Supporting Statement – Part A
Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals And Supporting Regulations in 42 CFR 414.800-806

CMS-10110, OMB 0938-0921

A. Background

In accordance with Section 1847A of the Social Security Act (the Act), Medicare Part B covered drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price of the drug or biological, beginning in CY 2005. The ASP data reporting requirements are specified in Section 1927 of the Act. The reported ASP data are used to establish the Medicare payment amounts. The reporting template has been revised in order to facilitate accurate collection of ASP data. An accompanying user guide with instructions on the template's use has also been created. It also includes an explanation of the data elements in the template.

B. Justification

1 . Need and Legal Basis

Section 1847A of the Act requires that the Medicare Part B payment amounts for covered drugs and biologicals not paid on a cost or prospective payment basis be based upon manufacturers' average sales price data submitted to the Centers for Medicare & Medicaid Services (CMS). The reporting requirements are specified in 42 CFR Part 414 Subpart J.

2. Information Users

CMS, specifically, the Division of Ambulatory Services, will utilize the ASP data to determine the Medicare Part B drug payment amounts for CY 2005 and beyond. The DHHS' Office of the Inspector General also uses the ASP data in conducting statutorily mandated studies.

3. Use of Information Technology

This collection of information will be via electronic media, e.g., CDs, and paper. Nearly all of the respondents submit ASP data using electronic media. The CMS is conducting business case and cost analyses to determine the feasibility and cost benefits for future electronic submission of all ASP data and signatures.

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 collection will not have a significant economic impact on small businesses. We do not believe the respondents to this collection are small businesses. If a respondent is a small business or other small entity or has few data to submit, that respondent will be able to submit their information via paper and not have to submit via a CD.

6. Less Frequent Collection

If the collection is not conducted quarterly, CMS will be unable to develop updated quarterly drug payment pricing files.

7. Special Circumstances

There are no Special Circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on July 19, 2011 (76 FR 42772). We are proposing to collect additional data elements based on our experience under the approved collection and based on our discussions with respondents.

9. Payments/Gifts to Respondents

There will be no payments or gifts to respondents.

10. Confidentiality

This information collection is authorized under Section 1927 of the Act. Section 1927(b)(3)(D) provides that the ASP data "is confidential and shall not be disclosed by the Secretary …in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—

(i) as the Secretary determines to be necessary to carry out this section,
(ii) to permit the Comptroller General to review the information provided, and
(iii) to permit the Director of the Congressional Budget Office to review the information provided."

11. Sensitive Questions

There are not questions of a sensitive nature.

12. Burden Estimates (Hours & Wages)

The burden associated with the information collection is the time and effort required by

manufacturers of Medicare Part B drugs and biologicals to prepare and submit the required data to CMS. The current information collection is approved for 720 respondents. Based on the number of respondents currently submitting ASP data, we estimate that this requirement will affect approximately 180 manufacturers who will submit each quarter.

The current information collection is approved for 28,800 hours annually. We estimate that collection of the additional data elements it will take approximately 2 additional hours for each submission of data, or 8 additional hours per year per respondent, for a total of (12 hours per response x 4 quarters)48 hours per year per respondent. Therefore, we estimate the total annual reporting burden for the revised number of respondents to be approximately 34,560 hours.

13. Capital Costs

There are minimal capital costs associated with this collection. The total annual cost burden to all respondents is estimated to be $181,440. This estimate includes labor costs for manufactures to extract data from their information systems and to compile and submit the ASP data, including signature, to CMS via overnight mail. The estimate also includes the cost of the CD and overnight mail service used to report the data.

14. Cost to Federal Government

The estimated annualized cost to the Federal Government is $200,000. This cost will include the operational expense of processing the data and the electronic interface needed to evaluate the data.

15. Changes to Burden

The burden hours were increased due to agency discretion to include collection of additional data elements.

16. Publication/Tabulation Dates

N/A

17. Expiration Date

We plan to display the expiration date.

18. Certification Statement

There are no exceptions for the certification statement.

C. Collections of Information Employing Statistical Methods

There will be no statistical methods employed in the collection of information. The universe for

the data collection is all Medicare Part B drug manufacturers.