Supporting Statement – Part A
Medicare Prescription Drug Inflation Rebate Program under
Sections 11101 and 11102 of the Inflation Reduction Act (IRA)
CMS-10930, OMB 0938-1485

The contents of this Supporting Statement and the associated attachments have been reviewed to ensure that they are consistent with the Trump administration's policies, goals, and objectives.

Background

Sections 11101 and 11102 of the IRA of 2022 (P.L. 117-169) authorized the Medicare Part B Drug Inflation Rebate Program under section 1847A(i) of the Social Security Act ("the Act") and the Medicare Part D Drug Inflation Rebate Program under section 1860D-14B of the Act. The statutory provisions are codified under 42 CFR part 427 and part 428, respectively.

The purpose of this collection of information collection request is for the Centers for Medicare & Medicaid Services (CMS) to collect information to implement the Medicare Part D Drug Inflation Rebate Program pursuant to the proposed policies in the Calendar Year (CY) 2027 Physician Fee Schedule rule ("CY 2027 PFS proposed rule") (CMS-1848-P, RIN 0938-AV82).

Part D Drug Inflation Rebate Program

In accordance with section 1860D-14B of the Act, for each 12-month applicable period, starting with the applicable period beginning October 1, 2022, a manufacturer of a Part D rebatable drug will owe a rebate, to be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund, if the annual manufacturer price exceeds the inflation-adjusted payment amount. Section 1860D-14B(b)(3) of the Act specifies that the inflation-adjusted payment amount is equal to the benchmark period manufacturer price increased by the percentage by which the applicable period Consumer Price Index for All Urban Consumers (CPI-U) exceeds the benchmark period CPI-U.

As defined in section 1860D-14B(g)(1) of the Act, a "Part D rebatable drug" means, with respect to an applicable period, a drug or biological described at section 1860D-14B(g)(1)(C)[1] that is a covered Part D drug as defined under section 1860D-2(e) of the Act. A drug approved under an abbreviated new drug application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) is only subject to the Part D inflation rebate if it meets certain sole source criteria described at sections 1860D-14B(g)(1)(C)(ii)(I)–(IV) of the Act. As described in section 1860D-14B(g)(1)(B), the definition of a Part D rebatable drug does not include a drug or biological if, as determined by the Secretary, the "average annual total cost" for such drug or biological under Part D for a year per individual that uses such a drug or biological is less than the applicable threshold.

[1] A drug or biological described in section 1860D-14B(g)(1)(C) is a drug or biological that, as of the first day of the applicable period involved is: (1) a drug approved under a New Drug Application (NDA) under section 505(c) of the FD&C Act; (2) a drug approved under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act that meets certain criteria in section 1860D-14B(g)(1)(C)(ii) of the Act; or (3) a biological licensed under section 351 of the Public Health Service (PHS) Act.

The total rebate amount is equal to the product of the per unit rebate amount and the total number of units dispensed of such drug under Part D (except in the case of a line extension of a Part D rebatable drug that is an oral solid dosage form, for which the total rebate amount is detailed at § 428.201(a)(1)(ii)).

Medicare Part D Claims Data 340B Repository

Section 1860D-14B(b)(1)(B) of the Act requires that beginning with plan year 2026, CMS shall exclude from the total number of units for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provided a discount under the 340B Program.

In the CY 2026 PFS final rule (90 FR 49748-49755), CMS adopted its proposal to establish a Medicare Part D Claims Data 340B Repository (hereinafter, "340B repository") and allow 340B covered entities (hereinafter, "covered entities"), beginning in 2026 for 340B claims with a date of service on or after January 1, 2026, to optionally begin submitting to the 340B repository data elements associated with Part D claims for which the covered entity dispensed (either directly or indirectly, including via retrospective replenishment and contract pharmacy arrangements) units of a drug for which the manufacturer provides a discount under the 340B Program (hereinafter "Part D 340B claims"). In the final rule, we noted that we expect the 340B repository to launch in Fall 2026. We noted that covered entities will need time to develop a process for collecting the 340B data elements to submit to the 340B repository and prepare the data in a form and manner prescribed by CMS. Additionally, given the variety in the scope of provider types and organizations that participate in the 340B Program, we stated that we recognize the amount of preparation time varies. We strongly encouraged all covered entities to submit data elements to the 340B repository during the testing period beginning in 2026 in the CY 2026 PFS final rule (90 FR 49750), noting that this participation would allow for robust testing of data quality and completeness and provide an opportunity for covered entities to develop and test their data submission processes.

