

## Supporting Statement Part A

### **Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program – Contracting Forms CMS-10744; OMB Control Number 0938-1408**

#### **Background**

Since 1989, Medicare has been paying for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) (other than customized items) using fee schedule amounts that are calculated for each item or category of DMEPOS identified by a Healthcare Common Procedure Coding System (HCPCS) code. Payments are based on the average DMEPOS 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 (HHS) have reported that these fees are often highly inflated and that Medicare has paid higher than market rates for several different types of DMEPOS. Due to reports of Medicare overpayment of DMEPOS, 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 the successful competitive bidding demonstrations, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (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 (the Program).

CMS conducted its first round of bidding, Round 1, for the Program in 2007 with the help of its contractor, the Competitive Bidding Implementation Contractor (CBIC). CMS published a Request for Bids (RFB) and instructions for DMEPOS 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 to furnish competitively bid item(s) to Medicare beneficiaries residing or traveling to Round 1 CBAs. CMS evaluated these bids and contracted with those bidders that met all program requirements. Round 1 was successfully implemented on July 1, 2008.

On July 15, 2008, however, Congress delayed the Program in section 154 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). MIPPA mandated certain changes to the Program which included, but was not limited to: a delay of Round 1 (competition to begin in 2009) and Round 2 of the Program (competition to begin in 2011 in 70 specific MSAs); the exclusion of Puerto Rico and negative pressure wound therapy from Round 1 and Group 3 complex rehabilitative power wheelchairs from all rounds of competition; a process for providing feedback to bidders regarding missing financial documentation; and a requirement for contract suppliers to disclose to CMS information regarding subcontracting relationships. Section 154 of MIPPA specified that the competition for national mail-order (NMO) items and services may be phased in after 2010. 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 NMO competition for diabetes testing supplies (DTS) at the same time as Round 2. The Round 2 and NMO DTS contracts and prices were implemented on July 1, 2013.

The MMA requires the Secretary to recompetete contracts not less often than once every three years. The Round 1 Rebid contract period for all product categories except NMO DTS expired on December 31, 2013. (Round 1 Rebid contracts for NMO DTS ended on December 31, 2012.) The competition for the Round 1 Recompete began in August of 2012 and contracts and prices became effective on January 1, 2014. The Round 1 Recompete contract period expired on December 31, 2016. Round 1 2017 contracts were effective on January 1, 2017, and expired on December 31, 2018. Round 2 and NMO DTS contracts and prices expired on June 30, 2016. Round 2 Recompete and the NMO DTS Recompete contracts became effective on July 1, 2016, and expired on December 31, 2018.

On October 31, 2018, CMS issued a final rule (CMS-1691-F) requiring changes to bidding and pricing methodologies to be implemented under the next round of the Program. As a result, starting January 1, 2019, there was a temporary gap in the entire Program that lasted two years until December 31, 2020. When the program resumed in January 2021, CMS implemented a consolidated round of competition to include most Round 1 2017 and Round 2 Recompete CBAs for Round 2021. However, due to the 2019 novel coronavirus (COVID-19) pandemic, and the unexpected bid evaluation results, CMS only awarded Round 2021 contracts for two product categories: Off-The-Shelf (OTS) Back and OTS Knee Braces. As a result, this Paperwork Reduction Act (PRA) package reflects a significant reduction in burden, compared to previous packages, for Round 2021 which was implemented on January 1, 2021, and will concluded on December 31, 2023. This package is based on data from the first year of Round 2021 (January 1, 2021- December 31, 2021).

## **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 DMEPOS 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.

### **2. Information Users**

#### **Form C**

Form C collects prospective information on the brands of products contract 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 Medicare.gov to help customer service representatives at 1-800-MEDICARE, clinicians, beneficiaries, caregivers, etc. locate contract suppliers that furnish specific products.

### **Subcontracting**

By law, contract suppliers must disclose each subcontracting relationship they have for furnishing items and services under their contract within 10 days of entering into their competitive bidding contract with CMS. Contract suppliers are also required to disclose with CMS, within 10 days, all subsequent subcontracting relationships entered into during the competitive bidding contract period of performance. The contract supplier must report the name of the subcontractor, the services the subcontractor will perform, and whether the subcontractor is accredited, if applicable. Subcontractors must be accredited if they set up or provide instructions on the use of the equipment. CMS uses the information collected on the subcontracting disclosure form to verify subcontracted suppliers are accredited based on the services they will perform. The subcontracting reporting requirement has assisted CMS in monitoring the use of subcontractors by contract suppliers and that the subcontractors are accredited, if applicable.

### **Change of Ownership**

CMS collects information from DMEPOS suppliers going through a Change of Ownership (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 regulation. 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.

