Request For Bids (RFB) Supporting Statement – Part A

Supporting Statement for Paperwork Reduction Act Submissions

A. Background of the Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program and Forms A & B (CMS-10169A & CMS-10169B)

Since 1989, Medicare has been paying for durable medical equipment (DME) and supplies (other than customized items) using fee schedule amounts that are calculated for each item or category of DME identified by a Healthcare Common Procedure Coding System (HCPCS) code. Payments are based on the average supplier charges on Medicare claims from 1986 and 1987 and are updated annually on a factor legislated by Congress. For many years, the Government Accountability Office and the Office of Inspector General of the U.S. Department of Health and Human Services have reported that these fees are often highly inflated and that Medicare has paid higher than market rates for several different types of DME. Due to reports of Medicare overpayment of DME and supplies, Congress required that the Centers for Medicare & Medicaid Services (CMS) conduct a competitive bidding demonstration project for these items. Accordingly, CMS implemented a demonstration project for this program from 1999-2002 which produced significant savings for beneficiaries and taxpayers without hindering access to DMEPOS and related services. Shortly after a successful demonstration of the competitive bidding program, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("Medicare Modernization Act" or "MMA") and mandated a phased in approach to implement this program over the course of several years beginning in 2007 in 10 metropolitan statistical areas (MSAs). This statute specifically required the Secretary to establish and implement programs under which competitive bidding areas (CBAs) are established throughout the United States for contract award purposes for the furnishing of certain competitively priced items and services for which payment is made under Medicare Part B. This program is commonly known as the "Medicare DMEPOS Competitive Bidding Program"

CMS conducted its first round of bidding for the Medicare DMEPOS Competitive Bidding Program in 2007 with the help of its contractor, the competitive bidding implementation contractor (CBIC). CMS published a Request for Bids (RFB) instructions and accompanying forms for suppliers to submit their bids to participate in the program. During this first round of bidding, DMEPOS suppliers from across the U.S. submitted bids identifying the MSA(s) to service and the competitively bid item(s) they wished to furnish to Medicare beneficiaries. CMS evaluated these bids and contracted with those suppliers that met all program requirements. The first round of bidding was successfully implemented on July 1, 2008.

On July 15, 2008, however, Congress delayed this program in section 154 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). MIPPA mandates certain changes to the competitive bidding program which included, but are not limited to: a delay of Rounds 1 (bidding to begin in 2009) and 2 of the program (bidding to begin in 2011 in 70 specific MSAs); the exclusion of Puerto Rico and negative pressure wound therapy (NPWT) from Round 1 and group 3 complex rehabilitative power wheelchairs from all rounds of competition; a process for providing feedback to suppliers regarding missing financial documentation; and a requirement for contract suppliers to disclose to CMS information regarding subcontracting relationships. Section 154 of the MIPPA specifies that the competition for national mail order items and services may be phased in after 2010 and establishes a rule requiring that a bidder demonstrate that its bid covers 50 percent (or higher) of the types of diabetic testing strips, based on volume (the "50 percent rule") for national mail order competitions.

The Affordable Care Act (ACA), enacted on March 23, 2010, expanded the Round 2 competition by adding an additional 21 MSAs, bringing the total MSAs for Round 2 to 91.

As required by MIPPA, CMS conducted the competition for the Round 1 Rebid in 2009. The Round 1 Rebid contracts and prices became effective on January 1, 2011. The CMS has completed a significant amount of analysis to prepare for

Round 2 and the national mail order competition for diabetic supplies. This effort intensified after the Round 1 Rebid program implementation on January 1, 2011 and has continued since that time. A substantial effort has been placed into evaluating the results of the Round 1 Rebid and feedback on program implementation from Congressional Offices, the Program Advisory Oversight Committee (PAOC), the Competitive Acquisition Ombudsman (CAO), and the DMEPOS supplier community. Much of this work has focused on evaluating numerous options for sub-regulatory program changes based on feedback from these sources.

Based on our analysis of savings realized from the Round 1 Rebid and the potential for substantial savings in both administrative costs to the program and savings in program dollars, CMS has recently decided to hold the national mail order competition for Diabetic Testing Supplies at the same time as Round 2. This process has required extensive programmatic review to incorporate the competition into the Round 2 processes. Much of this work has focused on ensuring the existing systems processes would allow CMS to meet the statutory requirements associated with this competition.

Based on our experience from Round 1 Rebid, we have considered several program changes. In evaluating these changes, CMS weighed the burden of changing the reporting requirements to ensure that any change added to the utility of information gained from the additional reporting requirements. Based on this analysis, CMS has decided not to incorporate any substantive changes to the forms and no new reporting requirements have been added. Therefore, no new collection requirements have been added.

Based on our experience from Round 1 Rebid, CMS has made nonmaterial and non-substantive changes to the RFB instructions and accompanying forms to make these documents more user-friendly for DMEPOS suppliers. These changes provide clarifying language to incorporate changes in terminology and plain writing principles and eliminate obsolete or duplicative information.

