

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 (ASP) of the drug or biological, beginning in Calendar Year (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 was revised in CY 2011 in order to facilitate accurate collection of ASP data. An accompanying user guide with instructions on the template's use was also created and included 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 Department of Health and Human Services' 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 continue to utilize Microsoft Excel spreadsheets that are typically submitted to CMS via electronic media, such as: CDs and DVDs. In the future, CMS is planning to migrate the submission of ASP data and signatures to an internet-based automated system. The data that is being collected will not change.

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 (that is, manufacturers that produce drugs and biologicals that are typically administered by injection in the physician's office) are small businesses.

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 07/21/2015. We are proposing to continue to collect ASP data 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. Confidentiality requirements appear in Section 1927(b)(3)(D) which states 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

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- (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 no sensitive questions.

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. 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. In this submission, we are correcting an arithmetic error contained in the last approved OMB submission. This correction is a downward burden adjustment. There are only 180 respondents rather than the 720 that were previously approved; however, each respondent will have quarterly submissions. The total number of responses across all respondents will be 720 (180 respondents x 4 responses per respondent).

We estimate that it will take each respondent a total of 12 hours per response and 48 hours annually. We estimate the total annual reporting burden for the number of respondents to be approximately 8,640 hours (180 respondents x 48 annual hours per respondent). The total annual cost burden to all respondents is estimated to be \$224,640. This estimate includes labor costs for manufacturers 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.

13. Capital Costs

We estimate capital costs to be \$2,000,000 for the operation and maintenance costs for the automated internet-based data intake system that has not yet been implemented.

14. Cost to Federal Government

The estimated annualized cost to the Federal Government is \$2,239,300. This cost includes \$239,300 for the operational expense of processing and receiving the data using the existing submission process. The cost estimate also includes \$2,000,000 for the operation and maintenance costs for the automated internet-based data intake system that has not yet been implemented.

15. Changes to Burden

The burden has been adjusted to correct an arithmetic error. In previously approved versions of this information collection request, the burden was miscalculated to be 34,560. The total adjustment is a decrease of 25,920 hours. This correction was also announced in the final rule that published on November 28, 2011 (76 FR 73443).

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.