

Supporting Statement – Part A
Grandfathering Provisions of the Medicare DMEPOS Competitive Bidding Program
CMS-10309 (OCN 0938-1079)

Background of the Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program and Grandfathering

Section 1847(a)(4) of the Social Security Act (the Act) requires that in the case of covered durable medical equipment (DME) items for which payment is made on a rental basis under section 1834(a) of the Act, and in the case of oxygen for which payment is made under section 1834(a)(5) of the Act, the Secretary shall establish a grandfathering process by which covered items and supplies that were rented by suppliers before the implementation of a competitive bidding program may be continued.

We established the grandfathering process in the April 10, 2007 final rule for competitive bidding (72 FR 17992) for rented DME and oxygen and oxygen equipment when these items are included under the Medicare DMEPOS Competitive Bidding Program. This process only applies to suppliers that rented DME and oxygen and oxygen equipment to beneficiaries who maintain a permanent residence in a competitive bidding area (CBA) before the implementation of the competitive bidding program. We subsequently published sub-regulatory guidance in the Medicare Claims Processing Internet Only Manual (IOM) to establish notification guidelines for these suppliers. In summer 2010, we incorporated this notification process outlined in the IOM in a notice of proposed rulemaking and sought public comment on making these mandatory requirements.

On November 25, 2009, we issued a regulation (71 FR 61738) that finalized the requirements for suppliers to provide written notification to beneficiaries of their intention to be a grandfathered supplier for certain items.

The notification the noncontract supplier must send to the beneficiary if they elect to become a grandfathered supplier must meet the following requirements:

- It must be sent by the supplier to the beneficiary at least 30 business days before the start date of the implementation of the competitive bidding program in the CBA in which the beneficiary resides. The 30-day notice is necessary to give the beneficiary sufficient time before the start of the competitive bidding program to consider whether or not to continue to use their current supplier.
- It must identify the grandfathered items that the supplier is willing to continue to rent to the beneficiary.
- It must be sent by letter or postcard. The supplier must maintain documentation that the notification was sent including the date it was sent.
- It must state that the supplier is offering to continue to furnish certain rented DME, oxygen and oxygen equipment, and supplies that the supplier is currently furnishing to the beneficiary (i.e., before the start of the competitive bidding program) and is willing to continue to provide these items to the beneficiary for the remaining rental months.
- It must state that the beneficiary has the choice to continue to receive a grandfathered item(s) from the grandfathered supplier or may elect to receive the item(s) from a contract supplier after the end of the last month for which a rental payment is made to the noncontract supplier.

- It must provide the supplier's telephone number and instruct the beneficiaries to call the supplier with any questions and to notify the supplier of his/her election.
- It must state that the beneficiary can obtain information about the competitive bidding program by calling 1-800-MEDICARE or accessing www.medicare.gov on the internet.

In the event that the beneficiary chooses not to continue with the current supplier or the noncontract supplier does not agree to become a grandfathered supplier then the supplier must provide two notices to the beneficiary regarding the pick-up of equipment. The two notices include a 10-day and 2-day notice prior to picking up the equipment.

The November 25, 2009 regulation also specified that suppliers that wish to become a grandfathered supplier provide written notification to CMS of their choice to become a grandfathered supplier. However, we have determined that we can determine a supplier's grandfathering election through claims data. Therefore, to avoid unnecessary and duplicative reporting and to reduce burden on suppliers, CMS no longer requires noncontract suppliers to notify CMS of their intent to grandfather.

A. Justification

1. Need and Legal Basis

Section 1847(a)(4) of the Act requires that in the case of covered DME items for which payment is made on a rental basis under section 1834(a) of the Act, and in the case of oxygen for which payment is made under section 1834(a)(5) of the Act, the Secretary shall establish a grandfathering process by which covered items and supplies that were rented by suppliers before the implementation of a competitive bidding program may be continued.

We established the grandfathering process in the April 10, 2007 final rule for competitive bidding (72 FR 17992) for rented DME and oxygen and oxygen equipment when these items are included under the Medicare DMEPOS Competitive Bidding Program. This process only applies to suppliers that rented DME and oxygen and oxygen equipment to beneficiaries who maintain a permanent residence in a CBA before the implementation of the competitive bidding program.

The competitive bidding program will require some beneficiaries to change their suppliers. In order to avoid a beneficiary being without medically necessary equipment we felt it necessary to establish this notification process.

2. Information Users

a. Notification to Beneficiaries

The notification to the beneficiaries is a beneficiary protection that will keep them informed of whether or not they can continue to rent an item from their current supplier or go to a contract supplier. The notification will also provide information to the beneficiary as to how to find a contract supplier in their

CBA. In the event that the beneficiary must go 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

a. Notification to Beneficiaries

CMS will require that 100% of the 30-day notification be submitted to the beneficiary in hardcopy format. An electronic means for suppliers to provide this information to the beneficiary is not feasible because it would be difficult to determine if the beneficiary would be able to receive the notification electronically.

