

Supporting Statement – Part A

Supporting Statement For Paperwork Reduction Act Submissions

A. 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. This summer we incorporated this notification process outlined in the IOM in a notice of proposed rulemaking and sought public comment on making these mandatory requirements.

This regulation, CMS-1413-FC, finalizes the requirements for suppliers to provide written notification to beneficiaries of their intention to be a grandfathered supplier for certain items. It also specifies that suppliers that wish to become a grandfathered supplier provide written notification to CMS of their choice to become a grandfathered supplier.

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.

The notice that a noncontract supplier must provide to CMS if it elects to become a grandfathered supplier must meet the following requirements:

- It must state that the supplier agrees to continue to furnish certain rented DME, oxygen and oxygen equipment that it is currently furnishing to beneficiaries (i.e., before the start of the competitive bidding program) in a CBA and will continue to provide these items to these beneficiaries for the remaining months of the rental period.
- It must include the following:
 - Name and address of the supplier;
 - National Supplier Clearinghouse (NSC) number of the supplier; and
 - product category(s) by CBA for which the supplier is willing to be a grandfathered supplier.
- It must state that the supplier agrees to meet all the terms and conditions pertaining to grandfathered suppliers specified in the Medicare Claims Processing IOM Chapter 36 section 20.6.
- It must be provided by the supplier to CMS in writing at least 30 business days before the start date of the implementation of the Medicare DMEPOS Competitive Bidding Program.
- The process involves the supplier first deciding if they want to become a grandfathered supplier and continue renting an item to a beneficiary in a CBA. Suppliers that agree to be a grandfathered supplier for an item must agree to be a grandfathered supplier for all beneficiaries who request to continue to rent that item from them. In §414.408(j)(4) we established that Medicare beneficiaries have the choice of deciding whether they would like to continue renting from the grandfathered supplier or if they would like to switch to a contract supplier. If the grandfathered supplier is not willing to continue furnishing the item under these terms, a beneficiary must select a contract supplier that must agree to furnish the item.
- In addition, the beneficiary may elect, at any time, to transition from a grandfathered supplier to a contract supplier. In this case, the contract supplier would be required to accept the beneficiary as a customer regardless of how many rental months the grandfathered supplier has received for this item.

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.

B. 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 CMS

The notification to CMS will enable CMS to compile a list of grandfathered suppliers that will be renting DME, oxygen and oxygen equipment to beneficiaries in a CBA(s) which will also assist beneficiaries who call 1-800 Medicare.

b. 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 CMS

CMS will require that 100% of these notifications be submitted to the Competitive Bidding Implementation Contractor (CBIC) in hardcopy format for the 2009 round of competitive bidding. CMS will consider electronic means for the submission of this notification for future rounds.

b. Notification to Beneficiaries

CMS will require that 100% of the 30-day notification be submitted to the beneficiary in hardcopy

format for the 2009 round of competitive bidding. 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

In our April 2007 rule on competitive bidding, we estimated that at least 90% of DME suppliers are small suppliers. As a result, 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 requiring that two out of the three notices to the beneficiaries are made via telephone.

6. Less Frequent Collection

a. Notification to CMS

If CMS is not notified of the noncontract supplier's intention to become a grandfathered supplier, then we will not be able to administer the program effectively and beneficiaries may be vulnerable. CMS will use this information to respond to beneficiary questions about the status of their current supplier of rented equipment. It is important that CMS have a complete list of all suppliers who have chosen to become grandfathered suppliers and the grandfathered items they will provide. We are only requiring a one-time notification from the supplier.

b. Notification to Beneficiaries

The notification to beneficiaries of the supplier's choice of whether or not they will be 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 be a grandfathered supplier. If the supplier chooses not to be 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 as part of the proposed rule. The proposed rule, CMS-1413-P, published on July 13, 2009 (74 FR 33520).

