosis resulting from injury or trauma or which is neuromuscular in nature are appropriate for a competitive bidding program.

MED also recommends that CMS exclude wheelchair cushions, adaptive seating and positioning products and speech generating devices from the competitive bidding program. Clients in need of complex rehab or assistive technology typically require a complete system to meet their functional and medical needs. A complete system means various pieces of equipment, each meeting a specific medical or functional need, have been determined to be compatible technologies.

12.) "Criteria for Item Selection"- **Exclude Manual Wheelchairs, Power Wheelchairs, And Related Accessories From First Round of CB.** The methodology that CMS proposes for item selection relies on historical data and does not take into account recent and expected 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. The same can be said for plans for expanded manual wheelchair codes. 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.

MED recommends that CMS exclude all manual and power wheelchair and accessory codes from the 2007 round of competitive bidding. This would allow time for CMS to implement new HCPCS codes for power and manual wheelchairs, gain accurate utilization data and assess how the coding changes impact cost before attempting to determine which if any of these products would produce adequate savings while ensuring Medicare beneficiaries achieve their desired clinical outcome. MED recognizes that power wheelchairs are high in utilization and cost. However, we also believe that significant savings will result from the vast changes in coverage and conditions for payment that have occurred in this product category over the last year and the additional coding, coverage and payment changes that are imminent. There must be ample time to analyze the true impact of the changes before determining if any of these products are appropriate for competitive bidding.

13.) "Submission of Bids under the Competitive Bidding Program"- **Only Companies Currently Servicing 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. Only those entities should be eligible for consideration in the bidding process.

14.) "Submission of Bids under the Competitive Bidding Program"- **The Current HCPCS Codes Are Inadequate To Effectively Implement Competitive Bidding.** (proposed §414.412) CMS proposes not to require suppliers to provide every brand of products included in a HCPCS code. However, regardless of what brands the contract supplier furnishes, the single payment amount for the HCPCS code would apply. The current code sets are inadequate and therefore requiring suppliers to only supply an item that meets the descriptor of the code will not adequately meet the needs of Medicare beneficiaries.

The current coding system, especially for complex rehab and assistive technology, groups items into very general codes. In many cases the items are designed for a similar use, but because of anatomical anomalies, asymmetries, tone, functional limitations etc., beneficiaries must have access to a specific device within a code. Unfortunately due to differences in design, product cost and other factors, the costs associated with the devices are fundamentally different.

A basic example of problems within the current HCPCS code set is the current code for headrests- E0955. This code currently is used for all levels of headrests. However, an extremely broad range of technology falls within this code. The most basic item, a flat single pad with no adjustability and fixed, non-adjustable hardware, would be the item most suppliers would base their bid on. However, this same code represents products with multiple pads that are independently adjustable and contoured to allow intimate interface with the beneficiary's head, and includes hardware that is adjustable in multiple directions that will also swing out of the way for transfers. The price differential between a basic headrest that merely supports the head when the beneficiary is tilted or reclined is significantly less than the headrest that controls the head, keeps it in proper alignment to prevent tonal reflexes and allows the beneficiary to drive a power wheelchair using an alternative input device controlled with precise head movements.

While focused and aggressive efforts are occurring that will hopefully develop an appropriate code set for rehab and assistive technology devices, the current HCPCS code set is grossly inadequate to support competitive bidding.

15.) "Submission of Bids under the Competitive Bidding Program"- **Product Categories Must Be Narrowly Defined.** (proposed §414.412) 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 product categories narrowly, to make sure that they are consistent and representative of the products that a supplier might actually furnish.

For example, 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. 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.

16.) "Conditions for Awarding Contracts"- **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.

17.) "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.

18.) "Conditions for Awarding Contracts"- **A Bidding Company Should Be Required To Submit Specific Financial Information To Verify Financial Capability.** This information should consist of: (A.) Two year comparative financial statements prepared in accordance with Generally Accepted Accounting Principles or another recognized basis of financial reporting. The financial statements must be accompanied by a "review" report from an independent Certified Public Accountant (CPA). The CPA should be a member in good standing of the American Institute of Certified Public Accountants. Audited financial statements should not be required as they place an undue expense on the bidding company. (B.) Certificate of Insurance verifying a minimum of $1,000,000 in general liability coverage and listing other appropriate insurance policies in force. (C.) Letters from two primary product suppliers confirming a satisfactory business relationship. Specific steps also need to be established to allow a consistent evaluation of all companies. These steps should be published in the final rule.

19.) "Conditions for Awarding Contracts"- **A Factor Of 130% Should Be Used 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.

20.) "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.

21.) "Conditions for Awarding Contracts"- **Provisions Must Be Developed To Guard Against Unrealistic Bid Amounts.** (proposed §414.414) 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.

22.) "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 products provided to Medicare beneficiaries the previous year. Overly aggressive claims of additional capacity will be very difficult to validate and reasonable parameters must be set.

23.) "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.

24.) "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.

25.) "Conditions for Awarding Contracts"- **Establish The Single Payment Amount At The Pivotal Bid Level.** 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 de monstration p rojects. M ore im portantly, w e b elieve 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. No contract supplier should be forced to accept a payment amount that is lower than its bid.

26.) "Conditions for Awarding Contracts"- **Allow For Appropriate Transfer Of Awarded Contract As Part Of Business Sale.** Do not make it harder for providers to sell their businesses. 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 requirements, the contracted supplier and its new ownership should retain the contract.

27.) "Conditions for Awarding Contracts"- **Judicial and Administrative Remedies Must Be Provided.** CMS should include a procedure for debriefing suppliers who did not win a bid and provide 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.

28.) "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 t o t he b eneficiary. T here 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 F raud Al erts a nd Adv isory O pinions t hat a ny w aiver o f c o-pays l ikely violates both the Anti-Kickback Statute and the Beneficiary Inducement Statute.

29.) "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.

30.) "Terms of Contract"- **Modify Requirement That Winning Supplier Must Repair Patient-Owned Equipment.** (proposed §414.422(c)) It is appropriate for winning suppliers to be required to service any equipment they provide. However, this requirement should not be placed on equipment that is supplied by others. The current reimbursement rates for service and repair are inadequate and it is impossible for a bidding supplier to factor these unknown costs into their bids.

31.) "Terms of Contract"- **Eliminate Limitation That Only Winning Suppliers May Repair Patient-Owned Equipment.** (proposed §414.422(c)) Any Medicare supplier should retain the opportunity to service and repair durable medical equipment should they so choose.

32.) "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.

33.) "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.

34.) "Opportunity for Participation by Small Suppliers"- **Require That A Minimum Number Of Small Suppliers Be Included As Wining Contract Suppliers.** At a minimum, small business suppliers in an amount equal to the number of other winning bidders should be allowed to participate in the contract assuming they submitted a bid at or below the current allowable amount. In addition, any small business that submits a bid within 110% of the pivotal bid should be allowed to participate if they are willing to accept the payment amount and meet all other requirements.

35.) "Opportunity for Networks"- **Clarify Network Regulations To Maximize Small Business Participation.** (proposed §414.418) The regulations covering networks should be clarified to provide for the following: (A.) CMS should permit existing legal entities to coordinate the formation of networks and to establish whatever participation criteria they choose so long as they meet the related bidding standards and criteria. These entities should be

responsible for forming the network, submitting bids, quality control, and ongoing communication and management. (B.) Individual network members should be able to do their own billing and collecting operating under the awarded Network Contract. This would protect small suppliers from having to incur additional expenses from having to pay a network to do the activities they are capable of performing. (C.) If a network member falls out of compliance with accreditation or quality standards, the network should be able to terminate that member's contract and, if necessary, recruit one or more new members to provide coverage in the terminated member's service area. This would also apply if a network member elects to drop out of the network. Provisions must be made should these events occur within the contract period.

36.) "Opportunity for Networks"- **The Market Share Limitations Of Networks Should Be Increased To 50%.** (proposed §414.418) Market share limitations for networks should be increased to 50%. Anything less than that places network members at a disadvantage as compared to other large single legal entities that may bid. This would penalize small suppliers. Capping it at 50% still provides adequate competition in the area and also meets the legislative requirement that there be at least two winning bidders.

37.) "Gap-filling"- **HCPCS Changes Within CB Product Categories During The CB Contract Must Be Priced At Realistic Levels.** 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 an equitable or logical solution. A new code would be created due to a difference in the product or technology. It is unreasonable to expect suppliers to be able to provide two different products at the same cost. A more appropriate procedure must be developed that would allow pricing based on the costs of each separate item.

38.) "Gap-filling"- **Different Alternatives To Gap-Filling Must Be Developed.** (proposed §414.210(g)) It is good to see the acknowledgement of the problems and inappropriateness of the gap-filling pricing methodology. However, 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.

39.) "Regulatory Impact Analysis"- **The Data And Assumptions Used Dramatically Understate The Negative Impact On Medicare Suppliers.** This section paints a much more optimistic view of the eventual number of suppliers in the group of winning bidders. It is completely unrealistic to use the results of two very limited demonstration projects impacting only a small number of suppliers for projecting the impact of a national program involving over 100,000 suppliers. Given the significant problems with the provisions of the NPRM, it is extremely unlikely that the projection of approximately 50% of bidding suppliers being awarded a contract would occur. This underlies the necessity of significant changes to the NPRM. The true potential results will be contingent on CMS's incorporation of the above recommendations and those received from others during the public comment period.

Thank you for your detailed review of these comments and those submitted by other industry associations, providers and other stakeholders. The implementation of Competitive Bidding is fraught with potential land mines and we have very strong concerns on its current status and timeline. It is critical additional time be allowed to address the many regulatory, operational, and educational issues that have been presented during the comment period.

We look forward to the inclusion of the recommendations in the final published standards and the related implementation of mandatory accreditation. We also stand ready to work collaboratively with CMS on this matter and other Medicare DMEPOS issues. Please feel free to contact me directly if we can be of further assistance.

Sincerely,

Don Clayback

Donald E. Clayback
Senior Vice President- Networks
The MED Group
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Submitter : Mr. Robert Jasak

Date: 06/30/2006

Organization : American Association of Orthopaedic Surgeons

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1103-Attach-1.DOC

#1103

AAOS American Association of Orthopaedic Surgeons®
317 Massachusetts Avenue NE 1st Floor Washington, D.C. 20002-5701 Telephone 202/546-4430 Fax 202/546-5051

June 30, 2006

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

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

Dear Dr. McClellan:

The American Association of Orthopaedic Surgeons (AAOS) would like to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on the recently proposed rule on the competitive acquisition program (CAP) for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). This proposed rule, however, poses a significant danger of interference with the continuity of patient care and the primacy of the patient-physician relationship and significantly increases the administrative burden of many physicians participating in the Medicare program.

I. Introduction

We understand that Social Security Act (the Act) §1847(a) and (b) require CMS to implement a competitive acquisition program for durable medical equipment and supplies[1], off the shelf orthotics[2], and other equipment and supplies as defined in §1842(s)(2)(D)[3]. We also understand that some of the impetus for the program is to eliminate overpayments to suppliers for the larger dollar and volume supplies for which Medicare pays. While we acknowledge those mandates and concerns, we believe that CMS' decision to subject physicians to the bidding process is contrary to the program's goals.

Therefore, the AAOS believes that ***CMS should remove the administrative costs and burden of bidding by exempting physician-suppliers from the CAP***. CMS is likely to

[1] Social Security Act §1847(a)(2)(A)
[2] Social Security Act §1847(a)(2)(C)
[3] Social Security Act §1847(a)(2)(B). This section, however, excludes parenteral nutrients, equipment, and supplies from the competitive acquisition program.

achieve its greatest savings from large corporate suppliers, especially those that provide services nationally. Individual physician practices cannot distort the supply market given their extremely weak market power, and it is for this reason that we are confused as to why CMS would subject physicians to the program. Given the increased costs of delivering care, capital necessary for implementing health information technology, and the never-ending reimbursement cuts, it is inappropriate for CMS to impose another burden on physicians who are simply trying to provide care, services, and items necessary for patient care in the most appropriate and convenient setting.

In addition, the statute *requires* that the "Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section."[4] In many cases, physicians will be considered those small suppliers. It appears that CMS' rationale for concluding that it has complied with this provision is by creating the opportunity to submit "network" bids[5] which would, as argued, give small suppliers increased competitiveness with larger suppliers. For physicians to participate in a network, it would require physicians in a particular Metropolitan Statistical Area (MSA) to band together to essentially create a supply cooperative, thereby sharing pricing and supply information. We strongly encourage CMS to reevaluate this as its rationale for ensuring the inclusion of small suppliers by examining its own criteria for submitting a network bid. In particular, we would call your attention to the requirement that "the network cannot be anti-competitive." Encouraging physicians to join together to share pricing information, even if just for DMEPOS, seems, at best, an ill-advised suggestion given the potential antitrust complications that would result from physicians sharing financial information.

II. Exclusionary List & Criteria

It is our belief that the program is inherently flawed as applied in several particular areas. Given CMS' authority to exclude some products from the CAP, ***the AAOS recommends that CMS proactively create and publish a list of products that will not be required to be competitively bid.*** While CMS would of course maintain authority to change the list of excluded products, it would still provide a reasonable expectation of whether physicians will be required to participate in the CAP from year-to-year and with regard to which products.

Given possible weaknesses in coding categories and placement of particular items within product categories, we also believe that CMS should make changes to the exclusionary list through an open and transparent process. In addition, given the fact that there is no regulatory or judicial review for product selection and placement provided for in the regulations,[6] CMS should take every possible step to make the process as responsive and

[4] Social Security Act §1847(b)(6)(D)
[5] *Federal Register*, Vol. 71, No. 83, 25683 (May 1, 2006)
[6] *Federal Register*, Vol. 71, No. 83, 25682 (May 1, 2006).

transparent as possible. A unilateral system that disrupts the patient-physician relationship and endangers access to necessary items without appropriate input should be reconsidered.

