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)

Notes: This June 2026 iteration is being submitted to OMB for approval with non-substantive changes. With the exception of this paragraph, please note that we are not proposing any other changes to this Supporting Statement. Instead, the non-substantive change is limited to the Bona Fide Service Fee Certification form, Certifier User Guide, and Submitter User Guide that was approved by OMB on June 17, 2026. For details, see the attached Justification for Non-Substantive Change.

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. 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.

This collection of information request is associated with a stand-alone non-rule 30-day notice that published in the Federal Register on April 7, 2026 (91 FR 17657). Overall, this iteration proposes to add 1,500 responses and 11,000 hours. See section 15 of this Supporting Statement for details.

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

As indicated below in section 10, the reported information may contain proprietary, sensitive, or other confidential information. Otherwise, this information collection request does not include any other special circumstances. Specifically, this information collection does not require 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

As noted, our 60-day notice published in the Federal Register on December 30, 2025 (90 FR 61154). That notice indicated that the comment period would not be supplemented with a subsequent 30-day notice or comment period. However, comments were received and we identified that we should account for additional burden for a secretary/administrative assistant to follow-up with fee recipients and monitor certification amendments. We also identified that we should account for new burden and include legal/compliance review. We also revised our Bona Fide Service Fee Certification form. See section 15 of this Supporting Statement for details.

Given the above, we published a subsequent 30-day notice on April 7, 2026 (91 FR 17657). Comments were received on/by May 7. The comment period will not be supplemented with a subsequent 30-day notice or comment period.

We received public comments on the collection of information notice's burden estimates. After reviewing these comments, we did not identify any additional burden that would need to be accounted for.

9. Payments/Gifts to Respondents

There will be no payments or gifts to respondents.

10. Confidentiality

CMS would keep the information collected confidential, according to statutory requirements. Information provided as part of this information collection request that the submitter indicates is confidential commercial or financial information would be protected from disclosure if the information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(3), (4)).[1]

Additionally, section 1847A(f)(2) of the Social Security Act requires manufacturers without a Medicaid drug rebate agreement to report their ASP data for certain Part B drugs to CMS. Section 1847A(f)(2)(D) specifies that this information is confidential and will not be disclosed by the Secretary except as specifically authorized by law.

Section 1927(b)(3)(D) of the Act protects drug pricing data submitted by drug manufacturers to CMS under the MDRP. The protection applies to information such as the AMP, which is needed to calculate Medicaid rebates and to determine federal payment rates. The provision ensures that the sensitive pricing data is not disclosed publicly, though certain government entities may be granted access for specific purposes, like audits or oversight.

[1] See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates

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
Lawyers	23-1011	87.86	87.86	175.72
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 secretaries/administrative assistants will be responding to the information collection requirements. The secretary/administrative assistant compiles the data and submits it to CMS, the lawyer conducts legal and compliance analysis of the submissions, and the CEO/COO who certifies the data. Some manufacturers use contractors to compile their ASP reports.

Information Collection Requirements and Associated Burden Estimates

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

We estimate that it will take 12 hours per quarter at $45.80/hr for a secretary/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 with the CMS Portal. We previously estimated these tasks to take 13 hours. However, after further evaluation, we shifted one hour from the secretary/administrative assistant to the CEO/COO to account for the burden of certification the ASP data. We estimate it will take 1 hour per quarter at $252.82/hr for a chief executive to complete these tasks.

In aggregate based on the current number of manufacturers reporting ASP data to CMS, we estimate an annual burden of 26,000 hours (500 respondents x 4 responses/year x 13 hr/response) at a cost of $1,604,840 (2,000 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 ($/hr)	Total Cost ($)
Secretary/Administrative Assistant	500	2,000 (500 x 4 responses/yr)	12	24,000	45.80	1,099,200
Chief Executive	500	2,000 (500 x 4 responses/yr)	1	2,000	252.82	505,640
Total	**500**	**2,000**	**varies**	**26,000**	**varies**	**1,604,840**

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

Section 414.804(a)(5) expands 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 in accordance with the definition of "bona fide service fee" at § 414.802 and the submission requirements at § 414.804.