B. Justification

1. Need and Legal Basis

Section 302 of the MMA amended section 1847 of the Social Security Act (the Act) to require the implementation of the DMEPOS competitive bidding program. The regulations implementing the competitive bidding program were published on April 10, 2007 (72 FR 17992).

Section 154 of the MIPPA amended section 1847 of the Act to require the competition for Round 2 of the DMEPOS competitive bidding program to occur in 2011 in 70 MSAs. Section 154 of MIPPA further specifies that the competition for national mail order items and services may be phased in after 2010 and establishes a rule requiring that a bidder demonstrate that its bid covers 50 percent (or higher) of the types of diabetic testing strips, based on volume (the "50 percent rule") for national mail order competitions.

In the January 16, 2009 Federal Register (74 FR 2873), we incorporated the MIPPA requirements to conduct the supplier competition for Round 2 in 2011 in 70 MSAs and national mail order competitions after 2010 into our regulations. We also indicated that we would streamline financial documents collected as part of the RFB to include 1 year of documents instead of the 3 years collected in the 2007 Round 1 competition.

Section 6410 of the ACA amended section 1847 of the Act to add 21 MSAs to the 70 MSAs MIPPA designated for the Round 2 competition, for a total of 91 MSAs.

In the November 29, 2010 **Federal Register** (75 FR 73611) we incorporated the statutory requirement to conduct the Round 2 competition in 91 MSAs into our regulations and established the requirements for conducting a national competition for furnishing diabetic testing suppliers on a mail order basis. Due to the significant potential for

administrative cost savings and significant program savings associated with competitive bidding for diabetic testing supplies, CMS has decided to hold the national mail order competition at the same time as Round 2.

As was done in the other rounds of bidding, we will use bidding forms to gather information about bidders and their bids. Based on our experience from the Round 1 Rebid, we have made non-substantive changes to these forms to better clarify the bidding requirements. Any delays in implementing the program will significantly impact the cost savings currently projected at $2 billion annually.

2. Information Users

The information collected will be used by CMS and its agents to choose the contract suppliers in the CBAs. DMEPOS suppliers will submit bids in Round 2 and the national mail order competition in order to compete to become a contract supplier to furnish competitively bid items to Medicare beneficiaries who live in a CBA. CMS will publish RFB instructions to guide suppliers in submitting their bids and on the competitive bidding program requirements. Bids will be submitted electronically via DBidS, the Medicare DMEPOS Competitive Bidding Program online bidding system. The bids submitted before the close of the 60 day bid window will be evaluated to determine which suppliers will become contract suppliers. All information submitted by the suppliers is considered and evaluated. In addition, a thorough analysis is performed of all information submitted to determine the financial viability and quality of the supplier. Bid prices that are submitted as part of a supplier's bid are used by CMS to establish the single payment amounts for competitively bid items and services.

3. Use of Information Technology

All bidding suppliers must submit their bids using the on-line system, (DBidS). This system allows suppliers to easily and consistently provide the necessary information. Suppliers are allowed to make changes to their bids at any time prior to the close of the bid window, at which time suppliers are required to complete, approve and certify their bids. The CBIC will use the appropriate technology to secure the safety of the bidding information transmitted to them. Assistance and technical support is available to help suppliers throughout the competitive bidding process. The DBidS system has been enhanced for Round 2 and the national mail order competition for diabetic testing supplies to assist suppliers in completing the required bid information. These enhancements make the system more user friendly by clarifying the questions and information collection requirements.

Suppliers will be required to submit supporting documentation such as financial documents and network agreements to the CBIC in hardcopy. This information will be submitted in the same exact manner as it was requested in the 2007 & 2009 rounds of competition. Enhancements to the bidding system to accept electronic attachments for Round 2 and national mail order is not feasible due to the significant costs and timeframe to establish such a system.

CMS is making one clarification regarding the technology used to collect information on diabetic testing supplies. DMEPOS suppliers are currently required to report the brand (Manufacturer, Make, and Model) of competitively bid items, including diabetic test strips, they plan to provide to Medicare beneficiaries. This information is collected during the bidding process through DBidS and has previously received OMB approval under the PRA. The MIPPA mandated that suppliers ensure their bid for diabetic test strips cover at least 50% of the products by Manufacturer, Make, and Model that are available in the market. The requirements to comply with this mandate were finalized after the deadline to make coding changes in the DBidS system; so DBidS cannot be used to collect this information. Therefore, CMS has developed an online form to collect this information for diabetic testing supplies. The form will automatically calculating the percentage of market share for diabetic testing supplies for each supplier as they enter their information. The modification in reporting method will assist suppliers by clarifying the rules and identifying the specific information they must report by allowing suppliers to select brand information from a pre-populated list rather than the free text format in DBidS. Suppliers will mail the form with other required hardcopy documents that are already part of the approved collection.

CMS will utilize a variety of electronic means to educate suppliers and keep them informed of program announcements during Round 2 and the national mail order competition for diabetic testing supplies. For example, CMS will use list serve messages and web postings to keep suppliers well informed of educational information, deadlines, and timelines.

