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 column "Descriptive Data Corrected" is being removed from the Addendum A template of the data collection instrument because it is no longer needed. Changes in descriptive data are identified by other quality check measures that are performed when analyzing the data. In addition, the drop down list in the column instructions for the "FDA Approval Type" column of the data collection instruments and instructions will be revised to better classify products.

The cost burden estimate has increased to allow for an increase in the number of respondents due to growth in the number of Part B drugs, more niche drugs from smaller manufacturers, and payments for ESRP, OTP, etc.

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 quarterly 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 (DAS), will utilize the ASP data (ASP and number of units sold as specific in section 1847A of the Act) to determine the Medicare Part B drug payment amounts for CY 2005 and beyond. The manufacturers submit their ASP data for all of their NDCs for Part B drugs. DAS compiles the data, analyzes the data and runs the data through software to calculate the volume-weighted ASP for all of the NDCs that are

grouped within a given HCPCS code. The formula to calculate the volume-weighted ASP is the Sum (ASP * units) for all NDCs/Sum (units * bill units per pkg) for all NDCs. DAS provides ASP payment amounts for several components within CMS that utilize 1847(A) payment methodologies to implement various payment policies including, but not limited to, ESRD, OPPS, OTP and payment models. 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 addition, CMS is migrating 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. However, DAS will be requiring the manufacturer to submit the ASP data simultaneously via electronic media and the internet-based automated system.

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. As stated in section 1847A of the Social Security Act, the ASP payment limits are adjusted based on actual marketplace prices submitted each quarter by manufacturers to the CMS.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published to the Federal Register May 29, 2020 (85 FR 32397).
No public comments were received during the 60-day comment period.

The 30-day Federal register notice published to the Federal Register August 10, 2020 (85 FR 48255)

9. Payments/Gifts to Respondents

There will be no payments or gifts to respondents. Manufacturers that have a Medicaid Rebate Agreement are required to report ASP data of Part B drugs. All other manufacturers can submit voluntarily.

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 —

(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. The current information collection is approved for 720 responses. Based on the number of ASP submissions currently received, we estimate that this requirement will affect approximately 300 manufacturers who will submit each quarter. Therefore, there are 300 respondents, which report 4 times per year, equal to 1200 responses.

We estimate the total annual reporting burden for the number of respondents to be approximately 15,600 hours (1200 x13 annual hours per response). We estimate the total quarterly reporting burden for the number of respondents to be approximately 3,900 (300 x 13 quarterly hours per

response). We believe that administrative assistants will be responding to the information collection requirements. Based on the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2018) http://www.bls.gov/oes/current/oes_md.htm for Category 436014 (Secretaries and Administrative Assistants), the mean hourly wage for an administrative assistant is $18.28. [1] We have added 100% of the mean hourly wage to account for fringe and overhead benefits, which calculates to $36.56 ($18.28 + $18.28). We estimate the total annual cost to be $570,336.00 (15,600 hours x $36.56/hour) and the quarterly burden cost to be $142,584 (3,900 hours x $36.56/hour). 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 the internet-based automated system and electronic media. We estimate that it will take 10 hours to review instructions and search existing data resources; and 3 hours to gather the data, compile the data, submit via electronic media and upload to the automated system. This estimate also includes the cost of the CD and overnight mail service used to report the data. Time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection.

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

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. This cost estimate also includes $2,000,000 for the operation and maintenance costs for the automated internet-based data intake.

15. Changes to Burden

The column “Descriptive Data Corrected” is being removed from the Addendum A template of the data collection instrument because it is no longer needed. Changes in descriptive data are identified by other quality check measures that are performed when analyzing the data. In addition, the drop down list in the column instructions for the “FDA Approval Type” column of the data collection instruments and instructions will be revised to better classify products.

These minor revisions to the data collection instruments do not impact the 13 burden hours currently approved for the collection and reporting of the data, thus there are no changes to this burden (10 hours to review instructions and search existing data resources; and 3 hours to gather the data, compile the data, submit via electronic media and upload to the automated system) However, the total annual reporting burden hours has been updated to reflect an increase in the

number of respondents due to growth in the number of Part B drugs, more niche drugs from smaller manufacturers, and payments for ESRP, OTP, etc. The current information collection is approved for 720 responses and 9,360 annual reporting burden hours. Based on the number of ASP submissions currently received, we estimate that this requirement will affect approximately 300 manufacturers who will submit each quarter. Therefore, there are 300 respondents, which report 4 times per year, equal to 1200 responses.

We estimate the total annual reporting burden for the number of respondents to be approximately 15,600 hours (1200 x13 annual hours per response). The respondents will be required to submit ASP data through both, the electronic media submission and the automated internet-based data intake system, simultaneously until we have fully transitioned to the automated internet-based data intake system. Screenshots of the automated internet-based system are located within the ASP Data Collection Validation Macro User Guide.

16. Publication/Tabulation Dates

Manufacturer reporting requirements are described in section 1847A(f) of the Social Security Act which points to section 1927(b)(3). ASP data is considered confidential as described in subparagraph (D). We are not permitted to release manufacturers' ASP data.

The Medicare Part B ASP website lists the calculated ASP+6% that includes ASP data from all manufacturers (once CMS calculates prices for products categorized into the same HCPCS code). The published data is the volume weighted average of manufacturer submitted data for products within the same HCPCS code. The reported ASP for an individual manufacturer's product is not listed.

17. Expiration Date

We plan to display the expiration date on both applications internet based and electronic based.

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.