In order to be as transparent and principled as possible in the selection of products to be competitively bid, we propose the utilization of the following exclusionary criteria. We believe that each individual criterion is of sufficient weight so as to warrant exclusion of products that fall into any one category. While the list of exclusionary criteria may be longer than submitted here, we believe that, at the very least, these criteria should be used to exempt particular items from the competitive acquisition program.

A. DMEPOS with costs under a set *de minimus* dollar amount should be excluded from the CAP.

There will be little to no benefit to Medicare if it subjects low cost DMEPOS to the CAP. For that reason, CMS should set a *de minimus* dollar amount that will ensure that the CAP focuses on the supplies where there is a greater likelihood of abuse and financial benefit to Medicare. The set amount should then be anchored to an index that will allow for the amount to rise with inflation. The natural indices would be either the Medicare Economic Index (MEI) or the Consumer Price Index (CPI).

The AAOS submits that CMS set an initial *de minimus* cost threshold where products under that threshold are exempted from the CAP. While we would be willing to have further discussions on how to calculate the threshold, we believe that a fair number is one that would ensure that larger ticket items are the focus of the CAP. We also believe that setting this number would be within CMS' authority given the statutory language allowing the Secretary to exempt from the program "items and services for which the application of competitive acquisition is not likely to result in significant savings."[7]

B. DMEPOS with Medicare volumes under a set *de minimus* volume should be excluded from the CAP.

In addition to low dollar amount DMEPOS, those products with significantly low volumes should be excluded because the low volume characteristic does not lend itself well to competitive bidding program and Medicare is not likely to achieve significant savings.

The AAOS submits that the initial *de minimus* volume threshold be set. Again, we believe that proactively removing products of low volume would be within CMS' authority given the statutory language that allows the Secretary to exempt items or services that "are not likely to result in significant savings."[8]

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[7] Social Security Act §1847(a)(3)(B)
[8] *Ibid.*

C. DMEPOS essential for patient mobility should be excluded from the CAP.

One of the largest concerns about the CAP is the potential impact on continuity of care for Medicare patients. As physician-suppliers are forced out of the program due to the inability to assume the added administrative costs of bidding in the CAP and the inability to compete as a small supplier, patients may be forced to seek products from other suppliers that have been typically provided by their physicians.

Therefore, products that are essential for patient mobility should be removed from the CAP process. For instance, patients suffering from fractures, joint dislocations, and other conditions in need of immediate stabilization should not be forced to leave their physician's office without the necessary products because they have to go seek out a "bid winner" - nor should patients be asked to make pre-determined site-of-care choices based on whether a physician was a "DMEPOS CAP winner."

D. DMEPOS inherent to immediate patient care should be excluded from the CAP.

The current proposal for the program has the potential to inappropriately disassemble services available to Medicare patients causing tremendous inconvenience to patients, many of whom already struggle to arrive at their initial physician visit. The ability of a physician to address a patient's condition *during* the physician-patient encounter, knowing that the patient has received the appropriate DMEPOS and been properly instructed on its utilization and application is integral to the quality and efficiency of patient care. However, to require a patient to go elsewhere to receive products that might otherwise be delivered in a physician's office may lead to disjointed care without the input or expertise of the treating physician.

Therefore, products that are inherent to immediate patient care should be removed from the CAP. While we would hope that CMS would already be excluding these types of products, it is their existence on an exclusionary list that will assure Medicare beneficiaries and their physicians that appropriate care will not be disrupted.

III. Other Issues in the Proposed Rule

A. Definition of "off-the-shelf orthotics"

As previously stated, the Act provides for the inclusion of "off-the-shelf orthotics" in the CAP.[9] The Act defines "off-the-shelf orthotics" as orthotics such as "leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required

[9] Social Security Act §1847(a)(2)(C)

because of a change in the patient's physical condition,"[10] but only those that "require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual."[11] We ask that CMS be extremely cautious in its assignment of these categorizations. These are products designed to treat functions essential to patient mobility. Given the fact that CMS has asserted that there is no judicial or administrative review of which products are included in the CAP,[12] ***the AAOS recommends that CMS seek the input of the physician community to assess which items fall into which categories and assess the impact on patient care and convenience rather than resorting to unilateral decision-making.***

B. Limit on the Number of Contractors

The proposed rule cites the Social Security Act in its authority for awarding "winners" based on matching market supply and market demand.[13] While we understand the mandate, we see a potential conflict with the requirement that the Secretary ensure the participation of small suppliers.[14] Attempting to award contracts based on aligning market demand with market supply will immediately put small suppliers, including physicians, at a disadvantage in the award process. It is also unclear how CMS will incorporate the supply capacity of small physician suppliers compared with other suppliers when physician suppliers are unique in that "they will not be required to furnish these items to beneficiaries who are not their patients if they choose not to function as commercial suppliers."[15]

For these reasons, ***the AAOS recommends that CMS exempt physicians from the CAP or develop a much more detailed plan of how it plans to incorporate physicians into the CAP.***

IV. Conclusion

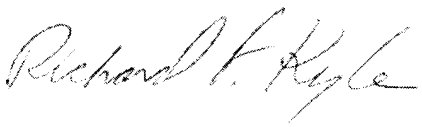
In addition to the above requests, we ask that CMS constantly review patient access to care and physician ability to prescribe treatments for patients. This is an incredibly complex program that is likely to confuse patients and add yet another burden on physician practice. We ask that CMS proceed with extreme caution, consider the impact

[10] Social Security Act §1861(s)(9)
[11] Social Security Act §1847(a)(2)(C)
[12] *Federal Register,* Vol. 71, No. 83, 25682 (May 1, 2006).
[13] *Federal Register,* Vol. 71, No. 83, 25675 (May 1, 2006); Social Security Act §1847(b)(4).
[14] Social Security Act §1847(b)(6)(D) states, "In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section."
[15] *Federal Register*, Vol. 71, No. 83, 25672 (May 1, 2006).

of the program on physician-suppliers, and exempt physicians as well as products that meet the aforementioned criteria from the DMEPOS CAP.

We look forward to working with you on this issue. Should you have any questions, please contact Bob Jasak via e-mail at jasak@.aaos.org or phone at 202-546-4430.

Sincerely,



Richard F. Kyle, MD
President

Submitter : Ms. Melodie Robinson **Date:** 06/30/2006

Organization : health care reimbursement solutions, inc

Category : Health Care Industry

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

See attachement

CMS-1270-P-1104-Attach-1.DOC

June 30, 2006

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

Re: Centers for Medicare & Medicaid Services (CMS)
42 CFR Parts 411, 414 and 424
(CMS-1270-P) RIN 0938-AN14
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

VIA: **www.cms.hhs.gov/eRulemaking**

Dear Colleagues:

As a Billing Service for Home Medical Equipment Suppliers, we welcome the opportunity to comment on this proposed rule which would implement competitive bidding programs for certain items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) throughout the United States in accordance with sections 1847(a) and (b) of the Social Security Act.

As a Billing Service, we represent the home care industry in 5 states, for stand alone and hospital based providers of home medical equipment. The following comments reflect the our collective years of experience and our assessment of the impact the above rule would have upon beneficiaries of the Medicare/Medicaid program, in addition to the impact on the providers of home medical equipment, their employees and our employees.

COMMENTS/ISSUES/QUESTIONS:

It is our view that the term "Competitive Bidding" is a misnomer for a flawed system which might more aptly be described as "Selective Acquisition." It is also our belief that the two pilot projects have demonstrated significant negative consequences for beneficiaries by effectively eliminating the normal, healthy competition that currently exists between the DMEPOS provider community to provide beneficiaries with fast, efficient, and effective products and services. Along with this comes the fact that the majority of beneficiaries are supplied by small businesses. These small businesses are our clients. Due to their size, which diminishes their ability for affording accreditation, their minimal service locations and size of delivery area many of them will be excluded from the bidding process. This exclusion will in the end result in the closing of many providers r esulting in the increase in Unemployment throughout the United States. It is important to mention at this point that the United States was founded on freedom and entrepreneurship. This basically eliminates the freedom from the Medicare Beneficiary. This eliminates the entrepreneurship from the American Public as small business involvement in the Home Medical Equipment industry will be virtually eliminated.

Reasonable and significant cost-savings from providers can and should ultimately be achieved without eliminating normal competition in the marketplace and without eliminating virtually the entire, existing DMEPOS provider panel. The bottom line, we believe, that creation of a "limited provider panel" through the proposed national competitive bidding (NCB) program is bad policy for

beneficiaries and providers alike. While this NCB option may, in some instances, result in product price reduction, it will at the same time severely reduce overall patient access, choice and service, ultimately shifting increased care costs to other areas of the hospital system and health care continuum; e.g., increased length of stay in inpatient/acute settings and/or increased patient re-admission frequency or disease severity, etc. from moving to a "low price" model being encouraged by NCB..

On this point, we ask that CMS concur in the general understanding that any potential product cost savings gained through National Competitive Bidding for DMEPOS---including oxygen, wheelchairs, beds, respiratory equipment, wound care, diabetic supplies etc.---will ultimately be offset by increased costs in both the tertiary inpatient and outpatient care settings.

As the experience of DMEPOS providers demonstrates, these costs are recognized through increased administrative, oversight and program management expense, and often prevent patients from getting the most efficient and optimal health care available.

RECOMMENDATIONS: We recommend that CMS should stagger the bidding in MSAs in 2007 to allow for an orderly rollout of the program. This will actually allow CMS to identify problems that occur in the competitive bid areas and to work with providers and patients alike to help correct them before the problems become even more widespread. In addition to this staggering, CMS should move back implementation of the 2007 date, due to the questions remaining about the program, e.g. accrediting bodies and MSA's involved.

The initial MSA's and products selected should be clearly and distinctly identified in the final rule. Unfortunately however, under the current proposed CMS timeline, it appears that small DMEPOS providers will not have enough time to create legitimate and functional networks, which will ultimately eliminate, as mentioned above, "small" DMEPOS providers that want to participate, regardless of their industry knowledge, experience, and/or specialized expertise

CMS' process to determine the number of suppliers to meet projected demand in an MSA, along with its defined methodology to estimate supplier capacity, appears to heavily favor the large, high volume regional suppliers, rather than the smaller, independent DMEPOS providers, again as stated earlier, eliminating the small business and entrepreneurship of the American Public.

CMS' assertion that the NPRM provides an "equal" opportunity for small suppliers to participate is questionable, and there appears to be no guarantee that any of the winning bidders might be a small business, or even a network of small business providers.

We would urge that CMS consider the significant and potential negative impact that the NPRM may/will ultimately have on small DME businesses and upon the actual, "true" competitiveness of the second and third rounds of the competitive bidding process.

CMS should consult with the Small Business Administration to better assess the impact the NPRM will have on small businesses as both tax-paying members and constituents of the communities that they serve. Again, as mentioned above, the impact on Unemployment in those areas should be considered as well.

CMS should further explain and clarify the specific methodology that will be used to determine whether an MSA is "competitive" during the 2008 - 2009 bid expansion process.

CMS Bid scoring still needs to be improved, and more clearly defined. Suppliers need to know exactly what factors are/will be utilized and what weights will be given to these factors, especially if/when providers are attempting to bid subsets of a major product category.

CMS should explain and clarify what specific measures will be used to decide and how much an item's potential savings could be as a result of competitive bidding.

QUESTIONS: Annual Medicare DMEPOS allowed charges - Is there a specific volume/quantity, or simply a dollar threshold expenditure level that will trigger "competitive acquisition" for a particular product and/or product category? Alternatively, is there a specific threshold growth percentage in a product category that will determine whether it will be subject to competitive acquisition and/or will it vary by the overall dollar expenditures within the product category?

How will CMS determine the appropriate number of suppliers for a product category in each MSA? What specific supplier capacity thresholds will be used to determine this and how will those "capacity" thresholds be specifically determined?

How will potential "cost savings" through Competitive Acquisition be statistically determined and/or validated by actual data for the vast majority of products and categories that were not included in the two initial Demonstration Projects in FL and TX? What reports and/or types of data will be reviewed and considered when evaluating potential cost-savings? Who (either within or outside of CMS) will review the studies and determine their actual statistical validity and applicability for modeling potential future Medicare program savings? Anticipating roll out of the bid price to all areas, not just the MSA's, has CMS considered that the rural provider has significantly higher costs due to the distances traveled to deliver product to the Medicare Beneficiary?

Lack of Established Quality Standards and/or qualified "Accrediting Bodies"

The NPRM clearly states that providers must meet "quality standards," yet the proposed "final" versions of the DMEPOS provider quality standards have not yet been released. It is, therefore, difficult at best, if not impossible, to fully articulate and provides clear comments on these proposed rules for competitive biding when these rules refer to quality standards that have not been fully defined and released.

Ultimately, in the interest of establishing and providing some type of a baseline "provider standard," only accredited providers should be eligible to submit and be awarded "winning bids". In addition, accreditation MUST be affordable for the small provider. Current accrediting bodies' standards are significantly higher than those expected from CMS and their cost reflects that. CMS should not proceed with competitive bidding until it is certain that all of this is possible. CMS needs to clearly identify and establish both the objective and subjective criteria that it will use to identify and deem the accrediting bodies now, before proceeding with trying to implement the actual competitive acquisition processes.

