

Supporting Statement Part A

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

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), instructions, and accompanying forms 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 (NPWT) 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 the 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 recompete 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 Re compete 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 is a temporary gap in the entire Program that will last two years until December 31, 2020. When the program resumes in January 2021, CMS will be implementing a consolidated round of competition to include all Round 1 2017 and Round 2 Recompete CBAs for Round 2021.

The Program, combined with other CMS fraud, waste, and abuse initiatives, when implemented has saved Medicare over \$2 billion per year.

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.

2. Information Users

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 Medicare.gov to help customer service representatives at 1-800-MEDICARE, clinicians, beneficiaries, and caregivers 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. 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, when applicable, 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

Non-contract suppliers notifying beneficiaries if they've elected to become a grandfathered supplier is critical so beneficiaries are aware if they can continue to rent an item(s) from their current supplier or if they must switch to a contract supplier. The notification also provides beneficiaries information on how to locate contract suppliers in their CBA. In the event a beneficiary must switch to a contract supplier, the notification will identify the procedure for the pick-up of their current equipment and delivery of new equipment.

3. Use of Information Technology

Form C

Product brand information that contract suppliers enter during bidding will be used to pre-populate the Supplier Directory on Medicare.gov. Suppliers will 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 Supplier Directory with any changes to the brands of products suppliers' offer. Form C must be digitally signed in Connexion by a contract supplier's Authorized Official (AO). Assistance and technical support is available to help suppliers in completing Form C. CMS will use electronic methods such as listserv messages to communicate information regarding Form C.

Subcontracting

For suppliers that are awarded a contract, CMS, through the CBIC, will collect this information online 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. Contract suppliers will 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

Suppliers going through a CHOW will be required to complete the CHOW Notification form online in Connexion. This form is designed to make it easier for 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. Suppliers are required to submit this form, along with other associated documentation, to the CBIC. The CHOW Notification form requires an electronic signature in Connexion from each organization's AO.

Grandfathering

CMS will require that the 30-day notification to the beneficiary must be in writing (e.g., by letter or postcard) and must be sent at least 30 business days prior to the implementation of the program. An electronic method for suppliers to provide this information to the beneficiary is not permitted because it would be difficult to determine if the beneficiary would be able to receive the notification electronically.

CMS will require that the two additional notices to the beneficiary prior to picking up the equipment must be made via telephone due to the short time frame between the phone call and picking up the equipment (10 days prior to pick up and

then 2 days prior to pick up).

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 will occur 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 will utilize applicable information that is available in enrollment records or on file from the bidding process and will only request updated information when it is not on file or out of date.

Grandfathering

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

5. Small Businesses

These information collections will 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 will remain in effect for future rounds of competition.

6. Less Frequent Collection

Form C

Contract suppliers will be 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 will provide suppliers adequate opportunity to keep their information current and will provide 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 suppliers and CMS.

Grandfathering

The notification to beneficiaries of the supplier's choice of whether or not they will become a grandfathered supplier is critical in keeping the beneficiary informed and ensuring continuity of care. CMS is only requiring a one-time notification to beneficiaries if the non-contract supplier elects to become a grandfathered supplier. If the non-contract supplier does not elect to become a grandfathered supplier or the beneficiary chooses not to continue renting the item from their current supplier, the non-contract supplier will only have to send one letter to the beneficiary. They will also have to make at least two phone calls to coordinate the pickup of the old equipment and the delivery of new equipment so that the beneficiary will not have medically necessary equipment taken from their home unexpectedly.

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 Federal Register notice published July 1, 2020 (85 FR 39568). No comments were received.

The 30-day Federal Register notice published November 4, 2020 (85 FR 70166).