In the CY 2027 PFS proposed rule, CMS is proposing at § 428.203(c) to require all Medicare providers and suppliers that are covered entities as defined at 42 CFR 10.3 (hereinafter collectively "340B providers" unless otherwise noted) to submit data elements set forth at proposed § 428.203(c) from their Part D 340B claims for all covered Part D drugs billed to Medicare Part D by such covered entity or its contractor(s) beginning with claims with a date of service on or after January 1, 2027. Such reporting would fulfill a 340B provider's obligation to provide access to documentation relating to covered Part D drugs written or ordered by such 340B provider as a condition of continued enrollment in Medicare, as we are proposing at § 424.516(f)(4) in accordance with our authorities in sections 1842(h)(9) and 1866(a)(1)(X) of the Act. As described in this ICR, each 340B provider would be required to submit data elements specified by CMS at proposed § 428.203(c) related to Part D 340B claims with dates of service on or after January 1, 2027. CMS would require that 340B providers report data at minimum within one calendar quarter following the close of the relevant calendar quarter. For example, for claims with a date of service between October 1, 2027, through December 31, 2027, 340B providers would be required to submit the data elements from Part D 340B claims to the 340B repository no later than March 31, 2028. As stated above, CMS strongly encourages 340B

providers to begin submitting data to the 340B repository voluntarily in 2026 to test operational processes.

Each 340B provider would submit 340B claims data with a date of service during the applicable period directly to the 340B repository. CMS would consider all data elements received by the 340B repository to be associated with Part D 340B claims consistent with the 340B provider requirement to certify the accuracy of such submissions. Under this process, CMS would require, as part of every submission, a certification from 340B providers (or an individual or contractor with the delegated authority as an authorized representative of the 340B provider to perform the certification), that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the 340B provider's knowledge, their submission includes all Part D 340B claims for the 340B provider at the time of submission for dates of service during the relevant period. 340B providers or their authorized representative would be required to certify the completeness and accuracy of the data submitted and to certify that the submitter is authorized to submit on behalf of the 340B provider. CMS understands that covered entities typically contract with vendors, such as 340B third-party administrators (TPAs), to determine 340B eligibility of claims using data provided by covered entities and their contract pharmacies. CMS would allow 340B providers to arrange for TPAs or other vendors to submit certain data elements to the 340B repository on their behalf. 340B providers would ultimately be responsible for the accuracy of the data submitted to the 340B repository, even if a 340B provider has an arrangement with a vendor to submit on its behalf.

CMS would not use data submitted to the 340B repository to remove units for the purpose of calculating Part D inflation rebates unless and until a policy to do so is proposed and finalized. If we determine that the data reported to the repository is usable and reliable and, in the future, propose and finalize a policy to use such data to exclude 340B units from rebate calculations, then units associated with PDE transactions that match to data elements stored in the 340B repository would be considered those for which the manufacturer provided a discount under the 340B Program and would be used to remove 340B units from the total number of units used to calculate the total rebate amount specified in the Preliminary Rebate Report and Rebate Report detailed at § 428.401(b) and (c).

Data Elements

340B providers submitting data to the 340B repository must provide information identifying the 340B provider, specifically the 340B ID and name as designated in the 340B Office of Pharmacy Affairs Information System (OPAIS) database, when submitting claim information to the 340B repository.[2] CMS would use the collected identifying information to (1) perform analyses to assess the reliability of the data for future use in removing 340B units, (2) provide a means to follow up with the 340B provider on questions related to claims data submission, and (3) perform other internal analyses to assess efficiencies across various programs.

