

June 30, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW.
Washington, DC 20201

VIA COURIER

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 Power Mobility Coalition (PMC), a nationwide association of manufacturers and suppliers of motorized wheelchairs and power operated vehicles (POVs), we are submitting the following comments concerning the Notice of Proposed Rule Making entitled, *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues* (herein referred to as the “NPRM”) that was published in the Federal Register on March 1, 2006. 71 Fed. Reg. 25654-25703. In essence, the NPRM seeks to establish and phase-in new quality standards and a competitive bidding reimbursement environment for Medicare DMEPOS suppliers.

While the PMC understands that the Centers for Medicare and Medicaid Services (CMS) was mandated by legislation to establish a competitive bidding program for DMEPOS¹, the system as set out in the NPRM is complex, overly restrictive and needlessly anti-competitive. Robert Baum and David Van Sleet, members of the Program Advisory and Oversight Committee (PAOC) who manage aspects of the Department of Veteran’s Affairs (VA) competitive bidding program, remarked at the PAOC meeting on May 23, 2006, that they were concerned with the unyielding nature of the NPRM. Baum and Van Sleet noted that the VA competitive bidding program affords greater flexibility by allowing suppliers to go outside the contract to meet the

¹ See the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (P.L. 109-173) § 302(b)(1).

needs of the beneficiary. It is the PMC's hope that CMS' final rule will reflect this more flexible approach, thereby ensuring quality DMEPOS is provided to eligible beneficiaries.

With this in mind, the PMC has identified the following specific concerns:

P. Quality Standards and Accreditation for Suppliers of DMEPOS

All Suppliers Must be Accredited Prior to Competitive Bidding Implementation

The PMC is very supportive of CMS' draft quality standards and the new accreditation requirement established in the MMA. Such new standards are imperative to preserve program integrity and ensure that there is a meaningful barrier of entry into the Medicare program for lawful suppliers. Yet, under the NPRM, suppliers will be allowed to submit bid applications and be awarded contracts even if they are not accredited.

Program integrity is paramount to ensure Medicare beneficiaries receive the highest quality of products and services from lawful suppliers. Stringent quality standards coupled with mandated accreditation of suppliers will rid the Medicare program of unscrupulous actors and reinforce the integrity of those suppliers who play by the rules.

Implementing competitive bidding and allowing non-accredited suppliers to participate in the bidding process is contrary to CMS' priority to safeguard Medicare resources and beneficiaries. Allowing non-accredited suppliers to bid and be awarded contracts will cause major disruption if the contracted supplier cannot obtain accreditation and the contract must then be terminated and subject to a rebid. In addition, non-accredited suppliers would have lower overhead and, as a result, would be able to submit lower bids which could artificially lower the single payment amount for accredited contracted suppliers.

Quality Standards should be Subject to Meaningful Notice and Comment

According to the NPRM, the new quality standards for DMEPOS suppliers will be issued through Medicare program instruction and will not be subject to the safeguards inherent in the Administrative Procedures Act.

CMS has afforded the opportunity for stakeholders to comment on the draft quality standards that were released that year, and the PMC is appreciative of the changes to the draft standards that were articulated at the PAOC meeting held in May. Stakeholders, however, will have no further opportunity to comment on these standards even if the final standards diverge greatly

from the draft standards.

At a minimum, DMEPOS stakeholders should have an opportunity to provide meaningful comment on the final quality standards and accreditation process prior to its implementation.

DMEPOS Stakeholders Should Have Other Meaningful Opportunities to Comment Prior to Competitive Bidding Implementation

In many ways, the NPRM poses more questions to DMEPOS suppliers than it answers. For example, the NPRM fails to name the final quality standards; fails to mention the MSAs and product areas that will be subject to competitive bidding; and fails to name the nationally-recognized accreditation bodies. Mandatory accreditation and competitive bidding mark major sea changes in the way DMEPOS suppliers conduct business. DMEPOS stakeholders must have the opportunity to comment on these major changes, or at a minimum, the PAOC should meet upon release of the final rule and be afforded the opportunity to comment and suggest changes to the final competitive bidding rule prior to implementation.

J. Administrative or Judicial Review

Non-Winning Suppliers Must Have Expedited Appeal Rights

The NPRM states that “Section 1847(b)(10) of the Act provides that there will be no administrative or judicial review ... for the ... [a]warding of contracts under a competitive bidding program” 71 Fed Reg 25682. Suppliers who have a reasonable grievance should be able to challenge a determination of the Competitive Bidding Implementation Contractor (CBIC) before an independent entity or Administrative Law Judge to ensure fairness and due process.

