

**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 (GAO) and the Office of Inspector General (OIG) of the United States (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 successful competitive bidding demonstrations, 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 U.S. 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 diabetes 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 Diabetes 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.

Since implementation of Round 1 Rebid in January 1, 2011, CMS has saved approximately \$220 million per year in the nine Round 1 metropolitan statistical areas (MSAs) and \$3.6B in the first two years of the Round 2 areas which began on July 1, 2013 due to competitive bidding and other CMS fraud, waste and abuse initiatives.

The MMA requires the Secretary to re-compete contracts not less often than once every three years. The Round 1 Rebid contract period for all product categories except mail-order diabetes testing supplies expired on December 31, 2013. (Round 1 Rebid contracts for mail-order diabetes testing supplies ended on December 31, 2012.) The competition for the Round 1 Re-compete began in August of 2012 and contracts and prices became effective on January 1, 2014. The Round 1 Re-compete contract period expires on December 31, 2016. Round 1 2017 contracts will become effective on January 1, 2017 and will expire on December 31, 2018. Round 2 and national mail-order contracts and prices expired on June 30, 2016. Round 2 Re-compete and the national mail-order re-compete contracts became effective on July 1, 2016, and will expire on December 31, 2018, at which point CMS will be implementing a consolidated round of competition to include all Round 1, Round 2, and national mail-order competitive bidding areas, referred to as Round 2019.

Additionally, Section 1847(a)(1)(G) of the Social Security Act (the Act), added by section 522(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114-10) (MACRA), now requires a bid surety bond for bidding entities beginning not earlier than January 1, 2017 and not later than January 1, 2019. The addition to the Act states that a bidding entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has (1) obtained a bid surety bond, in the range of \$50,000 to \$100,000 and (2) provided the Secretary with proof of having obtained the bid surety bond for each CBA in which the entity submits its bid(s). Based on the passage of MACRA, we put forth proposed additions to §414.412, "Submission of bids under a competitive bidding program," to add a new paragraph (h) that would allow CMS to implement section 1847(a)(1)(G) of the Act, as amended by section 522(a) of MACRA, to state that an entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has obtained a bid surety bond for the CBA. CMS published the proposed rule CMS-1651-P on June 30, 2016. The comment period on this rule closed on August 23, 2016. CMS published the final rule CMS-1651-F on November 4, 2016.

The most recent approval for this information collection request (ICR) was issued by the Office of Management and Budget (OMB) on June 8, 2016. That ICR included a "non-material or non-substantive change to a currently approved collection". We are now seeking approval to update our burden estimates to all Forms to account for the consolidation of all rounds in Round 2019. For Round 2019 and the proposed rule, CMS will publish a slightly modified version of Form A so that suppliers will be better able to identify and understand the new requirement related to surety bonds. We have made no changes to Forms B, C, D, Change of Ownership (CHOW) Contract Supplier Notification and Purchaser Forms, and Subcontracting Disclosure Form. However, the burden has been adjusted to account for the increase in the number of respondents due to the consolidation of all CBAs into Round 2019 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 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 three 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 three 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 one year of documents instead of the three 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.

Section 1847(a)(1)(G) of the Act, added by section 522(a) of the MACRA, now requires a bid surety bond for bidding entities beginning not earlier than January 1, 2017 and not later than January 1, 2019. The addition to the Act states that a bidding entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has (1) obtained a bid surety bond, in the range of \$50,000 to \$100,000 and (2) provided the Secretary with proof of having obtained the bid surety bond for each CBA in which the entity submits its bid(s).

Based on the passage of MACRA, we put forth proposed additions to §414.412, "Submission of bids under a competitive bidding program," to add a new paragraph (h) that would allow CMS to implement section 1847(a)(1)(G) of the Act, as amended by section 522(a) of MACRA, to state that an entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has obtained a bid surety bond for the CBA.

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 the DMEPOS Bidding System (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 that the supplier has met all program requirements, including licensure, financial and quality standards. 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 Round 2019, we have made changes to Form A to better clarify the new bidding requirement related to bid surety bonds for DMEPOS suppliers. The changes to Form A provide new instructions in accordance with §414.412(h), allowing the bidder to attest that they have obtained a bid surety bond for each Competitive Bidding Area (CBA) for which they are submitting a bid.

