**SUPPORTING STATEMENT - PART A**
**PAPERWORK REDUCTION ACT**
**INFORMATION COLLECTION REQUIREMENT**

**PHONE SURVEYS OF PRODUCTS/SERVICES**
**FOR**
**MEDICARE PAYMENT VALIDATION**
**CMS-10112, OMB 0938-0939**

## A. Background

Title XVIII of the Social Security Act (the Act) contains various methodologies for making payment for non-physician, Medicare Part B services. For example, payment for durable medical equipment (DME) is based on a fee schedule as set forth in section 1834 of the Act. Payment for clinical diagnostic laboratory services (CDLS) is based on a fee schedule as set forth in subsection 1833(h) of the Act. Payment for prescription drugs is based on a percentage of advertised wholesale price. Ambulance services are paid on the basis of a fee schedule as set forth in 42CFR414 Subpart H. However, the Act also authorizes payment for these and other services based on other factors, when it is determined that the normal payment methodology results in allowances that are grossly excessive or grossly deficient. When this authority is applied, payment is said to be based on inherent reasonableness (IR). The current IR regulatory authority is found at 42CFR405.502(g) and (h). The regulations are based on Secs. 1842(b)(8) and (9) of the Social Security Act.

## B. JUSTIFICATION

### 1. Need and Legal Basis

The process for determining whether or not Medicare payment amounts are reasonable requires knowledge about the prices of the services in non-Medicare and the costs incurred to provide those services. The regulations governing the inherent reasonableness process of determining special payment limits require that we use valid and reliable information in our decision making. To collect price, cost, or product identification information for items or services, we need to survey the providers of those items or services. We will utilize telephone surveys based on paid Medicare claims.

The survey initiatives for which this request for clearance is being sought are considered high priorities. The surveys are intended to strengthen the Medicare program by improving the appropriateness of Medicare payment allowances. As a result, Medicare will directly benefit through improved provider relations when grossly deficient payment amounts are increased and through reductions in program costs when grossly excessive payment amounts are reduced.

The current IR regulatory authority is found at 42 CFR 405.502(g) and (h). The regulations are based on Secs. 1842(b)(8) and (9) of the Social Security Act.

## 2. Information Users

The collections of information to be used under the clearance will be in identical formats for each item surveyed, but the formats for different items may vary. For example, the data necessary to validate the payment for an item of durable medical equipment may consist of information on elements such as the wholesale cost of the item, the brand and model of the item, and the costs of delivery. In contrast, the data necessary to validate the payment for a clinical diagnostic laboratory service may consist of information on the brand and model of the instrument that was used to perform the test, the cost of testing supplies, and the costs of personnel that performed the test. We are obtaining approval of general areas to be surveyed and related abstract concepts to be employed. Therefore, prior to implementation of each survey we will submit a change request (83-C) for each item to be surveyed. The 83-C will contain the specific survey tool, related methodology, and burden estimates. The collected information will be used to validate the appropriateness of current Medicare payment amounts and to determine the necessary revision of those payment amounts when they are found to be excessive or deficient.

Only organizations (i.e. suppliers, providers, commercial health care vendors, etc.) that have provided the surveyed items to Medicare beneficiaries will be solicited for response. Further, the information solicited will pertain to specific Medicare paid claims of those organization for services provided to beneficiaries.

While decisions have not been made regarding which items will be surveyed, listed below are the top 20 categories by Medicare expenditures for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). This listing will be given careful consideration, along with other factors, in selecting items to be surveyed.

| | |
|---|---|
| Oxygen & Oxygen Equipment | Power Wheelchairs |
| Manual Wheelchairs | Nebulizers |
| Diabetic Supplies (Test Strips & Lancets) | Enteral Nutrition |
| Lower Limb Prosthetics | Hospital Beds |
| Lower Limb Orthotics | Support Surfaces |
| Ostomy Supplies | Parenteral Nutrition |
| Continuous Positive Airway Pressure Devices | Infusion Pumps |
| Respiratory Assist Devices | Diabetic Shoes |
| Eyeglasses & Lenses | Walkers |
| Upper Limb Orthotics | Spinal Orthotics |

## 3. Improved Information Technology

The collection of information does not involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. In light of the limited amount of information to be collected and the limited frequency of collection, the use of such techniques and technology are not warranted at this time. Since this will be a telephone survey, respondents will not be asked to provide any written information or to create any written record. No reduction in paperwork burden hours is assumed.