In addition to this identifying information, 340B providers must submit the following data elements associated with each claim for units of a covered Part D drug billed to Medicare Part D by the covered entity associated with such 340B provider or its contractor(s) for which a

[2] For purposes of this ICR, the 340B ID represents the covered entity that purchased the drug.

manufacturer provides a discount under the 340B Program to such covered entity: (1) Date of Service (that is, the date the prescription was filled by the pharmacy); (2) Prescription or Service Reference Number; (3) Fill Number (that is, the code indicating whether the prescription is an original or a refill; if a refill, the code indicates the refill number); (4) Dispensing Pharmacy National Provider Identifier (NPI); and (5) NDC-11. CMS would use these data elements to match claims to PDE transactions and perform further analyses to assess the reliability of the data for future use in removing 340B units from Part D inflation rebate calculations. Such data shall be submitted to CMS in a form and manner provided by CMS.

A. Justification

1. Need and Legal Basis

Section 1860D-14B(b)(1)(B) of the Act requires that beginning with plan year 2026, CMS shall exclude from the total number of units used to calculate the inflation rebate for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provided a discount under the 340B Program.

Data on which units dispensed under Part D and covered by Part D plan sponsors were purchased under the 340B Program is unavailable from the data sources specified at section 1860D-14B(d) of the Act (that is, information submitted by manufacturers, States, and Part D plan sponsors), and CMS does not currently have access to this data through other means. In the CY 2026 PFS final rule, CMS adopted its proposal to establish a 340B repository for voluntary submission from covered entities of 340B Part D claims data, and beginning in CY 2027, is proposing to require 340B providers to report data from Part D 340B claims to CMS to assess the reliability of the data for future use in removing 340B units in accordance with § 428.203(b)(2), which describes how CMS will exclude from the total number of units used to calculate the total rebate amount for a Part D rebatable drug those units of the Part D rebatable drug for which a manufacturer provides a discount under the 340B Program. We are proposing to require such reporting in accordance with our authorities under sections 1842(h)(9) and 1866(a)(1)(X) of the Act and as proposed at §§ 424.516(f)(4) and 428.203(c). By transitioning from voluntary submission to mandatory participation in the 340B repository, CMS would be able to ensure more complete and reliable data submissions, thereby improving its ability to accurately assess use of the 340B repository to exclude 340B units from Part D rebate calculations, consistent with its obligations under section 1860D-14B(b)(1)(B) of the Act.

2. Information Users

The information collected by CMS from 340B providers would be used by the Medicare Drug Rebate and Negotiations Group within the Center for Medicare to assess the usability of the data to identify the PDE transactions and corresponding units which section 1860D-14B(b)(1)(B) of the Act excludes from the total Part D inflation rebate amount. The Medicare Drug Rebate and Negotiations Group may also use the information to conduct other internal program analyses, such as those related to the Medicare Drug Price Negotiation Program. Specifically, as stated in section 40.4.5 of final guidance for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027, CMS is exploring the feasibility of incorporating

340B-related transactional data from 340B covered entities or their TPAs identifying claims eligible under section 1193(d)(1) of the Act into MTF processes in the future. In this same final guidance, consistent with requirements discussed in section 90.2, CMS may also consider analyzing data submitted to the 340B repository to inform our monitoring of access to the MFP, including applicability of the exception under section 1193(d)(1) of the Act.

CMS understands covered entities typically contract with vendors, such as 340B TPAs, to evaluate 340B eligibility of claims using data submitted by covered entities and their contract pharmacies. CMS would allow 340B providers to arrange for TPAs or other vendors to submit certain data elements to the 340B repository on their behalf. 340B providers would ultimately be responsible for the accuracy of the submission of data elements to the 340B repository, even if the 340B provider's associated covered entity has an arrangement with a vendor to submit on its behalf. The data collected from 340B providers, or TPAs on their behalf, would then be matched to PDE transactions from the CMS claims data system for Part D rebatable drugs dispensed with a date of service during the relevant period to assess the usability of the data to identify PDE transactions and their corresponding units to be removed from the rebate calculation for a Part D rebatable drug as required by section 1860D-14B(b)(1)(B) of the Act. Additional information related to how 340B providers should submit data elements to the 340B repository is located in the 340B Repository Data Elements Reporting Instructions.