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 Medicare.gov to help customer service 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, the estimated number of respondents and per response burden has been adjusted to account for Round 2019 under this ICR and a decrease in reporting from quarterly to semi-annually. We intend to continue use of this form in 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. However, the estimated number of respondents and per response burden has been adjusted to account for Round 2019 under this ICR. We intend to continue use of this form in 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 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. However, the estimated number of respondents and per response burden has been adjusted to account for Round 2019 under this ICR. We intend to continue its use in 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 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. . However, the estimated number of respondents and per response burden has been adjusted to account for Round 2019 under this ICR. We intend to continue use of this form in 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 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 safely obtain and secure the bidding information that is transmitted. Assistance and technical support is available to help suppliers throughout the competitive bidding process. Suppliers will be required to submit supporting documentation such as required financial documents and network agreements to the CBIC.

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 submitted 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. For the national mail-order recompetes, the survey will be completed with 2,000 beneficiaries in each 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 to the CBIC. 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 submit these forms along with other associated CHOW documents to the CBIC. 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 CBAs 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, frequently asked questions (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 three 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 October 14, 2016. We did not receive any comments specific to the information contained within this submission.

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. In accordance with section 1847(c)(5), the PAOC was terminated on December 31, 2011.

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 U.S. Federal Government 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 includes information for all locations that will be included with the supplier's bid(s). In preparation for Round 2019, this form will also provide new instructions in accordance with proposed §414.412(h), allowing the bidder to attest that they have obtained a bid surety bond for each CBA for which they are submitting a bid. We have estimated the time to obtain a bond from a surety company (including contacting the company, filling out forms, submitting forms, filing paperwork, etc.) to be 11 minutes. Additionally, we estimate that the time to assemble and complete the new bid surety bond section of Form A to be 5 minutes. The time to submit the bid surety bond documentation is estimated to take an additional 5 minutes. Therefore, the total time to complete Form A has changed from eight hours to eight hours and 21 minutes. We have estimated the number of respondents (bidders) for Round 2019 based on our experience from prior rounds of competition. Each bidder 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 \$41.40. This wage is based on the May 2015 Occupational Employment Statistics from the Bureau of Labor Statistics. We estimate the burden for each

bidder to complete Form A to be eight hours 21 minutes and \$345.69. We do not know how many suppliers will bid in Round 2019; 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. We estimate there will be approximately 1,500 bidders in Round 2019 and each bidder will complete Form A once for a total of 12,525 hours and a total cost of \$518,535. Our total and annualized burden estimates for Form A are as follows:

| Form A | | | |
|--------------------------------------|--------------------------------|--------------------|-------------------|
| Competition | Total Number of Bidders | Total Hours | Total Cost |
| Round 2019 | 1,500 | 12,525 | \$518,535 |
| Annualized Total | 500 | 4,175 | \$172,845 |
| Annual Number of Responses | 500 | | |
| Annual Frequency of Responses | 1 | | |

Bidding Form B

Suppliers will use Form B to submit bids for DMEPOS items included in the DMEPOS Competitive Bidding Program. This form will be completed once for each CBA/product category combination with an estimated completion time of 11.5 hours. For Round 2019, we do not know how many bids suppliers will submit; however, for purposes of this paperwork burden estimate, we will assume that each Round 2019 bidder will complete 23 Form B's. We anticipate that this form will be completed by the equivalent of an Administrative Services Manager with a median hourly wage of \$41.40. This wage is based on the May 2015 Occupational Employment Statistics from the Bureau of Labor Statistics. Our total burden estimate includes 1,500 bidders completing an average of 23 Form B's each for a total of 34,500 Form B's. The burden for each form B is 12 hours multiplied by 34,500 Form B's resulting in a total burden of 414,000 hours. The cost burden is based upon the mean hourly wage of \$41.40 multiplied by 414,000 hours for a total cost of \$17,139,600. Each supplier completing 23 Form B's will have a total burden of 276 hours and \$11,426. Our total and annual burden estimates for Form B are as follows:

| Form B | | | | |
|--------------------------------------|--|--|--------------------|-------------------|
| Competition | Total Estimated Number of Bidders | Total Estimated Number of Form Bs | Total Hours | Total Cost |
| Round 2019 | 1,500 | 34,500 | 414,000 | \$17,139,600 |
| Annualized Total | 500 | 12,000 | 138,000 | \$5,713,200 |
| Annual Number of Responses | 11,500 | | | |
| Annual Frequency of Responses | 8 | | | |