## 4. Duplication of Similar Information

The collected information will be used by CMS to validate Medicare program payments. CMS does not anticipate the occurrence of a duplication of effort or information collected because all of the solicitations pertain to the Medicare program. As a precaution, CMS will implement an internal review process that will review each survey to insure there is no internal duplication of effort.

## 5. Small Businesses

This information collection will affect small entities as well as larger businesses since providers vary from sole proprietorships to large retail chains. To minimize the burden, we have decided to structure our information collection efforts as telephone surveys so as to lessen the respondents burden. There is no requirement on respondents to provide any written response or to maintain any record.

## 6. Less Frequent Collection

The information is to be collected on an as needed basis. If the information were collected less frequently, CMS would not be able to obtain the information necessary to implement the congressionally authorized methods of assuring valid and appropriate payment amounts for Medicare services.

## 7. Special Circumstances

Each solicited respondent will be contacted by phone to alert them to the survey. Each solicited respondent will receive a written copy of the survey questions and will have the option to also receive an electronic copy by email. Each solicited respondent will be contacted by phone, two weeks after the survey questions are sent, to provide verbal responses surveyors. Each solicited respondent will also be given the option to, but will not be asked nor be required to, submit a written response (either by mail or email) in addition to the phone response if the respondent wishes to do so.

Each solicited respondent may regard their responses to be confidential. CMS will protect the confidentiality of any proprietary information to the fullest extent of the law. The collected information will be stored in a locked area with restricted access. Any reports pertaining to the collected information will be in aggregate and anonymous form.

## 8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice published on January 28, 2011 (76 FR 5179). No public comments were received.

We did not consult with persons outside the agency or representing those from whom information is to be solicited. Since the information to be collected is specific to particular

Medicare claims, it is clear that there is no alternative source for the data other than the actual providers of the services for which the claims were made. The frequency could be no less than the proposed one time per item. There is no record keeping or reporting format at issue.

Further, should the information collected lead to a decision to pursue a special limit, the process of determining such a limit has its own requirement for consultation with affected parties.

**9. Payments/Gifts to Respondents**

There will be no payments or gifts to respondents for any of the collection of information.

**10. Confidentiality**

As a matter of policy to protect the proprietary information of respondents, CMS will prevent the disclosure of individually identifiable information contained in the applications to the fullest extent of the law. Any reports pertaining to the collected information will be in aggregate and anonymous form.

**11. Sensitive Questions**

Other than the proprietary information noted above in section 10, there are no sensitive questions included in the information request.

**12. Burden Estimate (Total Hours and Wages)**

We estimate that, on average, the response time for each survey is 1 hour, which includes reading the instructions and survey, responding to questions over the phone, and research on individual claims. The "Total Annual Hours Requested" calculates to:

1.0 hr/survey x 4 surveys per year = 4 hrs
4,000 respondents x 4 hrs = 16,000 annual burden hours

The total annual estimated public cost is $800,000 (16,000 hr x $50.00/hr) assuming an estimated response time for each survey of 1.0 hours, a total of 4,000 respondents for each survey, the salaries of the respondents to be $50.00 per hour, and 4 surveys per year.

**13. Capital Costs (Maintenance of Capital Costs)**

There is no capital cost required for the collection of information.

**14. Cost to Federal Government**

The total direct salary cost to the government per survey is $18,000 assuming an estimated 600 hours for contacts, surveys and reporting and an hourly rate of $30.00.

**15. Changes to Burden**

There are no changes to burden.

**16. Publication and Tabulation Dates**

There are no publication and tabulation dates.

**17. Expiration Date**

CMS intends to display the expiration date.