

July 5, 2006

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Regulations Development and Issuances Group
Attn: William Parham
Room C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Office of Management and Budget
Office of Information and Regulatory Affairs
Room 10235
New Executive Office Building
Washington, DC 20503
Attn: Carolyn Lovett

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

Dear Mr. Parham and Ms. Lovett:

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 comments in response to the forms released in conjunction with 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 were published in the Federal Register on May 5, 2006. 71 Fed. Reg. 26,543. Our comments will address the proposed collections of information, specifically their usefulness in carrying out the objective of the NPRM, the accuracy of the burden of this NPRM, as well as the quality, utility and clarity of the information to be collected. In addition, the PMC will provide recommendations to minimize the burdens on PMD suppliers, as well as how best to convey the bidding information required under the NPRM to the Centers for Medicare and Medicaid Services (CMS) with greater efficiency.

Some of PMC's concerns with the administrative and cost burdens under the NPRM include:

Form A: Bidding Application

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: Bid 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.

Accreditation Information Requested is Not Required by the NPRM

While CMS requires suppliers provide information on its accreditation status, *see* Form A, Bid Application, p. 2, the NPRM, however, allows for an unspecified "grace period" that will allow suppliers to submit Bid Application without being properly accredited as mandated by law.

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. As a result, the PMC recommends that the NPRM require all suppliers to become accredited prior to submission of a bid application.

No Supplier Should Be Subjected to the Audit Requirement

While the PMC appreciates that CMS recognized the burden on small suppliers and exempted them from having to submit audited financial reports, the PMC feels that audited financial statements are not necessary for any supplier and will significantly add to the cost of a supplier's bid application. Moreover, the larger the supplier, the more complex, costly and time-consuming an audit will be. The PMC, therefore, recommends that CMS removes the audit requirement for suppliers referred to in the bid application form. *See Form A, Bid Application, p. 4.*

Section V, D. Program Savings

Large Net Program Savings Will Fail to Materialize

CMS estimates "large savings," calling for an average of 20% in price reduction for DMEPOS items subject to competitive bidding. Yet, there is never any mention of net savings, where program costs are subtracted from the reduction in Medicare costs. CMS cites that it will take approximately \$1 million in fixed costs for contractor start-up and system changes for the first round of competitive bidding. This estimate seems highly unrealistic and assumes no glitches in the roll-out of the program (i.e. legal challenges, legislative changes).

According to some analysts, however, the CMS competitive bidding projects have experienced high start-up costs, skewing the actual cost savings figures. A senior CMS official involved in the Polk County demonstration project testified before an Institute of Medicine (IoM) panel that the Polk County project cost the Medicare program \$700,000 to achieve \$1 million in savings. While CMS expressed satisfaction with this cost-benefit ratio, some on the IoM panel questioned whether the savings were compelling enough to move toward competitive bidding as a national program. The PMC agrees that any "savings" derived from competitive bidding be determined as "net savings" where program costs are discounted from actual savings amounts.

Section V, E. Effect on Beneficiaries

CMS Fails to Acknowledge Impact on Beneficiaries in Rural or Underserved Areas

CMS characterizes the impact of the NPRM as negligible on beneficiaries, given that capacity would be safeguarded and that the “grandfathering” aspects of the rule will allow for minimal disruption of relationships between current suppliers and long-time beneficiaries. In its analysis, however, CMS fails to acknowledge the impact of beneficiaries who reside in rural or underserved areas that are primarily served by smaller suppliers. Given the detrimental impact of the NPRM on small suppliers, as well as the lack of incentive for small suppliers to participate in competitive bidding, it is likely that implementation of the NPRM will see fewer small suppliers in these rural and underserved areas, directly impacting beneficiary care in those areas. Further, even if these small suppliers are not directly subject to competitive bidding, CMS’ proposal to use competitive bidding data to suppress pricing in non-competitive bidding areas will have the impact of driving rural and other “niche” suppliers from the market, therefore impacting access to beneficiaries who reside in those areas.

Section V, F. 2. Small Suppliers

CMS Has Underestimated Administrative and Cost Burdens on Small Suppliers

CMS acknowledges that small suppliers will be more adversely impacted by competitive bidding than other suppliers and have provided a number of “options” to small suppliers to minimize the impact of competitive bidding; CMS’ efforts will most likely fall short. In a proprietary environment, it is unlikely that small suppliers will enter into networks with other suppliers that were once considered competitors. In addition, even if suppliers did form networks, CMS has put an arbitrary limit on a networks allowed market share, further complicating the ability of small suppliers to work together.

Small suppliers play an integral role in serving beneficiaries, especially in rural and underserved areas. If a small supplier goes out of business or decides to no longer participate in the Medicare program, beneficiary access to DMEPOS could be compromised. For these reasons, the PMC makes the following recommendations that will ease the regulatory and cost burdens on 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.

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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