

DMEPOS Competitive Bidding Program 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

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 mandated certain changes to the competitive bidding program which included, but are not limited to: a delay of Rounds 1 (competition to begin in 2009) and 2 of the program (competition 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 specified that the competition for national mail order items and services may be phased in after 2010 and established 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. 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 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. The competition for Round 2 began in December 2011. CMS also began a competition for National Mail Order of Diabetic Testing Supplies (DTS) at the same time as Round 2. The Round 2 and National Mail-Order contracts and prices have a target implementation date of July 1, 2013.

The MMA requires the Secretary to re-compete contracts not less often than once every 3 years. The Round 1 Rebid contracts will expire on December 31, 2013. Consequently, we are preparing to re-compete competitive bidding contracts in the Round 1 Rebid areas.

We are seeking approval of the previously approved Forms A – D and the Subcontracting Disclosure Form. We are submitting the PRA documents in “Parent-Child” packages to cover different timeframes associated with different rounds of competition. This current application will serve as the Parent package and include the bidding forms (Form A & B) for the Round 1 Recompete; contract maintenance forms (Form C & Subcontracting) for the Round 1 Rebid and the Round 1 Recompete; and the beneficiary Survey (Form D) for the Round 1 Recompete, Round 2, and National mail-order competitions. Because there is no way to accurately anticipate the number of Round 2 and National mail-order contract suppliers, it is impossible to estimate the burden associated with contract maintenance forms for those competitions. Therefore, we will submit a Child package to cover contract maintenance forms for these competitions at a later date. The burden for Form D is based on the number of CBAs and is independent of the number of contract suppliers; therefore, the burden estimates associated for Form D for the Round 2 and National mail-order competitions will be included in this package.

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 Act provided the program requirements for the submission of bids in establishing payment rates and the awarding of contracts; and a requirement for the Secretary to re-compete contracts not less often than once every 3 years. These regulations were published on April 10, 2007 (72 FR 17992).

Section 154 of the MIPPA amended the 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 each subcontractor meets accreditation requirements, if applicable to the subcontractor

In the January 16, 2009 Federal Register (74 FR 2873), we incorporated a number of provisions in the MIPPA related to the Round 2 and National Mail-Order Competitions. 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.

2. **Information Users**

Bidding Forms A & B:

The information collected has been used by CMS and its agents to choose the contract suppliers. DMEPOS suppliers submit bids in order to compete to become a contract supplier to furnish competitively bid items to Medicare beneficiaries who live in a CBA. CMS has published RFB instructions to guide suppliers in submitting their bids and on the competitive bidding program requirements. Bids are 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 are 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 the winning suppliers' bids are used by CMS to establish the single payment amounts for competitively bid items and services.

In preparing for the Round 2 and National Mail-Order competitions, we made "*no material and non-substantive changes*" to the RFB instructions and accompanying Forms A & B to make these documents more user-friendly and to better clarify the bidding requirements for DMEPOS suppliers. The changes provided clarifying language to incorporate changes in terminology and plain writing principles to eliminate obsolete or duplicative information. The Office of Management and Budget approved this request on November 2, 2011, and no changes have been made to these since that time.

Quarterly Reporting Form C:

Form C was originally designed to collect retrospective information on the brand and approximate number of each competitively bid items furnished to beneficiaries during the previous quarter. The information collection was established as a contract term intended to help CMS monitor the program and to provide current product information in the Supplier Directory of the Medicare

website. However, it proved impossible to collect the information in a way that would allow it to be standardized, so the data could not be used for their intended purpose. In addition, contract suppliers found the reporting requirements to be very burdensome.

During the implementation of the Round 1 Rebid contracts, we instituted a comprehensive monitoring system, including real-time claims analysis, which more effectively collects the desired information needed to monitor the program. Our monitoring system eliminates the need for retrospective reporting of product information by contract suppliers. Therefore, we have modified Form C to eliminate the reporting of information from the previous quarter. Form C will collect prospective information on brands of products suppliers intend to offer during the upcoming quarter. The revised form will be completed each quarter but will only require updated product information if there is a change in the brands that will be offered. The brands each contract supplier reports on Form C will be posted on the Internet to help customer services representatives at 1-800-MEDICARE, clinicians, beneficiaries, and caregivers locate contract suppliers that furnish specific products.