### **Grandfathering**

In the previous package, CMS indicated that non-contract suppliers would be required to notify beneficiaries if they've elected to become a grandfathered supplier so beneficiaries would be aware if they can continue to rent an item(s) from their current supplier or if they must switch to a contract supplier. In Round 2021 there are no rented items. Therefore, in this package based on Round 2021 statistics, CMS removes the Grandfathering form, as well as removes the burden discussion as this collection of information did not occur for Round 2021 of the Program.

## **3. Use of Information Technology**

### **Form C**

Contract suppliers fill out Form C online in Connexion, the Program's secure portal, throughout the contract period of performance. Form C is required semi-annually to update the Medicare.gov Supplier Directory with any changes to the brands of products contract suppliers' offer. Form C must be digitally signed in Connexion by a contract supplier's Authorized Official (AO), Backup Authorized Official (BAO), or End User (someone whom the contract supplier trusts to conduct company business and can assist the AO and BAO by signing and submitting Form C in Connexion). Assistance and technical support is available to help contract suppliers in completing Form C. CMS uses electronic methods such as listserv messages to communicate information regarding Form C.

### **Subcontracting**

Subcontracting information from contract suppliers is collected in Connexion 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 performing (i.e., inventory, delivery and set up, and/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. When applicable, a contract supplier's AO, BAO, or EU can fill out the Subcontracting Disclosure form online in Connexion throughout the contract period of performance, when necessary. No signature is required on this form.

### **Change of Ownership**

Contract suppliers going through a CHOW are required to complete the CHOW Notification form online in Connexion. This form is designed to make it easier for contract suppliers to notify CMS of impending CHOWs as required by regulation. This form also provides CMS with pertinent information to describe the CHOW and provides suppliers with a checklist of additional required information they must provide for CMS to consider approving the CHOW. Contract suppliers are required to submit this form, along with other associated documentation, to the CBIC via Connexion. The CHOW Notification form requires an electronic signature in Connexion from each organization's AO or BAO.

## **4. Duplication of Efforts**

### **Form C**

This information collection does not duplicate any other effort, and the information cannot be obtained from any other source. The information collection occurs on a semi-annual basis in the months of January and July throughout the contract period. After the first data collection of the contract period, each contract supplier is required to report any new updates or "no updates" during the subsequent semi-annual data collections.

### **Subcontracting**

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 42 CFR §414.422(d)(1)(ii), a successor entity in a CHOW is not required to duplicate previously submitted information if the previously submitted information is current. CMS utilizes applicable information that is available in enrollment records or on file from the bidding process and only requests updated information when it is not on file or out of date.

## **5. Small Businesses**

These information collections impact small businesses. However, CMS has attempted to reduce the burden on small suppliers by requiring them to submit only those forms that are essential to implement 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, and online forms with checklists of other required documents.

In developing bidding and contract award procedures, section 1847 (b)(6)(D) of the Act requires CMS to take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the 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. 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 remain in effect for future rounds of competition.

## **6. Less Frequent Collection**

### **Form C**

Contract suppliers are able to update their product information on a semi-annual basis throughout the contract period of performance. We believe that semi-annual updating of product information provides contract suppliers adequate opportunity to keep their information current and provides beneficiaries timely information on the products available to them.

### **Subcontracting**

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 award. Contract suppliers are required to notify CMS any time there is a change in subcontractors during the contract period of performance.

### **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 Program. These requirements include Medicare enrollment, licensure, quality standards, accreditation, and financial standards. The CHOW process ensures the proper transfer of contractual obligations between DMEPOS contract suppliers and CMS.

## **7. Special Circumstances**

There are no special circumstances related to the collection of information for the Program.

## **8. Federal Register/Outside Consultation**

### *Federal Register*

The 60-day notice published in the Federal Register on August 5, 2022 (87 FR 48030)

### *Outside Consultation*

There was no outside consultation related to the collection of information for the Program.

## **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 maintains the confidentiality of proprietary and financial information to the extent provided by law and follows the procedure stated in 45 CFR §5.65. CMS will not share information about any bidder with other entities. However, an independent evaluator may be granted access to a bidder's information as permitted by law. Any reports that are created to evaluate the Program will be reported in an anonymous or aggregate format. Bidder information may be reviewed as required by law by the GAO and the HHS OIG, and by the Department of Justice. CMS will request that any reports created to evaluate the Program by the GAO and HHS/OIG will report information in an anonymous or aggregate format.