Form C

We have made no changes to Form C, however, the estimated number of respondents and per response burden has been adjusted to account for Round 2019 under this ICR. 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 semi-annual 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 \$17.55. This wage is based on the May 2015 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 \$11.58. 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. We estimate that there were be 637 respondents for Round 2 Recompete, nine for the national mail-order recompete , and 198 for Round 1 2017. Based on previous experience, we estimate that there will be 750 respondents for Round 2019. To calculate the annual number of responses, we total the number of respondents for each round (637+9+188+750=1594) then multiply by two for semi-annual reporting to reach 3,188 responses annually. To describe the burden estimates for CY 2017, we used the following detailed description. Round 1 2017 includes 198 suppliers multiplied by the annual burden to complete the form 0.66 (0.33 semi-annually) for a total of 132 burden hours. This calculation is repeated for each round (column) for CY2017 then the total burden hours is multiplied by the hourly wage of \$17.55 to reach the annual burden cost which is then added across all years for the total burden which is then annualized over the 3 year PRA cycle.

| Form C | | | | | | |
|--|---------------------|--------------------------|--------------------------------------|-------------------|--------------------|-------------------|
| Annual Burden Hours & Costs | | | | | | |
| Calendar Year | Round 1 2017 | Round 2 Recompete | National Mail Order Recompete | Round 2019 | Total Hours | Total Cost |
| CY 2017 | 132 | 425 | 6 | 0 | 563 | \$9,881 |
| CY 2018 | 132 | 425 | 6 | 0 | 563 | \$9,881 |
| CY 2019 | 0 | 0 | 0 | 500 | 500 | \$8,775 |
| CY 2020* | 0 | 0 | 0 | 250 | 250 | \$4,388 |
| Total | 264 | 850 | 12 | 750 | 1,876 | \$39,925 |
| Average Annual Cost | \$10,975 | | | | | |
| Average Annual Hour Burden | 625 | | | | | |
| Annual Number of Responses | 3,188 | | | | | |
| Annual Frequency of Responses | 2 | | | | | |

*PRA approval period for approximately 3 months of the calendar year

Form D

We have made no changes to Form D or the frequency of collection from the previously approved ICR. However, the estimated number of respondents and per response burden has been adjusted to account for Round 2019 under this 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 each round. 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 CBA. For the national mail-order recompete, the survey will be completed with 2,000 beneficiaries. The sample was increased under this ICR as the national mail-order recompete for diabetes testing supplies includes all parts of the U.S., including the 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa. Due to the timing of the pre- and post-surveys, we will only be allocating burden associated with the Round 2017 post-survey, the National Mail-Order post-survey, and the Round 2019 pre- and post-surveys.

| Form D | | |
|-------------------------------|---------------------|--------------|
| Round | Number of Responses | Burden Hours |
| Round 1 2017 | 2,600 | 1,300 |
| National Mail Order Recompete | 1,000 | 500 |
| Round 2019 | 60,000 | 30,000 |
| Total (per 3 years) | 63,600 | 31,800 |
| Annualized Total | 21,200 | 10,600 |
| Annual Frequency of Responses | | 1 |

Contract Supplier's Disclosure of Subcontractors

We have made no changes to the contract supplier's disclosure of subcontractors form or the frequency of collection from the previously approved ICR. However, the estimated number of respondents and per response burden has been adjusted to account for Round 2019 under this 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 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 Round 1 2017, Round 2 Recompete and the national mail-order recompete, we determined that 22 percent of contract supplier locations reported subcontracting relationships. These locations disclosed an average of two subcontracting relationships each. We estimate that subcontracting relationships will remain stable after the initial disclosure with only about two percent of suppliers reporting changes in subcontracting throughout the three year contract period. Based on previous experience, we do not anticipate that national mail-order recompete contract suppliers will use subcontractors. However, for Round 2019, we estimate that 22 percent of contract supplier locations will report subcontracting relationships and those locations will also disclose an average of two subcontracting relationships each.

We have previously estimated that the burden for contract suppliers to disclose the first subcontracting relationship to be approximately 20 minutes. This time includes 10 minutes for locating and completing the online form and 10 minutes to verify the subcontractor's accreditation. An additional 10 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 \$17.55 based on the May 2015 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 \$8.78. The burden for subsequent disclosures is 20 minutes and \$5.80.

