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AdvaMed
Advanced Medical Technology Association

June 18, 2009

Office of Management and Budget
Office of Information and Regulatory Affairs
Attn: CMS Desk officer
E-mail: OIRA_submission@omb.eop.gov

RE: CMS-10169 Agency Information Collection Activities: Submission for OMB Review; Comment Request

Dear Sirs,

The Advanced Medical Technology Association (AdvaMed) submits the following comments on the May 19, 2009 CMS-10169 Paper Work Reduction Act Agency Information Collection Activities for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

Inadequate Information Required for Bid Submission and Need for Greater Transparency in Bid Evaluation Process

The Supporting Statement accompanying the modified version of the request for bids (RFB) and accompanying forms for DMEPOS competitive bidding notes that no new collection requirements have been added to the modified RFB instructions and accompanying forms, apart from information for contract suppliers to disclose information about subcontracting relationships, as required by MIPPA. AdvaMed maintains that more information is necessary in a number of critical areas both for the RFB forms and bid evaluation process, in order for beneficiaries to be assured that they will have access to a wide selection of appropriate quality products and technologies. Furthermore, additional information is necessary in order to establish a more transparent bidding and evaluation process than we saw for the original Round 1 bid. Some of the more crucial deficiencies in information include the following:

- Bidders are not required to submit supporting materials to validate their capacity calculations. In this regard, bidders should indicate how their capacity estimates take into account growth in beneficiary population and their changing medical needs.
- While the RFB indicates that CMS may require that a supplier submit additional information, such as manufacturer invoices to verify that the supplier can furnish an item for the bid price, it does not indicate how CMS will evaluate whether a bid is bona fide or not. In addition, CMS indicates that a bid price must be "rational,' but does not define or indicate what "rational" means.
- CMS does not indicate how it will evaluate bidders with limited or no experience with a product category or a competitive bidding area, although CMS officials made clear at the June 4th Program Advisory and Oversight Committee (PAOC) that bidders with little or no experience can be selected as winning bidders as they were in the original Round 1. Our concern here is both with a supplier actually being able to offer the product but also being able to support its service and to make available persons to adequately train beneficiaries in its use.
- Suppliers are not bound to offer the products enumerated in their certified bids. In the original Round 1, this caused considerable confusion and disruption for beneficiaries, their physicians, and other referral agents. CMS should either require winning bidders to offer the products enumerated in their bids or develop a plan for evaluating how actual product offerings compare to those included in the bid, and the impact of actual offerings on beneficiary care. Also, with respect to diabetes testing supplies, CMS should implement the MIPPA requirement that suppliers provide those supplies that comprise at least 50% of the existing market during Round 1.

Proposed Rule-Making for a New Supplier Selection Methodology

These several issue areas point to the need for more information in the RFB process, as well as for a new proposed rule in order to establish a new supplier selection methodology for DMEPOS competitive bidding. Each of the deficiencies cited above was the subject of extensive discussion at the June 4th PAOC meeting. Their satisfactory resolution is too critical to expect that they can be rectified simply through changes to RFB instructions and bidding forms. At the PAOC meeting, CMS officials signaled that that will move forward with a Round 1 Rebid only after deliberative consideration of stakeholder concerns. Given CMS' interest in getting the Rebid process "right this time around," it is premature to move forward with the proposed forms until more consideration can be given to issues about the bidding process's adequacy for protecting beneficiary access to quality products and technologies.

Sincerely,

Ann-Marie Lynch