Suppliers will be staking resources and, in certain instances, survival of their business on contracts awarded by the CBIC. Despite the most vigilant of oversight, it is not impossible to conceive situations where the bidding process could be circumvented or in some way compromised. As a result, suppliers must be afforded the right to contest questionable determinations. To ensure no disruption in DMEPOS to beneficiaries, however, any independent appeals process must be expedited.

H. Determining Single Payment Amounts for Individual Items

Section 414.416(c)-Rebate Program

The Rebate Program Is Impractical

The program established by the NPRM will “allow contract suppliers that submitted bids for an item below the single payment amount to provide the beneficiary with a rebate.” 71 Fed Reg 25680. Contracted suppliers could provide the difference between the single payment amount and their winning bid price as a “rebate” to beneficiaries; however, this arrangement is on tenuous legal footing, establishes a poor precedent, and provides no real benefit to either suppliers or beneficiary.

Current law prohibits suppliers from offering inducements and other incentives for the purpose of enticing beneficiaries to receive services from a specific Medicare supplier. The “rebate” program, by codifying the allowance of inducements in the form of a rebate, is contrary to these important safeguards. The NPRM prohibits suppliers from advertising the inducement, instead allowing CMS to promote the suppliers’ rebate programs on the Medicare website. This just makes CMS complicit with and a conduit for possible violations of the Federal Anti-Kickback statute. For these reasons and others, the PMC recommends that CMS eliminate the rebate program as part of the NPRM.

C. Payment Basis

Section 414.408(e)-Authority to Adjust Payments in Other Areas

CMS Lacks the Authority to Fix Fee Schedule Amounts with Competitive Bidding Rates

The NPRM indicates that after 2009, CMS plans to utilize data collected from competitive bidding pricing to adjust the fee schedule that is the basis of payment for DMEPOS in non-competitive bidding areas. 71 Fed Reg 25664. It is unclear on what basis that CMS derives the authority to set DMEPOS pricing using competitive bidding data. Moreover, Congress decidedly limited competitive bidding to the largest Metropolitan Statistical Areas (MSAs) in the MMA.

Providing and servicing DMEPOS items in rural and underserved areas (those MSAs most likely not to be directly affected by competitive bidding) are often times more expensive than providing DMEPOS in larger MSAs. These areas experience increased transportation costs, more difficulty in employing and retaining qualified personnel and increased cost in recruiting and maintaining beneficiary referrals.

CMS already has inherent reasonableness authority to adjust DMEPOS pricing if they can

demonstrate that Medicare is paying too much (or too little) for a particular item or product. Competitive bidding should not be used to circumvent specified inherent reasonableness authority so that CMS can unilaterally depress DMEPOS pricing without valid statistical evidence or input from impacted stakeholders.

Section 414.408(f)-Limitation on Beneficiary Liability

Competitive Bidding Must have No Impact on Cash Sales of PMDs

Many DMEPOS suppliers, especially suppliers of power mobility devices (PMDs), sell directly to beneficiaries through cash sales at retail outlets. Most of these beneficiaries do not meet the Medicare definition of medical necessity, yet still benefit from access to PMDs.

Even in such cash sales, suppliers are mandated to submit a claim to the Medicare program yet the NPRM places a limitation on beneficiary liability for DMEPOS furnished by non-contracted suppliers. This provision must be amended to ensure that retail sales of DMEPOS can continue to Medicare beneficiaries who wish to purchase a PMD even if they do not meet the Medicare national coverage determination.

I. Terms of Contract

Section 414.422(c)-Repairs and Replacement of Patient Owned Items

Contracted Suppliers Should be Compensated Via Fee Schedule to Repair or Replace Beneficiary-Owned DMEPOS

The NPRM requires a contracted supplier to repair and/or replace items of beneficiary owned DMEPOS in a competitive bidding area. Suppliers will have no idea how many repairs or replacement DMEPOS they will need to supply. As a result, it will be impossible for suppliers to factor these costs into their bids. To ensure fairness, therefore, the PMC recommends that CBICs reimbursement for repairs and replacement of beneficiary-owned DMEPOS items (not originally supplied by the contracted supplier) be subject to the fee schedule amount (adjusted for inflation).

Section 414.422(d)-Change in Ownership

Competitive Bidding Should Have No Impact on a Supplier's Ability to Change Ownership

While CMS has a fiduciary duty to ensure that every supplier is accredited and meets quality standards, CMS cannot deny contracted supplier status, or unreasonably withhold its approval of new ownership, on the basis that the new ownership may not meet the capacity stated in the contract. Contracted suppliers in competitive bidding areas will most likely experience an increase in the value of their businesses and, therefore, should be able to take advantage of the market place without interference from government agencies, if they wish to lawfully transfer ownership.