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 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 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 Round 2021 estimates for Form C are based on the combined total number of respondents for Round 2 Recompete and Round 1 2017. Round 2021 will include all CBAs from both Round 2 Recompete and Round 1 2017 for a total of 130. 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 will be 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, suppliers will still be required to report on this requirement on a semi-annual basis. We anticipate that this form will be completed by the equivalent of an Administrative Assistant with a median hourly wage of \$17.61. This wage is based on the May 2018 Occupational Employment Statistics from the Bureau of Labor Statistics¹. We estimate the burden for each supplier to complete Form C to be .2 hours² semi-annually for an annual cost of \$7.04 (\$3.52 x 2 to complete Form C twice a year). Our total burden estimates for Form C are listed in the table below. There were 600 respondents for Round 2 Recompete and 183 for Round 1 2017 across 130 CBAs. We therefore estimate that there will be 783 respondents for Round 2021 and that we will have 100% compliance with this requirement. To calculate the annual number of responses, we multiply the 783 respondents by two for the semi-annual reporting to reach 1,566 responses annually. We anticipate that each response will take .2 hours, for a total of 313.2 burden hours annually. Over the three year Round 2021 period of performance, the total hourly burden is 939.6 hours.

Calendar Year	Total Hours ((.2 hours x 2 semiannual reports) x 783 suppliers)	Total Cost ((\$3.52 x 2 semiannual reports) x 783 suppliers)
2021	313.2 hours	\$5,512.32
2022	313.2 hours	\$5,512.32
2023	313.2 hours	\$5,512.328
TOTAL over 3 year period	939.6 hours	\$16,536.96
Average Annual Cost per supplier	\$7.04	
Average Annual Hour Burden per supplier	.4 hours	
Annual Number of Responses	1,566	
Annual Frequency of Responses	Semiannual	

Subcontracting

Suppliers 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. 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

¹ <https://www.bls.gov/oes/2018/may/oes436014.htm>

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

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.

In Round 1 2017, an average of 14% of contract suppliers reported subcontracting relationships. In Round 2 Recompete, an average of 9% of contract suppliers reported subcontracting relationships. Of the suppliers reporting subcontracting relationships in Round 1 2017 and Round 2 Recompete, there was an average of six subcontracting relationships per supplier. Accounting for suppliers that participated in both Round 1 2017 and Round 2 Recompete, we estimate that 82 Round 2021 contract suppliers will report subcontracting relationships and each of those 82 suppliers will disclose an average of six subcontracting relationships.

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 six subcontractors is 1.4 hours (.4 hours for first subcontracting relationship + 1 hour for five subsequent subcontracting relationships). We anticipate this form will be completed by the equivalent of an Administrative Assistant with a median hourly wage of \$17.61 based on the May 2018 Occupational Employment Statistics from the Bureau of Labor Statistics³. We estimate the total burden for each supplier to complete the subcontracting disclosure to be 1.4 hours and \$24.65. We estimate that 82 suppliers will disclose approximately six subcontracting relationships each, for a total burden of 114.9 hours at a total cost of \$2,021.30 over the three year Round 2021 period of performance. The annual total burden is 38.3 hours at a cost of \$673.77 for all suppliers disclosing their subcontracting relationships.

Subcontracting Cost – Per Supplier

Task	Number of Hours to Complete Task	Level of Staff to Complete Task	Hourly Wage	Cost to the Supplier to Perform Task
Disclose initial subcontracting relationship	.4 hours	Administrative Assistant	\$17.61	\$7.04 (.4 hours x \$17.61 per hour)
Disclose five subsequent subcontracting relationship	.2 hours per notification x 5 subsequent notifications = 1 hour	Administrative Assistant	\$17.61	\$17.61 (1 hour x \$17.61 per hour)
Total	1.4 hours	Administrative Assistant	\$17.61	\$24.65

Subcontracting Annualized Cost - All Suppliers

Year	Hours	Cost
2021	38.3 hours	\$673.77
2022	38.3 hours	\$673.77
2023	38.3 hours	\$673.77
Total	114.9 hours	\$2,021.30

Change of Ownership

In accordance with Article V of the Program contract and §414.422(d), a contract supplier participating in a CHOW must

³ <https://www.bls.gov/oes/2018/may/oes436014.htm>

provide CMS with notice 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, the notice and novation agreement must be provided to CMS within 10 days of the effective date of the CHOW.