3. Use of Information Technology

340B providers would submit to the 340B repository data elements from Part D 340B claims on a quarterly basis (though they may choose to submit more frequently). 340B providers are required to submit data using the CMS-specified format. CMS would receive and intake the claims data elements provided from the 340B providers. CMS would match submitted claims data from 340B providers to PDE transactions from the CMS claims data system. CMS would assess the usability of this data to identify units associated with PDE transactions that match to data elements stored in the 340B repository and that would be removed from the total number of units used to calculate the total Part D inflation rebate amount in a future applicable period.

4. Duplication of Efforts

This information collection does not duplicate any other effort, and 340B providers do not otherwise transmit information to CMS that identifies Part D 340B claims.

5. Small Businesses

The requirement for covered entities to submit data to the 340B repository does not impose any greater burden on small businesses with access to TPAs than on large businesses with access to TPAs because all covered entities regardless of size must be able to verify the status of an eligible 340B transaction to fulfill participation requirements for the 340B Program. Businesses without access to TPAs would need to initially establish processes to produce the ongoing data elements submissions. The collection instrument includes the minimum necessary information to ease reporting burden among all 340B providers.

6. Less Frequent Collection

340B providers would submit to the 340B repository the data fields specified by CMS using the CMS-specified format on a quarterly basis (though they may choose to submit more frequently) within one calendar quarter following the close of the relevant calendar quarter. For example, for claims with a date of service between October 1, 2027, through December 31, 2027, 340B providers would submit the data elements from Part D 340B claims to the 340B repository no later than March 31, 2028. Quarterly submissions are necessary so CMS has timely information to assess the reliability of the data for future use in removing 340B units. In addition, quarterly submissions may also minimize the burden on 340B providers by reducing the amount of data included in each submission and the amount of quality assurance necessitated for each submission as compared to an annual submission.

7. Special Circumstances

See Section 10 below for the confidentiality aspects of the information submitted using the CMS-specified format. Otherwise, this information collection request does not include any special circumstances that would require respondents to:

- Report information to the agency more often than quarterly;
- Require respondents to 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

Federal Register

Serving as the 60-day notice, the CY 2027 PFS proposed rule (CMS-1848-P, RIN 0938-AV82) filed for public inspection on July 14 and published in the Federal Register on July 16, 2026 (91 FR 43842). Comments must be received by September 14, 2026.

Outside Consultation

In the development of the Medicare Prescription Drug Inflation Rebate Program ICR, CMS sought input from other federal agencies.

9. Payments/Gifts to Respondents

No payments or gifts will be given to respondents for completing the information collection. The information submitted by the 340B provider will be used to test the 340B repository for use in identifying the appropriate number of 340B units that CMS would exclude from Part D inflation rebate calculations.

10. Confidentiality

CMS will keep confidential, to the extent allowable under law, proprietary information submitted by 340B providers using the CMS-specified format. Information provided as part of the 340B repository data elements submission will be protected from disclosure under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(3) and (4)).[3] In addition to the protections under the FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 U.S.C. 1905 requires executive branch employees to protect such information. CMS will protect confidential and proprietary information as required by applicable law. If additional information beyond what is outlined in this collection request is submitted to CMS, CMS would not use extraneous data that is submitted.

11. Sensitive Questions

There are no sensitive questions associated with this collection. See Section 10 (above) for the confidentiality aspects of the information reported using the CMS-specified format.

12. Burden Estimates

Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2025 National Occupational Employment and Wages Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (consisting of a 100 percent increase) and our adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
General and Operations Managers	11-1021	64.87	64.87	129.74
Software Quality Assurance Analysts	15-1253	53.60	53.60	107.20

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

and Testers				

As noted, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, 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. We believe that doubling the hourly wage to estimate the total cost for the form is a reasonably accurate estimation method.