Beneficiary Survey Form D:

Form D is a previously approved beneficiary survey. This form has been used in the Round 1 Rebid areas to monitor beneficiary satisfaction with the program and to assist CMS in determining if the program is meeting its objectives. Data have been collected from beneficiaries in the nine Round 1 Rebid CBA's and nine comparator CBA's. No changes have been made to this form from the previously approved version. We intend to continue use of this Form in the current and future rounds of competition.

Subcontracting Disclosure:

By law, each contract supplier must 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. Contract suppliers are also required to disclose within 10 days each subsequent subcontracting relationship entered during the 3 year contract period with CMS. The subcontracting reporting requirement has assisted us in monitoring the use of subcontractors by contract suppliers and subcontractor compliance with quality standards and accreditation. No changes have been made to this form from the previous version and we intend to continue its use in the current and future rounds of competition. CMS intends to require contract suppliers to use this form when reporting subcontracting relationships.

3. Use of Information Technology

Bidding Forms A & B:

The information collection required for the Round 1 Re compete has not changed since the Round 2 and national mail order competitions. All bidding suppliers must submit their bidder information, bids, and signature/s electronically into Forms A & B 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. Suppliers will be required to submit supporting documentation such as financial documents and network agreements to the CBIC in hardcopy.

Quarterly Reporting Form C:

Product brand information that contract suppliers enter during the bidding process will be used to pre-populate the Supplier Directory on the Medicare website. The suppliers will fill out Form C online at the CBIC website to update any changes to the products the supplier plans to make available during the upcoming quarter. The online form will be printed and mailed or faxed (preferred) to the CBIC where it will be uploaded to the Medicare Website. This form must be signed by a company official. Assistance and technical support is available to help suppliers in completing Form C. CMS will use electronic methods such as web postings and listserv messages to communicate information regarding Form C. CMS intends to allow for electronic submission of documents in the near future. We are actively engaged in the development of infrastructure to support electronic document transfers and expect to complete the process prior to 2014.

Beneficiary Survey Form D:

The beneficiary survey (Form D) will be conducted telephonically. A random sample of beneficiaries will be identified to obtain a sample size of 400 respondents per CBA. The six question survey will be completed via Computer Assisted Telephone Interview (CATI) by a CMS contractor. Results will be stored in an electronic database using commonly available software.

Subcontracting Disclosure:

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, or 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 ensure that subcontractors meet applicable accreditation requirements. Suppliers are required to print and submit the subcontracting disclosure form in hardcopy format to the CBIC by fax (preferred) or mail. No signature is required on this form. CMS intends to allow for electronic submission of documents in the near future. We are actively engaged in the development of infrastructure to support electronic document transfers and expect to complete the process prior to 2014.

4. Duplication of Efforts

Bidding Forms A & B:

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

Quarterly Reporting Form C:

This information collection does not duplicate any other effort, and the information cannot be obtained from any other source. The information collection will only be required when suppliers need to update information related to the brands of products they offer.

Beneficiary Survey Form D:

This information collection does not duplicate any other effort, and the information cannot be obtained from any other source. Additionally, the information is needed to evaluate the program and to compare results between CBA's and to areas where the program has not been implemented.

Subcontracting Disclosure:

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

5. Small Businesses

For the Round 1 Rebid of the Competitive Bidding Program, small suppliers, those with gross revenues of \$3.5 million or less, make up about 51 percent of the contract suppliers. As a result, our information collections will impact small businesses. However, CMS has attempted to reduce the burden on these suppliers by requiring them to submit only those forms that are essential to implement and monitor the program according to regulations.

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. 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 future rounds of competition.

We developed our 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.

6. Less Frequent Collection

Bidding Forms A & B:

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. The Secretary is required to recompetete contracts not less often than once every 3 years. During the bidding process, 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.

Form C:

Contract suppliers will be able to update their product information on a quarterly basis throughout the 3-year contract period. We believe that quarterly updating of product information (Form C) will provide suppliers adequate opportunity to keep their information current and will provide beneficiaries timely information on the products available to them.