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

## **11. Sensitive Questions**

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

## **12. Burden Estimates (Hours and Wages)**

### **Form C**

The Form C response rate estimates for calendar year 2022 and 2023 are based on the actual Form C response rate during the first year of Round 2021 (January 1, 2021 – December 31, 2021). The burden estimates for Form C are based on the estimated time to update product brand information the contract supplier is planning to offer to Medicare beneficiaries. Contract suppliers are required to review the manufacturer and make of products and update any information that has changed since the previous semi-annual submission. Even if there are no updates to this information, contract suppliers are still required to report on this requirement on a semi-annual basis. We believe this form is completed by the equivalent of an Administrative Assistant with a mean hourly wage of \$19.75. This wage is based on the May 2021 Occupational Employment Statistics from the Bureau of Labor Statistics<sup>1</sup>. We estimate the burden for each contract supplier to complete Form C to be .2 hours<sup>2</sup> semi-annually for an annual cost of \$7.90 (\$3.95 x 2 to complete Form C twice a year). Our total burden estimates for Form C are listed in the table below. We estimate that there will be 347 respondents for Round 2021 and that we will have 100% compliance with this requirement. To calculate the annual number of responses, we multiply the 347 respondents by two for the semi-annual reporting to reach 694 responses annually. We anticipate that each response will take .2 hours, for a total of 138.8 burden hours annually. Over the two years remaining in the Round 2021 period of performance, the total hourly burden is 277.6 hours.

---

<sup>1</sup> <https://www.bls.gov/oes/current/oes436014.htm>

<sup>2</sup> For purposes of calculating hours, we assume that .1 hours = 6 minutes, .2 hours = 12 minutes, .3 hours = 18 minutes, etc.

<b>Calendar Year</b>	<b>Total Hours</b> (.2 hours x 2 semiannual reports) x 347 suppliers)	<b>Total Cost</b> ((\$3.95 x 2 semiannual reports) x 347 suppliers)
<b>2022</b>	138.8 hours	\$2,741.30
<b>2023</b>	138.8 hours	\$2,741.30
<b>TOTAL</b> <b>(over 2-year period)</b>	277.6 hours	\$5,482.60
<b>Average Annual Cost</b> <b>per supplier</b>	\$7.90	
<b>Average Annual Hour</b> <b>Burden per supplier</b>	.4 hours	
<b>Annual Number of</b> <b>Responses</b>	694	
<b>Annual Frequency of</b> <b>Responses</b>	Semiannual	

### Subcontracting

Contract suppliers 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. Pursuant to §414.422(f) the required disclosure must 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 2021 we estimate, based on actual data from the first year of the Program, that 19 Round 2021 contract suppliers will report subcontracting relationships that will include, on average, 8 subcontracting relationships per disclosure each year during the remaining two years of Round 2021 for a total of 152 disclosures.

We estimate the burden for contract suppliers to disclose the first subcontracting relationship to be approximately .4 hours. This time includes .2 hours for locating and completing the online form and .2 hours to verify the subcontractor's accreditation. An additional .2 hours is included for each additional subcontractor included with the form. The total time for the average subcontracting disclosure consisting of eight subcontractors is 1.8 hours (.4 hours for first subcontracting relationship + 1.4 hours for seven subsequent subcontracting relationships). We believe this form is completed by the equivalent of an Administrative Assistant with a mean hourly wage of \$19.75 based on the May 2021 Occupational Employment Statistics from the Bureau of Labor Statistics<sup>3</sup>. We estimate the total burden for each supplier to complete the subcontracting disclosure to be 1.8 hours and \$35.55. The annual total burden is 34.2 hours at a cost of \$675.45 for all suppliers disclosing their subcontracting relationships. We

<sup>3</sup> <https://www.bls.gov/oes/current/oes436014.htm>

estimate that over the two years remaining in Round 2021, the total burden is 68.4 hours for a total cost of \$1,350.90 for 38 contract supplier subcontractor disclosures, each with eight subcontracting relationships.

#### **Subcontracting Cost – Per Supplier**

<b>Task</b>	<b>Number of Hours to Complete Task</b>	<b>Level of Staff to Complete Task</b>	<b>Hourly Wage</b>	<b>Cost to the Supplier to Perform Task</b>
<b>Disclose initial subcontracting relationship</b>	.4 hours	Administrative Assistant	\$19.75	\$7.90 (.4 hours x \$19.75 per hour)
<b>Disclose seven subsequent subcontracting relationships</b>	.2 hours per notification x 7 subsequent notifications = 1.4 hour	Administrative Assistant	\$19.75	\$27.65 (1.4 hours x \$19.75 per hour)
<b>Total</b>	1.8 hours	Administrative Assistant	\$19.75	\$35.55

#### **Subcontracting Annualized Cost**

<b>Year</b>	<b>Hours</b>	<b>Cost</b>
<b>2022</b>	34.2 hours	\$675.45
<b>2023</b>	34.2 hours	\$675.45
<b>Total</b>	68.4 hours	\$1,350.90

#### **Change of Ownership**

In accordance with Article VI of the Program contract and §414.422(d), a contract supplier participating in a CHOW must provide CMS with notice prior to the effective date of the transaction. 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. Additionally, a signed novation agreement must be provided to CMS no later than 10 days after the effective date of the CHOW.

