

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

\*\*\*URGENT\*\*\* We are requesting OMB to perform their review concurrent with the 30 day public comment period. If this package is not cleared by the deadline of June 10, 2013, there will be insufficient time for us to review the subcontractor disclosures and ensure that the subcontractors are accredited. This could create potential harm for beneficiaries. In addition, if contract suppliers are not able to update their brand offering using Form C, referral agents and others will not have current information when selecting a contract supplier.

**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."

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 recompete contracts not less often than once every 3 years. Most Round 1 Rebid contracts will expire on December 31, 2013. (Round 1 Rebid contracts for mail-order diabetic testing supplies ended on December 31, 2012.) Consequently, we are currently in the process of recompeting the competitive bidding contracts in the Round 1 Rebid areas.

The most recent approval for this information collection request (ICR) was issued by OMB on October 10, 2012. Since then, CMS has decided to sequentially update the paperwork burden necessary to administer the program as it expands nationally and cycles through multiple rounds of competition. Specifically, we are now seeking to update our burden estimates for certain contract maintenance forms for Round 2 and the national mail-order competitions. These include Form C and the Contract Supplier's Disclosure of Subcontractors form. We are also requesting approval of two additional forms: the Change of Ownership (CHOW) Purchaser Form and the CHOW Contract Supplier Notification Form, which will be utilized in all rounds of competition. Finally, we are retaining without change Forms A, B, and D and their associated burden under this ICR. We note that the information collection for Forms A and B is already complete. We intend to continue use of the Forms in future rounds of competition.

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## **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.

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## **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.

The approved information collection for these forms is already complete. We intend to continue use of the forms in future rounds of competition.

### **Quarterly Reporting Form C:**

Form C collects prospective information on the brands of products suppliers intend to offer to Medicare beneficiaries during the upcoming quarter. The form will be completed each quarter but will only require updated product information if there is a change in the brands of products 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. We have made non substantive modifications to the online form so that it can be used for multiple rounds. There have been no changes to the information that is being collected. We are including this form in the current package to describe the burden associated with program expansion.

### **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. . We have made non substantive modifications to the online form so that it can be used for multiple rounds. There have been no changes to the information that is being collected. 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. We are including this form in the current package to describe the burden associated with program expansion.

### **Change of Ownership**

CMS will collect information from DMEPOS suppliers participating in a CHOW that involves a competitive bidding contract. Information will be collected through a combination of Internet based forms and hardcopy submission of documentation associated with a merger or acquisition. CMS will evaluate 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.

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## **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.

### **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 throughout the 3-year contract period. This form is required quarterly 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 future.

**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 future.

**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).

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**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 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.

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**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.

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**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 recompete 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.

**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.

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**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.

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**8. Federal Register/Outside Consultation**

*Federal Register*

The 60-day Federal Register notice published on March 1, 2013 (78 FR 13878). No comments were received.

### 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.

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### **9. Payments/Gifts to Respondents**

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

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### **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.



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## 11. Sensitive Questions

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

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## 12. Burden Estimates (Hours & Wages)

### **Bidding Forms A & B**

#### Round 1 Rebid/Recompete and Round 2/NMO – 2013-2014

We have made no changes to Forms A and B from the previously approved versions. Collection is already complete. We intend to continue use of the Forms in future rounds (see 2015 Round 2 Recompete below) of competition.

#### Round 2 Recompete – 2015

We want to keep the Bidding forms active and anticipate the use of these forms during the Round 2 Recompete of the competitive bidding program. This is inline with OMB's regular 3-year approval period (2013 through 2015). We will revise our burden estimates prior to the collection of information.

### **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. 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 \$15.87. This wage is based on the May 2011 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 \$21.11. 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 and we have listed the burden by calendar year. On January 30, 2013, CMS offered contracts to 867 Round 2 bidders and 15 national mail –order bidders. Because we have not yet completed the contracting process and cannot be certain of the final number of contract suppliers, we will estimate the number of respondents as the number of bidders offered contracts. This form is completed four times annually by each Round 2 and National Mail Order respondent requiring 20 minutes to complete the form each time.