We agree that Accreditation is and should be required, yet affordable, for any provider to service patients under the proposed rules, but again, no final, specific accreditation standards and criteria and/or approved accrediting bodies have yet been clearly identified. The proposed rule appears to still allow non-accredited organizations to bid and be awarded a bid prior to being accredited.

It remains unknown if any of the accreditation bodies will even be interested and/or have the functional accrediting capacity to undertake the standards and criteria which are yet to be specifically defined and established by this proposed rule. Therefore, accreditation organizations, as well as the associated standards, should be in place prior to any further movement towards any competitive bid. Only providers that have attained accreditation should be allowed to bid or be awarded any bid, without these organizations being named, the time constraint to meet this is clearly faulty. Patient safety and care dictates that providers should not be awarded a bid and be able to provide equipment and supplies without first demonstrating competency and proficiency in this area.

CMS should however, grandfather any/all providers that are already accredited by organizations that meet the new criteria that CMS identifies. However, CMS should then allow additional time for providers to analyze the quality standards in conjunction with the overall NPRM rule. The quality standards and cost of accreditation will ultimately affect the overall cost of servicing beneficiaries and are an integral part of the bid process. Therefore, CMS should consider further extending the NPRM comment period and any subsequent implementation plan(s), at least until those "definitive" quality standards are available and have completed the actual rule making process.

It is unrealistic to classify this process as a competitive bid when bidders are ultimately being encouraged, and essentially being forced to bid below a pre-determined price level. The result of this rule could result in bid awards that are established at unrealistic and unsustainable pricing levels. To maintain the integrity of the bidding process, CMS should have some way to objectively evaluate bids for statistical validity, sustainability and overall economic reasonableness. A mechanism for unreasonable bids needs to be incorporated in the final rule to weed out and eliminate purely "lowball" bids.

The prohibition on entities' ability to change ownership during specific periods of the bid award seems overly intrusive and an infringement on an entity's basic business rights.

FUNDAMENTAL ISSUES: The proposed rule appears to primarily utilize cost and volume for product selection. Unfortunately, the potential negative impacts in terms of overall patient access and inclusion and continuity with established care plans and protocols does not appear to be addressed. Consideration to overall medical appropriateness needs to be considered, as well as overall patient access to care and services.

Potential cost considerations that will affect many other areas of the overall health care continuum do not appear to be adequately considered or addressed. There appears to have been no examination of negative cost implications for physicians, home health nursing care providers, hospice, inpatient and outpatient hospitals, integrated healthcare delivery systems and owned-providers, as well as multiple and various other healthcare providers. It is obviously critical that protections and minimization of overall cost impacts throughout the health care service and cost continuum are clearly identified, discussed, and fairly addressed in the final rules. Pushing "costs" out of products alone will most certainly result in detrimental cost-shifting and even cost-increases in other areas of the continuum.

<u>REBATE COMMENTS/ISSUES:</u>

The NPRM mentions a rebate option that contracted providers may choose to underbid and utilize based upon the idea of increasing patient volume...We believe that the potential use of "rebates" to beneficiaries in health care delivery is ultimately an unwise and potentially fraud-encouraging concept

that is without clear or reasonable legal precedent. The provision of rebates to beneficiaries is actually contradictory to other laws and regulations applicable to the Medicare program, including the Anti-Kickback Statute and the beneficiary inducement statute.

We therefore strongly encourage the elimination of this proposed "rebate" provision. Rebates could and would potentially encourage an increase in over utilization and could result in beneficiaries placing pressure on their healthcare providers to order unnecessary products and services. It is fairly certain that Congress did not intend competitive biding to include cash rebates to consumers with the potential of increasing unnecessary product utilization. We question as to whether this feature is consistent with the law.

RECOMMENDATION: The actual items that will be put up for bid should be identified now to solicit and allow further provider-based discussions and comments. We have great concern that products will be grouped-based on product categories. This approach doesn't address the individual medical policy groupings that do not always follow product groupings. Even in the best grouping situations, patients and providers, along with inpatient and outpatient referring entities could feasibly be placed at a significant disadvantage, since they would have to deal with multiple providers of different products for the same patient. Multiple providers of DMEPOS in a home are not only dangerous from a patient safety perspective, but extremely inefficient for the provider and physician who are supervising and coordinating the patient's overall care.

The bid process needs to allow for economically realistic and sustainable bids, rather than simply encouraging "lower priced" bids. In the demonstration projects, some items were bid higher than the current Medicare allowable at that time. Mandating that all "winning" bids below the current Medicare level is ultimately short-sighted and unrealistic in that it effectively could negate reasonable and sustainable pricing levels which are based upon actual activity-based operational costs.

A statistically valid and accurate screening mechanism needs to be developed to completely remove and eliminate unreasonably low and ultimately unsustainable bids. The proposed rule appears to have a loophole where bidders can "low ball" their bid to grantee inclusion, yet not have to honor that "low ball" bid as their actual price paid. The use of statistical models to prevent this situation should be clearly established, defined and implemented prior to the actual biding process.

The determination of supplier's potential service capacity also needs to be better defined. It is still somewhat unclear exactly how CMS will determine a supplier's potential capacity. The proposed rule appears to discriminate and favor the large, regional providers, while the small and medium providers will effectively be shut out of the bidding process as it is currently proposed.

The process for the establishment of networks needs better definition. It is unclear as to the required corporate structure, the responsibilities of the network providers to the network administrator, the patient and CMS. The accreditation requirements for potential established or new provider networks are also still very unclear.

The two initial Competitive Acquisition demonstration projects in TX and FL ultimately neglected to look at the overall impact and costs that NCB will place on other areas of the healthcare continuum.

What economic provider relief is being considered for other areas of the healthcare continuum that will ultimately be exposed to increased costs and administrative burdens posed by NCB? Since none of these impacts were apparently evaluated or studied during the demonstration projects, there is certainly

additional potential negative care and cost implications that will likely be the result of the implementation of widespread NCB.

The NPRM in effect will result in an unfunded federal mandate for other associated members of the healthcare continuum as they seek to move and transition patients to the most clinically appropriate and cost-effective setting of care, not to mention decreased Tax Revenue due to decreased providers and employees and increased Unemployment. To rapidly facilitate acute-care inpatient and/or outpatient facility discharges, the implementation of an NCB mandate has the potential to disadvantage patients within physicians networks, hospitals, integrated healthcare delivery systems, home health, hospice, o utpatient a nd long t erm c are s ettings who w ill s imply ha ve t o e mploy de trimental c ost-shifting.

This concludes our comments. We value our partnership with CMS in our common mission to provide quality health care services and products for Medicare beneficiaries.

Sincerely,

Melodie Robinson
Office Manager
Heath Care Reimbursement Solutions, Inc.
365 Mill Street, P O Box 865
Ortonville, MI 48462
(248) 627-5416

Submitter : **Dr. Jeffery Deacon**

Organization : **Dr. Jeffery Deacon**

Category : **Physician**

Date: 06/30/2006

Issue Areas/Comments

GENERAL

GENERAL

Jeffery S. Deacon, D.P.M.
Diplomate, American Board of Podiatric Surgery
Fellow, American College of Foot and Ankle Surgeons

June 30, 2006

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

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). 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. The closest MSA to our rural area is at least 75-100 miles.

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 or walking cast boot is necessary to stabilize the ankle and crutches may be 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. I am one of the few physicians in my area (MDs and DOs included), that treats these types of injuries and conditions.

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

Sincerely,

Jeffery S. Deacon, D.P.M., F.A.C.F.A.S.

1009 West Cherry Street 7 Marion, IL 62959 7 (618) 993-0333 7 Fax (618) 993-0545

Submitter : Mr. Robert Jasak **Date:** 06/30/2006

Organization : AAOS, ACS, AUA

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1106-Attach-1.DOC

#1106

June 30, 2006

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

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

Dear Dr. McClellan:

The American Association of Orthopaedic Surgeons (AAOS), the American College of Surgeons (ACS), and the American Urological Association (AUA), would like to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on the recently proposed rule on the competitive acquisition program (CAP) for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). This proposed rule, however, poses a significant danger of interference with the continuity of patient care and the primacy of the patient-physician relationship and significantly increases the administrative burden of many physicians participating in the Medicare program.

I. Introduction

We understand that Social Security Act (the Act) §1847(a) and (b) require CMS to implement a competitive acquisition program for durable medical equipment and supplies[1], off the shelf orthotics[2], and other equipment and supplies as defined in §1842(s)(2)(D)[3]. We also understand that some of the impetus for the program is to eliminate overpayments to suppliers for the larger dollar and volume supplies for which Medicare pays. While we acknowledge those mandates and concerns, we believe that CMS' decision to subject physicians to the bidding process is contrary to the program's goals.

Therefore, we believe that ***CMS should remove the administrative costs and burden of bidding by exempting physician-suppliers from the CAP***. CMS is likely to achieve its greatest savings from large corporate suppliers, especially those that provide services nationally. Individual physician practices cannot distort the supply market given their extremely weak market power, and it is for this reason that we are confused as to why

[1] Social Security Act §1847(a)(2)(A)
[2] Social Security Act §1847(a)(2)(C)
[3] Social Security Act §1847(a)(2)(B). This section, however, excludes parenteral nutrients, equipment, and supplies from the competitive acquisition program.

CMS would subject physicians to the program. Given the increased costs of delivering care, capital necessary for implementing health information technology, and the never-ending reimbursement cuts, it is inappropriate for CMS to impose another burden on physicians who are simply trying to provide care, services, and items necessary for patient care in the most appropriate and convenient setting.

In addition, the statute *requires* that the "Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section."[4] In many cases, physicians will be considered those small suppliers. It appears that CMS' rationale for concluding that it has complied with this provision is by creating the opportunity to submit "network" bids[5] which would, as argued, give small suppliers increased competitiveness with larger suppliers. For physicians to participate in a network, it would require physicians in a particular Metropolitan Statistical Area (MSA) to band together to essentially create a supply cooperative, thereby sharing pricing and supply information. We strongly encourage CMS to reevaluate this as its rationale for ensuring the inclusion of small suppliers by examining its own criteria for submitting a network bid. In particular, we would call your attention to the requirement that "the network cannot be anti-competitive." Encouraging physicians to join together to share pricing information, even if just for DMEPOS, seems, at best, an ill-advised suggestion given the potential antitrust complications that would result from physicians sharing financial information.

II. Exclusionary List & Criteria

It is our belief that the program is inherently flawed as applied in several particular areas. Given CMS' authority to exclude some products from the CAP, ***we recommend that CMS should proactively create and publish a list of products that will not be required to be competitively bid***. While CMS would of course maintain authority to change the list of excluded products, it would still provide a reasonable expectation of whether physicians will be required to participate in the CAP from year-to-year and with regard to which products.

Given possible weaknesses in coding categories and placement of particular items within product categories, we also believe that CMS should make changes to the exclusionary list through an open and transparent process. In addition, given the fact that there is no regulatory or judicial review for product selection and placement provided for in the regulations,[6] CMS should take every possible step to make the process as responsive and transparent as possible. A unilateral system that disrupts the patient-physician relationship and endangers access to necessary items without appropriate input should be reconsidered.

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[4] Social Security Act §1847(b)(6)(D)
[5] *Federal Register*, Vol. 71, No. 83, 25683 (May 1, 2006)
[6] *Federal Register,* Vol. 71, No. 83, 25682 (May 1, 2006).

In order to be as transparent and principled as possible in the selection of products to be competitively bid, we propose the utilization of the following exclusionary criteria. We believe that each individual criterion is of sufficient weight so as to warrant exclusion of products that fall into any one category. While the list of exclusionary criteria may be longer than submitted here, we believe that, at the very least, these criteria should be used to exempt particular items from the competitive acquisition program.

A. DMEPOS with costs under a set *de minimus* dollar amount should be excluded from the CAP.

There will be little to no benefit to Medicare if it subjects low cost DMEPOS to the CAP. For that reason, CMS should set a *de minimus* dollar amount that will ensure that the CAP focuses on the supplies where there is a greater likelihood of abuse and financial benefit to Medicare. The set amount should then be anchored to an index that will allow for the amount to rise with inflation. The natural indices would be either the Medicare Economic Index (MEI) or the Consumer Price Index (CPI).

We submit that CMS set an initial *de minimus* cost threshold where products under that threshold are exempted from the CAP. While we would be willing to have further discussions on how to calculate the threshold, we believe that a fair number is one that would ensure that larger ticket items are the focus of the CAP. We also believe that setting this number would be within CMS' authority given the statutory language allowing the Secretary to exempt from the program "items and services for which the application of competitive acquisition is not likely to result in significant savings."[7]

B. DMEPOS with Medicare volumes under a set *de minimus* volume should be excluded from the CAP.

In addition to low dollar amount DMEPOS, those products with significantly low volumes should be excluded because the low volume characteristic does not lend itself well to competitive bidding program and Medicare is not likely to achieve significant savings.

We submit that the initial *de minimus* volume threshold be set. Again, we believe that proactively removing products of low volume would be within CMS' authority given the statutory language that allows the Secretary to exempt items or services that "are not likely to result in significant savings."[8]

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[7] Social Security Act §1847(a)(3)(B)
[8] *Ibid.*

C. DMEPOS essential for patient mobility should be excluded from the CAP.

One of the largest concerns about the CAP is the potential impact on continuity of care for Medicare patients. As physician-suppliers are forced out of the program due to the inability to assume the added administrative costs of bidding in the CAP and the inability to compete as a small supplier, patients may be forced to seek products from other suppliers that have been typically provided by their physicians.

