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

CMS is requesting a Revision approval type from OMB due to changes to the currently approved instruments.

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. Manufacturers that have a Medicaid Rebate Agreement are required to report ASP data of Part B drugs. Section 401 of Division CC of Title IV of the Consolidated Appropriations Act (CAA), 2021 amended section 1847A of the Social Security Act (the Act) to add new section 1847A(f)(2) of the Act, which requires manufacturers without a Medicaid drug rebate agreement to report average sales price (ASP) information to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological. The reported ASP data are used to establish the Medicare payment amounts.

As part of an ASP modernization effort, the data collection system has been modified and enhanced to improve the design and flow through the use of Human-Centered Design best practices. These modifications include changes to the design and function of the data collection system, the addition of new data fields, and revisions to the product and financial data templates. The field "Marketing Start Date" is being added so that the user can input the marketing date for the drug. The marketing date of the drug is used to determine how the payment will be calculated and to assign the benchmark quarter used to calculate inflation adjusted coinsurance and rebates per IRA 11101.

The field "AWP" (Average Wholesale Price) is being added so that the user can input the AWP of the product. The AWP is used to calculate AWP-based payment limits.

The field "Alternate ID Website URL" is being added so that manufacturers of skin products can provide a reliable public website that can be used to verify skin products for which they provide ASP data.

The field "package type" is being added so that we can accurately identify single-use products and apply the drug wastage provision.

The "CAP units" field was removed from the data collection instrument because the CAP program was not implemented.

Although new data is being requested, there is no anticipated increase to the burden as users are no longer required to enter product data every quarter. Product data will only need to be entered for any new products. Financial data will continue to be collected every quarter. Additionally, drop down boxes for selection and hover-over definitions are being provided to every possible field to improve the quality of the data and reduce the time required for input.
The ASP user guide has also been updated to reflect the modifications and enhancements to the system. In addition, the ASP user guide has been split into 3 different guides based on user role: Registration User Guide, Submitter User Guide and Certifier User Guide. Each guide includes updated screenshots and more in-depth instructions for ASP data submission and certification.

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 Data Analysis and Market-based Pricing (DDAMBP) 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 National Drug Codes (NDC) for Part B drugs. DDAMBP 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. DDAMBP 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. CMS will also use reported ASP and units to calculate inflation adjusted coinsurance and rebates. The

Department of Health and Human Services' Office of the Inspector General also uses the ASP data in conducting studies.

3. Use of Information Technology

CMS migrated the submission of ASP data and signatures to an internet-based automated system in July 2020. ASP data is manually entered via data entry screens or uploaded via product and financial templates into the ASP automated system. The data that is being collected will not change. However, some new data is being requested so that DDAMBP can accurately calculate payment amounts for the components within CMS that utilize 1847(A) payment methodologies to implement various payment policies, calculate the inflation adjusted coinsurance and rebates, and apply the drug wastage provision.

A CMS User ID is required to access the ASP Application. To obtain a CMS User ID, you must complete the Application for Access to the Centers for Medicare & Medicaid Services (CMS) Computer Systems (Form CMS-20037). If you already have a CMS User ID, then you must submit a request to access the ASP Application. The Application for Access to the Centers for Medicare & Medicaid Services (CMS) Computer Systems (Form CMS-20037) can be downloaded from the CMS Website at: http://www.cms.gov/Research-Statistics-Data-andSystems/CMS-Information-Technology/InformationSecurity/Downloads/EUAaccessform.pdf Users that have been approved for access to the ASP application are assigned a CMS user ID and a password. Users are required to access the CMS Portal @ https://portal.cms.gov/ to begin the authentication and role assignment process. Users enter their assigned user ID in the User ID field and enter ASP User in the Request field in the CMS portal. Users are then directed to the EIdM (Enterprise Identity Management) Authentication System. The EIdM Authentication System performs identity proofing on the user. The EIdM Authentication System will prompt the user to create a username and password that conforms to the system's policies; this user ID and password is not affiliated with the user's CMS user ID and password. After the user successfully creates a username and password, the EIdM Authentication System will begin the identity proofing process. After the user's identity is verified, the CMS Portal will push the user's data to the ASP application. Users are assigned a role, assigned organization codes, and the NDCI contact is applied to the user.