CMS will require that 100% of the two equipment pick up notices must be made electronically via the telephone due to the short time between the call and the action of picking up equipment (10 days prior and then two days prior).

4. Duplication of Efforts

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

5. Small Businesses

This information collection request will impact small businesses. However, we have reduced the burden on these suppliers by requiring only those notifications that are essential to ensuring access to all beneficiaries. We have also minimized the burden by offering sample forms for the written notification and by requiring that two out of the three notices to the beneficiaries are made via telephone.

6. Less Frequent Collection

a. Notification to Beneficiaries

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. We are only requiring a one-time notification to beneficiaries if the supplier wishes to become a grandfathered supplier. If the supplier chooses not to become a grandfathered supplier or the beneficiary chooses not to continue renting the item from their current supplier, the supplier will have to send one letter to the beneficiary. They will also have to make at least two phone calls to coordinate the pickup of 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 for the collection of this information.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on April 1, 2016.

9. Payments/Gifts to Respondents

Noncontract suppliers who wish to be grandfathered suppliers are required to disclose this information. We will not be providing gifts or any payments (other than remuneration under the contract) to respondents.

10. Confidentiality

a. Notification to Beneficiaries

There is no need for confidentiality of this information. This disclosure does not contain proprietary information, but rather information that suppliers make accessible to the public.

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

Based on Medicare claims data, there were approximately 2,045 suppliers with 3,970 locations, on average, that rented competitively bid DME items or oxygen at different points in time during the Round 1 Recompete. Conducted from January 1, 2014 – December 31, 2016.

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 will assume that suppliers will prepare and issue all notifications from one location. Therefore, we are using the number of suppliers that rented items during the Round 1 Re-compete to estimate how many suppliers would be renting a DME or oxygen competitively bid item at the start of Round 1 2017 . We do not know how many of these suppliers will not become contract suppliers for particular product categories; however, for purposes of this PRA request, we estimate, there could be 1,023 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 the total suppliers that rented oxygen or DME competitively bid items during Round1 Recompete.

Of the 1,023 suppliers we estimate will need to prepare and issue beneficiary notifications for Round 1 2017, we expect that 90% or 921 will offer to become grandfathered suppliers (.90 x 1,023 = 921) and 10% or 102 (.10 x 1,023 = 102) of the suppliers will choose not to grandfather. As a result, we assume most suppliers will not be required to pick up their items before the end of the full rental period.

In addition, based on 2015 Medicare claims data, we estimate that there will be 200,000 beneficiaries who reside in a CBA and will be renting DME and oxygen competitively bid items at the start of Round

1 2017. Based on Round 1 Re-compete experience, we estimate that there would be 100,000 (200,000 x 0.50 = 100,000) beneficiaries who would be renting items from a noncontract supplier during Round 1 2017. Of the 100,000 beneficiaries, we assume that approximately 100% of these beneficiaries will accept the offer to continue to rent competitively bid items from the noncontract supplier that offers to be a grandfathered supplier. We base the assumption that beneficiaries will choose to continue to rent from a grandfathered supplier if given the choice, because it offers convenience, assures continuity of care, and eliminates the need to have equipment taken from their home.

**Approximate Number of Suppliers to Beneficiaries in
Relation to the Grandfathering Process for Round 1 2017**

Suppliers that Choose to Grandfather	
Number of Suppliers	921
Number of Beneficiaries	100,000
Suppliers that Choose Not to Grandfather	
Number of Suppliers	102
Number of Beneficiaries	9,996

a. Notification Requirements for Suppliers that Choose to Grandfather

- **Notification to the Beneficiary**

To help reduce burden on suppliers that are required to develop and send notifications to beneficiaries, we will make sample forms available on the Competitive Bidding Implementation Contractor (CBIC) website.

The following chart summarizes the estimated time and cost for a supplier that chooses to grandfather to develop and send the notification to beneficiaries for Round 1 2017.

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	.25 hours	Clerical staff	\$17.30 (based on May 2014 data from the Bureau of Labor Statistics plus an increase for overhead and fringe benefits of 40%.)	\$4.33 (.25 hours x \$17.30 per hour)
Send the notification to Beneficiary	5 minutes per notification	Clerical staff	\$17.30 (based on May 2014 data from the Bureau of Labor Statistics plus an	\$1.44 (0.083 hour to send the notification x \$17.30 per hour) + \$2.00 for

			increase for overhead of 40%)	supplies = \$3.44 per notification
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As demonstrated in the chart above, we expect that the per beneficiary cost of developing the 30-day notification would equal \$4.33. We expect the cost of sending the 30-day notification per beneficiary to equal \$3.44 per notification. Based upon the estimated number of suppliers and beneficiaries, we estimate that there would be, on average, 98 beneficiaries per supplier (100,000 beneficiaries/1,023 suppliers = 98). As a result, we estimate that each supplier that chooses to grandfather would send the 30-day notification on average to 98 beneficiaries. Therefore, we estimate the average cost of \$342 per supplier (\$3.44 x 98 beneficiaries plus the development cost for the letter of \$4.33). The estimated aggregate cost for the 921 suppliers to provide the 30-day notification to their beneficiaries, is \$314,982 (\$342 per supplier x 921 suppliers = \$314,982).