The burden is comprised of 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.

Although overestimated, we anticipate that all 500 manufacturers will submit reasonable assumptions and warranty/certification letters to accompany their ASP data.

The Financial and Product Data Templates are taken into account in ASP submission burden.

Reasonable Assumptions: The reasonable assumptions explain the methodology used by the manufacturer to calculate ASP. It is a required component of the quarterly ASP data submission.

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.

Based on our review of voluntarily submitted reasonable assumption data, we estimate that it will take 19 hours annually at $45.80/hr for a secretary/administrative assistant to coordinate and submit the reasonable assumption information into ASP Data Collection System. Our 19-hour estimate is comprised of: 10 hr to compile and/or update the information, 5 hr to review the information approximately once annually, and 4 hr annually (at 1 hr per quarter) to submit the reasonable assumptions to CMS.

In addition, we estimate that preparation of reasonable assumptions would require 4 hours annually at $175.72/hr for a lawyer to review, and 4 hours annually of CEO/COO time at $252.82/hr, including finance senior leaders, to review.

In aggregate based on the current number of manufacturers reporting ASP data to CMS, we estimate an annual burden of 13,500 hours (500 respondents x 1 responses/year x 27 hr/response) at a cost of $1,292,180 (500 responses x [(19 hr x $45.80/hr) + (4 hr x $175.72/hr) + (4 hr x $252.82/hr)].

Reporting of Reasonable Assumptions	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Secretary/Administrative Assistant	500	500 (500 x 1 responses/yr)	19	9,500	45.80	435,100
Lawyer	500	500 (500 x 1 responses/yr)	4	2,000	175.72	351,440
Chief Executive	500	500 (500 x 1 responses/yr)	4	2,000	252.82	505,640
Total	**500**	**500**	**27**	**13,500**	**varies**	**1,292,180**

Warranty or Certification Letter: The warranty or certification from the recipient of a bona fide service fee is required as evidence of whether or not a fee is passed on.

We estimate the submission of the warranty/certification letter from the recipient of a bona fide service fee is 2 hours annually at $45.80/hr for a secretary/administrative assistant coordinate all involved parties to complete the warranty/certification letter.

We estimate that the warranty/certification letter requires 2 hours annually at $175.72/hr of legal review and consultation. In addition, we estimate 1 hour annually of CEO/COO at $252.82/hr to review, sign, and upload the document to the ASP Data Collection System.

A warranty/certification letter could be renewed up to every three years depending on the specific terms of each contract with the entity receiving the bona fide service fee and manufacturers will not submit a warranty/certification every contract each quarter. However, for the purposes of the burden calculation, we will estimate the maximum burden by assuming that

all manufacturers will submit one warranty/certification letter each quarter (that is, four warranty/certification letters annually).

In aggregate based on the current number of manufacturers reporting ASP data to CMS, we estimate an annual burden of 10,000 hours (500 respondents x 4 responses/year x 5 hr/response) at a cost of $1,391,720 (2,000 responses x [(2 hr x $45.80/hr) + (2 hr x $175.72/hr) + (1 hr x $252.82/hr)].

Reporting of Warranty/Certification Letter	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Secretary/Administrative Assistant	500	2,000 (500 x 4 responses/yr)	2	4,000	45.80	183,200
Lawyer	500	2,000 (500 x 4 responses/yr)	2	4,000	175.72	702,880
Chief Executive	500	2,000 (500 x 4 responses/yr)	1	2,000	252.82	505,640
Total	**500**	**2,000**	**5**	**10,000**	**varies**	**1,391,720**

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	500	2,000	13	26,000	varies	1,604,840
Reasonable Assumptions	500	500	27	13,500	varies	1,292,180
Warranty/Certification Letter	500	2,000	5	10,000	varies	1,391,720
TOTAL	**500**	**4,500**	**varies**	**49,500**	**varies**	**4,288,740**

