

**Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)
Competitive Bidding Program
Supporting Statement Part A
OMB#: 0938-1016; CMS-
10169**

Background

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," and it is projected to save \$17.2 billion for beneficiaries and \$25.8 billion for the Medicare program over the next 10 years.

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. This section of MIPPA also specified that competitions to phase in additional areas could occur after 2011.

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 were implemented on July 1, 2013.

The MMA requires the Secretary to re-compete contracts not less often than once every 3 years. The Round 1 Rebid contract period for all product categories except mail-order diabetic supplies expired on December 31, 2013. (Round 1 Rebid contracts for mail-order diabetic testing supplies ended on December 31, 2012.) The competition for the Round 1 Re-compete began in August of 2012. The Round 1 Re-compete contracts and prices became effective on January 1, 2014 and will expire on December 31, 2016. Round 2 and National Mail-Order contracts and prices will expire on June 30, 2016.

The most recent approval for this information collection request (ICR) was issued by OMB on June 10, 2013. That ICR included the estimated burden to collect the information in bidding Forms A and B for the Round 1 Re-compete. We are now seeking approval to collect the information in Forms A and B for competitions that will occur before 2017. For these upcoming competitions CMS will publish a slightly modified version of the RFB instructions and accompanying Forms A and B 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. 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 or Form A or B. We have made no changes to Form C or the estimated number of respondents. However, the per response burden and the frequency of collection will change, effective July 1, 2016, when the quarterly requirement changes from a quarterly (January, April, July, and October) submission to a semi-annual (January and July) submission. Finally, we are retaining without change the Change of Ownership (CHOW) Purchaser Form and the CHOW Contract Supplier Notification Form, the Subcontracting Disclosure Form, and Form D and their associated burden under this ICR. We intend to continue use of these Forms on an ongoing basis.

A. 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; provided the requirements for mergers and acquisitions; 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 is 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 preparation for future rounds of competition, we have made 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.

Semi-Annual Reporting Form C:

Form C collects prospective information on the brands of products suppliers intend to offer to Medicare beneficiaries. The form allows contract suppliers to update product brand information or to verify that there is no change in the brands of product that will be offered to Medicare beneficiaries. 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. No changes have been made to this form from

the previously approved version. However, effective July 1, 2016, we have changed the reporting frequency for Form C from quarterly to semi-annually which constitutes a decrease in burden to contract suppliers. We intend to continue use of this form in the current and future rounds of competition.

Beneficiary Survey Form D:

Form D is a previously approved beneficiary survey. This form is used to monitor beneficiary satisfaction with the program and to assist CMS in determining if the program is meeting its objectives. 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 previously approved version. We intend to continue its use in the current and future rounds of competition.

Change of Ownership

CMS collects information from DMEPOS suppliers participating in a CHOW that involves a competitive bidding contract. Information is collected through a combination of Internet based forms and hardcopy submission of documentation associated with a merger or acquisition. CMS evaluates this information to determine if a DMEPOS supplier that merges with or acquires a contract supplier meets the conditions for awarding a competitive bidding contract as specified in regulations. These conditions include compliance with Medicare enrollment requirements, state licensure requirements, quality standards, accreditation, and financial standards. The CHOW process ensures the proper transfer of contractual obligations between DMEPOS suppliers and CMS. 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.

3. Use of Information Technology

Bidding Forms A & B:

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.

Semi-Annual 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 throughout the

contract period. This form is required semi-annually to update any changes to the products the supplier plans to make available. 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.

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.

Change of Ownership

DMEPOS contract suppliers participating in a Change of Ownership will be required to complete the CHOW forms on the CBIC website. These forms include the Contract Supplier Notification Form (60-day notice) and the Purchaser Form (30-day notice). These forms were designed to make it easier for suppliers to provide the 60-day and 30-day notices required by regulations, to provide pertinent information to describe the CHOW transaction and to provide suppliers with a checklist of other required information. Suppliers are required to print and submit these forms in hardcopy format along with other associated CHOW documents to the CBIC by fax (preferred) or mail. The information collection requires the signature of each organization's Authorized Official (AO).

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.

Semi-Annual 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 CBAs 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.

Change of Ownership

In accordance with §414.422(d)(2)(ii), a successor entity in a CHOW is not required to duplicate previously submitted information if the previously submitted information is still current. However, each CHOW is unique having variations in the product categories and competitive bidding areas included in the competitive bidding contract being transferred. CMS must verify that the purchasing supplier meets all program requirements including enrollment requirements, financial standards, accreditation, and licensure requirements for each product category and CBA. This information collection is required to ensure the proper transfer of a competitive bidding contract to another DMEPOS supplier as a result of a CHOW. CMS will utilize applicable information that is available in enrollment records or on file from the bidding process and will only request information when it is not on file or current.