		<b>Form C</b>		
		<b>Burden Hours</b>		
<b>Calendar Year</b>	<b>Round 2</b>	<b>National Mail Order</b>	<b>Total Hours</b>	<b>Total Cost</b>
<b>CY 2013*</b>	578*	10	588	\$9,332
<b>CY 2014</b>	1,156	20	1,176	\$18,663

CY 2015	1,156	20	1,176	\$18,663
CY 2016*	578	10	588	\$9,332
<b>Total</b>	<b>3,468</b>	<b>60</b>	<b>3,528</b>	<b>\$55,989</b>
<b>Round 2/NMO Average Annual Cost</b>				\$18,663
<b>Round 1 Rebid/Recompete Average Annual Cost</b>				\$7,024
<b>New combined (R1RB/R1RC/R2/NMO) Average Annual Cost</b>				\$25,687.68
<b>Round 2/NMO Average Annual Hour Burden</b>			1,176	
<b>Round 1 Rebid/Recompete Average Annual Hour Burden</b>			474	
<b>New combined (R1RB/R1RC/R2/NMO) Average Annual Hour Burden</b>			1,650	

\* Contracts effective for six months of the calendar year

#### 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.

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

#### Contract Supplier's Disclosure of Subcontractors

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.

For the Round 1 Rebid, we determined that 22% of contract supplier locations reported subcontracting relationships. These locations disclosed an average of two subcontracting relationships each. During the first year of the program, the subcontracting relationships were stable with only 2% of suppliers reporting changes in subcontracting. We expect this pattern to continue throughout the three year contract period.

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. This wage is 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 will 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. On January 30, 2013, CMS offered contracts to 867 Round 2 bidders with 3,109 locations. Because we have not yet completed the contracting process and cannot be certain of the final number of contract suppliers, we will estimate the number of respondents using the locations associated with Round 2 bidders offered contracts. We do not anticipate that national mail-order contract suppliers will use subcontractors. Our total burden estimates for subcontracting notifications are as follows:

<b>Subcontracting</b>			
<b>Competition</b>	<b>Locations with Subcontractors</b>	<b>Initial Burden Hours</b>	<b>Subsequent Annual Disclosure Hours</b>
<b>Round 2</b>	684	342	21

<b>Subcontracting Burden Hours</b>			
<b>Calendar Year</b>	<b>Round 2</b>	<b>Total Hours</b>	<b>Total Cost</b>
<b>CY 2013*</b>	342	342	\$5,428
<b>CY 2014</b>	21	21	\$333
<b>CY 2015</b>	21	21	\$333
<b>CY 2016*</b>	10.5	10.5	\$167

<b>Total</b>	394.5	394.5	\$6,261
<b>Round 2 Average Annual Cost</b>			\$2,087
<b>Round 1 Rebid/Recompete Average Annual Cost</b>			\$417
<b>New Combined (R1RB/R1RC/R2) Average Annual Cost</b>			\$2,504
<b>Round 2 Average Annual Hour Burden</b>		131.5	
<b>Round 1 Rebid/Recompete Average Hour Burden</b>		28	
<b>New Combined (R1RB/R1RC/R2) Average Hour Burden</b>		159.5	

\* Contracts effective for six months of the calendar year

### Change of Ownership (CHOW) Forms

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.

Since the beginning of the Round 1 Rebid and through December 2012, there have been a total of 16 CHOWs completed. Several of these transactions were completed in 2010 just prior to program implementation. During this period, we recognized the need for a standardized reporting process to assist suppliers in meeting the reporting requirements. We developed Internet-based forms to meet these requirements and made these forms available for suppliers to use beginning in February 2011. These forms include the Change of Ownership Contract Supplier Notification Form (60 day notice) and the Change of Ownership Purchaser Form (30 day notice). We stated in the preamble of the final rule published on April 10, 2007 (72 FR 18069) that we would monitor this reporting requirement and seek OMB approval should the number of respondents surpass the PRA reporting threshold. We anticipate exceeding this threshold for PRA during the upcoming Round 2 and the national mail-order competitions. Therefore, we are submitting these forms for approval for all rounds of competition.

We estimate that it will take an 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 x \$55.04 x 2) \$36.60 each. The burden to complete and submit the CHOW Contract Supplier Notification Form is (0.17 hour x \$55.04) \$9.36 and to complete and submit the CHOW Purchaser Form (1.0 hour x \$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, since there have been 16 CHOWs for the Round 1 Rebid to date we will assume there will be eight CHOW transactions per year in the nine Round 1 CBAs. We will use a factor of 10 for the Round Two CBAs (100 CBAs) and a factor of 0.5 for the national mail-order competition. Total burden will be calculated for a 3 year PRA cycle beginning in July 2013 then annualized for a yearly amount.