Section 414.422(f)-Suspension or Termination of a Contract

Contracted Suppliers Should Be Allowed an “Opportunity to Cure” if They Are Found in Breach

The NPRM allows CMS to terminate a contract if the DMEPOS supplier is in breach. Suppliers, however, should be given an opportunity to cure the breach or appeal the determination before the contract is terminated. Often times, suppliers are unaware they are in breach of contract and can easily resolve the issue without necessitating termination which has the potential to disrupt access to DMEPOS by needy beneficiaries.

F. Submission of Bids

Section 414.408-Bidding Requirements

All Bid Costs, Including Cost of Accreditation, Must be Reflected in the Bid Price

The NPRM states that the bid price should only reflect the cost of providing and servicing the DMEPOS item. Yet, suppliers who wish to participate in the Medicare program must now adhere to new quality standards become accredited and incur costs in preparing and submitting bids. Costs of this overhead will be substantial and, among small suppliers, will represent a major capital expense just to participate in the Medicare program. Bids for DMEPOS, therefore, should include the cost of overhead and accreditation, as well as service and product costs.

Section 414.412-Product Categories for Bidding

Product Categories Must Be Defined Narrowly

The NPRM requires all suppliers to bid on every item within a particular product category. For PMD suppliers, it is imperative that product categories are defined narrowly. Many suppliers of

power wheelchairs and POVs do not deal with, or service complex high-end rehabilitation wheelchairs. High-end rehabilitation chairs are often custom fitted and require more skilled care than provided by PMD suppliers. If CMS includes a broad category of wheelchairs in the bid application, many suppliers would be precluded from bidding since they do not offer both the high-end rehabilitation chairs and the more standard PMDs.

R. Establishing Payment Amounts for New DMEPOS

Section 414.210(g)-Establishing Payment Amounts for New DMEPOS Items (Gap-Filling)

Gap Filling for New HCPCs Codes Fails to Incorporate Manufacturing Data

The NPRM suggests an alternative gap-filling methodology for the introduction of new product codes, like the new HCPC codes recently introduced for PMDs. This gap-filling methodology will be modified by:

- making effort to utilize existing fee schedule amounts, if applicable, in establishing payment amounts for new HCPCS codes, including pricing from comparable items;
- discontinuing the practice of deflating supplier prices back to the time of the fee schedule base period;
- using functional technology assessment, in part or in whole, as another pricing method.

While the PMC appreciates CMS' recognition of the past problems plaguing other gap-filing methodologies, the methodologies presented in the NPRM are not objective and fail to directly make a price/value assessment of the product. Specifically, none of the methodologies discussed in the final rule incorporates manufacturer data, instead relying on "technical assessments" by experts in the therapeutic/technological aspects of the product, and not the pricing. It is imperative, therefore, to ensure that manufacturer and other stakeholder data is incorporated into any gap-filing methodology to ensure appropriate pricing for new HCPC codes.

G. Conditions for Awarding Contracts

Section 414.414(b)-Supplier Eligibility

Information Requested of Suppliers Is Overly Broad

The PMC asks that CMS define sanctions further to allow suppliers to understand which occurrences to report on bid applications. The language of the NPRM states that a supplier must disclose information pertaining to debarments, sanctions or other legal actions affecting the supplier. However, the draft “Form A: Application” goes further and asks suppliers to disclose information about prior or pending investigations. *See* “Form A: Application, p. 5. This has expanded the scope of certification beyond precedent. Federal Acquisition Regulation Certification, 48 C.F.R. § 52.209-5, requires disclosure of civil judgments, criminal convictions, and indictments but does not go so far as to require disclosure of the existence of a mere investigation. The greatly expanded scope of inquiry included in the proposed form is arbitrary and vague and greatly exceeds the also vague language included in proposed 42 C.F.R. §414.414(b). We have great concern that a supplier’s eligibility to submit bids may be affected without adequate process.

The PMC agrees with the NPRM that suppliers who are disbarred from any federal health care program should not be eligible to bid. Federal investigations, however, are merely fact-finding tools. Suppliers have the right, like every other American, to be presumed innocent and should not be negatively impacted in the bidding process based on such criteria.

Section 414.414(d)-Financial Standards

Financial Information Needs to be Clearly Stated and Evaluated Prior to Bid Submission

Part of the new quality standards include financial criteria to ensure that suppliers have the necessary capital to participate in the Medicare program. This determination of financial viability, therefore, should be established prior to submission of bids. In addition, the PMC feels that audited financial statements are not necessary as part of the bidding process and will add considerable cost to the supplier’s bid application.

Section 414.414(e)-Composite Bids

More Details Needed to Explain the Composite Bid Calculation

In determining bid applications, the NPRM suggests that the CBICs use a “composite bid” to aggregate the supplier’s bid over an entire product category. The NPRM, however, fails to

indicate how the bids for each product will be weighted. Suppliers need to know what weighted factors will go into the composite bids so suppliers will be better able to determine how best to bid each HCPCS code within a particular product category.