Form D:

The beneficiary survey will be conducted twice for each round of competition. This survey will be administered by the CBIC pre and post-implementation of competitive bidding. A random-sampling procedure will be used to select beneficiaries for the survey.

Subcontracting Disclosure:

This information is collected on a schedule that is required by law. Contract suppliers are required to notify CMS of any subcontracting relationships that involve items or services provided under a competitive bidding contract. The initial subcontracting notification occurs within 10 days of contract awards. Contract suppliers are required to notify the CBIC any time there is a change in subcontractors during the 3-year contract period.

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. Additionally, the Act requires competitions to occur not less than every three years.

Bidders may regard their bids, including prices and other business information, for the DMEPOS Competitive Bidding Program to be confidential. CMS has stated that it will protect the confidentiality of this information to the extent permitted by law. This protection of the businesses' bids will maintain the confidentiality of proprietary information of the bidding suppliers. The information collected will be stored in a locked area with restricted access. CMS and its contractors, as well as the Government Accountability Office (GAO) and the Office of Inspector General (OIG) will have access to the data, but will report information about the bids and bidders only in an aggregate or anonymous form.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice was published on May 7, 2012. Comments were received from one regulatory clearinghouse. The comments have been addressed.

9. Payments/Gifts to Respondents

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

contract) to respondents. Additionally, beneficiaries completing surveys to evaluate the program will not be given gifts or any payments.

10. Privacy

CMS will maintain the confidentiality of proprietary bidding and financial information to the extent provided by law and will follow the procedure stated in 45 CFR 5.65. CMS will not share information about any bidder's proposal with other bidders.

However, an independent evaluator may be granted access to bidders' or networks' bidding information as permitted by law. Any reports that are created to evaluate the program will be reported in an anonymous or aggregate format. Bidding information may be reviewed as required by law by the U.S. Government Accountability Office (GAO) and the Department of Health and Human Services (DHHS) Office of Inspector General (OIG), and by the Department of Justice (DOJ) as permitted by law. CMS will request that any reports created to evaluate the program by the GAO and DHHS/OIG will report bidding information in an anonymous or aggregate format.

All contractor staff with access to bid information will be required to sign a statement agreeing to maintain the confidentiality of each bidder's information.

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)

Bidding Form A

We anticipate that the bidding forms for the Round 1 Recompete will be collected in a single calendar year, but we have also provided an annualized burden estimate to comply with reporting requirements. Form A is used to identify the bidding supplier. This form will include information for all locations that will be included with the supplier's bid/s. Each bidding supplier will be required to complete one Form A with an estimated completion time of 8 hours. We anticipate that this form will be completed by the equivalent of an Administrative Services Manager with a median hourly wage of \$37.45. This wage is based on the May 2010 Occupational Employment Statistics from the Bureau of Labor Statistics. We estimate the burden for each bidder to complete Form A to be eight hours and \$299.60. We do not know how many suppliers will bid in the Round 1 Recompete; however, for purposes of this paperwork burden estimate, we will assume that the number of bidders for the Round 1 Recompete will be the same as the Round 1 Rebid. Our total burden estimates for Form A are as follows:

Form A			
Competition	Number of Bidders	Total Hours	Cost
Round 1 Recompete	1,011	8,088	\$302,896
Annualized Total	337	2,696	\$100,965

Bidding Form B

Form B will be utilized by suppliers to submit bids for DMEPOS Products. This form will be completed once for each competition (CBA/PC) with an estimated completion time of 12 hours. Form B was completed an average of six times by suppliers bidding in the Round 1 Rebid. We do not know how many bids suppliers in the Round 1 Recompete will submit; however, for purposes of this paperwork burden estimate, we will assume that each Round 1 Recompete bidder will submit an average of 6 bids. We anticipate that this form will be completed by the equivalent of an Administrative Services Manager with a median hourly wage of \$37.45. This wage is based on the May 2010 Occupational Employment Statistics from the Bureau of Labor Statistics. We estimate the burden for each bidder to complete Form B to be 72 hours and \$2696.40. Our total burden estimates for Form B are as follows:

Form B				
Competition	Bidders	Bids	Bid Completion Time (Hours)	Total Cost
Round 1 Recompete	1,011	6,066	72,792	\$2,726,060
Annualized Total	337	2,022	24,264	\$908,687

