

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 CBA before the implementation of the competitive bidding program. We subsequently published subregulatory 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 that finalized the requirements for suppliers to provide written notification to beneficiaries of their intention to be a grandfathered supplier for certain items. (See 74 FR 61738.)

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 competitive bidding area (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 will no longer require 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 4, 2013 (78 FR 20323). No comments were received.

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 2,300 suppliers with 3,688 locations, on average, that rented competitively bid DME items or oxygen at different points in time during the Round 1 Rebid. 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 Rebid to estimate how many suppliers would be renting a DME or oxygen competitively bid item at the start of Round 1 Recompete. 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 1,150 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 R1 Rebid. At the start of Round 2 of the competitive bidding program, we estimate that an average of 8,900 suppliers with 13,500 locations will be renting a DME or oxygen competitively bid item. This number is based on 2011 Medicare claims data. We do not know how many of these suppliers will not become contract suppliers for specific product categories or who will choose to prepare and issue notifications from one location versus a single location; however, for purposes of this PRA request, we estimate there could be 6,942 noncontract suppliers that would be renting DME or oxygen competitive bid items at the time the program is implemented. This represents approximately 78% of the total suppliers that rented competitively bid oxygen or DME items in 2011.

Of the 1,150 suppliers we estimate will need to prepare and issue beneficiary notifications for the Round 1 Recompete, we expect that 90% or 1,035 will offer to become grandfathered suppliers ($.90 \times 1,150 = 1,035$) and 10% or 115 ($.10 \times 1,150 = 115$) of the suppliers will choose not to grandfather. For Round 2 of the competitive bidding program, of the 6,942 suppliers we estimate will need to prepare and issue beneficiary notifications, we expect that 90% or 6,248 will offer to become grandfathered suppliers ($.90 \times 6,942 = 6,248$) and 10% or 694 ($.10 \times 6,942 = 694$) 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 2011 Medicare claims data, we estimate that there will be 100,000 beneficiaries who reside in a CBA and will be renting DME and oxygen competitively bid items at the start of the Round 1 Recompete. Based on Round 1 Rebid experience, we estimate that there would be 50,000 ($100,000 \times 0.50 = 50,000$) beneficiaries who would be renting items from a noncontract supplier during Round 1 Recompete. Of the 50,000 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. At the start of Round 2 of the competitive bidding program, we estimate that there will be 2 million beneficiaries who reside in a CBA and are renting Round 2 competitively bid DME and oxygen items. This number is based on 2011 Medicare claims data. We estimate that there would be 1,560,000 ($2,000,000 \times .78 = 1,560,000$) beneficiaries who would be renting items from a noncontract supplier during Round 2. Of the 1,560,000 beneficiaries, we assume 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 the Round 1 Recompete**

Suppliers that Choose to Grandfather	
Number of Suppliers	1,035
Number of Beneficiaries	50,000
Suppliers that Choose Not to Grandfather	
Number of Suppliers	115
Number of Beneficiaries	4,945

**Approximate Number of Suppliers to Beneficiaries in
Relation to the Grandfathering Process for the Round 2**

Suppliers that Choose to Grandfather	
Number of Suppliers	6,248
Number of Beneficiaries	1,560,000
Suppliers that Choose Not to Grandfather	
Number of Suppliers	694
Number of Beneficiaries	173,500

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 the Round 1 Recomplete and Round 2.

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	\$15.87 (based on May 2011 data from the Bureau of Labor Statistics plus an increase for overhead and fringe benefits of 40%.)	\$3.97 (.25 hours x \$15.87 per hour)
Send the notification to Beneficiary	5 minutes per notification	Clerical staff	\$15.87 (based on May 2011 data from the Bureau of Labor Statistics plus an increase for overhead of 40%)	\$1.32 (0.083 hour to send the notification x \$15.87 per hour) + \$2.00 for supplies = \$3.32 per notification

As demonstrated in the chart above, we expect that the per beneficiary cost of developing the 30-day notification would equal \$3.97. We expect the cost of sending the 30-day notification per beneficiary to equal \$3.32 per notification. Based upon the estimated number of suppliers and beneficiaries, we estimate that there would be, on average, 43 beneficiaries per supplier (50,000 beneficiaries/1,150 suppliers = 43). As a result, we estimate that each supplier that chooses to grandfather would send the 30-day notification on average to 43 beneficiaries. Therefore, we estimate the average cost of \$147 per supplier (\$3.32 x 43 beneficiaries plus the development cost for the letter of \$3.97). The estimated aggregate cost for the 1,035 suppliers to provide the 30-day notification to their beneficiaries, is \$151,866 (\$146.73 per supplier x 1,035 suppliers = \$151,866).

For Round 2, we estimate that there would be, on average 250 beneficiaries per supplier (1,560,000 beneficiaries/6,248 suppliers = 250). As a result, we estimate that each supplier that chooses to grandfather would send the 30-day notification on average to 250 beneficiaries. Therefore, we estimate the average cost of \$834 per supplier ($\3.32×250 beneficiaries plus the development cost for the letter of $\$3.97$). The estimated aggregate cost for the 6,248 suppliers to provide the 30-day notification to their beneficiaries is $\$5,210,645$ ($\$833.97$ per supplier \times 6,248 suppliers = $\$5,210,645$).

