SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT INFORMATION COLLECTION REQUIREMENT

PHONE SURVEYS OF PRODUCTS/SERVICES FOR MEDICARE PAYMENT VALIDATION

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)&(h). The regulations are based on Secs. 1842(b)(8)&(9) of the Social Security Act. The text of the current regulations and statutory provisions are attached (Attachments 1 and 2, respectively).

A. 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 42CFR405.502(g)&(h). The regulations are based on Secs. 1842(b)(8)&(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
Manual Wheelchairs
Diabetic Supplies (Test Strips & Lancets)
Lower Limb Prosthetics
Lower Limb Orthotics
Ostomy Supplies
Continuous Positive Airway Pressure Devices
Respiratory Assist Devices
Eyeglasses & Lenses
Upper Limb Orthotics
Power Wheelchairs
Nebulizers
Enteral Nutrition
Hospital Beds
Support Surfaces
Parenteral Nutrition
Infusion Pumps
Diabetic Shoes
Walkers
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

A 60-day Federal Register notice was published on January 28, 2008. No public comments were received for the 60-day Federal Register notice.

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)

The total annual estimated public cost is $1,000,000 or $250,000 per survey, assuming an estimated response time for each survey of 1.0 hours, a total of 500 respondents for each survey, the salaries of the respondents to be $50.00 per hour and 4 surveys per year. 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:

1hr/survey **x** 4 surveys per year = 4 hrs

2000 respondents **x** 4 hrs = 8000 annual burden hours

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. Program Changes

The Supporting Statement to OMB Form 83I from the last submission included the correct hours while the Form 83I overstated hours by 8,000 hours. This has been corrected for this submission on OMB Form 83I Part I, item "Information Collection Budget". There are no other program changes included in this submission.

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16. Publication and Tabulation Dates

There are no publication and tabulation dates.

17. Expiration Date

CMS intends to display the expiration date.

B. Collection of Information Employing Statistical Methods

We will randomly sample Medicare claims to select the providers that will be surveyed. We will stratify our sample by rural and non-rural localities. We will further stratify to assure that less populous states (the states at or below the 25th percentile population) are fully represented. Finally, we will stratify to assure an appropriate balance of areas with high, low and average consumer prices (our proxy indicator for this purpose will be the Medicare Geographical Practice Cost Index (GPCI) for the locality). We will stratify at the 1st- 25th percentile, the 26th – 75th percentile and the 75th- 100th percentile of the range of GPCIs. Within each stratum, we will sample based on the last digits of the health insurance claim number (which generally correspond to the Social Security number of the beneficiaries) to achieve the sample size desired (e.g., for a 2% sample we would select two numbers between 00 and 99 and then use claim numbers ending with those two numbers).

Our sample size will be selected with the intent of achieving mean results with 2% error rates and 95% confidence. We will use the mean and standard deviation of submitted charges to as our initial estimate for the associated cost variance to choose our sample size. As we develop trends for items and services, we will revise our estimated variances accordingly.

Attachment 1

IR Regulatory Authority – 42CFR405.502 (g)&(h)

(g) Determination of payment amounts in special circumstances—

(1). General.

(i). For purposes of this paragraph, a ``category of items or services" may consist of a single item or service or any number of items or services.

(ii). CMS or a carrier may determine that the standard rules for calculating payment amounts set forth in this subpart for a category of items or services identified in section 1861(s) of the Act (other than physician services paid under section 1848 of the Act and those items and services for which payment is made under a prospective payment system, such as outpatient hospital or home health) will result in grossly deficient or excessive amounts. A payment amount will not be considered grossly excessive or deficient if it is determined that an overall payment adjustment of less than 15 percent is necessary to produce a realistic and equitable payment amount. For CMS initiated adjustments, CMS will publish in the Federal Register an analysis of payment adjustments that exceed $100 million per year in compliance with Executive Order 12866. If CMS makes adjustments that have a significant effect on a substantial number of small entities, it will publish an analysis in compliance with the Regulatory Flexibility Act.

(iii). If CMS or the carrier determines that the standard rules for calculating payment amounts for a category of items or services will result in grossly deficient or excessive amounts, CMS, or the carrier, may establish special payment limits that are realistic and equitable for a category of items or services. If CMS makes a determination, it is considered a national determination. A carrier determination is one made by a carrier/intermediary or groups of carriers/intermediaries even if the determination applies to all State fees.

(iv). The limit on the payment amount is either an upper limit to correct a grossly excessive payment amount or a lower limit to correct a grossly deficient payment amount.

(v). The limit is either a specific dollar amount or is based on a special method to be used in determining the payment amount.