We estimate that it will take 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 will take 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 forms, 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 will be completed by a General or Operations Manager. Based on the May 2018 Occupational Employment Statistics from the Bureau of Labor Statistics, the median hourly wage for a General or Operations Manager is \$48.52⁴. 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 \$29.11 (.3 hours x \$48.52 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 \$48.52 (1 hour x \$48.52). The total time and cost for each transaction is estimated to be 1.6 hours) and \$77.63.

Based on previous experience during Round 1 2017 and the Round 2 Recompete, we estimate that we will receive 13 CHOW requests in Round 2021. The annualized burden estimates for these requests are included in the following table:

Calendar Year	CHOWs (Rounded)	Total Hours (Rounded)	Total Cost (Rounded)
2021	4.33	6.9	\$336.40
2022	4.33	6.9	\$336.40
2023	4.33	7	\$336.40
Total	13	20.8	\$1,009.19

Grandfathering

Based on Medicare claims data, there were approximately 4,212 suppliers with 7,208 locations, on average, that rented competitively bid DME or oxygen at different points in time during Round 1 2017 and the Round 2 Recompete. We do not know if suppliers will choose to use individual locations to prepare and issue beneficiary notifications from individual locations versus using a single location. However, for purposes of this PRA request, we assume that suppliers will prepare

⁴ <https://www.bls.gov/oes/2018/may/oes111021.htm>

and issue all notifications from one location. Therefore, we are using the number of suppliers that rented items during Round 1 2017 and Round 2 Recompete to estimate how many suppliers would be renting competitively bid DME or oxygen at the start of Round 2021. We estimate there will be 2,106 suppliers that will not be awarded contracts for a product category that includes DME or oxygen that they are renting to beneficiaries at the time the program is implemented and would therefore need to prepare and issue beneficiary notifications. This represents approximately 50% of all suppliers that rented competitively bid DME or oxygen during Round 1 2017 and Round 2 Recompete.

Of the 2,106 suppliers we estimate will need to prepare and issue beneficiary notifications for Round 2021, we expect 90% or 1,895 will elect to become grandfathered suppliers ($.90 \times 2,106 = 1,895$) and 10% or 211 ($.10 \times 2,106 = 211$) will choose not to grandfather.

In addition, based on September 1, 2018 to August 31, 2019 Medicare claims data, we estimate there will be 1,350,000 beneficiaries who reside in a CBA and will be renting competitively bid DME and oxygen at the start of Round 2021. Based on Round 1 2017 and Round 2 Recompete data, we estimate 675,000 ($1,350,000 \times .50 = 675,000$) beneficiaries will be renting competitively bid DME and oxygen from non-contract suppliers during Round 2021. Of the 675,000 beneficiaries, we assume 100% will continue to rent competitively bid DME and oxygen from their current supplier who elected to be a grandfathered supplier. However, since we assume 10% of non-contract suppliers will not elect to be a grandfathered supplier, we must assume only 607,500 ($675,000 \times .90 = 607,500$) beneficiaries will have the option to continue using their current supplier. The assumption that 100% of beneficiaries, if given the choice, will choose to continue renting from a grandfathered supplier is because it offers convenience, assures continuity of care, eliminates the need to have equipment removed from their home, and eliminates the burden of locating a new supplier.

**Approximate Number of Suppliers to Beneficiaries in
Relation to the Grandfathering Process for Round 2021**

Suppliers that Choose to Grandfather	
Number of Suppliers	1,895
Number of Beneficiaries	607,500
Suppliers that Choose Not to Grandfather	
Number of Suppliers	211
Number of Beneficiaries	67,500

To help reduce burden on non-contract suppliers that are required to develop and send notifications to beneficiaries, CMS will provide sample forms on the CBIC website.

The following table summarizes the estimated time and cost for all non-contract suppliers eligible to grandfather, to develop and send the appropriate 30-day notification (informing the beneficiaries the service if they are either choosing to grandfather, or choosing not to grandfather) to beneficiaries for Round 2021.

