

Supporting Statement – Part A

Supporting Statement For Paperwork Reduction Act Submissions

Specific Instructions

A. Background of the Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program

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 include, 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); the exclusion of

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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. CMS issued an interim final rule with comment period (IFC) on January 16, 2009 to incorporate into existing regulations these specific statutory requirements contained in MIPPA related to the competitive bidding program.

This IFC, which became effective on April 18, 2009, indicates that bidding for the Round 1 Rebid will begin in 2009. For the Round 1 Rebid, CMS will publish a slightly modified version of the RFB instructions and accompanying forms so that suppliers will be better able to identify and understand the requirements of the program. We decided to modify the RFB instructions and forms based on our experience from the last round of competition when we received feedback from suppliers that were confused about certain requirements in these documents. The end result is expected to produce more complete and accurate information to evaluate suppliers. No new collection requirements have been added to the modified RFB instructions and accompanying forms. These documents were modified from the first round of competitive bidding in order to make the documents more reader-friendly and to clarify the requirements that suppliers were unable to understand last round.

The only information collection requirement that is new for this new round of competition is the MIPPA requirement for contract suppliers to disclose information about subcontracting relationships.

B. Justification

1 .Need and Legal Basis

a. Round 1 Rebid

Section 154 of MIPPA amended section 1847 of the Social Security Act and requires that CMS conduct the Round 1 Rebid in the same manner as the 2007 round 1 competition except that Puerto Rico is to be excluded as an area and NPWT is to be excluded as an item. As a result, the competition, which is to begin in 2009, will occur in 9 out of the 10 MSAs and product categories. The statute also excluded group 3 complex rehabilitative power wheelchairs from all rounds of competition, however, group 2 complex rehabilitative power wheelchairs will remain as a competitively bid item.

b. Subcontracting Relationships

Section 154 of MIPPA also amended section 1847 of the Social Security Act to require each supplier that is awarded a contract in the competitive bidding program to disclose each subcontracting relationship the supplier has in furnishing items and services under its contract within 10 days of entering into its contract with CMS. The statute also requires that contract suppliers disclose within 10 days each subsequent subcontracting relationship entered during the 3 year contract period with CMS. The contract supplier must also provide information on whether

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each subcontractor meets accreditation requirements, if applicable to the subcontractor.

2. Information Users

a. Round 1 Rebid

DMEPOS suppliers will submit bids in the Round 1 Rebid 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 on the competitive bidding program requirements and considerations to participate in the program. However, bids will be submitted electronically via DBidS, the Medicare DMEPOS Competitive Bidding Program online bidding system. Hardcopy RFB forms will be available upon request for those suppliers that are unable to access the electronic system. These forms will be posted on the Internet along with the RFB instructions to help guide suppliers as to the information that will be requested via DBidS. The bids submitted before the close of the bid window will be evaluated to determine those suppliers that will become contract suppliers. A thorough analysis is performed of the supplier's submitted bid 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.

b. Subcontracting Relationships

For suppliers that are awarded a contract, CMS, through the CBIC, will collect this information to keep records of subcontracting relationships. This information includes the name, address and telephone number of the subcontractor, the type of work that the subcontractor will be providing (i.e., inventory, delivery and set up, and repair) and evidence of accreditation by a CMS approved accreditation organization. The purpose of collecting this information is to comply with the disclosure requirement on subcontractors in MIPPA and to insure that subcontractors meet applicable accreditation requirements. The CBIC will retain this information for seven (7) years.

3. Use of Information Technology

a. Round 1 Rebid

CMS requires that 100% of the bids submitted in the Round 1 Rebid be submitted through the online bidding system, DBidS. Suppliers will be required to complete, approve and certify their bids online prior to close of the bidding window. The CBIC will use the most current technology to secure the safety of the information transmitted for the competitive bidding program. Hardcopy RFB forms will be available upon request if any supplier should experience technical difficulties in accessing this system. Assistance and technical support will be available to help suppliers throughout the competitive bidding process. Although CMS required suppliers to submit bids electronically during the 2007 round of competition, the system for the Round 1 Rebid has been enhanced to help ease the burden on suppliers to complete the required bid information. These enhancements make the system more user friendly for suppliers and help clarify the information requirements; no new collection requirements have been added to the system. These enhancements

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will help reduce the response and implementation time.