Section 414.414(e)-Market Demand and Supplier Capacity

Safeguards Must Be Put in Place to Ensure Suppliers Can Meet Capacity

It is imperative that contracted suppliers are able to serve the entire capacity of a competitive bidding area. The number of beneficiaries who may need DMEPOS is not static. As Hurricane Katrina demonstrated, a major national disaster could have a huge impact on a competitive bidding area if a large number of persons relocate into that area (as many residents of New Orleans moved to Houston and other regions after the hurricane). To ensure that capacity is met, the PMC recommends that the CBICs use a factor of 130% to identify need. This would ensure that more suppliers will remain in the competitive bidding area and that a contract would not have to be rebid if a supplier is terminated or even if a cataclysmic event occurs that results in a shift in population.

Section 414.414(f)-Assurance of Savings

Suppliers Should be Allowed to Bid Above Fee Schedule

By mandating that no supplier bid be above the current fee schedule, the NPRM is overly restrictive, anti-competitive and smacks of price fixing by CMS. Costs of DMEPOS fluctuate and are dependent on a number of different factors, some of whose costs may increase to an extent that out paces the fee schedule amount. Most recently, the price of gasoline has close to doubled in the past year, severely impacting the delivery costs to DME suppliers and subsequently increasing their overhead. Annual inflation updates often fail to completely capture every price increase, especially if the cost of the item (i.e. gasoline) increases faster than the overall economy.

Safeguards Must Be Put In Place to Deter Suppliers from Undermining the Bidding Process

Unscrupulous actors could undermine the bidding process by bidding at an unrealistic low rate to ensure inclusion in the market. Unfortunately, this strategy could artificially lower the single bid price, making it difficult for all winning suppliers to serve beneficiaries at such reduced rates. CBIC personnel must be on the lookout for bids that are well-below the historical fee schedule

amount and be leery of suppliers trying to undercut the market rate just to gain market share.

CMS Should Allow Any Willing Supplier to Participate in the Medicare Program

If a Medicare participating supplier is willing to meet the terms of the contract for a particular DMEPOS product or service, including reimbursement amount, that supplier should be able to serve beneficiaries in the competitive bidding area. Such a provision would make the competitive bidding program more flexible while preserving the cost-savings priorities of the Medicare program. Moreover, such an arrangement will ensure the viability of a greater number of smaller suppliers who are at a distinct disadvantage under competitive bidding. Allowing any willing supplier to participate in Medicare will also allow beneficiaries to resume continuing relationships with their existing supplier and will ensure beneficiary access since capacity will not be compromised.

K. Opportunities for Participation by Small Suppliers

Access to SBA loans for Capital Improvements and Cost of Accreditation for Small Suppliers

To be considered as part of the competitive bidding pool, DMEPOS suppliers will now be required to be accredited and adhere to new quality standards. Yet, such requirements constitute an unfunded mandate to suppliers to pay for administrative functions and services that supplement the duties performed by CMS contractors like the National Supplier Clearinghouse (NSC). While some larger suppliers can afford to pay for such services, many smaller suppliers are “mom and pop” operations that lack the resources to pay the large fees charged by accreditation bodies or to make the capital improvements necessary to get accredited.

Failure to help small suppliers with the costs associated with accreditation and quality standards will adversely limit participation in any national acquisition bidding program to large suppliers who may already possess a competitive advantage in their ability to offer lower bids as a result of their volume purchasing. Moreover, many small suppliers serve rural and underserved urban communities where larger suppliers may not operate. If CMS fails to provide some special consideration to these smaller players, like providing access to low-interest Small Business Administration (SBA) loans, Medicare beneficiaries in these more difficult to reach areas, are at risk as access is being compromised.

A Minimum Number of Small Suppliers Should Be Included in Every Awarded Contract

CMS is required, under statute, to “take the appropriate steps to ensure that small suppliers have an opportunity to be considered for participation” in competitive bidding. One way to ensure this participation is to set aside at least one contract for each bidding item for a small supplier (as defined by the SBA as having less than \$6 million in receipts). This would afford small suppliers some hope that they can “compete with the big boys” and that “mom and pop” suppliers will remain viable even in a competitive bidding areas.

L. Opportunity for Networks

CMS Should Not Place Limitations on Small Supplier Networks

CMS indicated that they will allow small suppliers to form networks in an effort to ensure greater participation by small suppliers. Yet, by imposing an arbitrary 20% limitation on the market share of the network, CMS is curtailing the ability of small suppliers to form networks and participate in competitive bidding. The NPRM should eliminate this 20% restriction and, instead, provide more incentives that encourage small supplier networks to flourish.

Respectfully Submitted,

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