5. Small Businesses

These 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. CMS has made an effort to minimize the burden associated with the process by publishing guidance with fact sheets, FAQ's, and providing online forms with checklists of other required documents.

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.

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 semi-annual basis throughout the contract period. We believe that semi-annual 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.

Change of Ownership

This information is collected only when a contract supplier undergoes a CHOW. The purpose of CMS collecting information associated with a CHOW is to evaluate whether a supplier that acquires or merges with a contract supplier is willing to accept the responsibilities and liabilities of a competitive bidding contract and meets the requirements for becoming a contract supplier under the Medicare DMEPOS Competitive Bidding Program. These requirements include Medicare enrollment, licensure requirements, quality standards, accreditation, and financial standards. The CHOW process ensures the proper transfer of contractual obligations between DMEPOS suppliers and CMS.

7. Special Circumstances

Suppliers may regard CHOWs as confidential. CMS has stated that it will protect the confidentiality of supplier information to the extent permitted by law. 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 only in an aggregate or anonymous form.

8. Federal Register/Outside Consultation

Federal Register

The 60-day Federal Register notice published on April 18, 2014.

Outside Consultation

Section 1847(c) of the Act required 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) authorized 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 represented a broad range of stakeholders in the competitive bidding program. We met with the PAOC numerous times since 2004 and consulted with them on virtually all aspects of the program. We did not receive any advice from the PAOC that would indicate a need to change the information collection discussed in this ICR.

9. Payments/Gifts to Respondents

We will not be providing gifts or any payments (other than remuneration under the contract) to contract suppliers.

10. Privacy

CMS will maintain the confidentiality of proprietary 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 supplier with other suppliers.

However, an independent evaluator may be granted access to a supplier's information as permitted by law. Any reports that are created to evaluate the program will be reported in an anonymous or aggregate format. Supplier 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 information in an anonymous or aggregate format.

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

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). We have estimated the number of respondents (bidders) for upcoming rounds of competition (e.g., the Round 2 Recompete, the National Mail-Order (NMO) Recompete, and the next Round 1 competition for contracts that will start in 2017) based on our experience from prior rounds of competition. Each bidding supplier will be required to complete one Form A for each round in which it bids. We anticipate that this form will be completed by the equivalent of an Administrative Services Manager with a median hourly wage of \$38.98. This wage is based on the May 2012 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 \$311.84. We do not know how many suppliers will bid in a given round of competition; however, for purposes of this paperwork burden estimate, we will assume that the number of bidders will be roughly the same as in previous rounds of competition. Our total burden estimates for Form A are as follows:

Form A			
Competition	Number of Bidders	Total Hours	Cost
Round 2	2,640	21,120	\$823,258
National Mail-Order	245	1,960	\$76,401
Round 1	1,011	8,088	\$315,270
Total	3,896	31,168	\$1,214,929
Annualized Total	1,299	10,389	\$404,976

Bidding Form B

Suppliers will use Form B to submit bids for DMEPOS Products. This form will be completed once for each CBA/product category combination with an estimated completion time of 12 hours.

We do not know how many bids suppliers will submit; however, for purposes of this paperwork burden estimate, we will assume that each Round 2 Recompete bidder will complete 18 Form Bs, each National Mail-Order bidder will complete one Form B, and each bidder for Round 1 2017 contracts will complete 6 Form Bs. We anticipate that this form will be completed by the equivalent of an Administrative Services Manager with a median hourly wage of \$38.98. This wage is

based on the May 2012 Occupational Employment Statistics from the Bureau of Labor Statistics. Our total burden estimates for Form B are as follows:

Form B				
Competition	Estimated Number of Bidders	Estimated Number of Form Bs	Total Hours	Total Cost
Round 2	2,640	47,520	570,240	\$22,227,955
National Mail-Order	245	245	2,940	\$114,601
Round 1	1,011	6,066	72,792	\$2,837,432
Total	3,896	53,831	645,972	\$25,179,988
Annualized Total	1,299	17,944	215,324	\$8,393,329

Form C

We have made no changes to Form C or the estimated number of respondents. However, effective July 1, 2016, the per response burden and the frequency of collection will change when the quarterly (January, April, July, and October) Form C submission requirement is reduced to a semi-annual (January and July) submission requirement. The burden estimates for Form C are based on time to update product brand information the contract supplier is planning to make available to Medicare beneficiaries. Contract 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 \$17.30. This wage is based on the May 2014 Occupational Employment Statistics from the Bureau of Labor Statistics. We estimate the burden for each supplier to complete Form C to be 20 minutes semi-annually for an annual cost of \$11.52. Our total burden estimates for Form C are listed in the table below. It should be noted that burden estimates cover the PRA approval period and we have listed the burden by calendar year. Based on experience, we estimate that there will be 867 respondents for Round 2, 15 for the National Mail-Order program, and 365 for the Round 1 Recompete.