4. Duplication of Efforts

This information collection does not duplicate any other effort, and the information cannot be obtained from any other source. CMS has made an effort to identify and eliminate duplicate information collection and has removed a small number of questions for which information can be obtained through other existing processes.

5. Small Businesses

In developing bidding and contract award procedures, section 1847 (b)(6)(D) of the Act requires us to take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. Section 1847(b)(2)(A)(ii)) of the Act also states that the needs of small suppliers must be taken into account when evaluating whether an entity meets applicable financial standards.

CMS developed an online bidding system during the first round of competition in 2007. Based on feedback from the supplier community, the bidding system was enhanced for the Round 1 Rebid in order to ease the burden on all suppliers during the bid submission process. The bidding system will continue to include the Round 1 Rebid enhancements. As discussed elsewhere in this package, we are making non-substantive modifications to clarify requirements. These non-substantive modifications will assist all suppliers in submitting information. We note that CMS has also implemented numerous regulatory provisions to reduce burden on small suppliers. These provisions are described in the April 10, 2007 and January 16, 2009 regulations and will remain in effect for Round 2 and the national mail order competition for diabetic testing supplies.

6. Less Frequent Collection

Section 1847 of the Act requires suppliers to submit a bid for every new round of competitive bidding in order to be considered for the award of a contract. For Round 2 and the national mail order competition for diabetic testing supplies, bids will be submitted once during the three year contract period. Each bidder will be required to submit one Form A. Bidders will be required to submit one Form B for each product category/competitive bidding area for which a bid is submitted. The statute provides no options for less frequent collection. Failure to collect this information will result in non-compliance with statutory requirements and the loss of billions of dollars in savings that are already included in the federal budget baseline.

7. Special Circumstances

Section 1847 of the Act requires suppliers to submit a bid for every new round of competitive bidding in order to be considered for the award of a contract. There are no special circumstances for the collection of bid information submitted. CMS expects to conduct the bidding in the same manner as the 2007 and 2009 rounds of competition.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice, 74 FR 2878, was published on January 16, 2009. We did not receive public comment on the information collection requirements in this notice. The 30-day Federal Register notice was published on May 19, 2009 (74 FR 23415). OMB asked us to review certain comments received on the May 19, 2009 Federal Register notice. These comments were either outside of the scope of the Paperwork Reduction Act or were based on incorrect understanding of or the competitive bidding program. Therefore it was not necessary to make any changes to the information collection based on the comments received.

Section 1847(c) of the Act requires the Secretary to establish a Program Advisory and Oversight Committee (PAOC) to provide advice to the Secretary with respect to the following functions:

The implementation of the Medicare DMEPOS Competitive Bidding Program;
The establishment of financial standards for entities seeking contracts under this program and taking into account the needs of small suppliers;
The establishment of requirements for collection of data for the efficient management of the program;
The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d) of the Social Security Act) and individuals; and
The establishment of quality standards for DME suppliers under section 1834(a)(20) of the Act.

In addition, section 1847(c)(3)(B) authorizes the PAOC to perform additional functions to assist the Secretary in carrying out the Medicare DMEPOS Competitive Bidding Program as the Secretary may specify. As authorized under section 1847(c)(2), the PAOC members were appointed by the Secretary of Health and Human Services and represent a broad range of stakeholders in the competitive bidding program. We have met with the PAOC numerous times since 2004 and have consulted with them on virtually all aspects of the program, including the DBidS system and the information collected. We have not received any advice from the PAOC that would indicate a need to change the DBidS system or the information collection for Round 2 or the national mail order competition for diabetic testing supplies.

9. Payments/Gifts to Respondents

Bidding suppliers are statutorily required to disclose this information. We will not be providing gifts or any payments (other than remuneration under the contract) to respondents.

10. Privacy

CMS will maintain the confidentiality of proprietary and financial information to the extent provided by law; a confidentiality statement is included in the RFB instructions.

11. Sensitive Questions

There are no questions of a sensitive nature related to the collection of information for the Medicare DMEPOS Competitive Bidding Program.

12. Burden Estimates (Hours & Wages)

Because the changes made to Forms A and B are non-substantive, the burden to complete the forms has not changed.-

13. Capital Costs

The information required in Round 2 is information that is readily available to the contract suppliers, and the suppliers should have the equipment necessary to collect and furnish the information. The equipment needed to process these forms is the same equipment that would be needed to provide routine business functions for a DMEPOS business. As a result, there should be no extra capital cost to respondents for recordkeeping resulting from the collection of this information.

14. Cost to Federal Government

The government incurs approximate annual costs of $1 million for contractor work to operate and maintain the DBidS system. These costs are more than offset by the $2 billion in annual savings resulting from program implementation.

15. Changes to Burden

The nonmaterial and non-substantive changes included in this request are not expected to create any changes to the currently approved burden.

16. Publication/Tabulation Dates

There are no plans to publish any of the information collection detailed in this package.

17. Expiration Date

The current versions of the RFB forms expire on July 31, 2012.

18. Certification Statement

Not applicable.