- **Total Burden to Suppliers that Choose to Grandfather**

The following chart summarizes the approximate time and cost for suppliers that choose to grandfather to comply with the mandatory notification requirements for Round 1 2017.

Approximate Burden to Suppliers that Choose to Grandfather

	Hours		Cost	
	Per Supplier	Aggregate	Per Supplier	Aggregate
Round 1 2017 30-Day Notification to Beneficiary	.25 hours for development + (5 minutes per notification x 98 beneficiaries) = 8.4 hours	(.25 hours + .083 x 98) x 921 = 7,722 hours	\$342	\$342 x 921 = \$314,982

b. Notification Requirement for Suppliers that Choose Not to Grandfather

- **30-day Notification to the Beneficiary**

We assume that suppliers that choose not to grandfather, which we estimate will represent 10% of the suppliers that will be renting competitively bid DME or oxygen to beneficiaries when the program goes into effect for a round, 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 \$34,884 (\$342 total cost per supplier x 102 non-grandfathered suppliers = \$34,884) for Round 1 2017. The estimate of 102 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.

- **10-day and 2-day Notification**

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 15 minutes to discuss that the beneficiary must switch to a contract supplier, the schedule for picking up the current equipment by the noncontract 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 15 minutes 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 \$4.33 (0.25 of an hour x \$17.30 per hour for clerical staff based on the 2014 Bureau of Labor Statistics including overhead and fringe benefits = \$4.33). We assume the cost of the 2-day notification to total \$4.33, as well. Therefore, the 10-day and 2-day notifications for each beneficiary would cost approximately \$8.66. For Round 1 2017, the total cost for each supplier would be approximately \$849 (\$8.66 x 98 beneficiaries = \$849). The estimated aggregate cost for all suppliers to make the 10-day and 2-day notifications during Round 1 2017 would be approximately \$86,598 (102 suppliers x \$849 per supplier = \$86,598).

- **Total Burden to Suppliers that Choose Not to Grandfather**

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

Approximate Burden to Suppliers that Choose Not to Grandfather

	Hours		Cost	
	Per Supplier	Aggregate	Per Supplier	Aggregate
Round 1 2017 30-Day Notification to Beneficiary	.25 hours for development + (5 minutes per notification x 98 beneficiaries) = 8.4 hours	(.25 hours + .083 x 98) x 102 = 855 hours	\$342 per supplier	\$342 x 102 = \$34,884
Round 1 2017 10-Day and 2-Day Notifications	30 minutes x 98 beneficiaries = 49 hours	49 hours x 102 = 4,998	\$849 per supplier	\$849 x 102 = \$86,598
Round 1 2017 Aggregate for 30-day notification to the Beneficiary and the 10-Day & 2-Day Notifications	57.4 hours (8.4 hours + 49 hours)	5,853 hours (855 hours + 4,998 hours)	\$1,191 (\$342 + \$849)	\$121,482 (\$34,884 + \$86,598)

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

	Respondents (suppliers)	Responses (per respondent)	Total Responses	Total Time	Total Responses (Annualized)	Total Time (Annualized)
Suppliers that Choose to Grandfather - Round 1 2017 (30-Day Notification to Beneficiary)	921	98	90,258	7,752	33,334	2,584
Suppliers that Choose Not to Grandfather - Round 1 2017 (30-Day Notification to Beneficiary)	102	98	9,996	855	3,332	285
Suppliers that Choose Not to Grandfather - Round 1 2017 (10-Day and 2-Day Notifications)	102	98	9,996	4,998	3,332	1,666
TOTAL					39,998	4,535

13. Capital Costs

The suppliers should have the equipment necessary to collect information regarding the beneficiary’s choice to continue or to not to continue renting equipment from the supplier. The supplier should also have the equipment necessary to send the notifications. 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

a. Notification to Beneficiaries

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

15. Changes to Burden

a. Notification to Beneficiaries

The burden associated with this ICR is decreasing and adjusted by annualizing the one-time burden estimates.

For this approval period, the burden estimates have been updated by removing the estimates that were related to Round 2 and updating the estimates for the implementation of Round 1 2017. The burden estimates to develop and send the 30-day notification to beneficiaries for Round 1 has changed from the previous version because we estimate that there will be more beneficiaries who reside in a CBA and will be renting DME and oxygen competitively bid items at the start of Round 1 2017. This increases the

time required to develop and send the notification. Additionally, the cost to the supplier to develop and send the notifications has increased as the median hourly wage for clerical staff has increased according to the May 2014 data from the Bureau of Labor Statistics.

16. Publication/Tabulation Dates

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

17. Expiration Date

CMS has provided an expiration date for purposes of approval however, the form is a sample and suppliers may elect to develop their own forms (provided it contains all required elements)

B. Collection of Information Employing Statistical Methods

The use of statistical methods does not apply.