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 CMS

CMS will maintain the confidentiality of proprietary and financial information to the extent provided by law.

b. 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)

While difficult to estimate, based on 2008 data, we believe there were approximately 1,850 suppliers, on average, that rented competitively bid items at different points in time during 2008. Therefore, we are using this number to indicate how many suppliers would be renting a DME competitively bid item at the start of the Round 1 rebid competitive bid program. Since not all suppliers will be awarded contracts and some may not choose to submit a bid, we estimate that in the worst case scenario, there will be 1,450 suppliers that will not be awarded contract and that would be renting DME competitive bid items at the time the program is implemented. This represents approximately 78% of the total suppliers that rented competitively bid items in 2008.

Based on our experience from the competitive bidding demonstrations, of the 1,450 suppliers that are not awarded a contract, we expect 90% or 1,305 of these noncontract suppliers will offer to be grandfathered suppliers ($.90 \times 1,450 = 1,305$) and 10% or 145 ($.10 \times 1,450 = 145$) 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 2008 data, we estimate that there will be 96,000 beneficiaries who reside in a CBA and are renting competitively bid items from suppliers at the start of the round 1 rebid. Based on the 2007 round 1 of the competitive bidding program, we estimate that there would be 74,880 ($96,000 \times 0.78 = 74,880$) beneficiaries who would be renting items from a noncontract supplier during the next round of competition. Of the 74,880 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 the Round 1 Rebid**

| Suppliers that Choose to Grandfather | |
|---|--------|
| Number of Suppliers | 1,305 |
| Number of Beneficiaries | 74,880 |
| Suppliers that Choose Not to Grandfather | |
| Number of Suppliers | 145 |
| Number of Beneficiaries | 7,540 |

a. Notification Requirements for Suppliers that Choose to Grandfather

- **Notification to CMS**

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

| 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 CMS | 2 hours | Skilled administrative staff | \$44.80 (based on 2009 data from the Bureau of Labor Statistics plus an increase for overhead and fringe benefits of 40%.) | \$89.60 (2 hours x \$44.80 per hour) |
| Send the notification to CMS | .25 hour | Clerical staff | \$22.02 (based on 2009 data from the Bureau of Labor Statistics) | \$5.51 (0.25 hour to send the notification x |

| | | | | |
|--|--|--|---------------------------------------|--|
| | | | plus an increase for overhead of 40%) | \$22.02 per hour = \$5.51) + \$2.00 for supplies |
|--|--|--|---------------------------------------|--|

The total individual costs for each supplier to notify CMS would be \$97.11 (\$89.60 for development of the letter + \$7.51 for preparing and sending each notification = \$97.11). Therefore, the estimated aggregate cost for the 1,305 suppliers, to notify CMS, is \$126,728.55 (\$97.11 per supplier x 1,305 suppliers = \$126,728.55).

- **Notification to the Beneficiary**

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

| 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 | Skilled administrative staff | \$44.80 (based on 2009 data from the Bureau of Labor Statistics plus an increase for overhead and fringe benefits of 40%.) | \$89.60 (2 hours x \$44.80 per hour) |
| Send the notification to Beneficiary | .25 hour per notification | Clerical staff | \$22.02 (based on 2009 data from the Bureau of Labor Statistics plus an increase for overhead of 40%) | \$5.51 (0.25 hour to send the notification x \$22.02 per hour) + \$2.00 for supplies = \$7.51 per notification |

As demonstrated in the chart above, we expect that the cost of developing the 30-day notification to a beneficiary would be equivalent to the cost of developing the 30-day notification to CMS (\$89.60 per notification). We also expect the cost of sending the 30-day notification per beneficiary to be equivalent to sending the 30-day notification to CMS (\$7.51 per notification). Based upon the number of suppliers and beneficiaries, we estimate that there would be, on average, 52 beneficiaries per supplier that was not awarded a contract (74,880 beneficiaries/1,450 suppliers = 52). As a result, we estimate that each noncontract supplier that chooses to grandfather would send the 30-day notification on average to 52 beneficiaries. Therefore, we estimate the average cost of \$472 per supplier (\$7.51 x 52 beneficiaries plus the development cost for the letter of \$89.60). The estimated aggregate cost for the 1,305 suppliers, to

provide the 30-day notification to their beneficiaries, is \$626,556 (\$480.12 per supplier x 1,305 suppliers = \$626,556).