Therefore, products that are essential for patient mobility should be removed from the CAP process. For instance, patients suffering from fractures, joint dislocations, and other conditions in need of immediate stabilization should not be forced to leave their physician's office without the necessary products because they have to go seek out a "bid winner" - nor should patients be asked to make pre-determined site-of-care choices based on whether a physician was a "DMEPOS CAP winner."

D. DMEPOS inherent to immediate patient care should be excluded from the CAP.

The current proposal for the program has the potential to inappropriately disassemble services available to Medicare patients causing tremendous inconvenience to patients, many of whom already struggle to arrive at their initial physician visit. The ability of a physician to address a patient's condition *during* the physician-patient encounter, knowing that the patient has received the appropriate DMEPOS and been properly instructed on its utilization and application is integral to the quality and efficiency of patient care. However, to require a patient to go elsewhere to receive products that might otherwise be delivered in a physician's office may lead to disjointed care without the input or expertise of the treating physician.

Therefore, products that are inherent to immediate patient care should be removed from the CAP. While we would hope that CMS would already be excluding these types of products, it is their existence on an exclusionary list that will assure Medicare beneficiaries and their physicians that appropriate care will not be disrupted.

III. Other Issues in the Proposed Rule

A. Definition of "off-the-shelf orthotics"

As previously stated, the Act provides for the inclusion of "off-the-shelf orthotics" in the CAP.[9] The Act defines "off-the-shelf orthotics" as orthotics such as "leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required

[9] Social Security Act §1847(a)(2)(C)

because of a change in the patient's physical condition,"[10] but only those that "require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual."[11] We ask that CMS be extremely cautious in its assignment of these categorizations. These are products designed to treat functions essential to patient mobility. Given the fact that CMS has asserted that there is no judicial or administrative review of which products are included in the CAP,[12] ***we recommend that CMS seek the input of the physician community to assess which items fall into which categories and assess the impact on patient care and convenience rather than resorting to unilateral decision-making.***

B. Limit on the Number of Contractors

The proposed rule cites the Social Security Act in its authority for awarding "winners" based on matching market supply and market demand.[13] While we understand the mandate, we see a potential conflict with the requirement that the Secretary ensure the participation of small suppliers.[14] Attempting to award contracts based on aligning market demand with market supply will immediately put small suppliers, including physicians, at a disadvantage in the award process. It is also unclear how CMS will incorporate the supply capacity of small physician suppliers compared with other suppliers when physician suppliers are unique in that "they will not be required to furnish these items to beneficiaries who are not their patients if they choose not to function as commercial suppliers."[15]

For these reasons, ***we recommend that CMS exempt physicians from the CAP or develop a much more detailed plan of how it plans to incorporate physicians into the CAP.***

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[10] Social Security Act §1861(s)(9)
[11] Social Security Act §1847(a)(2)(C)
[12] *Federal Register,* Vol. 71, No. 83, 25682 (May 1, 2006).
[13] *Federal Register,* Vol. 71, No. 83, 25675 (May 1, 2006); Social Security Act §1847(b)(4).
[14] Social Security Act §1847(b)(6)(D) states, "In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section."
[15] *Federal Register*, Vol. 71, No. 83, 25672 (May 1, 2006).

IV. Conclusion

In addition to the above requests, we ask that CMS constantly review patient access to care and physician ability to prescribe treatments for patients. This is an incredibly complex program that is likely to confuse patients and add yet another burden on physician practice. We ask that CMS proceed with extreme caution, consider the impact of the program on physician-suppliers, and exempt physicians as well as products that meet the aforementioned criteria from the DMEPOS CAP.

We look forward to working with you on this issue. Should you have any questions, please contact Bob Jasak via e-mail at jasak@.aaos.org or phone at 202-546-4430.

Sincerely,

American Association of Orthopaedic Surgeons

American College of Surgeons

American Urological Association

Submitter : **Dr. John Crist** **Date: 06/30/2006**

Organization : **Dr. John Crist**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 30, 2006

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

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I am a podiatric physician and prescribe and would like to begin to 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 never 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 will be 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. Speaking from experience, this would be a cruel burden on my patients. Can you imagine an 85year old patient with a significant foot or ankle injury, requiring non weight bearing, trying to hop out of the office.

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

Sincerely,

John A Crist DPM

Submitter : Mrs. Pamela Guy **Date:** 06/30/2006

Organization : Guy's Family Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I, as I am sure many other independent pharmacists, am very concerned about the GAO's recommendation to use mail order as a way to implement a DMEPOS competitive bidding strategy. As independent pharmacists, we see problems every day with mail order programs. There is no way that mail order can take the place of hands on measuring of patients by our staff for crutches, wheelchairs, support hose, braces, ostomy products and many other products. We are there to make sure the patient gets properly fitted and is educated on how to use the device. Plus the patient has a name and a phone number to call and knows who they are dealing with and talking to if they have a problem or a concern or need more information. The other big big problem we see with mail order is the time lag that is often associated with the patient receiving the product or when they DO receive the product, it is the wrong medication or supply item. All too often we have patients who come to us to get more medicine or diabetic supplies to hold them over, or get the RIGHT medicine or supply item until their mail ordered medicines and supplies arrive. Also, many accidents happen on weekends, with patients going into the hospital and arriving at our store with prescriptions for DME products for instant service --something you can forget about with mail order. We have so many good relationships with our medicare customers and they trust us to provide them with quality DME and supplies. Enforcing mail order is another way of forcing these patients to sever the trusting relationships they already have with their local pharmacies. And you all say that you "recognize the importance of the relationship between the DMEPOS supplier and the medicare beneficiaries" then why not use actions to back those words and not enforce a mail order program? It would definately not be a step forward on improving the quality standards and service for your beneficiaries.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

I totally agree with a set a quality standards to abide by. That should already be practiced by suppliers. It is unfortunate when a supplier engages in fraudulent practices. But I do have concerns about what kind of costs (time, documentation and money-wise) are going to be added on to independent pharmacies who are DMEPOS suppliers. I agree there ought to be some sort of quality standards program to ensure business integrity and provide quality products and service to beneficiaries in an honest way, but it must also be fair as to not increase cost burdens to suppliers who are already being forced to cut costs on yet another avenue of our businesses (first the reductions in our gross margins from Medicare D and now having to submit competitive bids on our reimbursment for DMEPOS items).

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

There is little explanation of the bidding process--- I have concerns that if we happen to submit a bid that is not low enough, will we get another opportunity to meet a set price for different products? The bidding and selection process is pretty vague.

Submitter : Mr. John Miller **Date:** 06/30/2006

Organization : Miller's Rental

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attachment

4 1109

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. Gerry Dickerson, ATS, CRTS **Date:** 06/30/2006

Organization : Mr. Gerry Dickerson, ATS, CRTS

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-1110-Attach-1.DOC

CMS-1270-P-1110-Attach-2.DOC

#1110

Sent electronically to http://www.cms.hhs.gov/Rulemaking

June 30, 2006

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

Re: Proposed Rule to Improve Medicare's Payment for Certain DMEPOS
CMS-1270-P

Providing complex rehab and assistive technology products and services consists of highly individualized clinical services involving the design and development of individually configured devices, often from many different sources to meet the specific functional needs of the person with a disability. Complex Rehab and assistive technology products and services are provided by clinicians and suppliers with extensive training in working with clients requiring these products and services to meet a variety of needs including communication (both expressive and written), mobility, postural support, sensory impairments as well as addressing issues related to transportation.

When price becomes the sole determining factor in securing products and services, the range and quality of professional services provided to the client is sacrificed in order to put forth a low bid. Complex Rehab and assistive technology products and services are configured and selected for each client – they are not generic. They are configured and designed to address the specific medical and functional needs of each client. To that end, I support the comments of NCART, The Clinician Task Force, Resna, NYMEP, PAOC committee members and presenters (at the February 2006 meeting) and others that recommended the exemption of complex rehab and assistive technology devices from competitive bidding.

Having participated in, read and agreed with the many other very thoughtful comments produced by the above mentioned organizations, I'll limit my personal comments to a few additional key points:

Have Accreditation and Standards in Place before Starting

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 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.

Only companies that are accredited should be allowed to bid.

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.
This is nothing but a disincentive to quality and professionalism, opening the door to another wave of fraud and abuse.

Competitive Bidding Areas (Proposed §414.410)
I agree with others and would recommend that one MSA be selected from each DMERC region for consideration in 2007. Additionally, I would recommend one product group be selected for each MSA to gain further experience with different product groups without trying to manage multiple product groups in any one area. Power wheelchairs should be excluded from the first round due to the fact that new powered wheelchair coding was not even completed until 2006. There is still no pricing information for these new codes and it will be impossible to determine cost savings potential for this item.

In closing, my personal comments touched on only a few key issues. I encourage CMS to study carefully the comments posted by The Clinician Task Force, NCART, Resna, NYMEP, The MedGroup, VGM, AAHomecare and others. Competitive Acquisition of DME will have a profound impact on the provision of systems and devices to those who need them the most.

Thank you for your time,

Gerry Dickerson, ATS, CRTS
Director of Rehab Technology
Medstar Surgical, Inc.
1540 128th St.
College Point, NY 11356

#1110

Sent electronically to http://www.cms.hhs.gov/Rulemaking

June 30, 2006

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

Re: Proposed Rule to Improve Medicare's Payment for Certain DMEPOS
CMS-1270-P

Providing complex rehab and assistive technology products and services consists of highly individualized clinical services involving the design and development of individually configured devices, often from many different sources to meet the specific functional needs of the person with a disability. Complex Rehab and assistive technology products and services are provided by clinicians and suppliers with extensive training in working with clients requiring these products and services to meet a variety of needs including communication (both expressive and written), mobility, postural support, sensory impairments as well as addressing issues related to transportation.

When price becomes the sole determining factor in securing products and services, the range and quality of professional services provided to the client is sacrificed in order to put forth a low bid. Complex Rehab and assistive technology products and services are configured and selected for each client – they are not generic. They are configured and designed to address the specific medical and functional needs of each client. To that end, I support the comments of NCART, The Clinician Task Force, Resna, NYMEP, PAOC committee members and presenters (at the February 2006 meeting) and others that recommended the exemption of complex rehab and assistive technology devices from competitive bidding.

Having participated in, read and agreed with the many other very thoughtful comments produced by the above mentioned organizations, I'll limit my personal comments to a few additional key points:

Have Accreditation and Standards in Place before Starting

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 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.

Only companies that are accredited should be allowed to bid.

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.
This is nothing but a disincentive to quality and professionalism, opening the door to another wave of fraud and abuse.

Competitive Bidding Areas (Proposed §414.410)
I agree with others and would recommend that one MSA be selected from each DMERC region for consideration in 2007. Additionally, I would recommend one product group be selected for each MSA to gain further experience with different product groups without trying to manage multiple product groups in any one area. Power wheelchairs should be excluded from the first round due to the fact that new powered wheelchair coding was not even completed until 2006. There is still no pricing information for these new codes and it will be impossible to determine cost savings potential for this item.

In closing, my personal comments touched on only a few key issues. I encourage CMS to study carefully the comments posted by The Clinician Task Force, NCART, Resna, NYMEP, The MedGroup, VGM, AAHomecare and others. Competitive Acquisition of DME will have a profound impact on the provision of systems and devices to those who need them the most.

Thank you for your time,

Gerry Dickerson, ATS, CRTS
Director of Rehab Technology
Medstar Surgical, Inc.
1540 128th St.
College Point, NY 11356

Submitter : **Mr. Robert Jasak** **Date: 06/30/2006**

Organization : **Musculoskeletal Specialty Societies**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1111-Attach-1.DOC

1111

June 30, 2006

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

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

Dear Dr. McClellan:

The undersigned organizations, representing a large cross-section of musculoskeletal professional societies, would like to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on the recently proposed rule on the competitive acquisition program (CAP) for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). This proposed rule, however, poses a significant danger of interference with the continuity of patient care and the primacy of the patient-physician relationship and significantly increases the administrative burden of many physicians participating in the Medicare program.

I. Introduction

We understand that Social Security Act (the Act) §1847(a) and (b) require CMS to implement a competitive acquisition program for durable medical equipment and supplies[1], off the shelf orthotics[2], and other equipment and supplies as defined in §1842(s)(2)(D)[3]. We also understand that some of the impetus for the program is to eliminate overpayments to suppliers for the larger dollar and volume supplies for which Medicare pays. While we acknowledge those mandates and concerns, we believe that CMS' decision to subject physicians to the bidding process is contrary to the program's goals.

Therefore, we believe that ***CMS should remove the administrative costs and burden of bidding by exempting physician-suppliers from the CAP.*** CMS is likely to achieve its greatest savings from large corporate suppliers, especially those that provide services nationally. The ability of individual physician practices cannot distort the supply market given their extremely weak market power, and it is for this reason that we are confused as

[1] Social Security Act §1847(a)(2)(A)
[2] Social Security Act §1847(a)(2)(C)
[3] Social Security Act §1847(a)(2)(B). This section, however, excludes parenteral nutrients, equipment, and supplies from the competitive acquisition program.

to why CMS would subject physicians to the program. Given the increased costs of delivering care, capital necessary for implementing health information technology, and the never-ending reimbursement cuts, it is inappropriate for CMS to impose another burden on physicians who are simply trying to provide care, services, and items necessary for patient care in the most appropriate and convenient setting.