<b>CHOW 60 &amp; 30 Day Notices</b>					
<b>Burden Hours</b>					
<b>Calendar Year</b>	<b>Round 1</b>	<b>Round 2</b>	<b>National Mail Order</b>	<b>Total Hours</b>	<b>Total Cost</b>
<b>CY 2013*</b>	7.3	73.2	3.7	84.2	\$4,633
<b>CY 2014</b>	14.6	146.4	7.3	168.4	\$9,267
<b>CY 2015</b>	14.6	146.4	7.3	168.4	\$9,267
<b>CY 2016*</b>	7.3	73.2	3.7	84.2	\$4,633
<b>Total</b>	43.9	439.2	22.0	505.2	\$27,800
<b>Average Annual Cost</b>					<b>\$9,267</b>
<b>Average Annual Hour Burden</b>				<b>168</b>	

\* Contracts effective for six months of the calendar year

**Annual Burden Summary:**

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

<b>Burden Summary</b>		
<b>Form</b>	<b>Annual Hours</b>	<b>Annual Cost</b>
<b>Form A</b>	0	\$0
<b>Form B</b>	0	\$0
<b>Form C</b>	1650	\$25,687.68
<b>Form D</b>	7,333	\$0
<b>Subcontracting</b>	159.5	\$2,504

<b>CHOW</b>	168	\$9,267
<b>Total</b>	9,310.5	\$37,458.68

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### **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.

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### **14. Cost to Federal Government**

#### **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 with a projected annual cost to process Form C is \$160,000. 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 costs for Round 2 and the national mail-order competitions are contingent upon the number of contract suppliers.

#### **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.

#### **Subcontracting Costs**

Costs to the Federal government include both labor and operational expenses incurred by the 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 reports the cost to process initial subcontracting disclosures for contract suppliers in the Round 1 Rebid to be \$50,000. The CBIC also reports a cost of \$4000 to process additional Round 1 Rebid disclosures for the remainder of the contract period. The costs for Round 2 and the national mail-order competitions are contingent upon the number of contract suppliers.

#### **Change of Ownership**

Costs to the Federal government include both labor and operational expenses incurred by the CBIC. It is estimated that the average CHOW takes approximately 26.5 hours to process. This cost estimate is based on average time to process a CHOW of moderate complexity. The operational costs include time for document control, data system modifications, posting reports, review of program requirements, legal review, financial assessment, correspondence, and postage. The estimated total cost per CHOW is

\$2519.00.

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## **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 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 program's planned expansion into additional areas. We are revising this package to adjust the burden accordingly. The burden estimates to complete each individual Form C and the Subcontracting Disclosure form have not changed from the currently approved versions. In the Background section, we have described the method to report the total burden associated with use of these forms for the Round 2 and national mail-order competitions.

1-The Round 1 burden for Form C is 1,424 responses and 474 hours. The Round 2 and NMO estimated burden is 3,528 responses and 1,176 hours for a new combined total of 4,952 responses and 1,650 hours. We are revising this package to include new burden for Form C due to the implementation of Round 2 and NMO.

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2-The Round 1 burden for Subcontractor Disclosure form is 100 responses and 28 hours. The Round 2 burden is 290 responses and 131.5 hours for a new combined total of 390 responses and 159.5 hours. We are revising this package to include new burden for Subcontractor Disclosure due to the implementation of Round 2 and NMO.

3-The Round 1 burden included estimates for Forms A, B, and D. We have made no changes to Forms A, B and D from the previously approved versions. Collection for Forms A and B is already complete and their burden for Round 1 is now obsolete. We intend to continue use of Forms A and B in future rounds of competition and to continue the use of Form D as previously approved.

4- We stated in the preamble of the final rule published on April 10, 2007 (72 FR 18069) that we would monitor the CHOW reporting requirement and seek OMB approval should the number of respondents surpass the PRA reporting threshold. We anticipate exceeding this threshold during the upcoming Round 2 and national mail-order competitions. Therefore, we are submitting these forms for approval for all rounds of competition and have their associated burden added to the total for this ICR.

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## **16. Publication/Tabulation Dates**

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

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## **17. Expiration Date**

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

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**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.