Once granted access to the ASP application, users can log into the ASP application and set up NDC1s they will use, enter ASP data into data entry screens or upload their ASP data using the product and financial data templates. The submitter then saves the data and the system generates a one-time password (OTP) for the submitter to send to the certifier. The certifier then logs onto the system using the OTP (first time only), reviews the data, and certifies the data each quarter.

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

Quarterly data collection is required to meet the objectives of market-based pricing. 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 that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB; • Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published to the Federal Register 02/20/2024 (89 FR 12844). No comments were received during the comment period.

The 30-day Federal register notice published to the Federal Register TBD (89 FR).

9. Payments/Gifts to Respondents

There will be no payments or gifts to respondents.

10. Confidentiality

This information collection is authorized under Section 1847 and 1927 of the Act. Confidentiality requirements for manufacturers with a Medicaid rebate agreement 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, to carry out section 1847A (including the determination and implementation of the payment amount and the rebate), or to carry out section 1847B, section 1192(f), including rebates under paragraph (4) of such section, or section 1860D–14B,
(ii) to permit the Comptroller General to review the information provided,
(iii) to permit the Director of the Congressional Budget Office to review the information provided,
(iv) to States to carry out this title,
(v) to the Secretary to disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug in accordance with s ubsection (f),
(vi) in the case of categories of drug product or classification information that were not considered confidential by the Secretary on the day before the date of the enactment of this clause, and
(vii) to permit the Executive Director of the Medicare Payment Advisory Commission and the Executive Director of the Medicaid and CHIP Payment and Access Commission to review the information provided.

Confidentiality requirement for manufacturers without a Medicaid rebate agreement appear in Section 1847A(f)(2)(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 (including the determination and implementation of the payment amount), or to carry out section 1847B;
(ii) to permit the Comptroller General of the United States to review the information provided;
(iii)to permit the Director of the Congressional Budget Office to review the information provided;
(iv)to permit the Medicare Payment Advisory Commission to review the information provided; and
(v) to permit the Medicaid and CHIP Payment and Access Commission 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 register to the CMS portal, and to prepare and submit the required data to CMS. The current information collection is approved for 2,000 responses.

We estimate the total annual reporting burden for the number of respondents to be approximately 26,000 hours (2000 x13 annual hours per response). We estimate the total quarterly reporting burden for the number of respondents to be approximately 6,500 (500 x 13 quarterly hours per response). We believe that administrative assistants will be responding to the information collection requirements. The administrative assistant compiles the data and submits it and the CEO/COO certifies the data. Some manufacturers use contractors to compile their ASP reports. Based on the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2022) http://www.bls.gov/oes/current/oes_ntl.htm for Category 43-6014 (Secretaries and Administrative Assistants), the median hourly wage for an administrative assistant is $ $19.71. [1] We have added 100% of the median hourly wage to account for fringe and overhead benefits, which calculates to $39.42 ($19.71+19.71). We estimate the total annual cost to be $1,024,920 (26,000 hours x $39.42) and the quarterly burden cost to be $256,230(6,500 hours x $39.42). 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. 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, manually input or upload the data into the automated system, and certify the data. This estimate also includes the time to register to the CMS Portal.

13. Capital Costs

There are no capital costs associated with this collection.

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

As part of an ASP modernization effort, the data collection system has been modified and enhanced to improve the design and flow through the use of Human-Centered Design best practices. These modifications include changes to the design and function of the data collection system, the addition of new data fields, and revisions to the product and financial data templates. The field "Marketing Start Date" is being added so that the user can input the marketing date for the drug. The marketing date of the drug is used to determine how the payment will be calculated and to assign the benchmark quarter used to calculate inflation adjusted coinsurance and rebates per IRA 11101.

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There are no changes to the burden hours (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) and annual reporting burden hours. . The current information collection is approved for 2,000 responses and 26,000 annual reporting burden hours. 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 sections 1847 and 1927 of the Act. 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.

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.