Collection of Information Requirements and Associated Burden Estimates

CMS would provide 340B providers with a format to collect data elements from 340B Part D claims via the 340B repository. The Part D 340B claim data elements include: (1) Date of Service (that is, the date the prescription was filled by the pharmacy); (2) Prescription or Service Reference Number; (3) Fill Number; (4) Dispensing Pharmacy NPI; and (5) NDC-11. Additional information collected includes the 340B ID and name of the 340B provider as designated in 340B OPAIS database. 340B providers would be required to transmit the claim-level data elements and additional identifiers using the CMS-specified format for all 340B Part D claims from the relevant period.

Claim-level data elements from all Part D 340B claims with a date of service during the relevant period should be transmitted to the 340B repository on a quarterly basis by 340B providers (though they may choose to submit more frequently). For purposes of this burden estimate, CMS assumes 340B providers or their TPAs would have a dedicated Quality Assurance Analyst or team of analysts reviewing sample claim-level data elements, administering reporting to furnish the required data elements, and certifying that all data elements submitted are from verified 340B claims. CMS also assumes if a TPA submits claim-level data on behalf of a 340B provider, the 340B provider would not also submit this data.

For purposes of the burden estimates, CMS estimated the number of 340B providers that would respond by providing Part D 340B claims data to the 340B repository in 2027. We estimated that nearly 100 percent of 14,000 covered entities would respond by submitting data to the 340B repository in 2027. This range of numbers is representative of the unique 340B ID numbers in the 340B OPAIS database that are active (i.e., not terminated) with at least one (1) contract pharmacy association listed.[4] CMS understands that this is representative of an estimate based on the publicly available information from the 340B OPAIS database and that the number of respondents could be higher or lower than what is outlined here. Potential for underestimates of the number of respondents could include covered entities that do not meet the parameters described above, such as covered entities that have “in-house” pharmacies that are not registered in the 340B OPAIS database as 340B contract pharmacies. We also acknowledge that a small number of covered entities are not 340B providers and therefore may not submit to the 340B repository, but we believe this number is negligible as a percent of total covered entities.

CMS anticipates that TPAs would submit claims data to the 340B repository to support their covered entity clients, as is the practice in some state Medicaid 340B clearinghouses today.[5] As a

[4] See: https://340bopais.hrsa.gov/reports.
[5] See: https://www.oregon.gov/oha/HSD/OHP/Tools/340B%20State%20Policy.doc.

result, CMS expects the number of parties submitting claims data may be less than what is outlined below, which is representative of individual covered entities as potential respondents whereas TPAs may submit claims on behalf of multiple covered entities. CMS has not factored the potential operational efficiency gained in such a practice into the provided burden estimates.

For the purposes of the burden estimates, we estimated a specific number of 340B providers, rather than utilizing the range. This is because it is necessary to establish a specific population of 340B providers to use to estimate the burden of our policies. We expect that each submission will take 6 hours at $107.20/hr for a Software Quality Assurance Analyst and Tester and 2 hours at $129.74/hr for a General and Operations Manager. In addition to the recurring submissions, we estimate it would take a General and Operations Manager one hour at $129.74/hr to complete the one-time registration for the 340B repository. In aggregate, we estimate an initial year-one burden of 462,000 hours (14,000 340B providers x 8 hr/response x 4 responses/year + 14,000 340B providers x 1 hr/registration) at a cost of $52,366,440 (56,000 responses x [(2 hr x $129.74/hr) + (6 hr x $107.20/hr)] + 14,000 registrations x (1 hr x $129.74/hr)).