(vi). Except as provided in paragraph (h) of this section, a payment limit for a given year may not vary by more than 15 percent from the payment amount established for the preceding year.

(vii). Examples of excessive or deficient payment amounts. Examples of the factors that may result in grossly deficient or excessive payment amounts include, but are not limited to, the following:

(A). The marketplace is not competitive. This includes circumstances in which the marketplace for a category of items or services is not truly competitive because a limited number of suppliers furnish the item or service.

(B). Medicare and Medicaid are the sole or primary sources of payment for a category of items or services.

(C). The payment amounts for a category of items or services do not reflect changing technology, increased facility with that technology, or changes in acquisition, production, or supplier costs.

(D). The payment amounts for a category of items or services in a particular locality are grossly higher or lower than payment amounts in other comparable localities for the category of items or services, taking into account the relative costs of furnishing the category of items or services in the different localities.

(E). Payment amounts for a category of items or services are grossly higher or lower than acquisition or production costs for the category of items or services.

(F).There have been increases in payment amounts for a category of items or services that cannot be explained by inflation or technology.

(G). The payment amounts for a category of items or services are grossly higher or lower than the payments made for the same category of items or services by other purchasers in the same locality.

(H). A new technology exists which is not reflected in the existing payment allowances.

(2). Establishing a limit. In establishing a payment limit for a category of items or services, CMS or a carrier considers the available information that is relevant to the category of items or services and establishes a payment amount that is realistic and equitable. The factors CMS or a carrier consider in establishing a specific dollar amount or special payment method for a category of items or services may include, but are not limited to, the following:

(i). Price markup. This is the relationship between the retail and wholesale prices or manufacturer's costs of a category of items or services. If information on a particular category of items or services is not available, CMS or a carrier may consider the markup on a similar category of items or services and information on general industry pricing trends.

(ii). Differences in charges. CMS or a carrier may consider the differences in charges for a category of items or services made to non-Medicare and Medicare patients or to institutions and other large volume purchasers.

(iii). Costs. CMS or a carrier may consider resources (for example, overhead, time, acquisition costs, production costs, and complexity) required to produce a category of items or services.

(iv). Use. CMS or a carrier may impute a reasonable rate of use for a category of items or services and consider unit costs based on efficient use.

(v). Payment amounts in other localities. CMS or a carrier may consider payment amounts for a category of items or services furnished in another locality.

(3). Notification of limits

(i). National limits. CMS publishes in the Federal Register proposed and final notices announcing a special payment limit described in paragraph (g) of this section before it adopts the limit. The notices set forth the criteria and circumstances, if any, under which a carrier may grant an exception to a payment limit for a category of items or services.

(ii). Carrier-level limits.

(A). A carrier proposing to establish a special payment limit for a category of items or services must inform the affected suppliers and Medicaid agencies of the proposed payment amounts, the factors it considered in proposing the particular limit, as described in paragraphs (g)(1) through (g)(4) of this section, and solicit comments. The notice must also consider the following:

(1). The effects on the Medicare program, including costs, savings, assignment rates, beneficiary liability, and quality of care.

(2). What entities would be affected such as classes of providers or suppliers and beneficiaries.

(3). How significantly would these entities be affected.

(4). How would the adjustment affect beneficiary access to items or services.

(B). The carrier must evaluate the comments it receives. The carrier must notify CMS in writing of any final limits it plans to establish. CMS will acknowledge in writing to the carrier that it received the carrier's notification. After the carrier has received CMS's acknowledgement, the carrier must inform the affected suppliers and State Medicaid agencies of any final limits it establishes. The effective date for a final payment limit may apply to services furnished at least 60 days after the date that the carrier notifies affected suppliers and State Medicaid agencies of the final limit.

(4). Use of valid and reliable data. In determining whether a payment amount is excessive or deficient and in establishing an appropriate payment amount, valid and reliable data will be used. To ensure the use of valid and reliable data, CMS or the carrier must meet the following criteria to the extent applicable:

(i). Develop written guidelines for data collection and analysis;

(ii). Ensure consistency in any survey to collect and analyze pricing data.

(iii). Develop a consistent set of survey questions to use when requesting retail prices.

(iv). Ensure that sampled prices fully represent the range of prices nationally.

(v). Consider the geographic distribution of Medicare beneficiaries.

(vi). Consider relative prices in the various localities to ensure that an appropriate mix of areas with high, medium, and low consumer prices was included.

(vii). Consider criteria to define populous State, less populous State, urban area, and rural area.

(viii). Consider a consistent approach in selecting retail outlets within selected cities.

(ix). Consider whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population.

(x). Consider the products generally used by beneficiaries and collect prices of these products.