- **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 the Round 1 Recompete and Round 2.

Approximate Burden to Suppliers that Choose to Grandfather

	Hours		Cost	
	Per Supplier	Aggregate	Per Supplier	Aggregate
Round 1 Recompete 30-Day Notification to Beneficiary	.25 hours for development + (5 minutes per notification \times 43 beneficiaries) = 3.8 hours	.25 hours + $(.083 \times 43) \times 1,035 = 3,953$ hours	\$146.73	$\$146.73 \times 1,035 = \$151,866$
Round 2 30-Day Notification to Beneficiary	.25 hours for development + (5 minutes per notification \times 250 beneficiaries) = 21 hours	.25 hours + $(.083 \times 250) \times 6,248 = 131,208$ hours	\$833.97	$\$833.97 \times 6,248 = \$5,210,645$

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 $\$16,874$ ($\$146.73$ total cost per supplier \times 115 non-grandfathered suppliers = $\$16,874$) for Round 1 Recompete. The estimate of 115 suppliers not choosing to be grandfathered suppliers represents 10% of the total number of suppliers. For Round 2, we also estimate that 10% of suppliers that could grandfather (694 suppliers) will choose not to do so. Therefore, the estimated aggregate cost for these suppliers to provide the 30-day notification to the beneficiary, is $\$578,775$ ($\$833.97$ total cost per supplier \times 694 non-grandfathered suppliers = $\$578,775$).

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 \$3.97 (0.25 of an hour x \$15.87 per hour for clerical staff based on the 2011 Bureau of Labor Statistics including overhead and fringe benefits = \$3.97). We assume the cost of the 2-day notification to total \$3.97, as well. Therefore, the 10-day and 2-day notifications for each beneficiary would cost approximately \$7.94. For the Round 1 Recompete, the total cost for each supplier would be approximately \$341.42 (\$7.94 x 43 beneficiaries = \$341.42). The estimated aggregate cost for all suppliers to make the 10-day and 2-day notifications during the Round 1 Recompete would be approximately \$39,263.30 (115 suppliers x \$341.42 per supplier = \$39,263.30). For Round 2, the total cost for each supplier would be approximately \$1,985 (\$7.94 x 250 beneficiaries = \$1,985). The estimated aggregate cost for all suppliers to make the 10-day and 2-day notifications during Round 2 would be approximately \$1,377,590 (694 suppliers x \$1,985 per supplier = \$1,377,590).

- **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 Recompete 30-Day Notification to Beneficiary	.25 hours for development + (5 minutes per notification x 43 beneficiaries) = 3.8 hours	.25 hours + (.083 x 43) x 115 = 439 hours	\$146.73 per supplier	\$146.73 x 115 = \$16,874
Round 1 Recompete 10-Day and 2-Day Notifications	30 minutes x 43 beneficiaries = 21.5 hours	21.5 hours x 115 = 2,472.5	\$341.42 per supplier	\$341.42 x 115 = \$39,263
Round 1 Recompete	25.3 hours	2,911.5	\$488	\$56,137

Aggregate for 30-day notification to the Beneficiary and the 10-Day & 2-Day Notifications		hours		
Round 2 30-Day Notification to Beneficiary	.25 hours for development + (5 minutes per notification x 250 beneficiaries) = 21 hours	.25 hours + (.083 x 250) x 694 = 14,574 hours	\$833.97 per supplier	\$833.97 x 694 = \$578,775
Round 2 10-Day and 2-Day Notifications	30 minutes x 250 beneficiaries = 125 hours	125 hours x 694 = 86,750	\$1,985 per supplier	\$1,985 x 694 = \$1,377,590
Round 2 Aggregate for 30-day notification to the Beneficiary and the 10-Day & 2-Day Notifications	146 hours	101,324 hours	\$2,819	\$1,956,365

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 Recompete (30-Day Notification to Beneficiary)	1,035	43	44,505	3,953	14,835	1,318
Suppliers that Choose to Grandfather - Round 2 (30-Day Notification to Beneficiary)	6,248	250	1,562,000	131,208	520,667	43,736
Suppliers that Choose Not to Grandfather - Round 1 Recompete (30-Day Notification to Beneficiary)	115	43	4,945	439	1,648	146
Suppliers that Choose Not to Grandfather - Round 1 Recompete (10-Day and 2-Day Notifications)	115	43	4,945	2,473	1,648	824
Suppliers that Choose Not to Grandfather - Round 2 (30-Day Notification to Beneficiary)	694	250	173,500	14,574	57,833	4,858
Suppliers that Choose Not to Grandfather - Round 2 (10-Day and 2-Day Notifications)	694	250	173,500	86,750	57,833	28,917

TOTAL					654,465	79,799
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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.

The burden estimates have also been updated to reflect implementation of the Round 1 Recompete and Round 2. The burden estimates to develop and send the 30-day notification to beneficiaries has changed from the previous version because we assume that suppliers will use the sample notification form CMS is providing rather than developing their own forms. This reduces the time required to develop and send the notification. We also believe that clerical staff, rather than skilled administrative staff, will be able to develop and send the notifications.

16. Publication/Tabulation Dates

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

17. Expiration Date

These collections do not lend themselves to the displaying of an expiration date.

B. Collection of Information Employing Statistical Methods

The use of statistical methods does not apply.