Collection of Information Instruments and Instruction/Guidance Documents

- Bona Fide Service Fee Certification form (revised, see attached)
- ASP Module Submitter User Guide (no changes)
- ASP Module Certifier User Guide (no changes)
- ASP Module Registration User Guide (no changes)
- Reasonable Assumptions form (no changes)

- FinancialDataTemplate Instructions (no changes)
- FinancialDataTemplate-FB (no changes)

- ProductDataTemplate Instructions (no changes)
- ProductDataTemplate FDA Approval Type (no changes)

- ProductDataTemplate Generic Name (no changes)
- ProductDataTemplate Unit for Strength (no changes)
- ProductDataTemplate Unit of Volume Per Item (no changes)
- ProductDataTemplate (no changes)

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 Collection of Information Requirements and Associated Burden Estimates

As noted, our 60-day notice published in the Federal Register on December 30, 2025 (90 FR 61154). Comments were received and we identified that we should account for additional burden for a secretary/administrative assistant to follow up with fee recipients and monitor certification amendments. We also identified that we should account for new burden and include legal/compliance review. We also revised our Bona Fide Service Fee Certification form.

This 30-day iteration (April 7, 2026; 91 FR 17657) proposes the following burden changes:

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

No Changes.

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

Reasonable Assumptions

-Removes signature requirement
-Adds 4 hours at $175.72/hr for a lawyer and 4 hours at $252.82/hr for a CEO/COO to review the reasonable assumptions.
-With 500 respondents, this change adds 4,000 hours (from 9,500 [Active] to 13,500 hr [Revised]).

Average Sales Price: Price Concessions and Bona Fide Service Fees	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)
Reasonable Assumptions				
Secretary/Administrative Assistant	No Change	No Change	No Change	No Change
Lawyer	No Change	No Change	+4	+2,000
CEO/COO	No Change	No Change	+4	+2000
Total	*No Change*	*No Change*	*+8*	*+4,000*

Warranty or Certification Letter

-Replaces ASP Price Concessions and Bona Fide Service Fees with Reporting of Warranty/Certification Letter
-Adds time for a Secretary/Administrative Assistant by plus 1,000 hours ([Active] 3,000 hr = 6 hr/response x 500 responses x 1 response/year to [Revised] 4,000 hr = 2 hr/response x 500 responses x 4 responses/year).
-Adds time for a lawyer by plus 4,000 hours (2 hr/response x 500 responses x 4 responses/year).
-Adds time for a CEO/COO by plus 2,000 hours (1 hr/response x 500 responses x 4 responses per year).
-This change adds 7,000 hours (from 3,000 [Active] to 10,000 hr [Revised]).

Average Sales Price: Price Concessions and Bona Fide Service Fees	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)
Warranty/Certification Letter				
Secretary/Administrative Assistant	No Change	+1,500	(4)	+1,000
Lawyer	No Change	+1,500	+2	+4,000
CEO/COO	No Change	+1,500	+1	+2,000
Total	*No Change*	*+1,500*	*varies*	*+7,000*

Burden Reconciliation

Burden Reconciliation	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)
Active	500	3,000	varies	38,500
Revision: Reasonable Assumptions	500	No Change	varies	+4,000
Revision: Warranty/Certification Letter	500	+1,500	Varies	+7,000
TOTAL (see Section 12 of this Supporting Statement)	**500**	**4,500**	**varies**	**49,500**

16. Publication/Tabulation Dates

The Medicare Part B ASP website lists the calculated payment limits for most drugs and biologicals payable under Medicare Part B, which is updated each quarter. Typically, the payment limit is ASP+6% of the volume-weighted average of all individual products cross walked to a particular billing and payment code (HCPCS code). The reported ASP for an individual manufacturer's product is not published.

17. Expiration Date

We plan to display the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

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