In addition, the statute *requires* that the "Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section."[4] In many cases, physicians will be considered those small suppliers. It appears that CMS' rationale for concluding that it has complied with this provision is by creating the opportunity to submit "network" bids[5] which would, as argued, give small suppliers increased competitiveness with larger suppliers. For physicians to participate in a network, it would require physicians in a particular Metropolitan Statistical Area (MSA) to band together to essentially create a supply cooperative, thereby sharing pricing and supply information. We strongly encourage CMS to reevaluate this as its rationale for ensuring the inclusion of small suppliers by examining its own criteria for submitting a network bid. In particular, we would call your attention to the requirement that "the network cannot be anti-competitive." Encouraging physicians to join together to share pricing information, even if just for DMEPOS, seems, at best, an ill-advised suggestion given the potential antitrust complications that would result from physicians sharing financial information.

II. Exclusionary List & Criteria

It is our belief that the program is inherently flawed as applied in several particular areas. Given CMS' authority to exclude some products from the CAP, ***we recommend that CMS should proactively create and publish a list of products that will not be required to be competitively bid***. While CMS would of course maintain authority to change the list of excluded products, it would still provide a reasonable expectation of whether physicians will be required to participate in the CAP from year-to-year and with regard to which products.

Given possible weaknesses in coding categories and placement of particular items within product categories, we also believe that CMS should make changes to the exclusionary list through an open and transparent process. In addition, given the fact that there is no regulatory or judicial review for product selection and placement provided for in the regulations,[6] CMS should take every possible step to make the process as responsive and transparent as possible. A unilateral system that disrupts the patient-physician relationship and endangers access to necessary items without appropriate input should be reconsidered.

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[4] Social Security Act §1847(b)(6)(D)
[5] *Federal Register*, Vol. 71, No. 83, 25683 (May 1, 2006)
[6] *Federal Register*, Vol. 71, No. 83, 25682 (May 1, 2006).

In order to be as transparent and principled as possible in the selection of products to be competitively bid, we propose the utilization of the following exclusionary criteria. We believe that each individual criterion is of sufficient weight so as to warrant exclusion of products that fall into any one category. While the list of exclusionary criteria may be longer than submitted here, we believe that, at the very least, these criteria should be used to exempt particular items from the competitive acquisition program.

A. DMEPOS with costs under a set *de minimus* dollar amount should be excluded from the CAP.

There will be little to no benefit to Medicare if it subjects low cost DMEPOS to the CAP. For that reason, CMS should set a *de minimus* dollar amount that will ensure that the CAP focuses on the supplies where there is a greater likelihood of abuse and financial benefit to Medicare. The set amount should then be anchored to an index that will allow for the amount to rise with inflation. The natural indices would be either the Medicare Economic Index (MEI) or the Consumer Price Index (CPI).

We submit that CMS set an initial *de minimus* cost threshold where products under that threshold are exempted from the CAP. While we would be willing to have further discussions on how to calculate the threshold, we believe that a fair number is one that would ensure that larger ticket items are the focus of the CAP. We also believe that setting this number would be within CMS' authority given the statutory language allowing the Secretary to exempt from the program "items and services for which the application of competitive acquisition is not likely to result in significant savings."[7]

B. DMEPOS with Medicare volumes under a set *de minimus* volume should be excluded from the CAP.

In addition to low dollar amount DMEPOS, those products with significantly low volumes should be excluded because the low volume characteristic does not lend itself well to competitive bidding program and Medicare is not likely to achieve significant savings.

We submit that the initial *de minimus* volume threshold be set. Again, we believe that proactively removing products of low volume would be within CMS' authority given the statutory language that allows the Secretary to exempt items or services that "are not likely to result in significant savings."[8]

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[7] Social Security Act §1847(a)(3)(B)
[8] *Ibid.*

C. DMEPOS essential for patient mobility should be excluded from the CAP.

One of the largest concerns about the CAP is the potential impact on continuity of care for Medicare patients. As physician-suppliers are forced out of the program due to the inability to assume the added administrative costs of bidding in the CAP and the inability to compete as a small supplier, patients may be forced to seek products from other suppliers that have been typically provided by their physicians.

Therefore, products that are essential for patient mobility should be removed from the CAP process. For instance, patients suffering from fractures, joint dislocations, and other conditions in need of immediate stabilization should not be forced to leave their physician's office without the necessary products because they have to go seek out a "bid winner" - nor should patients be asked to make pre-determined site-of-care choices based on whether a physician was a "DMEPOS CAP winner."

D. DMEPOS inherent to immediate patient care should be excluded from the CAP.

The current proposal for the program has the potential to inappropriately disassemble services available to Medicare patients causing tremendous inconvenience to patients, many of whom already struggle to arrive at their initial physician visit. The ability of a physician to address a patient's condition *during* the physician-patient encounter, knowing that the patient has received the appropriate DMEPOS and been properly instructed on its utilization and application is integral to the quality and efficiency of patient care. However, to require a patient to go elsewhere to receive products that might otherwise be delivered in a physician's office may lead to disjointed care without the input or expertise of the treating physician.

Therefore, products that are inherent to immediate patient care should be removed from the CAP. While we would hope that CMS would already be excluding these types of products, it is their existence on an exclusionary list that will assure Medicare beneficiaries and their physicians that appropriate care will not be disrupted.

III. Other Issues in the Proposed Rule

A. Definition of "off-the-shelf orthotics"

As previously stated, the Act provides for the inclusion of "off-the-shelf orthotics" in the CAP.[9] The Act defines "off-the-shelf orthotics" as orthotics such as "leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required

[9] Social Security Act §1847(a)(2)(C)

because of a change in the patient's physical condition,"[10] but only those that "require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual."[11] We ask that CMS be extremely cautious in its assignment of these categorizations. These are products designed to treat functions essential to patient mobility. Given the fact that CMS has asserted that there is no judicial or administrative review of which products are included in the CAP,[12] ***we recommend that CMS seek the input of the physician community to assess which items fall into which categories and assess the impact on patient care and convenience rather than resorting to unilateral decision-making.***

B. Limit on the Number of Contractors

The proposed rule cites the Social Security Act in its authority for awarding "winners" based on matching market supply and market demand.[13] While we understand the mandate, we see a potential conflict with the requirement that the Secretary ensure the participation of small suppliers.[14] Attempting to award contracts based on aligning market demand with market supply will immediately put small suppliers, including physicians, at a disadvantage in the award process. It is also unclear how CMS will incorporate the supply capacity of small physician suppliers compared with other suppliers when physician suppliers are unique in that "they will not be required to furnish these items to beneficiaries who are not their patients if they choose not to function as commercial suppliers."[15]

For these reasons, ***we recommend that CMS exempt physicians from the CAP or develop a much more detailed plan of how it plans to incorporate physicians into the CAP.***

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[10] Social Security Act §1861(s)(9)
[11] Social Security Act §1847(a)(2)(C)
[12] *Federal Register,* Vol. 71, No. 83, 25682 (May 1, 2006).
[13] *Federal Register,* Vol. 71, No. 83, 25675 (May 1, 2006); Social Security Act §1847(b)(4).
[14] Social Security Act §1847(b)(6)(D) states, "In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section."
[15] *Federal Register*, Vol. 71, No. 83, 25672 (May 1, 2006).

IV. Conclusion

In addition to the above requests, we ask that CMS constantly review patient access to care and physician ability to prescribe treatments for patients. This is an incredibly complex program that is likely to confuse patients and add yet another burden on physician practice. We ask that CMS proceed with extreme caution, consider the impact of the program on physician-suppliers, and exempt physicians as well as products that meet the aforementioned criteria from the DMEPOS CAP.

We look forward to working with you on this issue. Should you have any questions, please contact Bob Jasak via e-mail at jasak@.aaos.org or phone at 202-546-4430.

Sincerely,

American Association of Hip and Knee Surgeons
American Association of Orthopaedic Surgeons
American Orthopaedic Foot and Ankle Society
American Orthopaedic Society for Sports Medicine
American Shoulder and Elbow Surgeons
American Society for Surgery of the Hand
Arthroscopy Association of North America
Limb Lengthening and Reconstruction Society
Musculoskeletal Tumor Society
Orthopaedic Trauma Assocation
Pediatric Orthopaedic Society of North America
Ruth Jackson Orthopaedic Society

Submitter : Mr. Peter Clendenin **Date:** 06/30/2006

Organization : National Association for the Support of Long Term

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1112-Attach-1.DOC

1112

NASL Insight • Advocacy • Action

June 30, 2006

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

RE: Proposed Rule on Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues

Dear Dr. McClellan:

The National Association for the Support of Long Term Care (NASL) submits 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").

NASL is a trade association representing providers of ancillary products and services to the long-term care and home care industries. Our member companies provide therapy services, diagnostic services, software systems, medical equipment and supplies, and other ancillary services to those care settings.

The Proposed Rule directly impacts NASL members and their customers. Therefore, NASL is a stakeholder in this matter.

We have divided our comments into a section setting forth general concerns regarding the implementation of competitive acquisition for DMEPOS, and a section setting forth our comments on specific provisions of the Proposed Rule. Our general concerns will be discussed in further detail and focus on the following six issues:

1. **Stakeholders cannot adequately comment on a proposed rule they have not seen. In the absence of final DMEPOS Quality Standards that expressly define who is qualified to be a bidder and therefore interrelate with many of the most important provisions of the Proposed Rule, it is impossible to comment effectively.**

2. **The Proposed Rule should exempt products provided to patients of long-term care facilities. The Secretary has both the express and implied authority to grant this exemption, and the exemption will benefit the program.**

3. **CMS should delay implementation of the Proposed Rule to allow sufficient time for a well-conceived and appropriate plan for competitive bidding to ensure that quality and access are not compromised.**

4. **Product categories and items subject to competitive acquisition in 2007 should be minimized because of the program is untested and experimental.**

5. **Program costs to CMS and suppliers should be considered when evaluating the savings potential of competitive bidding.**

6. **The Proposed Rule does not adequately protect small suppliers.**

GENERAL CONCERNS

1. Comment Period Should be Extended Until After the Release of Quality Standards

Recommendation: ***We urge that the comment period on the proposed rule be extended until at least 90 days after the publication of the final DMEPOS Quality Standards, as there is not a complete record to provide comments.***

Rationale: It is simply not possible to comment fully on elements of the Proposed Rule that have a substantial impact on suppliers in the absence of final Quality Standards.

The Quality Standards set out the requirements to be a qualified supplier for purposes of bidding and supplying DMEPOS products. The Quality Standards interrelate with key elements of the Proposed Rule because, for example, the Quality Standards will have an impact on the type and number of suppliers that 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.

The exclusive use of the home care model reflected in the draft Quality Standards, if followed in the final quality standards, dramatically affects the application of the Proposed Rule to suppliers that are not home care providers and may dictate whether, among other things, a distinct bid process should be conducted for alternative methods of delivering DMEPOS to Medicare beneficiaries who are institutionalized.

Without having the final Quality Standards, it is not possible to even anticipate all of the interactions between the Proposed Rule and the Quality Standards that may be important and may need to be considered by CMS in the interest of Medicare beneficiaries and the Medicare program.

It was originally contemplated that the DMEPOS Supplier Quality Standards would be finalized prior to the comment period of the Proposed Rule. Since this did not happen, and because of the significance of the Quality Standards to competitive acquisition, **we submit that the comment period should be extended to not less than 90 days after the publication of the final DMEPOS Supplier Quality Standards.**

We have attached to these comments our prior request for extension of the comment period for the Proposed Rule as Appendix A to this letter, and incorporate it by reference.

2. The Rule Should Exempt Products Provided to Medicare Beneficiaries in Long-Term Care Facilities

Recommendation: ***Items furnished to long-term care facility residents should be exempted from competitive acquisition. In order to meet the unique needs of the high acuity and vulnerable patients who are receiving care in long-term care facilities, they should receive covered supplies and products with appropriate quality and access criteria. This cannot be done within the competitive bidding structure. We believe the Secretary should exercise the statutory authority within section 1847 to exempt items purchased by and delivered to Medicare beneficiaries residing in long-term care facilities from the competitive acquisition requirements.***

Rationale: Long-term care facility patients are of higher acuity than mobile, non-institutionalized patients, and they have special needs that cannot adequately be met by a distribution system designed for non-institutionalized patients. Institutionalized patients are often older and frailer than the typical beneficiary receiving DMEPOS.

Items furnished to long-term care facility patients typically are furnished by either the facility itself or by highly specialized suppliers. Arrangements for enteral nutrition, for example, involve high acuity patients in comparison to the typical beneficiary receiving DMEPOS. Either the facility directly administers the therapy or the supplier, working in a close clinical relationship with the facility's nursing personnel, furnishes the supplies for the therapy and is significantly involved in the patient's nutritional therapy. The level of clinical management and services related to the furnishing of DMEPOS to patients in institutionalized settings is substantially higher than that for non-institutionalized patients.

It is not in the best interest of beneficiaries for the facility to be forced into accepting a supplier that has prevailed in the bid process by bidding low margins, while betting on high volume and low service. Such a supplier may have little experience in the care of patients in long-term care facilities. Further, such a supplier will have little incentive to provide appropriate services and interaction with the facility's clinical staff, because this will adversely impact already low margins, and could cost more than the single payment amount established through competitive bidding. These considerations are precisely the same as those that led CMS to recognize the unique needs of patients in long-term care facilities covered under Part D of Medicare.

When CMS sought to implement the new Part D prescription drug benefit, it recognized correctly that patients in long-term care facilities have special needs that cannot adequately be met through a distribution process designed for beneficiaries who are mobile and not institutionalized.

As recognized in the implementation of Medicare Part D, CMS must balance its proposed policy changes with the existing federal requirements mandating that long-term care facilities assume responsibilities that "each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." 42 C.F.R. Part 483. Altering the acquisition of DMEPOS services could affect the ability of facilities to meet their regulatory obligations. The administrative and regulatory difficulties created for a facility by interference with the control over what suppliers have access to their patients are wholly unaddressed by the proposed rule. The same types of concerns that led the agency to adopt special rules for pharmacy procurement to beneficiaries in long-term care facilities should apply here.

