VIA E-MAIL: OIRA_submission@omb.eop.gov

June 18, 2009

Office of Management and Budget
Office of Information and Regulatory Affairs
725 17th Street, NW
Washington, DC 20503
Attention: CMS Desk Officer

RE: CMS-10169

Dear Sir or Madam:

On behalf of the Power Mobility Coalition (PMC), a nationwide association of manufacturers and suppliers of motorized wheelchairs and other power mobility devices (PMDs), we are submitting the following comments concerning the *Information Collection Activities; Submission for OMB Review; Comment Request*, which was published in the Federal Register on May 19, 2009. 74 Fed. Reg. 23,415. 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 DME claims.

The PMC appreciates recent efforts by CMS to increase transparency, promote program integrity, increase outreach efforts and extend the timeline for competitive bidding implementation. The ability of contracted suppliers to meet projected capacity, however, remains a major concern. Without an adequate number of suppliers servicing a particular Metropolitan Statistical Area (MSAs), eligible beneficiary's access to life enhancing DME could be compromised.

The following are some issues with the competitive bidding forms and information collection requirements that have been identified by PMC members:

Question 4b on Form B Needs to Be Modified

The proposed Question 4b on Form B currently reads as follows:

> Indicate the percentage increase in Medicare business that you would be capable of providing for this product category in this CBA during a projected 12-month period. ***The percentage increase may exceed 100%*** (emphasis added).

It's unrealistic to think that a supplier can expand business by 100%, especially in today's tight credit market. Suppliers would need access to capital, among other things, to increase and train staff, to purchase inventory, and to increase storage and distribution capabilities. Allowing suppliers to project such huge growth rates and awarding contracts based on such projections could lead to unfulfilled capacity and restriction in beneficiary access if a supplier's growth projections become unfounded.

In the preamble to the April 10, 2007 Final Rule, entitled "*Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*" (Final Rule), CMS addressed the issue of supplier capacity and emphasized a potential growth rate of 20 percent by an individual supplier. Stated CMS:

> *During the February 28, 2005 PAOC meeting, we asked the panel to discuss the issue of demand and capacity. Several members of the committee, based upon their expertise and knowledge of the industry, suggested that most DMEPOS suppliers would be able to easily increase their total capacity to furnish items by up to 20 percent and the increase could be even larger for products like diabetes supplies that require relatively little labor.*

The agency further added the following in the same preamble to the Final Rule.

> *Second, we might further adjust a supplier's capacity if, after making the initial adjustment discussed above, we conclude that the supplier's financial and business expansion documentation do not support the projected capacity stated in its bid. In determining whether this further adjustment is necessary, we will give consideration to the suggestion of the PAOC that a supplier's capacity could easily be increased by up to 20 percent. We believe, however, that this further adjustment may be necessary to limit the potential that we would award contracts to an inadequate number of suppliers based on inflated capacity projections that the suppliers would not be able to actually meet. If we believe that this further adjustment is necessary, we will lower the supplier's projected capacity to its*

historical capacity, as evidenced by its financial documentation and past claims data." [1]

Question 4b, as currently drafted, is inconsistent with prior CMS guidance and does not mesh with current market conditions in our country. The PMC recommends that Question 4b be amended so that the question limits total estimated growth to 20 percent. Further, any growth assumptions must be based on sound lending practices and credit standards; not just overly optimistic projections from suppliers seeking to win a Medicare contract.

The Terms "Legal Action" and "Sanction" Need to Be Clearly Defined

Form A, Question 1 asks suppliers to identify any "past or current legal actions, sanctions, including disbursements." The terms legal action and sanctions are overly broad and need to be clarified so that any matter that has nothing to do with the integrity of the supplier or the supplier's business will not be used to disqualify the supplier.

CMS previously provided the following clarification in the preamble to the April 10, 2007 Final Rule, entitled "*Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*" (Final Rule):

> We are revising proposed § 414.414(b)(2)(ii) so that it clarifies what disclosure a supplier must make in its response to the RFB. Specifically, we will require that each bidding supplier must disclose information regarding – (1) Any revocations of a supplier number; and (2) sanctions, program-related convictions as defined in section 1128(a)(1) through (a)(4) of the Act, exclusions, or debarments imposed against the supplier, its high-level employees, chief corporate officers, members of the board of directors, affiliated companies, and subcontractors by any Federal, State, or local agency.[2]

As set forth in our previous comments, the PMC urges CMS to comply with due process rules set forth in the federal acquisition regulation (FAR) and clarify that legal actions and sanctions refer solely to Medicare-program related convictions, exclusions or debarments. This will provide greater clarity and ensure that suppliers will not be deterred from submitting bids or unfairly

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[1] 72 Fed. Reg. 17,991, 18,039 (April 10, 2007).

[2] 72 Fed. Reg. 17,992, 18,036-18,037

disqualified.

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

The competitive biding forms require DME 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 highly-publicized cases of data breaches at government agencies have demonstrated, executive agencies have had a mixed record in 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.

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

As part of their bid applications, 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 "pro forma or prospective" financial statements while established supplier must supply submitted corporate tax records, verified credit reports and income statements.

It is unclear how CMS and its contractors will make award determinations based on "prospective" 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. At a minimum, we would recommend that CMS clearly define and publish what ratios are needed to qualify, who decides what constitutes adequate insurance documentation and coverage, and what score qualifies a company to have a positive credit history.

CMS has eliminated the requirement for the financial statements to be in accordance with Generally Accepted Accounting Principles (GAAP). GAAP is universally accepted in the accounting profession and would assure that all sets of financial records would be in a consistent format and use the same principles in their preparation. It would allow for ALL companies to

have their information to be considered on a more consistent basis.

We further recommend that CMS make public the manner in which the standards will be reviewed and what exactly will exclude a supplier from the bidding process.

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

CMS and its contractors must be wary of unscrupulous actors who 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.

An example of a major price anomaly can be found in the winning bids for power wheelchairs in the San-Bernardino-Riverside, CA. In the aborted first round, the contract price awarded for the standard power wheelchair ($3,072) is actually more than the reimbursement for the heavy duty bariatric power chairs ($1,856), a rate that is even lower than the manufacturer's costs for the item. No lawful supplier could possibly provide these chairs at such a loss.

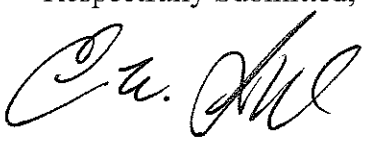
Given these low reimbursement rates and payment anomalies it will be difficult, if not impossible, for DMEPOS suppliers to comply with stringent Medicare quality and accountability standards while being reimbursed at competitive bidding rates. The Competitive Bidding Implementation Contractor personnel 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 to gain market share.

Definition of Key Personnel Unclear

Form A Section F requires suppliers to submit the names and current title of "key personnel." The attached instructions define the key personnel to "include such staff as officers, partners, directors, managing employees or members of the board of directors." CMS has given, as its only guidance, a list of titles. While instructions limit the list to five key personnel, there is no guidance on how to determine who should be on this list. CMS must clarify this data request.

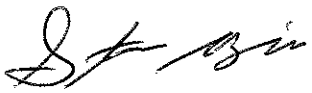
We greatly appreciate the opportunity to present our concerns with the competitive bidding forms and look forward to working with OMB, CMS and its contractors on this issue.

Respectfully Submitted,



Eric W. Sokol

PMC Director



Stephen M. Azia

PMC Counsel