(xi). When using wholesale costs, consider the cost of the services necessary to furnish a product to beneficiaries.

(5). If CMS or a carrier makes a payment adjustment of more than 15 percent spread over multiple years, CMS or the carrier will review market prices in the years subsequent to the year that the initial reduction is effective in order to ensure that further reductions continue to be appropriate.

(h) Special payment limit adjustments greater than 15 percent of the payment amount. In addition to applying the general rules under paragraphs (g)(1) through (g)(4) of this section, CMS applies the following rules in establishing a payment adjustment greater than 15 percent of the payment amount for a category of items or services within a year:

(1). Potential impact of special limit. CMS considers the potential impact on quality, access, beneficiary liability, assignment rates, and participation of suppliers.

(2). Supplier consultation. Before making a determination that a payment amount for a category of items or services is not inherently reasonable by reason of its

grossly excessive or deficient amount, CMS consults with representatives of the supplier industry likely to be affected by the change in the payment amount.

(3). Publication of national limits. If CMS determines under paragraph (h) of this section to establish a special payment limit for a category of items or services, it publishes in the Federal Register the proposed and final notices of a special payment limit before it adopts the limit. The notices set forth the criteria and circumstances, if any, under which a carrier may grant an exception to the limit for the category of items or services.

(i). Proposed notice. The proposed notice—

(A). Explains the factors and data that CMS considered in determining that the payment amount for a category of items or services is grossly excessive or deficient;

(B). Specifies the proposed payment amount or methodology to be established for a category of items or services;

(C). Explains the factors and data that CMS considered in determining the payment amount or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

(D). Explains the potential impacts of a limit on a category of items or services as described in paragraph (h)(1) of this section; and

(E). Allows no less than 60 days for public comment on the proposed payment limit for the category of items or services.

(ii). Final notice. The final notice—

(A). Explains the factors and data that CMS considered, including the economic justification for any uniform fee or payment limit established; and

(B). Responds to the public comments.

(Secs. 1102, 1814(b), 1833(a), 1842(b), and (h), and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, as amended, 79 Stat. 296, 302, 310, 331; 86 Stat. 1395, 1454; 42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1).

Attachment 2.

Statutory Authority – Secs. 1842(b)(8)&(9) of the Social Security Act

(8)(A)(i) The Secretary shall by regulation –

(I) describe the factors to be used in determining the cases (of particular items or services) in which the application of this title to payment under this part[201] (other than to physicians' services paid under section 1848) results in the determination of an amount that, because of its being grossly excessive or grossly deficient, is not inherently reasonable, and

(II) provide in those cases for the factors to be considered in determining an amount that is realistic and equitable.

(ii) Notwithstanding the determination made in clause (i), the Secretary may not apply factors that would increase or decrease the payment under this part during any year for any particular item or service by more than 15 percent from such payment during the preceding year except as provided in subparagraph (B).

(B) The Secretary may make a determination under this subparagraph that would result in an increase or decrease under subparagraph (A) of more than 15 percent of the payment amount for a year, but only if--

(i) the Secretary's determination takes into account the factors described in subparagraph (C) and any additional factors the Secretary determines appropriate,

(ii) the Secretary's determination takes into account the potential impacts described in subparagraph (D), and

(iii) the Secretary complies with the procedural requirements of paragraph (9).

(C) The factors described in this subparagraph are as follows:

(i) The programs established under this title and title XIX are the sole or primary sources of payment for an item or service.

(ii) The payment amount does not reflect changing technology, increased facility with that technology, or reductions in acquisition or production costs.

(iii) The payment amount for an item or service under this part is substantially higher or lower than the payment made for the item or service by other purchasers.

(D) The potential impacts of a determination under subparagraph (B) on quality, access, and beneficiary liability, including the likely effects on assignment rates and participation rates.

(9)(A) The Secretary shall consult with representatives of suppliers or other individuals who furnish an item or service before making a determination under paragraph (8)(B) with regard to that item or service.

(B) The Secretary shall publish notice of a proposed determination under paragraph (8)(B) in the Federal Register--

(i) specifying the payment amount proposed to be established with respect to an item or service,

(ii) explaining the factors and data that the Secretary took into account in determining the payment amount so specified, and

(iii) explaining the potential impacts described in paragraph (8)(D).

(C) After publication of the notice required by subparagraph (B), the Secretary shall allow not less than 60 days for public comment on the proposed determination.

(D)(i) Taking into consideration the comments made by the public, the Secretary shall publish in the Federal Register a final determination under paragraph (8)(B) with respect to the payment amount to be established with respect to the item or service.

(ii) A final determination published pursuant to clause (i) shall explain the factors and data that the Secretary took into consideration in making the final determination.