

January 16, 2007

OMB Human Resources and Housing Branch
Office of Management and Budget, Room 10235
New Executive Office Building
Attn: Carolyn Lovett, OMB Desk Officer
Washington, DC 20503

RE: CMS-684A-I and CMS-10169

Dear 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 the following comments concerning the *Information Collection Request: Request for Bids (RFBs) for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program* that was published in the Federal Register on December 15, 2006. 71 Fed. Reg. 75,553-75,554. In essence, the information collection being sought by the Centers for Medicare and Medicaid Services (CMS) is data from suppliers on the scope and nature of their bids for certain durable medical equipment (DME) under the Congressionally mandated competitive bidding reimbursement environment for Medicare DMEPOS suppliers. The following are some concerns with the RFB forms and information collection identified by PMC members:

PMDs Have Achieved Desired Cost-Savings and Should Be Carved-Out of Competitive Bidding

In 2006, CMS released new codes and fee schedule for PMDs. This new fee schedule represents an approximately 27% cut in reimbursement for the most popularly prescribed PMDs. This reduction is in line with the savings experienced in the competitive bidding demonstration project cited in CMS' Supporting Statement for Paperwork Reduction Submissions. It is doubtful that CMS could realize any additional savings given the breadth of the current cut in the PMD fee schedule. Even if some PMD suppliers are able to bid under the current fee schedule

amount, any additional costs savings (above the 27% cut reflected in the PMD fee schedule) will be more than offset by the administrative costs of implementing the competitive bidding program, reviewing and awarding submitted bids, and conducting oversight and compliance. Rather than establishing a new administrative bureaucracy and risk compromising beneficiary access to PMDs and PMD services for negligible cost savings, CMS should exempt PMD suppliers from competitive bidding.

All Suppliers Must be Accredited Prior to Competitive Bidding Implementation

The PMC is supportive of CMS' DME quality standards and the new accreditation requirement established in the Medicare Modernization Act. Such 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, the RFB forms and accompanying instructions, allow suppliers to submit bids so long as they have applied for accreditation and may 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' fiduciary duty 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.

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

The bid instructions state that suppliers are to include all "direct costs" associated with supplying the DME, including proper beneficiary follow-up, DME delivery costs, set-up and maintenance.

Yet, suppliers who wish to participate in the Medicare program are now mandated to adhere to new quality standards and become accredited. These costs are necessary and directly add to the cost of doing business in the Medicare program. Moreover, it's not just the cost of accreditation, but also the resources necessary to ensure compliance (i.e. increased staff training or the purchasing of new computer systems). Costs of compliance are substantial and, among small suppliers, will represent a major capital expense. Bids for DMEPOS, therefore, must include the cost of overhead and accreditation, as well as service and product costs.

CMS and its Contractors Must be Held Liable if Financial or Proprietary Information is Leaked to Third Parties

The RFB forms require DMEPOS suppliers to submit financial records, credit history, cash flow statements and other confidential information to CMS and its contractors. Such information and supporting documentation is highly proprietary and could be desirous to competitors or other business rivals. As recent highly-publicized cases at the Department of Veterans' Affairs have highlighted, government agencies have had a suspect record safeguarding privileged and personal information. To ensure that proper safeguards are in place, CMS and its contractors must be held liable for damages that result from any financial or proprietary information being leaked, intentionally or not, to third parties.

Credit Scores Maybe Difficult for Some Small Suppliers to Obtain

The RFB forms require suppliers to provide a credit score from one of the three major credit reporting firms may be difficult for some of the small suppliers who may not be rated. As an alternative, small suppliers should be allowed to provide the personal credit score of the individual or individuals who own the business.

It is Unclear How CMS will Use "Projected" Financial Data

In their RFBs, suppliers will be required to disclose a wide range of financial disclosure and supporting documentation. Different suppliers, however, will be required to submit different forms of financial data. For example, new suppliers may submit "projected" financial statements while established supplier must supply submitted corporate tax records, verified credit reports

and income statements. Yet, it is unclear how CMS and its contractors will make award determinations based on “projected” data. The PMC understands the need for flexibility when obtaining financial data from new suppliers, but existing suppliers with proven track records should not be undercut by new suppliers submitting unsubstantiated or unverified cost and income data.

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

CMS and its contractors must be wary of 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. The Competitive Bidding Implementation Contractor personnel must be on the lookout for bids that are well-below the historic fee schedule amount and be leery of suppliers trying to undercut the prevalent rate in an effort just to gain market share.

Definition of Sanctions Needs to be Clearly Defined

The RFB forms require that suppliers disclose any information about “current or past (within five years) sanctions or disbarments for which they were involved.” The definition of sanctions is broad and ill defined. In fact, the current definition of sanctions in the instructions would “include” but not be limited to “debarment from any Federal program, sanctions issued by the OIG, or sanctions issued at the State or local level. This includes any actions taken against any member of the board of directors, chief corporate officers, high level employees, affiliated companies, network members or subcontractors.”

The PMC agrees that suppliers who are disbarred from any federal health care program should not be eligible to bid. However, the impact of various sanctions and legal actions on the ability of a supplier to submit bids is never discussed. CMS must lay out the specific impact that such information will have on a supplier’s eligibility to participate in the competitive bidding program while ensuring that appropriate due process safeguards are provided to potential bidders.

Investigations should never be considered a sanction or legal action that can bar a supplier from the competitive bidding process. Federal investigations are merely fact-finding tools. Suppliers have the right, like every other American, to be presumed innocent and, should not be perceived as “tainted” as a result of a federal investigation. Moreover, federal investigations often last for several years, which would severely hamper a supplier’s ability to do business even if the investigation yields no evidence of wrongdoing. While the PMC appreciates the revisions in the RFB forms that eliminated the section requiring suppliers to list past or pending investigations, a clearer definition of what constitutes a sanction should be further spelled out in the form instructions.

We greatly appreciate the opportunity to present our concerns with the competitive bidding forms and look forward to working with CMS and its contractors in the implementation of an equitable and inclusive competitive bidding process.

Respectfully Submitted,

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PMC Director

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PMC Counsel