Moreover, as discussed below, competitive bidding for institutionalized patients would result in, at best, minimal savings. The anticipated cost savings, therefore, do not justify the adverse impact that competitive acquisition, as reflected in the Proposed Rule, would be likely to have on beneficiaries. Accordingly, we urge CMS to exclude long-term care facilities from the scope of the competitive bidding process.

At a minimum, CMS should study the affects that competitive acquisition will have on patients and institutions before extending competitive bidding to include long-term care facilities. It is our understanding that results from earlier demonstrations did not support the Proposed Rule. We believe that there is a burden on CMS to document the potential impact on the resident population and to set specific performance standards for safeguarding access to medically necessary DMEPOS items. CMS must affirm that competitive acquisition will not adversely affect the health and welfare of institutionalized beneficiaries. Until this is done, the implementation of these regulations to include long-term care facilities is premature.

We believe that section 1847 of the Social Security Act ("SSA") provides ample statutory authority to exempt items purchased by, and delivered to, Medicare beneficiaries residing in long-term care facilities from the competitive acquisition requirements.

a. The Secretary Has Authority to Exempt those Items and Services Where Savings are Small

The SSA expressly authorizes the Secretary to exempt those items or services for which the savings through competitive acquisition would be minimal. SSA § 1847(a)(3)(B). Where beneficiary acuity and the necessary services associated with the furnishing of DMEPOS is substantially different in an institutional treatment setting, items within the same HCPCS code

are appropriately treated as different. This is particularly justified where the facility already realizes significant savings by purchasing through a GPO. In other words, a single item can be viewed as two items depending on the circumstances under which it is purchased, the special handling needs of the purchaser, and the special access requirements of the purchaser (i.e., 24/7 access).

There is nothing in the legislative history or plain language of the Medicare Modernization Act (MMA) that would preclude the Secretary from interpreting the phrase "items and services for which the application of competitive acquisition is not likely to result in significant savings," to mean items or services purchased by an institution on behalf of beneficiaries from a group purchasing organization. SSA § 1847(a)(3)(B).

The purpose of the competitive acquisition program is to ensure low competitive pricing; it would be inconsistent with this purpose if the acquisition program resulted in higher pricing which could be the case if current institutional purchasing patterns were to be distorted. This distortion would likely have profound negative effect by forcing nursing homes to purchase their own supplies (i.e., for Part A residents) from one source (e.g., GPO) and those on behalf of residents (i.e., for Part B residents) from another source (i.e., competitive acquisition supplier). This will reduce the volume of Part A purchases, decrease the discount, and increase the net cost to nursing facilities.

If long-term care facilities are not exempted, bidders will have to take the cost of serving long-term care facility patients into account in their bids, which is likely to increase their bids over what they otherwise would be. In short, **if section 1847 were applied to nursing facilities, it would likely drive-up overall costs.** The exemption provision, if applied to purchases by nursing facilities on behalf of their residents, would preclude this from occurring.

b. Section 1847 Distinguishes Between Purchases by Individuals and Purchases by Institutions on Behalf of Individuals

It appears that section 1847 was never intended to apply to institutional purchasers and that the phrase "items or services" means those that are purchased directly by individuals and not by institutions on behalf of individuals. Institutions already purchase through competitive bidding albeit private. There is nothing to suggest that Congress intended to undermine institutional purchasing power when it enacted section 1847 or replace the current system of private competitive bidding with a public system. The language makes clear that section 1847 was designed to give individual beneficiaries similar, although not identical, purchasing leverage as enjoyed by institutional purchasers. **The section's goal is to bring down the price of items purchased by individuals rather than raising the price of items purchased by institutions, whether on their own behalf or on behalf of beneficiaries.**

The "individual" rather than the institutional focus of this section is highlighted by a provision that requires *"access of individuals to a choice of multiple suppliers in the area."* SSA § 1847(b)(2)(A)(iv). The law further states that the *"Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis."* SSA § 1847(b)(4)(A).

The fact that the section contemplates only purchases directly made by individuals is further underscored by the fact the *"Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program."* SSA § 1847(b)(8). Such a provision makes no sense in the context of purchases by nursing homes on behalf of beneficiaries.

We believe that the Secretary could reasonably interpret the section so that institutional purchasing on behalf of in-patients or residents is outside the scope of the section altogether. Indeed, one could argue that MMA, with its emphasis on the "individual," precludes the Secretary from extending competitive bidding to institutional providers.

*c. **Implied Authority***

The Secretary has broad rulemaking authority under the Social Security Act. See SSA §§ 1102(a) and 1871; Hennepin County v. Sullivan., 883 F.2d 85, 87 (D.C. Cir. 1989). In exercising that authority, the Secretary normally attempts to harmonize programs to accommodate beneficiaries and to avoid rules that create artificial and counterproductive classifications. The Part D drug program expressly provides that the implementing rules "may include standards with respect to access for enrollees who are residing in long-term care facilities." SSA § 1860D-4(b)(1)(C)(iv). The Part D provisions recognize the special needs of nursing facility residents.

Although the competitive acquisition provisions do not explicitly distinguish between nursing home residents and other beneficiaries, to ignore the distinction is to condone two levels of access—a heightened level for nursing home residents when it comes to purchasing drugs under Part D and a lower level for nursing home residents when it comes to purchasing items or services covered under Part B. This distinction, of course, makes no sense and therefore to avoid this irrational result, one must conclude that the Secretary has the authority under section 1847 to tailor his rules to accommodate the unique needs of nursing home residents.

3. The Implementation Timeframe for Competitive Acquisition Should Be Modified

Recommendation: ***In addition to extending the comment period until after the publication of the final DMEPOS Quality Standards, the implementation of competitive acquisition should be delayed as much as permitted by § 1847(a)(1) of the SSA.***

Rationale: The agency's original timeline projected publication of the Proposed Rule in Spring 2005. The timeline also set forth a comment period of Summer 2005, with the final rule to be published in Spring 2006. This original timetable would have allowed for more thoughtful consideration of the many complex issues raised by the Proposed Rule, both by stakeholders and by CMS.
The original timetable would have allowed CMS and the supplier community from Spring 2006 through the end of 2006 to do all of the following: (i) make arrangements for the implementation contract, (ii) process supplier accreditation, (iii) conduct beneficiary and supplier education, (iv) initiate and complete necessary system changes, (v) request, submit and evaluate bids, (vi) award contracts, and (vii) review any outstanding issues with POAC.

The delays in the development of the DMEPOS Supplier Quality Standards, and in the development of the Proposed Rule, show that the issues involved are complex and their resolutions difficult. The original timetable contemplated implementation for items and MSAs on January 1, 2007. That the development of Quality Standards and the Proposed Rule has taken far more time than originally envisioned by CMS demonstrates that it is unrealistic to expect the final rule to be published and all of the implementation steps to be completed by early 2007.

In addition, we have identified a number of significant issues that will be difficult to adequately resolve by early 2007. We expect that other comments will also address significant issues of concern that will be difficult to resolve by early 2007.

It is essential that the implementation of competitive acquisition be successful in achieving savings without compromising the quality of care or disrupting access and the delivery of care to Medicare beneficiaries. After the significant delays in development of the Quality Standards and Proposed Rule, a subsequent rush to implement competitive acquisition by an arbitrary deadline that is not required by Title XVIII of the SSA, will ensure failure and harm beneficiaries.

The SSA's requirements are satisfied if competitive bidding is implemented in 2007. SSA § 1847(a)(1)(B)(i)(I). Implementation toward the end of 2007 would be more consistent with the original timetable in terms of time allocated to tasks, and would afford a much greater opportunity for the program to achieve its objectives without adversely impacting beneficiaries.

4. The Number of Product Categories and Items Subject to Competitive Acquisition in 2007 Should be Minimized

Recommendation: ***The product groups initially subject to competitive bidding should be sharply limited until CMS, beneficiaries and suppliers gain experience with the program.***

Rationale: Section 1847(a)(1)(B) of the SSA permits a phase-in with respect to the items subject to competitive bidding, as CMS has acknowledged in the proposed rule. *See, e.g.,* 71 Fed. Reg. 25670. As discussed in more detail below, competitive bidding by HCPCS codes (at least by the current codes) is inappropriate for many items. In many cases a single code includes a wide variety of items that (i) are not clinical equivalents, and (ii) have widely varying costs. This is not a new issue and, in fact, it was identified by the Government Accountability Office in its September 2004 report on competitive acquisition in Medicare. GAO, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies,* GAO-04-765 (September 2004). A critical analysis of codes that may be appropriate for competitive bidding is necessary before items can be competitively bid.

An analysis of the items included in HCPCS codes for the purposes of the competitive acquisition program is in the interest of both the Medicare program and Medicare beneficiaries. If items with widely varying costs are included in a single code, suppliers bidding on the product category will need to include an amount related to the risk that the mix of items dispensed in that code will shift toward the more expensive items, particularly as physicians are able to prescribe particular brands and modes of delivery with a code under section 1847(a)(5)(A).

The over-inclusiveness of some codes will result in no program savings. At the same time, once bids are awarded, the winning suppliers will have incentives to shift the mix of items dispensed in that code toward the least expensive items without regard to durability or efficacy. Such shifts would not be in the best interest of beneficiaries where they are driven by supplier economics. Examples of such over inclusiveness include wheel chairs, wheel chair seat and back cushions, support surfaces, and negative pressure wound therapy pumps.

Until a critical analysis of the items included in certain HCPCS codes is completed, **competitive bidding should be limited to a product group or groups that include only codes or items that are truly generic and clinically equivalent.**

The fact that the program is new and experimental provides a compelling additional reason for CMS to limit the number of product categories initially subject to competitive bidding. Serious problems have been identified in the Proposed Rule. If these issues are not addressed, there is no data or experience to show that the program will accomplish its goals of saving money, while maintaining access and quality.

It is not enough to point to the demonstrations in Polk County, Florida and the San Antonio, Texas MSA. These demonstration projects were materially different from what is contemplated by the Proposed Rule.

One of the most striking differences is the use of the median of bids below the pivotal bid to establish single payment amounts for items included in the product group. This is substantially different from pricing in the demonstration projects. It also is likely that there will be far fewer contracted suppliers in each competitive bid area than there were in the demonstrations. **These significant differences, as well as others, show that the competitive bid program may adversely impact access and quality in varying ways.** CMS acknowledged this by eliminating New York, Chicago and Los Angeles from competitive bidding in 2007.

5. **Program costs should be considered when evaluating the savings potential of competitive acquisition of specific items and product categories to ensure that the savings estimate reflects actual net savings**

Recommendation: ***CMS, contractor and user costs must be taken into account in calculating a true cost analysis.***

Rationale: The Proposed Rule does not indicate that CMS and contractor costs will be taken into account in evaluating the savings potential for competitively bid items or product categories. Assuming that supplier costs will be absorbed and reflected in the bids, CMS and contractor costs that should be taken into account include the following: (i) the cost of administering the implementation of the bidding program for particular items and product categories, (ii) the cost of modifying systems and software, (iii) the cost of reviewing, selecting and managing accreditation organizations, (iv) the cost of ongoing administration of competitive acquisition once contract suppliers are chosen, (v) the cost of managing dual systems for competitive bid payments and fee for service payments. **We submit that an appropriate evaluation of savings potential must reflect the net of these costs. Only by doing this can we be sure that the total cost of competitive bidding for certain items or product groups does not exceed the gross savings.**

6. **Proposed Rule Should Allow Small Suppliers to Compete**

Recommendation: ***CMS should consider allowing any willing and qualified supplier to provide DMEPOS so long as payment is subject to the single payment amount determined through the competitive bidding process.***

Rationale: The Medicare Modernization Act requires some balancing of program savings through the competitive acquisition of DMEPOS with the protection of small suppliers. Although CMS references its concern for protecting small suppliers, the Proposed Rule offers no effective method of leveling the competitive playing field so that small suppliers are not disproportionately disadvantaged.

CMS states in the Proposed Rule that the law requires small supplies to be given an "opportunity to bid," but little regard is given toward enabling small suppliers to actually "win a bid." Further, the Proposed Rule's "Opportunity for Networks" (an attempt by CMS to aid small suppliers) would actually create an additional challenge for small suppliers who will already be hard-pressed to shoulder the inherent burdens of competitive bidding (especially during the first round of bidding).

The building of a network is no easy feat and it must be done with great caution and with even greater legal oversight. Assuming that a network can be constructed to meet the scrutiny of the Department of Justice (DOJ) and the Federal Trade Commission (FTC), the majority of small businesses will not be able to bear the additional expense of network-building, and will face the risk that disappointed suppliers will sue regardless of the DOJ and FTC views.

The network opportunity outlined in the Proposed Rule would require small suppliers to create the legal structure of any network prior to bidding. The investment of time and capital necessary to accomplish this task would likely discourage many small providers from undertaking the task. The antitrust litigation risk would further deter other small suppliers, who are ill equipped to fund antitrust litigation, from forming networks. In short, the proposal to allow small suppliers to form networks is unrealistic and unworkable, particularly under the abbreviated time frame proposed by CMS. As this proposal is the only attempt to assure the participation of small suppliers, it is respectfully suggested that the proposed rule has wholly failed to meet the requirements of the statute.