Task	Number of Hours to Complete Task	Level of Staff to Complete Task	Hourly Wage	Cost to the Supplier to Perform Task
Develop the 30-day notification to Beneficiary	.2 hours	Administrative Assistant	\$17.61	\$3.52 (0.2 hours x \$17.61 per hour)
Send the notification to Beneficiary	.1 hours per notification	Administrative Assistant	\$17.61	\$1.76 (0.1 hours x \$17.61 per hour) + \$2.00 for supplies = \$3.76 per notification

As demonstrated in the table above, we expect the per-beneficiary cost of developing the appropriate 30-day notification to equal \$3.52. We expect the cost of sending the appropriate 30-day notification to equal \$3.76 per notification sent. Based

upon the estimated number of suppliers and beneficiaries that choose to grandfather, we estimate that there would be, on average, 320 beneficiaries per supplier (607,500 beneficiaries/1,895 suppliers \approx 320). As a result, we estimate that each supplier that chooses to grandfather would send the 30-day notification on average to 320 beneficiaries. Therefore, we estimate the average cost of \$1,206.72 per supplier ($\3.76×320 beneficiaries plus the development cost for the letter of \$3.52). The estimated aggregate cost for the 1,895 suppliers to provide the 30-day notification to their beneficiaries, is \$2,286,734.40 ($\$1,206.72$ per supplier \times 1,895 suppliers = \$2,286,734.40).

The following table summarizes the approximate time and cost for suppliers that choose to grandfather to comply with the mandatory notification requirements for Round 2021.

Approximate Burden to Suppliers that Choose to Grandfather

	Hours		Cost	
	Per Supplier	Aggregate	Per Supplier	Aggregate
Round 2021 30-Day Notification to Beneficiary	.2 hours for development + (.1 hours per notification \times 320 beneficiaries) = 32.2 hours	$32.2 \times 1,895 = 61,019$ hours	\$1,206.72	$\$1,206.72 \times 1,895 = \$2,286,734.40$

We assume suppliers that choose not to grandfather, which we estimate will represent 10% of non-contract suppliers renting competitively bid DME or oxygen to beneficiaries when Round 2021 of the Program goes into effect, will incur the same per beneficiary cost of developing and sending the 30-day notification to a beneficiary as those suppliers that choose to grandfather. The estimated aggregate cost for suppliers that choose not to grandfather to provide the 30-day notification to the beneficiary is \$254,617.92 ($\$1,206.72$ total cost per supplier \times 211 non-grandfathered suppliers = \$254,617.92) for Round 2021. The estimate of 211 suppliers not choosing to be grandfathered suppliers represents 10% of the total number of suppliers.

Suppliers that choose not to become a grandfathered supplier will also incur the cost of the 10-day and 2-day notifications.

For the 10-day notification to a beneficiary, we assume the supplier would make at least one phone call that would take an average of .2 hours to discuss that the beneficiary must switch to a contract supplier, the schedule for picking up the current equipment by the non-contract supplier, and the delivery of new equipment by the contract supplier. For the 2-day notification to the beneficiary, we assume that the supplier would make at least one phone call that would take an average of .2 hours to ensure that all of the arrangements are finalized and to answer any last minute questions. We anticipate that clerical staff would perform both of these tasks.

The estimated per beneficiary cost of the 10-day notification totals \$3.52 (0.2 hours \times \$17.61 per hour for an administrative assistant based on the 2018 Bureau of Labor Statistics⁵ = \$3.52). Based upon the estimated number of suppliers and beneficiaries that choose not to grandfather, we estimate that there would be, on average, 320 beneficiaries per supplier (67,500 beneficiaries/211 suppliers \approx 320). For Round 2021, the total cost for each supplier would be approximately \$2,252.80 ($\3.52×320 beneficiaries = \$1,126.40). The estimated aggregate cost for all suppliers to make the 10-day notification during Round 2021 would be approximately \$237,670.40 (211 suppliers \times \$1,126.40 per supplier = \$237,670.40). These same costs would also apply for the 2-Day notification as well. The total cost for the 10-day and the 2-day notifications would be \$475,340.80 ($\$237,670.40 \times 2$).