We estimate that it takes approximately .3 hours for contract suppliers and purchasers to review the CHOW requirements. This time includes review of the CHOW fact sheet and CHOW frequently asked questions on the CBIC website. We estimate that it takes approximately 1 hour to complete the CHOW Notification Form and gather the required additional documentation (bill of sale/letter of intent, seller's organizational chart/structure and any additional documentation to assist with determining the distinct company (if applicable), copy of seller's certificate and articles of incorporation (if a corporation), tax return extract, PTAN(s) of distinct company being sold (if applicable), financial statements, licensure and accreditation information, etc.). Without the use of the standardized form, it would take suppliers much longer to assemble and organize the required information.

The CHOW Notification form is to be completed and submitted one time only for each CHOW transaction. We believe that the process to complete and submit the form is completed by a General or Operations Manager. Based on the May 2021 Occupational Employment Statistics from the Bureau of Labor Statistics, the mean hourly wage for a General or Operations Manager is \$55.41<sup>4</sup>. We estimate that the cost for both the contract supplier and purchasing supplier to review the fact sheet in order to familiarize themselves with the CHOW process is \$33.25

<sup>4</sup> <https://www.bls.gov/oes/current/oes111021.htm>



(.3 hours x \$55.41 x 2 suppliers – seller and purchaser). The burden to complete and submit the CHOW Notification form and to gather the required additional documentation (if applicable) is \$55.41 (1 hour x \$55.41). The total time and cost for each transaction is estimated to be 1.3 hours and \$88.66.

Based on the number of CHOWs submitted during the first year of Round 2021, we estimate that we will receive 4 CHOWs per year for the remaining two years of Round 2021:

<b>Calendar Year</b>	<b>CHOWs</b>	<b>Total Hours</b>	<b>Total Cost</b>
<b>2022</b>	4	5.2	\$354.64
<b>2023</b>	4	5.2	\$354.64
<b>Total</b>	8	10.4	\$709.28

### **Annual Burden Summary**

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

<b>Burden Summary</b>			
<b>Form</b>	<b>Annual Responses</b>	<b>Annual Hours</b>	<b>Annual Cost</b>
<b>Form C</b>	694	138.8	\$2,741.30
<b>Subcontracting</b>	152	34.2	\$675.45
<b>CHOW</b>	4	5.2	\$354.64
<b>Total</b>	850	178.2	\$3,771.39

### **13. Capital Costs**

The information required is information that is readily available to DMEPOS suppliers, and they 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. 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 C**

Costs to the Federal government is de minimis with the move to fully automating the collection of Form C.

#### **Subcontracting**

Costs to the Federal government include both labor and operational expenses incurred by the CBIC. Costs include time to review disclosures and communicate with suppliers on specific issues. The annual estimated cost to process subcontracting disclosures is \$2,283. The total cost over the remaining two years of Round 2021 is \$4,566.

### **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 \$1,952.25 per CHOW. The operational costs include time for document control, data system modifications, posting reports, review of program requirements, financial assessment, correspondence, and postage. Based on reviewing and approving 4 CHOWs in the first year of Round 2021, the estimated annual cost is \$7,809, and the total cost over the remaining two years of Round 2021 is \$15,618.

### **Annual Burden Summary**

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

<b>Form</b>	<b>Annual Cost</b>	<b>Total Cost (2 years)</b>
<b>Form C</b>	\$0	\$0
<b>Subcontracting</b>	\$2,283	\$4,566
<b>CHOW</b>	\$7,809	\$15,618
<b>Total</b>	\$10,092	\$20,184

### **15. Changes to Burden**

The variables impacting burden are unique to each round of competition. Variables contributing to the burden associated with the information collection for Round 2021 include the number of contract suppliers, number of product categories, and the number of CBAs. We have described the anticipated burden based on historical data and/or estimates from past calendar year of the current round of the Program.

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

The make, manufacturer, and model data collected from contract suppliers completing Form C is used in populating and updating the Supplier Directory on Medicare.gov.

### **17. Expiration Date**

CMS will display the expiration date on the first page in the upper right corner of each document as well as in the PRA Disclosure Statement at the end of each document.