			Form C		
			Annual Burden Hours & Costs		
Calendar Year	Round 1	Round 2	National Mail Order	Total Hours	Total Cost
CY 2014	474	1,156	20	1,650	\$26,186
CY 2015	474	1,156	20	1,650	\$26,186
CY 2016	243	578	10	831	\$14,376
CY 2017	243	578	10	831	\$14,376
Total Cost					\$81,124
Annual Cost					\$20,281

Form D

We have made no changes to Form D, the number of respondents, or the frequency of collection from the previously approved ICR. 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.

Form D		
Round	Number of Beneficiaries	Burden Hours
Round 1	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

Contract Supplier's Disclosure of Subcontractors

We have made no changes to the contract supplier's disclosure of subcontractors form, the estimated number of respondents, the per-response burden, or the frequency of collection from the previously approved ICR. 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 includes: 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 do not know how many contract suppliers will decide to use subcontractors. However, based on previous

experience, we estimate that approximately 684 Round 2 contract supplier locations and approximately 150 Round 1 Recompete contract supplier locations will disclose an average of two subcontracting relationships each. We estimate that subcontracting relationships will remain stable after the initial disclosure with only about 2% of suppliers reporting changes in subcontracting throughout the three year contract period. We do not anticipate that national mail-order contract suppliers will use subcontractors.

We have previously estimated 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 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 \$15.87 based on the May 2011 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 \$7.94. The burden for subsequent disclosures is 20 minutes and \$5.24.

Each supplier would complete one 30 minute episode to complete the initial reporting requirement. We use a fraction of this amount (1 hour annually) to illustrate the process for subsequent disclosures that may occur during the three year contract period. One hour would represent three individual updates of subcontracting relationships at 20 minutes per update. We do not anticipate that national mail-order contract suppliers will use subcontractors. Our total burden estimates for subcontracting notifications are as follows:

Competition	Locations with Subcontractors	Subcontracting	
		Initial Burden Hours	Subsequent Annual Disclosure Hours
Round 2	684	342	21
Round 1	150	75	4.7

Calendar Year	Round 1	Round 2	Subcontracting Burden Hours	
			Total Hours	Total Cost
CY 2014	75	21	96	\$1,524
CY 2015	4.7	21	26	\$413
CY 2016	4.7	352.5	357.2	\$5,669
Total Cost				\$7,606
Annual Total				\$2,535

We have made no changes to the Change of Ownership Forms, the estimated number of respondents, the per-response burden, or the frequency of response from the previously approved version. In accordance with Article V of the DMEPOS competitive bidding contract and §414.422(d), a contract supplier participating in a CHOW must provide CMS advance notice of the transaction. Suppliers are required to submit both a 60-day and 30-day advance notice in order to provide CMS enough time to adequately evaluate the purchasing supplier. This notice is required to ensure the successor entity in a transaction meets all program requirements and has agreed to accept all rights, liabilities, and obligations of the competitive bidding contract.

Contract suppliers must use the Change of Ownership Contract Supplier Notification Form (60 day notice) and the Change of Ownership Purchaser Form (30 day notice) forms to provide the required notice.

We estimate that it will take approximately 20 minutes to review the CHOW requirements. This time includes review of the CHOW Fact sheet and CHOW FAQ's on the CBIC website. We estimate that it will take approximately 10 minutes to complete the Change of Ownership Contract Supplier Notification Form and 60 minutes to complete the Change of Ownership Purchaser Form. Without the use of these standardized forms, it would take suppliers much longer to assemble and organize the required information.

Each form is to be completed and submitted one time only for each CHOW transaction. The Contract Supplier Notification Form will be completed by the seller and the Purchaser Form will be purchasing supplier. We believe that the process to complete and submit the two forms will be completed by a General or Operations Manager. Based on 2011 Bureau of Labor Statistics data, the mean hourly wage for a General or Operations Manager is \$55.04. We estimate that the cost for both the selling and purchasing supplier to review the fact sheet in order to prepare the forms is $(0.33 \times \$55.04 \times 2)$ \$36.60 each. The burden to complete and submit the CHOW Contract Supplier Notification Form is $(0.17 \text{ hour} \times \$55.04)$ \$9.36 and to complete and submit the CHOW Purchaser Form $(1.0 \text{ hour} \times \$55.04)$ \$55.04. The total time and cost for each transaction is estimated to be 1 hour and 50 minutes and \$101.00.