Form C

The burden estimates for Form C are based on time to update information related to the products contract suppliers are planning to make available beneficiaries. Suppliers will be required to review the manufacturer and make of products and update any information that has changed since the previous quarterly submission. We estimate the time required to complete this process to be 20 minutes for each submission. We anticipate that this form will be completed by the equivalent of an Administrative Assistant with a median hourly wage of \$14.82. This wage is based on the May 2010 Occupational Employment Statistics from the Bureau of Labor Statistics. We estimate the burden for each supplier to complete Form C to be 20 minutes each quarter for an annual cost of \$17.78. Our total burden estimates for Form C are listed in the table below. It should be noted that burden estimates cover the anticipated three year PRA approval period (7/2012 - 6/2015) and we have listed the burden by calendar year. The Round 1 Rebid burden will be replaced by the Round 1 Recompete on January 1, 2014. We do not yet know the number of contract suppliers for the Round 1 Recompete, but for purposes of this burden estimate, we will assume that we will select the same number of contract suppliers for the Round 1 Recompete as we did for the Round 1 Rebid (i.e., 356).

FORM C				
Annual Burden Hours & Costs				
Calendar Year	Round 1 Rebid	Round 1 Recompete	Total Hours	Total Cost
CY 2012	237	0	237	\$3,512
CY 2013	474	0	474	\$7,025
CY 2014	0	474	474	\$7,025
CY 2015	0	237	237	\$3,512
Total Cost				\$21,074
Annual Total				\$7,024
Annual Hours				474

Form D

Form D is the beneficiary survey that is utilized to evaluate satisfaction levels with the competitive bidding program and to assist CMS in determining if the program is achieving its stated goals. Form D is completed twice during each round of competition. The survey is conducted pre- and post-implementation of competitive bidding. The time to complete the survey is approximately 15 minutes each time it is administered. The survey will be completed with 400 beneficiaries in each Competitive Bidding Area. Since we know the number of beneficiaries that will be contacted, we have included the burden estimates for the Round 2 and national mail-order competitions in this PRA submission..

Form D		
Competition	Number of Beneficiaries	Burden Hours
Round 1 Recompete	3,600	1,800
Round 2	40,000	20,000
National Mail Order	400	200
Total (per 3 years)	44,000	22,000
Annualized Total	14,667	7,333

Subcontracting Form:

Section 414.422(f) states that a supplier 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.

At the time the Round 1 Rebid contracts went into effect, 150 of the 662 (23 percent) contract supplier locations disclosed subcontracting relationships. These locations disclosed an average of two subcontracting relationships each. During the first year that contracts were in effect, we received 14 (2%) additional subcontracting disclosures. We estimate that the burden for contract suppliers to disclose the first subcontracting relationship to be approximately 20 minutes. This time includes ten minutes for locating and completing the online form and an additional ten minutes to verify the subcontractor’s accreditation. An additional ten minutes is included for each additional subcontractor. The total time for the average subcontracting disclosure consisting of two subcontractors is 30 minutes. We anticipate that this form will be completed by the equivalent of an Administrative Assistant with a median hourly wage of \$14.82. This wage is based on the May 2010 Occupational Employment Statistics from the Bureau of Labor Statistics. We estimate the burden for each supplier to complete the initial subcontracting disclosure to be 30 minutes and \$7.41. The burden for subsequent disclosures is 20 minutes and \$4.89. As discussed above, we do not know how many contract suppliers will be selected in the Round 1 Recompete. We also do not know how many contract suppliers will use subcontractors. However, for the purposes of this paperwork burden estimate we will use Round 1 Rebid results for the Round 1 Recompete. Our total burden estimates for subcontracting notifications are as follows:

Subcontracting				
Competition	Number of Contract Supplier Locations	Contract Suppliers locations with Subcontractors	Initial Burden Hours#	Subsequent annual disclosure hours*
Round 1 Rebid	662	150	75	4.7
Round 1 Re-Compete	662	150	75	4.7

Subcontracting				
	Burden Hours			Cost
Calendar Year	Round 1 Rebid	Round 1 Recompete	Total Hours	Total Cost
CY 2012	2.4	0	2.4	\$36
CY 2013	4.7	0	4.7	\$70
CY 2014	0	75	75	\$1,112
CY 2015	0	2.4	2.4	\$36
Total Cost				\$1,252
Annual Total				\$417
Average Annual Hour Burden				28

Annual Burden Summary:

The following table includes the burden estimates associated with this PRA application.

