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)

Background

CMS is requesting a Revision approval type from OMB due to a change in the submission requirements and a change in the number of respondents.

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.

First, our 2026 Physician Fee Schedule proposed rule would make pay skin substitute products as incident-to supplies, which are not required to be paid under section 1847A of the Act. Accordingly, if this proposal is finalized, manufacturers of skins substitutes would no longer be required to report ASP data to CMS. Instead, ASP data reporting for manufacturers of skin substitutes would become voluntary. The proposal to shift the payment of skin substitute manufactures to incident-to supplies would decrease the number of manufacturers that are required to report ASP data to CMS each quarter, ultimately decreasing the overall burden of ASP data reporting.

Second, if finalized as proposed, 42 CFR 414.804(a)(5) will be revised to add additional submission requirements for the reporting of ASP data. As such, the submission requirement is being expanded to include a (1) reasonable assumptions form and (2) warranty/certification that a bona fide service fee is not passed on as a discount. The reasonable assumptions explain the methodology used by the manufacturer to calculate ASP and, in the absence of specific guidance in the Act or Federal regulations, the manufacturer may make reasonable assumptions in its calculations of the manufacturer's ASP, consistent with the general requirements and intent of the Act, Federal regulations, and its customary business practices. This document is currently optional and is submitted voluntarily by some manufacturers along with ASP data. Under the proposed regulatory changes, a reasonable assumptions form would be a required component of the ASP data submission. The warranty/certification form would provide an attestation that the recipient of a bona fide service fee is not pass on as a discount.

A. 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 limits 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-and-Systems/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 are 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

Serving as the 60-day notice, the NPRM (CMS-1832-P, OMB 0938-AV50) published in the Federal Register on July 16, 2025 (90 FR 32352).

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 subsection (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

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/2024/may/oes_nat.htm*). In this regard, the following table sets out BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Chief Executives	11-1011	126.41	126.41	252.82
Secretaries and Administrative Assistants	43-6014	22.90	22.90	45.80

There are many sources of variance in the average cost estimates, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

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.

B. Information Collection Requirements

Reporting of Drug Pricing Information for Part B (§§ 414.802 and 414.902)

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.

We believe that administrative assistants and chief executives will be responding to the information collection requirements. The administrative assistant compiles the data and submits it to the CEO/COO who certifies the data.

We estimate that it will take 12 hours at $45.80/hr for an administrative assistant to review instructions and search existing data resources, gather the data, compile the data, manually input or upload the data into the automated system. This estimate also includes the time to register to the CMS Portal. We also estimate it would take 1 hour at $252.82/hr for a chief executive to certify the data.

In aggregate, we estimate an annual burden of 22,620 hours (435 respondents x 4 responses/year x 13 hr/response) at a cost of $1,396,211 (1,740 responses x [(12 hr x $45.80/hr) + (1 hr x $252.82/hr)].

Reporting of Drug Pricing Information for Part B	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Administrative Assistant	435	1,740 (435 x 4) responses/yr	12	20,880	45.80	956,304
Chief Executive	435	1,740 (435 x 4) responses/yr	1	1,740	252.82	439,907
Total	435	1,740	No Change	22,620	varies	1,396,211

Proposed: Average Sales Price: Price Concessions and Bona Fide Service Fees (§§ 414.802 and 414.804)

See section 15, below.

Burden Summary

Section(s) Under Title 42 of the CFR	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Reporting of Drug Pricing Information for Part B	435	1,740 (435 x 4)	13	22,620	varies	1,396,211
NPRM (CMS-1832-P, OMB 0938-AV50)	435	435	6	10,875	45.80	498,075
TOTAL	435	2,175	varies	33,495	varies	1,894,286

Collection of information Instruments and Instruction/Guidance Documents

- Medicare Part B Average Sales Price (ASP) Module Submitter User Guide
- Medicare Part B Average Sales Price (ASP) Module Certifier User Guide

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

Our CY 2026 PFS NPRM (CMS-1832-P, OMB 0938-AV50) published in the Federal Register on July 16, 2025 (90 FR 32352). The following proposed changes fall under this collection of information request. See section 12 (above) for our net burden estimates.

a. Requiring Certain Manufacturers to Report Drug Pricing Information for Part B (§§ 414.802 and 414.902)

In the CY 2022 PFS final rule, it was stated that the new provisions finalized in that rule at §§ 414.802 and 414.806 implemented new statutory requirements under sections 1847A and 1927 of the Act, as amended by section 401 of Division CC, Title IV of the CAA, 2021 (for the purposes of this section of this proposed rule, hereinafter is referred to as "section 401"), which requires manufacturers without a Medicaid National Drug Rebate Agreement (NDRA) to report 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 (86 FR 65560). In that final rule, we estimated that an additional 568 respondents had products for which they would be required to report ASP data to CMS beginning January 1, 2022 (86 FR 65560), some of which are manufacturers of skin substitutes. Following the implementation of section 401, we estimated 500 respondents, 2,000 responses (500 respondents x 4 responses/yr), 26,000 hours (2,000 responses x 13 hr/response).