To address this inadequacy within the Proposed Rule, we recommend that CMS consider allowing any willing and qualified supplier to provide DMEPOS at the single payment amount determined through the competitive bidding process. **This program is intended to save money, not to put legitimate suppliers out of business, or to restrict patient access to quality goods and services.**

COMMENTS ON SPECIFIC PROVISIONS OF THE PROPOSED RULE

A. Use of the Term "Off the Shelf Orthotics" § 414.402

Recommendation: *The definition of the term "off the shelf orthotics" should be clarified to prevent infringement on state practice acts. We suggest that the standards of the Board for Certification in Orthotics/Prosthetics be applied to achieve consistency in the items that are "off the shelf orthotics" for purposes of the rule.*

Rationale: The preamble in the Proposed Rule suggests that where the intervention of a certified orthotist is required the item is not off the shelf orthotics. However, it is not clear whether CMS intends this to preempt state practice acts and current definitions of scopes of practice. There are wide variations in state laws and regulations with respect to items or activities requiring the involvement of an orthotist. Therefore, different items could constitute off the shelf orthotics in different competitive bid areas if the standard is defined by reference to state law. We do not believe the intent of CMS was to have this inconsistency.

We further urge caution in making changes that might negatively affect already heavily regulated long-term care facilities. These facilities require orthotic devices in order to comply with federal regulations that have been in effect since passage of the Omnibus Budget Reconciliation Act of 1987. Many of these devices are supplied by Certified Fitters working under the direct supervision of licensed therapists.

B. Payment Basis

1) Payment for Inexpensive or Routinely Purchased DME Furnished on a Rental Basis § 414.408(i)(5)

Recommendation: ***Where inexpensive or routinely purchased DME is included in competitive bidding, there should not be an option to have the equipment provided on a rental basis.***

Rationale: Rental billing for inexpensive or routinely purchased items is cost prohibitive even under the current fee schedule. Suppliers that furnish such items generally do so on a purchase basis, but not a rental basis.

To require suppliers to include in their bids furnishing inexpensive or routinely purchased DME on a rental basis will simply increase the bid amounts without any corresponding benefit. Suppliers will be forced to take into account the costs of billing and collection for 26 bills for such items under the Proposed Rule rather than two (13 months of rental multiplied by primary and secondary payer billing vs. one primary and secondary bill for a sale).

For inexpensive and routinely purchased items, the cost of billing and collection, if it must be done 26 times, can comprise a substantial portion of the total cost of the item. This necessarily will increase the bid prices. It is not in the interest of the Medicare program to require suppliers to incur these costs, as they will increase bid prices for the applicable items and thereby increasing program expenditures.

Any adverse impact on beneficiaries could be eliminated in cases of financial hardship by allowing beneficiaries to pay the beneficiary amount in installments, as is permitted in documented cases of financial hardship under current law.

Finally, the rule offers no consideration regarding the affect on suppliers in the following circumstances:

- Being required to rent products that are defined as "single patient use only" by the manufacturer.
- Being required to rent products that have very limited manufacturer's warranties.
- Having a patient expire during the rental period on a single patient use item.

Rental of inexpensive or routinely purchased items is not feasible from a practical or financial perspective and should be eliminated from the final rule.

2) Adjustment of Payment Amounts in Other Areas § 414.408(e)

Recommendation: ***It is not appropriate to use payment amounts determined in competitive bidding to make inherent reasonableness adjustments to payment amounts in other geographic areas, particularly in any formulaic manner as suggested in the Proposed Regulation.***

Rationale: There is no reason to suppose that competitive bid payment amounts will be reflective of the costs of providing the items in areas outside of the competitive bid areas. Competitive bid areas generally are more densely populated than other areas. In addition, winning bidders in competitive bid areas, in all probability, will pay less for the involved items than suppliers in other areas because of volume discounts.

The Proposed Rule also tacitly assumes that there will be some sort of uniformity or consistency in the payment amounts for items in the competitive bid areas. At best, this assumption is highly suspect. The costs of living in Northeast and Pacific Coast MSAs are dramatically different from those in Midwestern or plains MSAs. In the absence of uniformity or consistency in competitive bid payment amounts, there is even less basis for assuming that the single payment amounts have any relationship at all to "reasonable" payment outside of competitive bid areas, and it is not fair to use these amounts to make inherent "reasonableness" adjustments to payment amounts outside of the competitively bid MSAs. **Single payment amounts established for large MSAs on the basis of competitive bidding will have little relationship to appropriate payment amounts in areas outside of those MSAs.**

3) Payment Amount for Grandfathered Items § 414.408(k)

Recommendation: ***CMS should not change the payment amounts for Grandfathered items described in § 1847(a)(4) of the Act.***

Rationale: The section provides that CMS *"shall establish a process by which rental agreements for the covered items ... may be continued notwithstanding this section."* The price term of an agreement is not a peripheral detail, but a central term of the agreement.

The SSA plainly requires that the agreements be *continued* notwithstanding competitive acquisition. It does not state that the agreements may be continued as adjusted by competitive acquisition. CMS contends that Congress' direction to establish a "process" for continuing the agreements authorizes CMS to unilaterally change the contractual payment amounts for grandfathered items. This interpretation stretches the plain language of the law to the breaking point and beyond. A "process" is an administrative mechanism or methodology for continuation of the agreements, not an authorization to unilaterally modify agreements.

In addition, as a policy matter, it is not necessary to unilaterally reduce the price of grandfathered items. The higher co-payment associated with the unadjusted price will incentivize the suppliers to adjust the price, and if they do not, the lower single payment amount will provide an incentive for beneficiaries to change to the contract supplier. CMS should adhere to the plain language and meaning of the Act and provide for the continuation of agreements under § 1847(a)(4) without modification of the price.

Finally, CMS should apply grandfathering on an item basis at least for capped rental items. Under the SSA, CMS has the authority to establish a date of applicability of competitive bidding in a competitive bid area, and provide for implementation with respect to capped rental items after the expiration of the capped rental period. This alternative will save costs of administration related to DMERCs having to process claims with differing payment amounts.

C. Competitive Bidding Areas

1) Designation of Areas § 414.410

Recommendation: ***An area selection methodology should be used that initially results in a limited number of small competitive bid areas, consistent with the Act.***

Rationale: Since the competitive acquisition program is new and experimental, the method for selecting competitive bid areas should be modified. As CMS recognizes, the Act requires 10 of the largest MSAs, not the 10 largest. Due to the experimental nature of the program, and the challenges that will be encountered in its implementation, CMS has excluded New York, Chicago and Los Angeles.

In addition to the factors recognized by CMS, there are serious issues with the item selection and pricing methodologies of the Proposed Rule. All of these reasons demonstrate that an area selection methodology should be used that initially results in a limited number of small competitive bid areas, consistent with the SSA. This can reasonably be accomplished in several ways.

Under the methodology of the Proposed Rule, there is little geographic diversity in the competitive bid areas. They are disproportionately concentrated in DMERC Region C. The geographic diversity can and should be expanded to provide more useful information to be used in implementing the program in more areas in the future, as well as to minimize the consequences to Medicare beneficiaries of implementation challenges. The maximum number of competitive bid areas in a State should be limited to one instead of two.

The methodology should be changed to distribute the competitive bid areas to among the DMERC regions as evenly as possible, so that there are 3 areas in each of two of the DMERC regions, and 2 in each of the remaining two DMERC regions. This methodology would result in 10 of the largest MSAs for purposes of the Act.

In this way, better experience and less adverse impact on beneficiaries will result. The areas can be expanded as CMS, suppliers and beneficiaries develop more experience with the program, and can determine the features of the program that work best, and those that should be modified.

2) Nationwide or Regional Mail Order Competitive Bidding Program § 414.410(d)(2)

Recommendation: ***Different methods of delivery should not be treated differently.***

Rationale: As we have noted, the proposed rule does not include the DMEPOS Quality Standards. However, in describing the mail order competitive bidding program, the Proposed Rule refers to using mail order for the replacement of supplies. We strongly urge the final rule not treat different methods of delivery differently. Treating different methods of delivery differently, where this is not clinically necessary or appropriate, will only reduce the effectiveness of the competitive acquisition program in lowering costs and maximizing beneficiary choice.

Under this principle, mail order suppliers would bid in the same process as non-mail order suppliers both for initial and replacement DMEPOS. The methods of delivery would not be distinguished in the bid process or pricing. To the extent medically necessary, for example where professional services are required in initial fitting, the DMEPOS Quality Standards or Local Coverage Determinations could set forth appropriate requirements. This approach would most effectively achieve CMS' objectives of maximizing savings and beneficiary choice.

D. Criteria for Item Selection

1) Use of Medical Policies to Determine Product Categories

Recommendation: ***Product categories should be defined with reference to medical policies and clinical conditions.***

Rationale: Medical policies are created as much to categorize medical conditions and coverage, as they are to categorize products and codes. For example, if competitive bidding were considered from the standpoint of managing specific conditions, it would be unreasonable to consider combining a wound care patient group together with a patient group requiring a hospital bed or a wheelchair. From a simplistic approach it may seem appropriate to combine the medical policy for "wheelchair seating" with "wheelchairs" and "support surfaces" with "hospital beds" in forming a competitive bidding product category. However, there are stark contrasts in the medical necessity requirements between these medical policies and the beneficiaries that qualify for them.

In order to insure quality and access in a competitive bidding environment, CMS must ensure that the best providers have an opportunity to bid. Many providers structure their business around addressing specific disease states and conditions. It cannot be assumed that providers with a wound care expertise and focus are also wheelchair or hospital bed providers, nor can the reverse be assumed. The goal of competitive acquisition must be to reasonably reduce program and beneficiary costs while maintaining or enhancing quality and access.

Any combination of HCPCS codes from multiple medical policies lumped together into one competitive bidding product category will reduce the number of providers capable of bidding for specific goods and services. Those providers that carry the broadest product offering will benefit to the detriment of the specialty providers, and the level of competition will be reduced. Ultimately, the very providers most adept at providing quality goods and services for a specific medical policy may be prohibited from bidding due to combined medical policies that extend beyond their expertise and product offering.

The system may lose out on actual savings by inappropriately reducing the number of suppliers capable of bidding. Less competition will result in a seller's market and costs will increase. We understand CMS' goal that beneficiaries not be required to obtain related items from different suppliers. We submit that the use medical policies as described will achieve this goal.

The Proposed Rule lacks clarity regarding how product categories will be defined. Unless CMS adopts our recommendation that product categories be defined based on medical policies, we urge that the method of defining product categories be published for comment prior to the effective date of a final rule. As it stands, stakeholders are left in the dark. They can only make recommendations on how best to define product categories, and cannot provide comments to a method proposed by CMS.

2) The Sufficiency of Current HCPCS Codes for Competitive Bidding

Recommendation: ***Higher and lower priced items currently in a single HCPCS code should be separated into different HCPCS codes.***

Rationale: Certain current HCPCS codes are not sufficiently detailed and homogenous in order to be effectively bid. Clearly, bidding codes that include multiple items with widely varying costs, a variety of technologies and different clinical applications and efficacy would have a detrimental affect on patient care and access. Examples of these codes include support surfaces and wheelchair seating, which include within a single HCPCS code items of varying cost, configuration and complexity that are prescribed based on the patient's specific clinical condition. An example cited by the GAO is power wheelchairs, where different models represented by a single HCPCS code, range from $1,600 to nearly $17,000.

Competitive bidding of items in such codes will fail to maximize program savings because suppliers will have to include in their bids an amount reflecting the anticipated cost of the higher priced items in the code. The mix of higher and lower cost items within the code will be difficult for suppliers to accurately estimate because they do not have access to data regarding the mix in the competitive bid area; instead they only have their own mix data. In addition, the mix may be affected in amounts that are not possible to predict due to the SSA's provision that physicians may prescribe a specific brand or mode of delivery of product within a competitively bid code. *See* SSA § 1847(a)(5)(a).

Suppliers necessarily will be forced to add some amount of risk premium over the amounts that they would be able to bid for only the lower cost items, or for a known mix of lower and higher priced items. Program savings will be greater if higher and lower priced items currently in a single HCPCS code are separated into different HCPCS codes because these uncertainties and unknowns will be eliminated and suppliers will be able to bid their best prices for each of the lower and higher priced items.

In addition, **the use of HCPCS codes that include items of widely varying cost and clinical application will adversely affect the quality of care for the beneficiaries.** The use of such codes will result in a race to the bottom by suppliers, and diminish beneficiary access to medically necessary, higher cost or higher technology items that are included in HCPCS codes together with inexpensive items that may not be appropriate for some beneficiaries. This adverse impact on the quality of care was *specifically* cited by the GAO, and was the basis for its recommendation that CMS evaluate and "subdivide" codes where the characteristics and price range of items in the code "is too broad."

Once contracts are awarded to suppliers, the suppliers will have a significant incentive to furnish the lowest cost item within the code, unless the physician specifically prescribes a different item. This is particularly to be anticipated where highly competitive bidding results in a low single payment amount in comparison to the fee schedule amount. Suppliers may need to skew the mix of items toward the least expensive items in the code in order to be able to supply the items without suffering financial losses. Unlike prescription drugs, many items of DME included within the same HCPCS code are not directly interchangeable. The unique needs of the patient need to be addressed by the use of the correct product within any given HCPCS code. The Proposed Rule fails to address this issue.

Both of these effects can be avoided if competitive bidding is initially limited to codes that contain only homogenous, generic and clinically equivalent items. Many such codes offer significant opportunity for savings precisely because the included items are similar to each other in cost and technology. While competitive acquisition in product categories including such codes is implemented, a critical review of other codes should be conducted so that more appropriate codes can be established that do not include items of widely differing costs, technologies and clinical applications.