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 round of competition. At this time, DBidS will be used only for data entry of bid information. The online bidding system does not have the capability to accept hardcopy attachments. To enhance the system to accept hardcopy attachments for the Round 1 Rebid is not feasible because of time and cost constraints and since the system has already been completely developed.

CMS will generally use electronic means to educate suppliers and keep them informed of program announcements during the Round 1 Rebid. For example, CMS would use list serve messages and web postings to keep suppliers well informed.

b. Subcontracting Relationships

A secured email will be sent to all contract suppliers requesting information on any subcontracting relationship that they may have for the furnishing of items and services during the contract period. All of this information must be submitted electronically by either fax or secured email to the CBIC.

4. Duplication of Efforts

a. Round 1 Rebid

This information collection does not duplicate any other effort, and the information cannot be obtained from any other source.

b. Subcontracting Relationships

This information collection also does not duplicate any other effort, and the information cannot be obtained from any other source.

5. Small Businesses

a. Round 1 Rebid

In developing bidding and contract award procedures, section 1847 (b)(6)(D) of the Social Security 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 Social Security 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 in the 2007 round of competition that has been

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enhanced for the Round 1 Rebid in order to ease the burden on all suppliers during the bid submission process. With regard to small suppliers, CMS has minimized the burden of collecting this information by: 1) suppliers will only have to complete Form A once regardless of the number of bids submitted; 2) based on comments received, CMS has either consolidated or eliminated questions; 3) the amount of financial information required has been simplified, making it easier and less costly for small suppliers; 4) the option of submitting manual bids is allowed for small suppliers without access to a computer.

b. Subcontracting Relationships

The collection of this information is mandated by MIPPA. It applies to all contract suppliers that choose to use a subcontractor. We have minimized this burden for all contract suppliers by allowing them the option to submit this information via fax or email.

6. Less Frequent Collection

a. Round 1 Rebid

The MMA 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 the Round 1 Rebid, bids will be submitted during a bidding window. The bidding window was open for 60 days in the 2007 round of competition. We would likely expect to open the bidding window for the same number of days in the Round 1 Rebid. In addition to submitting bids, suppliers will be required to submit quarterly reports to ensure Medicare beneficiaries have access to quality products.

b. Subcontracting Relationships

MIPPA mandates the specific time frames for an initial and subsequent disclosure of this collection.

7. Special Circumstances

a. Round 1 Rebid

The MMA 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 round of competition.

b. Subcontracting Relationships

There are also no special circumstances for the collection of this information. The statute mandates that a contract supplier must disclose any subcontractors subsequent to the awarding of the contract to CMS within 10 days of entering into that relationship.

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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.

a. Round 1 Rebid

Section 1847(c) of the Social Security Act requires the Secretary to establish a Program Advisor and Oversight Committee (PAOC) that will 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 7 times since 2004.

CMS met with the PAOC in May 2006 to discuss the burden of some of the reporting requirements in the 2007 round of competition. Some members of this committee stated that it was not possible for most suppliers to provide the reviewed or audited financial statements that would be required. Several members noted that suppliers would face a very high burden and cost to report the manufacturer, model and model number of every product they sold. Some members cited the reporting burden, as well as the costs of accreditation and accepting late capped rental transfers, to suggest that suppliers' costs would increase to the point where they may be above the fee schedule. We developed our financial hardcopy document required based on the comments received during this meeting.

9. Payments/Gifts to Respondents

a. Round 1 Rebid

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.

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b. Subcontracting Relationships

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

10. Confidentiality

a. Round 1 Rebid

CMS will maintain the confidentiality of proprietary and financial information to the extent provided by law.

b. Subcontracting Relationships

There is no need for confidentiality of this information. This disclosure does not contain proprietary information but rather information that suppliers make accessible to the public.

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

a. Round 1 Rebid

For the 2007 round of competition, we had estimated that the burden associated with bidding would be 1,086,164 hours. This estimate was based on an average of 68 hours for a supplier to complete and submit a bid and that CMS would receive 15,973 bids. We expect the number of hours to generally remain the same (68 hours) for the Round 1 Rebid as the information collection requirements will be the same as the 2007 round of competition. However, we expect a fewer number of bids submitted in the Round 1 Rebid as we received less than 15,973 bids in the 2007 round of competition. For the 2007 round 1 of the competitive bidding program, we received approximately 6,500 bids. Therefore, we estimate that for the Round 1 Rebid, the estimated burden will be approximately 442,000 hours (68 hours x 6,500 bids).