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 included in the tables below.

| Subcontracting | | | | | | | | | | |
|---------------------------------|-----------------------------|---------|------------|-------------------------------|----------------------|--------------------------------|------------------------------------|-------------|------------|------------|
| Competition | Contract Supplier Locations | | | Subcontracting Subcontractors | Initial Burden Hours | Subsequent Reporting Locations | Subsequent Annual Disclosure Hours | Total Hours | Total Cost | Total Cost |
| | Round 1 | Round 2 | Round 2019 | | | | | | | |
| Calendar Year | 2017 | 2018 | 2019 | 515 | 258 | 48 | 16 | | | |
| Round 2 Recompete | 23 | 40 | | | | | | | | |
| Round 1 2017 | 67 | 60 | 5 | 133 | 67 | 12 | 4 | | \$1,457 | |
| CY 2017 | | | | 0 | 83 | | | | | |
| Round 2019 | 4 | 35 | 0 | 770 | 385 | 70 | 23 | | \$351 | |
| CY 2019 | | | | 0 | 20 | | | | | |
| Total Respondents | 0 | 0 | | 1418 | 385 | 130 | | | \$6,757 | |
| Annual Responses (1418 + 180/3) | 18 | 516 | 0 | 6 | 6 | | | | \$105 | |
| Total | 71 | 32 | | 391 | 494 | | | | \$8,670 | |
| Average Annual Cost | | | | | | | | | | \$2,890 |
| Annual Hour Burden | | | | | | | | | | 165 |

*PRA approval period for approximately 3 months of the calendar year

Change of Ownership (CHOW) Forms

We have made no changes to the Change of Ownership Forms, or the frequency of response from the previously approved version. However, the estimated number of respondents and per response burden has been adjusted to account for Round 2019 under this ICR. In accordance with Article V of the DMEPOS Competitive Bidding Program 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 completed by the 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 the May 2015 Occupational Employment Statistics from the Bureau of Labor Statistics, the median hourly wage for a General or Operations Manager is \$46.99. We estimate that the cost for both the selling and purchasing supplier to review the fact sheet in order to prepare the forms is \$31.01 (0.33 x \$46.99 x 2). The burden to complete and submit the CHOW Contract Supplier Notification Form is \$7.99 (0.17 hour x \$46.99) and to complete and submit the CHOW Purchaser Form is \$46.99 (1.0 hour x \$46.99). The total time and cost for each transaction is estimated to be one hour and 50 minutes and \$85.99.

We do not know how many CHOWs will occur annually. However, based on previous experience, we estimate that we will receive the following number of CHOW transaction each year: eight transactions for Round 1 2017, 80 transactions for Round 2 Recompete, four transactions for national mail-order recompete and estimate 75 when Round 2019 begins. The burden estimates for these forms are included in the following tables:

| CHOW 60 & 30 Day Notices | | | | | |
|-------------------------------------|---------------------|--------------------------|--------------------------------------|-------------------|------------------------|
| Annual Responses | | | | | |
| Calendar Year | Round 1 2017 | Round 2 Recompete | National Mail-Order Recompete | Round 2019 | Total Responses |
| CY 2017 | 8 | 80 | 4 | | 92 |
| CY 2018 | 8 | 80 | 4 | | 92 |
| CY 2019 | | | | 75 | 75 |
| CY 2020* | | | | 18 | 18 |
| Total | | | | | 277 |
| Annual Responses | | | | | 92 |

| CHOW 60 & 30 Day Notices | | | | | | |
|-------------------------------------|---------------------|--------------------------|--------------------------------------|-------------------|--------------------|-------------------|
| Burden Hours | | | | | | |
| Calendar Year | Round 1 2017 | Round 2 Recompete | National Mail-Order Recompete | Round 2019 | Total Hours | Total Cost |
| CY 2017 | 14.6 | 146.4 | 7.3 | 0 | 168.3 | \$7,908 |
| CY 2018 | 14.6 | 146.4 | 7.3 | 0 | 168.3 | \$7,908 |
| CY 2019 | 0 | 0 | 0 | 137.3 | 137.3 | \$6,452 |
| CY 2020* | 0 | 0 | 0 | 34.3 | 34.3 | \$1,612 |
| Total | 29.2 | 292.8 | 14.6 | 171.6 | 508.2 | \$23,880 |
| Average Annual Cost | | | | | | \$7,960 |
| Average Annual Hour Burden | | | | | | 169 |

*PRA approval period for approximately 3 months of the calendar year

Annual Burden Summary:

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

| Burden Summary | | | |
|-----------------------|-------------------------|---------------------|--------------------|
| Form | Annual Responses | Annual Hours | Annual Cost |
| Form A | 500 | 4,175 | \$172,845 |
| Form B | 12,000 | 138,000 | \$5,713,200 |
| Form C | 3,188 | 625 | \$10,975 |
| Form D | 21,200 | 10,600 | \$0 |
| Subcontracting | 516 | 165 | \$2,890 |
| CHOW | 92 | 169 | \$7,960 |
| Total | 36,996 | 153,734 | \$5,907,870 |

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 \$1.5 million for contractor work to operate and maintain the DBids system. These costs are more than offset by the savings resulting from program implementation: Since implementation of the DMEPOS Competitive Bidding Program on January 1, 2011, CMS has saved approximately \$220 million per year in the nine Round 1 metropolitan statistical areas (MSAs) and \$3.6 billion during the first two years in the Round 2 areas which began on July 1, 2013 due to competitive bidding and other CMS fraud, waste, and abuse initiatives.

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 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 \$25,000 per semi-annual period for all rounds of competition with a projected annual cost of \$50,000. For CY 2020, the projected cost under this PRA approval period is expected to be \$25,000 as there will only be one reporting period.

Form D Costs

Costs to the Federal government include both labor and operational expenses incurred by the CBIC. The CBIC subcontracts the beneficiary survey to another entity. The estimated cost to complete the survey for Round 1 2017 is \$61,000 and \$655,900 for Round 2 Recompete and the national mail order recompete. The estimated cost to complete the survey for Round 2019 is \$1,178,000.

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 \$56,000.

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 \$6,264 per CHOW. The operational costs include time for document control, data system modifications, posting reports, review of program requirements, financial assessment, correspondence, and postage.

Therefore, the total Cost to the federal government is \$2,798,264.

15. Changes to Burden

The variables impacting burden are unique to each round of competition. 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. We have described the anticipated variability based on historical data and/or estimates from past experience including the implementation of a consolidated round in 2019 and the new requirement for a bid surety bond for suppliers submitting a bid(s) for Round 2019.

The total burden for this package has decreased as a result of the implementation of a consolidated round of competition – Round 2019 – to include all Round 1, Round 2, and national mail-order CBAs. We are revising this package to adjust the burden accordingly. In the Background section, we have described the method to report the total burden associated with use of these forms.

The previous ICR reflected additional burden for Forms A and B because information had to be collected for Round 1 2017, Round 2 Recompete and the national mail-order recompete. This information has already been collected and therefore is not applicable for this ICR. Information collection for these forms will be applicable when bidding begins for Round 2019. In this ICR, the annual burden for Form A for Round 2019 is 500 responses and 4,175 hours. The annual burden for Form B for Round 2019 is 11,500 responses and 138,000 hours. A decreases in burden associated with these forms represent the consolidation of all CBAs into Round 2019 and more accurate estimates based on our experience from prior rounds of competition.

We have made no changes to Form C however, the estimated number of respondents and per response burden has been adjusted to account for Round 2019. The annual burden for Form C for all rounds of competition is 3,188 responses and 625 hours. Since the last ICR approval, a decrease in burden associated with a change in reporting frequency from quarterly to semi-annually, was approved under ICR 201508-0938-005.

We have made no changes to Form D however, the estimated number of respondents and per response burden has been adjusted to reflect program changes. During Round 2 Recompete we eliminated multi-state CBAs so that each CBA would exist within a single state. This was added as a program improvement for suppliers in meeting State licensure requirements. This change increased the number of CBAs from 9 to 13 in the Round 1 areas and from 100 to 117 in the Round 2 areas for a total of 140 CBAs for Round 2019. We note that we have made an adjustment to the burden estimates for the national mail-order recompete from the previous ICR. Since the beneficiary population for the competition is nationwide, a larger sample size is indicated to produce a more representative sample for this competition. Given these changes, the annual burden for Form D has increased and is projected to be 21,200 responses and 10,600 hours.

We have made no changes to the contract supplier's disclosure of subcontractors form however, the estimated number of respondents and per response burden has been adjusted to account for Round 2019. The annual burden for the Subcontractor Disclosure Form for all rounds of competition is 516 responses and 165 hours.

We have made no changes to the CHOW forms; however, the estimated number of respondents and per response burden has been adjusted to account for Round 2019. The annual burden for the CHOW Forms for all rounds of competition is 92 responses and 169 hours.

16. Publication/Tabulation Dates

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

17. Expiration Date

CMS will display the expiration date to all forms upon approval from OMB.

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.