- **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.

Approximate Burden to Suppliers that Choose to Grandfather

| | Hours | | Cost | |
|---|---|---|--------------|------------------------------|
| | Per Supplier | Aggregate | Per Supplier | Aggregate |
| 30-Day Notification to CMS | 2 hours and 15 minutes | (2 hours x 1,305) + (.25 hours x 1,305) = 2,936 hours | \$97.11 | \$97.11 x 1,305 = \$126,728 |
| 30-Day Notification to Beneficiary | 2 hours for development + (15 minutes per notification x 52 beneficiaries) = 15 hours | 2 hours + (.25 x 52) x 1,305 = 19,575 hours | \$480.12 | \$480.12 x 1,305 = \$626,556 |
| Aggregate for 30-day notification to CMS & Beneficiary | 17 hours and 15 minutes | 22,511 hours | \$577.23 | \$753,285 |

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 represents 10% of the total noncontract suppliers, will incur similar costs of developing and sending the 30-day notification to a beneficiary by those suppliers that choose to grandfather. The estimated aggregate cost for all suppliers to provide the 30-day notification to the beneficiary, indicating they choose not to grandfather, is \$69,617 (\$480.12 total cost per supplier x 145 non-grandfathered suppliers = \$69,617). The estimate of 145 suppliers not choosing to be grandfathered suppliers represents 10% of the total number of noncontract suppliers.

While the cost for the 30-day notification to beneficiaries will be exactly the same for all suppliers, those that choose not to become a grandfathered supplier will also incur the cost of the 10-day and 2-day notification.

- **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 cost of the 10-day notification totals \$5.51 (0.25 of an hour x \$22.02 per hour for clerical staff based on the 2009 Bureau of Labor Statistics including overhead and fringe benefits = \$5.51). We assume the cost of the 2-day notification to total \$5.51, as well. Therefore, the 10-day and 2-day notifications for each supplier would cost approximately \$11.02. The total cost for each supplier would be approximately \$573.04 (\$11.02 x 52 beneficiaries = \$573.04). The estimated aggregate cost for all suppliers to make the 10-day and 2-day notifications would be approximately \$83,090 (145 suppliers x \$573.04 per supplier = \$83,090).

- **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 |
| 30-Day Notification to Beneficiary | 2 hours for development + (15 minutes per notification x 52 beneficiaries) = 15 hours | 2 hours + (.25 x 52) x 145 = 2,175 hours | \$480.12 per supplier | \$480.12 x 145 = \$69,617 |
| 10-Day and 2-Day Notifications | 30 minutes x 52 beneficiaries = 26 hours | 26 hours x 145 = 3,770 | \$573.04 per supplier | \$573.04 x 145 = \$83,090 |
| Aggregate for 30-day notification to the Beneficiary and the 10-Day & 2-Day Notifications | 41 hours | 5,945 hours | \$1053 | \$152,707 |

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 CMS

The cost associated with this collection requirement is for the labor from the Competitive Bidding Implementation Contractor (CBIC) in collecting and reviewing the information and communicating with the contract supplier when there is missing information. We estimate that the CBIC will spend approximately 1 hour per contract supplier submission. Therefore, we estimate the cost to the Federal government would be approximately \$120,000 for 1,305 notifications.,

b. Notification to Beneficiaries

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

15. Changes to Burden

a. Notification to CMS

This is a new collection requirement due to a program adjustment to improve administrative functions.

b. Notification to Beneficiaries

We are amending our regulations to make the notification to the beneficiary a mandatory requirement. We implemented these notification requirements in the IOM Chapter 36 section 20.6.

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.