The 68 hours estimate is derived from comments received from suppliers that submitted bids in the DMEPOS Competitive Bidding Demonstration. These comments indicated that bidders spent anywhere from 40 to 100 hours to submit a bid. We, therefore, took the median number of hours which was 68, as the estimated time in hours in would take a supplier to complete and submit a bid. During this demonstration project, we also estimated that the response time for each form would be as follows:

Form A (Bid Application): 10 hours;
Form B (Bidding Form): 14 hours (completing on average 4 times = 56 hours);

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Form C (Quarterly Report): 2 hours; and
Form D (Beneficiary Survey): 15 minutes (to be completed by the beneficiary).

For the Round 1 Rebid bidding process, suppliers will only be required to submit one Form A and at least one Form B. Form C, which will be used to collect quarterly information on the items furnished from contract suppliers, has not been modified for the Round 1 Rebid. Forms C and D are not used to collect information during the bidding process. The time associated with the submission of the supporting documentation has been included in the above estimates.

We expect the cost associated with submitting a bid to generally be the same as we assumed in the 2007 round of competition. In the 2007 competition, we assumed that suppliers would incur a cost per hour of \$31.25 (in wages and overhead) with the public cost estimated at \$2,125.00 (\$31.25 per hour x 68 hours to submit the bid).

b. Subcontracting Relationships

Section 414.422(f) states that suppliers entering into a contract with CMS must disclose information on each subcontracting arrangement that the supplier has to furnish items and services under the contract and whether each subcontractor meets the accreditation requirements in §424.57, if applicable. Section 414.422(f) also requires that the required disclosure be made no later than 10 days after the date a supplier enters into a contract with CMS or 10 days after a supplier enters into a subcontracting arrangement after entering into a contract with CMS. The burden associated with the requirements in §414.422(f) is the time and effort necessary to disclose the information to CMS. This information will include:

- Name of subcontractor;
- Address of subcontractor locations servicing the competitive bidding area (CBA);
- Telephone number of subcontractor;
- A statement identifying the type of work the subcontractor will be performing for the contract supplier; and
- A copy of the subcontractor's accreditation certification from the CMS deemed accreditation organization.

We estimate that the burden for the winning suppliers that use subcontractors will be on average 1.5 hours to disclose each subcontracting arrangement to furnish items and services under the contract and whether each subcontractor meets the accreditation requirements in §424.57, if applicable. In the 2007 Round 1 competition, there were 329 winning suppliers. However, even though Puerto Rico and certain product categories have been excluded from the Round 1 rebid, we expect that we will have approximately 400 winning suppliers because of the greater awareness of the competitive bidding program. We expect less than 400 of these winning suppliers will have subcontracting relationships. Therefore, we estimate that the maximum number of suppliers that will report will be 400. The total estimated burden associated with these requirements is approximately 600 hours (1.5 hours X 400 winning suppliers).

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13. Capital Costs

The information required in the Round 1 Rebid and subcontracting relationship collection is information that is readily available to the contract suppliers, and the suppliers should have the equipment necessary to collect and furnish the information. 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

a. Round 1 Rebid

There are no additional costs to the government as a result of the Round 1 Rebid because Congress stated that MIPPA is budget neutral by including a 9.5% nationwide reduction in the Medicare fee schedule amount for all items competitively bid in round 1.

b. Subcontracting Relationships

The cost associated with this collection requirement is for the labor from the Competitive Bidding Implementation Contractor (CBIC) in collecting and reviewing the information and communicating with the contract supplier when there is missing information. We estimate that the CBIC will spend approximately ½ hour per contract supplier submission. The CBIC estimates that the hourly rate for an employee to perform this work would be \$45.00. Therefore, we estimate the cost to the Federal government to be \$9,000. (½ hour x \$45.00 x 400 suppliers = \$9,000)

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15. Changes to Burden

a. Round 1 Rebid

Information collected during the Round 1 Rebid bidding process has already been established in the April 10, 2007 final rule of the Medicare DMEPOS Competitive Bidding Program.

b. Subcontracting Relationships

The disclosure of subcontracting relationships is a new information collection requirement.

16. Publication/Tabulation Dates

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

17. Expiration Date

a. Round 1 Rebid

The RFB forms expire on April 10, 2010. This package is a request to extend/renew this expiration date.

b. Subcontracting Relationships

The collection of subcontracting disclosure information does not lend itself to the displaying of an expiration date as there is no data collection instrument for this requirement.

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