We do not know how many CHOWs will occur annually. However, we estimate that we will receive the following number of CHOW transaction each year: 8 transactions for Round 1, 80 transactions for Round 2, and four transactions for national mail-order.

CHOW 60 & 30 Day Notices					
Burden Hours					
Calendar Year	Round 1	Round 2	National Mail Order	Total Hours	Total Cost
CY 2014	14.6	146.4	7.3	168.4	\$9,267
CY 2015	14.6	146.4	7.3	168.4	\$9,267
CY 2016	14.6	146.4	7.3	168.4	\$9,267
Total	43.8	439.2	22.0	505.2	\$27,801
Average Annual Cost					\$9,267
Average Annual Hour Burden					168

Change of Ownership (CHOW) Forms

Annual Burden Summary:

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

Burden Summary		
Form	Annual Hours	Annual Cost
Form A	10,389	\$404,976
Form B	215,324	\$8,393,329
Form C	1,241	\$20,281
Form D	7,333	\$0
Subcontracting	160	\$2,535
CHOW	168	\$9,267
Total	235,024	\$8,836,293

13. Capital Costs

The information required is information that is readily available to 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 Costs**

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 \$17.2 billion for beneficiaries and \$25.8 billion for the Medicare program over the next 10 years.

Form C Costs

Costs to the Federal government include both labor and operational expenses incurred by the Competitive Bidding Implementation Contractor (CBIC). Costs include web development and deployment, document control and processing of hardcopy submissions, reporting, data analysis, web/listserv outreach and education, data transmission, and outreach to non-responding suppliers. The cost to process the Form C information is estimated to be \$108,250 per quarter for all rounds of competition with a projected annual cost of \$433,956. For 2016-2017, the cost to process the Form C information is estimated to be \$50,000 per quarter for all rounds of competition with a projected annual cost of \$350,000 in CY 2016 and \$200,000 in CY 2017.

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 estimated cost to complete the survey for Round 1 is \$175,000. The estimated cost to complete the survey for Round 2 and the National Mail Order Program is \$600,000.

Subcontracting Costs

Costs to the Federal government include both labor and operational expenses incurred by the CBIC. Costs include time to prepare and send reminder listserv messages, review disclosures, enter data, verify accreditation, and communicate with suppliers on specific issues. The annual estimated cost to process subcontracting disclosures for all rounds of competition is \$99,389.

Change of Ownership

Costs to the Federal government include both labor and operational expenses incurred by the CBIC. The cost to process CHOW information for a CHOW of moderate complexity is estimated to be \$2,519 per CHOW. The operational costs include time for document control, data system modifications, posting reports, review of program requirements, financial assessment, correspondence, and postage.

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 the number of bidders, the number of bids, contract suppliers, the number of subcontractors utilized by contract suppliers, and the frequency of ownership changes.

The total burden for this package has increased as a result of the necessity to collect bidding information for competitions that will occur before 2017. We are revising this package to adjust the burden accordingly and reflect the use of Forms A and B. In the Background section, we have described the method to report the total burden associated with use of these forms.

The previous ICR did not reflect any burden for Forms A and B because the information in these forms had already been collected for the Round 1 Recompete, Round 2 and the National Mail-order program. In this ICR, the burden for Form A for all upcoming rounds of competition is 1,299 responses and 10,389 hours. The burden for Form B for all rounds of competition is 1,299 responses and 17,944 hours.

We have made no changes to Form C or the estimated number of respondents. However, the per response burden and the frequency of collection will change, effective July 1, 2016, when the requirement changes from a quarterly (January, April, July, and October) submission to a semi-annual (January and July) submission. This change will constitute a decrease in burden to suppliers and will reduce the amount of resources and costs required to carry out Form C processes by the CBIC. The burden for Form C for all upcoming rounds of competition is 2,494 responses and 1,241 hours.

We have made no changes to the contract supplier's disclosure of subcontractors form, the estimated number of respondents, the per-response burden, or the frequency of collection from the previously approved ICR. We note that we have made a slight adjustment to the burden estimates for this form from the previous ICR since this ICR reflects 3 full years for Round 2. The previous ICR reflected 2.5 years for Round 2 due to the implementation date.

There are no changes or adjustments to the burden estimates for the contract supplier's disclosure of subcontractors form, Form D, or the CHOW forms from the previously approved ICR.

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.

18. Certification Statement

There are no exceptions to the certification statements.

B. Collection of Information Employing Statistical Methods

This collection of information does not employ statistical methods.