The following table summarizes the approximate time and cost for suppliers that choose not to grandfather to comply with the mandatory notification requirements.

⁵ <https://www.bls.gov/oes/2018/may/oes436014.htm>

Approximate Burden to Suppliers that Choose Not to Grandfather

	Hours		Cost	
	Per Supplier	Aggregate	Per Supplier	Aggregate
Round 2021 30-Day Notification to Beneficiary	.2 hours for development + (.1 hours per notification x 320 beneficiaries) = 32.2 hours	32.2 hours x 211 suppliers = 6,794.2 hours	\$1,206.72 per supplier	\$1,206.72 x 211 = \$254,617.92
Round 2021 10-Day Notifications	.2 x 320 beneficiaries = 64 hours	64 hours x 211 suppliers = 13,504 hours	\$1,126.40 per supplier	\$1,126.40 x 211 = \$237,670.40
Round 2021 2-Day Notifications	.2 x 320 beneficiaries = 64 hours	64 hours x 211 suppliers = 13,504 hours	\$1,126.40 per supplier	\$1,126.40 x 211 = \$237,670.40
Aggregate of Round 2021	160.2 hours	33,802.2 hours	\$3,459.52	\$729,958.72

Annualized Burden Estimates (Based on 3-year OMB Approval Period)

	Respondents (suppliers)	Responses (rounded per respondent)	Total Responses	Total Time (rounded hours)	Total Responses (Annualized)	Total Time (Annualized) (rounded hours)
Suppliers that Choose to Grandfather - Round 2021 (30-Day Notification to Beneficiary)	1,895	320	607,500	61,019 hours	202,500	20,340
Suppliers that Choose Not to Grandfather - Round 2021 (30-Day Notification to Beneficiary)	211	320	67,500	6,794 hours	22,500	2,264
Suppliers that Choose Not to Grandfather - Round 2021 (10-Day Notification)	211	320	67,500	13,504 hours	22,500	4,500
Suppliers that Choose Not to Grandfather - Round 2021 (2-Day Notification)	211	320	67,500	13,504 hours	22,500	4,500
TOTAL					270,000	31,604

Annual Burden Summary

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

Burden Summary			
Form	Annual Responses (Rounded)	Annual Hours (Rounded)	Annual Cost (Rounded)
Form C	1,566	470	\$8,268
Subcontracting	27	38	\$674
CHOW	4	7	\$336
Grandfathering	270,000	31,606	\$1,005,564
Total	271,597	32,121	\$1,014,842

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 include both labor and operational expenses incurred by the 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 \$47,260 per semi-annual period for all rounds of competition with a projected annual cost of \$94,520. The total cost over the three-year contract is \$283,560.

Subcontracting

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, data storage, and communicate with suppliers on specific issues. The annual estimated cost to process subcontracting disclosures is \$11,152. The total cost over the three-year contract is \$33,456.

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 \$150 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 13 CHOWs, the estimated annual cost is \$650 and the total cost over the three-year contract is \$1,950.

Grandfathering

There will be no cost to the government for this requirement.

Annual Burden Summary

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

Form	Annual Cost	Total Cost (3 years)
Form C	\$94,520	\$238,560
Subcontracting	\$11,152	\$33,456
CHOW	\$650	\$1,950
Grandfathering	\$0	\$0
Total	\$106,322	\$318,966

15. Changes to Burden

This is a new information collection request. The variables impacting burden are unique to each round of competition. Variables contributing to burden include the number of bidders, the number of bids, number of product categories, and the number of CBAs. We have described the anticipated burden based on historical data and/or estimates from past experience. Our next round of competition will include the Round 1 2017 and Round 2 Recompete CBAs, which provide a basis to estimate the anticipated burden associated with Round 2021. These assumptions also account for our experience from prior rounds of competition, more bidders who are experienced with the Program, information technology efficiencies in the bidding process, and the bidding methodology.

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 at the bottom of all forms upon approval from OMB. It will also be included in the PRA Disclosure Statement along with the OMB control number.