In the CY 2026 PFS NPRM, we are proposing that skin substitutes be paid as incident-to supplies, which are not required to be paid under section 1847A of the Act. Accordingly, if this proposal is finalized, manufacturers of skin substitutes will no longer be required to report ASP data to CMS. Instead, ASP data reporting for manufacturers of skin substitutes would become voluntary.

The proposed change would decrease the number of manufacturers that are required to report ASP data to CMS each quarter, ultimately decreasing the overall burden of ASP data reporting. Based on the most recent ASP data, 65 skin substitute manufacturers are reporting ASP data. Under the proposal to pay skin substitute products as incident-to supplies, the number of manufacturers required to report ASP data to CMS will reduce decrease manufacturer burden by minus 65 respondents, minus 260 responses (-65 respondents x 4 responses/yr) and minus 3,380 hours (-260 responses x 13 hr/response). When factoring in BLS' updated wage data, we estimate an increase of $11,076.

Section(s) Under Title 42 of the CFR	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Current (Active) Burden	500	2,000 (500 x 4 responses/yr)	13	26,000	39.42	1,024,920
Proposed Burden	435	1,740 (435 x 4) responses/yr	13	22,620	45.80	1,035,996
Change	(65)	(260)	No Change	(3,380)	+6.38	+11,076

b. Average Sales Price: Price Concessions and Bona Fide Service Fees (§§ 414.802 and 414.804)

In the CY 2026 PFS NPRM we proposed to revise § 414.804(a)(5) by expanding the ASP data reporting requirement to include: (1) **reasonable assumptions** for calculating the manufacturer's ASP and (2) **warranty or certification letter** from the recipient of a fee from a manufacturer as evidence that a fee was not passed on as a price concession in accordance with the proposed revised definition of bona fide service fee at § 414.802 and submission requirements at § 414.804.

Currently, in the absence of specific guidance in the Act or Federal regulations, the manufacturer may make reasonable assumptions in its calculations of the manufacturer's ASP, consistent with the general requirements and intent of the Act, Federal regulations, and its customary business practices. The reasonable assumptions explain the methodology used by the manufacturer to calculate ASP. This proposal would make the reasonable assumptions document, which is currently submitted voluntarily by some manufacturers along with ASP data, to a required component of the quarterly ASP data submission.

The warranty or certification from the recipient of a bona fide service fee is a new document that we are proposing to be required as evidence of whether or not a fee was passed on as a discount (that is, price concession).

The burden associated with these new proposed requirements would be the time and effort required by manufacturers of drugs and biologicals to prepare and submit the reasonable assumption document and warranty/certification letter to CMS.

We anticipate an increase in burden since all manufacturers would be required to submit reasonable assumptions and warranty/certification letters to accompany their ASP data submissions. Reasonable assumptions may vary in terms of the exact information that is provided and are generally updated by each manufacturer every 1 to 3 years depending on changes in the product line and various contract terms and conditions with intermediaries or consultants. With this in mind, we are adding 2 templates for submitting reasonable assumptions and bona fide service fee warranty/certifications.

Based on our review of voluntarily submitted reasonable assumption data, we estimate that it would take 19 hours annually at $45.80/hr for a Secretary/Administrative Assistant (10 hours to compile and/or update the information and 5 hours to review the information approximately once annually and 1 hour per quarter (or 4 hr annually) to submit the reasonable assumptions to CMS), including signature from the certifier, to CMS via ASP Data Collection System.

We estimate the disclosure and submission of the warranty/certification letter from the recipient of a bona fide service fee is 6 hours annually at $45.80/hr for a Secretary/Administrative Assistant (2 hours to review the warranty/certification letter approximately once per year and 1 hour per quarter (or 4 hr annually) to submit the warranty/certification letter including signature from the certifier, to CMS via the ASP Data Collection System. Although a warranty/certification letter could be renewed up to every three years depending on the specific terms of each contract, we will use a calculation of once annually to accommodate the burden in most circumstances.

The proposed requirements would result in a burden of 25 hours (19 hr + 6 hr) per response. In aggregate, we estimate a burden of 10,875 hours (435 responses x 25 hr/response) at a cost of $498,075 (10,875 hr x $45.80/hr).

Activity	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Current (Active) Burden	n/a	n/a	n/a	n/a	n/a	n/a
Reasonable Assumptions	435	435	19	8,265	45.80	378,537
Disclosure and Submission of the Certification Letter	435	435	6	2,610	45.80	119,538
TOTAL	n/a	+870	varies	+10,875	45.80	+498,075

c. Burden Summary

Activity	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Current (Active) Burden	500	2,000 (500 x 4 responses/yr)	13	26,000	39.42	1,024,920
Report Drug Pricing Information for Part B	(65)	(260)	13	(3,380)	45.80	(154,804)
Price Concessions and Bona Fide Service Fees	435	435	19	8,265	45.80	498,075
TOTAL	435	+2,175	varies	30,885	varies	1,248,653

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.

B. 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.