Burden Summary		
Form	Annual Hours	Annual Cost
A	2,696	\$100,965
B	24,264	\$908,687
C	474	\$7,024
D	7,333	\$0
Subcontracting	28	\$417
Total	34,795	\$1,017,093

13. Capital Costs

The information required is information that is readily available to the bidding and 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

Form A & B

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 savings resulting from program implementation which are estimated to be upwards of \$4 billion annually.

Form C Costs

Costs to the Federal government include both labor and operational expenses incurred by the Competitive Bidding Implementation Contractor (CBIC). The cost to process the Form C information is \$40,000 per quarter for the Round 1 Rebid CBAs. The costs include time to populate the information onto the CBIC website, send reporting listserv messages, analyze data, transmit data to Medicare.gov, and remedy reporting for non-responding suppliers. The projected annual cost to process Form C is \$160,000.

Form D Costs

Costs to the Federal government include both labor and operational expenses incurred by the Competitive Bidding Implementation Contractor (CBIC). The CBIC subcontracts the beneficiary survey to another entity. The cost to complete the survey during the Round 1 Rebid was \$175,000. The projected cost for Round 2 and the National Mail Order competition is \$600,000. The cost estimate associated with the Round 1 Recompete is \$175,000. The annualized cost is \$258,333.

Subcontracting Costs

Costs to the Federal government include both labor and operational expenses incurred by the Competitive Bidding Implementation Contractor (CBIC). The costs include time to prepare and send reminder listserv messages, review disclosures, enter data, verify accreditation, and communicate with suppliers on specific issues. The CBIC estimates the cost to process subcontracting disclosures for all contract suppliers in the Round 1 Recompete to be \$50,000. The CBIC estimates it will cost \$4000 to process additional Round 1 Rebid disclosures for the remainder of the contract period.

The total annual cost to the government for all forms is \$1,437,666.

Costs to the Federal Government	
Form	Annual Cost
A & B	\$1,000,000
C	\$160,000
D	\$258,333
Subcontracting	\$19,333
Total	\$1,437,666

15. Changes to Burden

The variables impacting burden are unique to each round of competition and we have described the anticipated variability based on historical data and/or estimates from past experience. Variables contributing to burden differences between rounds of competition include the number of bidders, the number of bids, and the number of contract suppliers.

The estimates of burden associated with the completion of Forms A & B have on average decreased by 2 hours for each form since these forms were initially approved. Our initial burden estimates were based on data from the demonstration projects when the competitions were conducted in two CBAs and the forms were completed manually using pen and paper. Since that time we have implemented the online bidding system (DBidS) and have streamlined the reporting requirements. We have decreased the time for Form A from ten hours to eight hours and Form B from 14 hours to 12 hours. These decreases in burden reflect the efficiency resulting from the use of technology for data entry and eliminating redundant or obsolete information.

We are reporting a one hour and forty minute decrease in the burden estimate associated with Form C. The reporting requirements for Form C have changed since the form was initially approved. Suppliers were initially required to report information each quarter on the products that they offer to beneficiaries. This process required data entry each quarter even when no changes of information were being reported. Suppliers are still required to report each quarter but will only enter information if there is a change in the products they offer to beneficiaries. We have decreased the burden estimate from two hours to 20 minutes. This time allows the supplier to review their information and provide updates utilizing the web-based form.

The burden estimates for subcontractor reporting have decreased by one hour and ten minutes. The CBIC has improved efficiency of reporting by creating an online form for suppliers to utilize. The burden estimates have decreased from 1.5 hours per subcontractor to 20 minutes for a single subcontracting disclosure and 10 minutes for each additional disclosure.

16. Publication/Tabulation Dates

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

17. Expiration Date

CMS would like to request an exemption from displaying an expiration date as these forms are used on a continuing basis.