With some of the current codes, any supplier wishing to win a competitive bid may be forced into a situation where it disregards quality and efficacy for price. Historically, ethical providers have strived to differentiate themselves by their level of quality and service. If an under-defined HCPCS code, which includes a wide variety of technologies, is bid, then such a provider will either have to reduce its standards or lose business.

By more finely dividing the items selected for bidding, and increasing the number of HCPCS codes, CMS may achieve the benefit of competitive bidding without jeopardizing access to higher cost, higher technology items.

E. Conditions for Awarding Contracts

1) Quality Standards and Accreditation § 414.414(c)

Recommendation: ***CMS should re-evaluate the implementation of its accreditation approach.***

Rationale: An accreditation mandate has been proposed although the capacity of accreditation organizations to enable suppliers to comply with this mandate is clearly inadequate. Under the most optimistic view, there is not nearly enough time for suppliers to have a reasonable opportunity to become accredited.

Not only will the capacity gap impair the agency's ability to achieve a robust and effective bid process, it will have a disproportionately adverse impact on small suppliers. Accreditation organizations are incentivized by the accreditation fee structure to first satisfy the accreditation needs of large suppliers. The negative impact on small suppliers is not consistent with the requirements of SSA § 1847(b)(6)(D).

2) Financial Standards § 414.414(d)

Recommendation: ***CMS should clarify, revise and reissue its proposed financial standards for comment as a separate rulemaking.***

Rationale: The financial standards are not detailed, so it is not possible to provide detailed comments. However, we wish to emphasize the importance of recognizing that many suppliers are small businesses, and that the Act specifically requires CMS to protect small suppliers. SSA § 1847(b)(6)(D). Therefore, small suppliers that are not financially troubled must be reasonably able to comply with the financial standards implemented by CMS without having to incur undue cost.

Moreover, the absence of any transparency with respect to the financial standards is not at all appropriate in view of the centrality of the standards in the bid process. Satisfaction of the standards is a precondition to bidding. If the standards are too restrictive, fewer suppliers will be able to participate in the bid process, diminishing beneficiary choice and potentially adversely affecting the single payment amount. If the standards are not restrictive enough, unsound suppliers may be awarded contracts. These suppliers may not be able to supply beneficiaries at the single payment amount, resulting in impaired access.

The method of assessing the financial capability of suppliers planning to meet demand through expansion should be known so that suppliers can assess their ability, and that of their competitors, to meet demand through expansion. The failure to specify financial standards leaves both beneficiaries and suppliers vulnerable, and CMS should specify standards in time for comment prior to the effective date of the Proposed Rule.

3) Market Demand, Supplier Capacity and Opportunity for Participation by Small Suppliers §§ 414.414(d), 414.414(g), 414.418

Recommendation: ***The proposed rule should provide adequate protections for small suppliers.***

Rationale: Despite the Act's requirement for protection of small suppliers, the Proposed Rule is likely to have a serious adverse impact on small suppliers, and it is questionable whether small suppliers will be successful bidders in any of the competitive bid areas. It appears that the Proposed Rule attempts to limit any requirement for small business participation to "the opportunity to bid," rather than offering meaningful participation and an opportunity to be a contract supplier.

We contend that the Act requires some balancing of program savings with the protection of small suppliers. This is missing from the Proposed Rule. Under the Proposed Rule, only a sufficient number of suppliers need be selected to meet demand, and CMS states that in some cases this could mean only two suppliers. The Act requires that awards be made in each competitive bid area for each product category to "multiple" suppliers, and "multiple" does not mean two. SSA § 1847(b)(4)(B).

Under the Proposed Rule, it is quite likely that two large suppliers could satisfy the demand for any product category in any competitive bid area. Moreover, large suppliers obtain DMEPOS items at lower unit cost than small suppliers, and enjoy economies of scale. Large suppliers not only will have capacity, but also they will be able to consistently underbid small suppliers. CMS may view this as a desirable result, but it is not the result required or intended by the Act.

The proposal that small suppliers be permitted to form partnerships to bid does not adequately address the small supplier issue. It does not solve the inventory cost issue although it arguably addresses the capacity issue. More importantly, however, it raises serious antitrust issues. Regardless of CMS' market share limitation, what the Proposed Rule contemplates may be a horizontal market allocation agreement, which is illegal *per se* under antitrust law. *See* 15 U.S.C. § 1 *et seq.*

Even if the DOJ and the FTC were to defer to CMS as a matter of policy, there is nothing to stop a competitor from suing and alleging a violation. This significant exposure should give any supplier substantial reservations regarding entering into the joint ventures contemplated by the Proposed Rule.

F. Determining Single Payment Amounts for Individual Items

1) Single Payment Amount §414.416(b)

Recommendation: ***To assure beneficiary access, the pivotal bid should be the payment amount. Furthermore, the proposed rule should contain standards for rejecting bids that are below cost.***

Rationale: The Proposed Rule's method for determining the single payment amount is fatally flawed. The use of the median amount below the pivotal bid will assure that some contract suppliers will drop out and will impair beneficiary access. In a competitive environment, suppliers will bid the lowest amounts at which they are able to provide the items. The pivotal bid is the bid of the supplier at which the demand is just met. The single payment amount for items in a product category therefore should be the amounts bid in the pivotal bid (or should be the highest amounts bid by suppliers bidding the product category at equal to or less than the pivotal bid).

The single payment amount, however, is not set at the pivotal bid, but instead is set at the median between the pivotal bid and the low bid. If the suppliers that bid between the median and the pivotal bid submitted the best bids they could make, which again is the only reasonable assumption in a competitive environment, then they will not be able to furnish the supplies at the median, which is lower than the amounts they bid. This is a fundamental inconsistency in the pricing method. **At the very least, it is highly doubtful that suppliers bidding between the median and the pivotal bid will be able to furnish the involved items at a payment amount equal to the median.** If a supplier bidding between the pivotal bid and the median is not able to provide the items at the median, the demand will not be met and access will be impaired.

The Proposed Rule's provision for selecting additional suppliers does not resolve this fundamental flaw. Under the Proposed Rule, suppliers added after the bid process must accept the single payment amount, which is not changed. **For the same reasons as set forth above, it is not likely that suppliers bidding over the pivotal bid will be able to accept the median between the pivotal bid and the low bid as the payment amount.**

Demonstration project experience cannot be used as a guide because the Proposed Rule's single payment amount method is different from the payment method used in the demonstration projects. **To assure beneficiary access, we propose that the pivotal bid be the payment amount.** This amount is likely to result in substantial savings to the Medicare program, while avoiding access and quality issues likely to arise from using the lower median amount.

In addition, predatory bidding should not be allowed. We urge that the Proposed Rule contain standards for rejecting bids that are below cost. In the absence of such standards, it would be possible for one or more large suppliers to bid below cost in order to become one of the few, perhaps two, contract suppliers in a competitive bid area. In the next bid cycle, after competing suppliers have been driven out of business, ologopolistic behavior could result in higher bid prices than would have occurred in a competitive environment. **A provider that bids below marginal cost should be rejected. This will protect the program from predatory bidding and will result in a lower aggregate cost to the program.**

Similarly, as noted above, the Proposed Rule should contain standards requiring credible third party capital and financing commitments to the extent that suppliers' project capacity based on expansion. The absence of such standards will distort the bid process and artificially lower the single payment amount. To the extent such suppliers are not able to meet projected demand, it is not reasonable to expect that more responsible suppliers will be able to provide the items at the artificially depressed single payment amount. For these reasons, it is common for governmental competitive acquisition programs to contain rules excluding bids that are not responsible, and CMS should include rules as described above in the DMEPOS competitive acquisition program.

2) Rebate §414.416(c)

Recommendation: ***The proposed rebate plan conflicts with anti-kickback requirements and must be eliminated.***

Rationale: There is no place in Medicare for inducements that distort utilization patterns and encourage overutilization. The rebate proposal raises significant inducement and anti-kickback issues. We do not believe the provisions of the Federal health care program anti-kickback statute or the Medicare anti-inducement statute can be repealed by a CMS regulation. The HHS Office of Inspector General has on numerous occasions expressed the view that the provision of things of value to beneficiaries violates these laws.

Assuming, however, that the OIG would approve the rebate proposal as an exception under these laws, we submit that the same policies underlying these laws militate against the rebate provision. The policies underlying the laws include that the rebate will have an adverse impact on the quality of care. The OIG has specifically cited a concern that such inducements lead to a "race to the bottom" which creates strong "incentives to cheat on the quality" of the involved items or services. HHS OIG Advisory Opinion 02-14 (September 30, 2002).

These incentives would be particularly pronounced in a competitive bidding environment with reduced payment amounts. The rebate provision also violates the single payment amount provision of the Act, by permitting different payment amounts for different contract suppliers. **Finally, we submit that suppliers will have more than adequate incentive to bid aggressively in the competitive acquisition program without the rebate provision, and that it therefore should be eliminated.**

G. <u>Establishing Payment Amounts for New DMEPOS (Gap-filling) § 414.210(g)</u>

Recommendation: ***References to the technology assessment as a part of gap-filling should be removed from the final rule and published for comment as a separate proposed rule.***

Rationale: 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. 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.

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

Due to 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.

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Thank you for your time in considering these comments and suggestions. NASL appreciates the agency's efforts to expand access to the regulatory process to providers and suppliers for the improvement of delivery of quality healthcare to the beneficiaries of the Medicare Program. We welcome the opportunity to work with CMS in resolving the issues contained in this document. Please feel free to contact me directly at the following phone number (703) 549-8500 with any questions that you may have.

Sincerely,

Peter C. Clendenin

Peter C. Clendenin
Executive Vice President

Appendix A

May 8, 2006

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

RE: Request for extension on Proposed Rulemaking for Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues (May 1, 2006).

Dear Mr. Kuhn:

The National Association for the Support of Long Term Care (NASL) hereby requests an extension to the comment period for the "Proposed Rulemaking on Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues," published in the Federal Register on May 1, 2006 (71 F.R. 25653-25704). NASL is a trade association comprised of more than 120 companies engaged in legislative and regulatory matters affecting the provision of ancillary services, products supply components, diagnostic testing and information systems to the post-acute care industry. NASL requests a 90-day extension of the Competitive Acquisition comment period, beginning upon release of finalized quality standards.

The proposed rule would implement competitive bidding programs for certain covered items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) throughout the United States in accordance with sections 1847(a) and (b) of the Social Security Act. Comments to the proposed rule are due no later than June 30, 2006.

A key component of the proposal involves the application of "quality standards" for all DMEPOS suppliers, including suppliers that participate in the DMEPOS competitive bidding program. The proposed rule would also detail requirements for CMS approved accreditation organizations that will be applying quality standards for all DMEPOS suppliers, including DMEPOS suppliers that participate in the DMEPOS competitive bidding program. Quality standards are a significant part of the proposal. **Indeed, "quality standards" are mentioned no less than sixty-three times in the proposed rule.**

Section 302(a)(1) of the Medicare Modernization Act of 2003 added section 1834(a)(20) to the Social Security Act, which requires the Health and Human Services Secretary to establish and implement quality standards for suppliers of certain items, including consumer service standards, to be applied by recognized independent accreditation organizations. Suppliers of DMEPOS must comply with the quality standards in order to furnish any item for which payment is made under Part B, and to receive and retain a provider or supplier billing number used to submit claims for reimbursement for any such item for which payment may be made under Medicare. CMS believes Section 1834(a)(20)(D) of the Social Security Act requires it to apply these quality standards to suppliers of items for which it deems the standards to be appropriate.

However, CMS has not finalized its quality standards. On September 26, 2005, CMS released its Draft Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), developed with Abt Associates. CMS provided a sixty-day public comment beginning September 23, 2005, and ending November 28, 2005.

As such, CMS has placed stakeholders in the unusual position of analyzing and commenting on a fundamentally incomplete proposal. The proposed quality standards in September 2005 are exhaustive. The quality standards may include performance management requirements to ensure the development, implementation, monitoring, and evaluation of policies, procedures, and products so that suppliers can maintain compliance with regulatory requirements and CMS policy instructions. The quality standards may also include language from current CMS standards and industry best practice standards for the following areas:

- Administration
- Financial management
- Human resource management
- Beneficiary services
- Performance management
- Environment and safety
- Beneficiary rights/ethics
- Information management

Finally, the supplier quality standards may include requirements for monitoring beneficiary satisfaction with products and suppliers' responses to beneficiary complaints.

Without finalized quality standards, NASL and its members are unable to ascertain the true and complete impacts of the May 1 Competitive Acquisition proposal. In addition, NASL is concerned with Administrative Procedure Act compliance. Administrative rulemaking must be sufficiently descriptive of subjects and issues involved so that interested parties may offer informed criticism and comments. Ethyl Corp. v. EPA, 541 F.2d 1, 35-37 (D.C. Cir. 1976). Agency notices must describe the range of alternatives being considered with reasonable specificity; otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decision-making. Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506 (D.C. Cir 1983). Finally, an agency commits a serious procedural error when it fails to reveal portions of technical basis for a proposed rule in time to allow for meaningful commentary. Connecticut Light and Power v. NRC, 673 F.2d 525 (D. C. Cir. 1982).

NASL is committed to working with CMS on this rulemaking. We plan on submitting detailed comments in response to the Proposed Rulemaking which we trust will assist CMS change the way that Medicare pays for items under Part B of the Medicare program. However, an extension of the comment period is warranted due to the pending quality standards. An extension would allow the regulated community the time it requires to appropriately respond to the proposed rulemaking.

Thank you for consideration of our request.

Sincerely,

Peter Clendenin
Executive Vice President