Total Burden For One Year of Testing[6]

Requirement	Occupation Title (Occupation Code)	Respondents	Total Responses	Time per Response (hours)	Total Time (hours)	Labor Cost ($/hr)	Total Cost ($)
340B Repository Registration	General and Operations Manager (15-1253)	14,000 340B providers	14,000	1	14,000	129.74	1,816,360
340B Repository Data Element Reporting	Software Quality Assurance Analyst and Tester (11-1021)	14,000 340B providers	56,000 (14,000 x 4 qtr)	6	336,000	107.20	36,019,200
	General and Operations Manager (15-1253)			2	112,000	129.74	14,530,880
TOTAL		14,000 340B providers	70,000 [(14,000 x4 qtr) + 14,000]	varies	462,000	varies	52,366,440

Collection of Information Instruments and Instruction/Guidance Documents

340B Repository Data Elements Reporting Instructions (Revised)

340B Repository Data Elements Reporting Example Form (Removed)

13. Capital Costs

[6] For purposes of establishing the population used in our burden estimate, we estimate an absolute number of respondents rather than a range.

There are no anticipated capital costs for respondents associated with this information collection.

14. Cost to Federal Government

The federal government estimated labor cost for directing policy and operations of the 340B repository is based on the efforts expended by CMS staff with the following assumptions to establish policy and review data from 340B providers and TPAs that submit claim-level data to the 340B repository.

To generate salary estimates, CMS used the 2026 General Schedule (GS) Locality Pay Tables published by the Office of Personnel Management (OPM) for the Washington-Baltimore-Arlington region.[7] In this regard, the following table presents the FTE equivalent of staff required for the task, the hourly wage (adjusted for the cost of fringe benefits and other indirect costs, calculated at 100 percent of salary), total time, and the total cost of the information collection.

The following estimates in the table below show the total labor cost to the government for operationalizing the 340B repository. This estimate does not include costs for design, development, implementation, or maintenance of the 340B repository or to receive and process data from 340B providers and TPAs.

Staffing estimates are based on CMS duties as follows:

- 340B providers and TPAs send submissions formatted in a standardized file template.
- Managing account creation and registration of 340B providers in the 340B repository.
- CMS would perform analyses on the submissions of data into the 340B repository, matching 340B providers' submissions to PDE transactions, and assess the usability of this data to calculate the appropriate number of 340B units to remove from the Part D inflation rebate calculation.
- Review and analyze the information submitted by 340B providers' and TPAs and perform follow up outreach for incomplete submissions. In such instance, CMS may request that the 340B provider resolve and resubmit the Part D 340B claims data in order to process the submission successfully.
- Conduct other internal program analyses, such as those related to the Medicare Drug Price Negotiation Program, as necessary.

The total labor cost to the federal government for directing policy and operations of the 340B repository in the first year of implementation is estimated at $1,277,346.

Total Labor Cost to Government Over One Year

	FTEs	Time/ FTE	Adjusted Hourly Wage ($/hr)	Total Time (hr)	Total Labor Cost ($)
GS-13 (step 1)	9	1,007.5	116.70	9,068	1,058,177
GS-14 (step 1)	3	505	137.92	1,515	208,949

[7] See: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2026/DCB_h.pdf.

GS-15 (step 1)	1	36	162.22	36	5,840
Senior Executive Service	1	23	190.43	23	4,380
TOTAL	14	varies	varies	10,642	1,277,346

15. Changes to Burden

The purpose of this collection of information collection request is for the Centers for Medicare & Medicaid Services (CMS) to collect information to implement the Medicare Part D Drug Inflation Rebate Program pursuant to the proposed policies in the Calendar Year (CY) 2027 Physician Fee Schedule rule ("CY 2027 PFS proposed rule") (CMS-1848-P, RIN 0938-AV82).

In section III.G.3.c.2.c. of this proposed rule, we are proposing to require all providers and suppliers that are covered entities as defined under § 10.3 (hereinafter collectively "340B providers" unless otherwise noted) to submit data elements from their Part D 340B claims to the 340B repository for all covered Part D drugs billed to Medicare Part D by such covered entity or its contractor(s) beginning in 2027 for Part D claims with dates of service on or after January 1, 2027. To allow sufficient time for 340B providers to gather, validate, and submit the specified data to the 340B repository, we propose to require that 340B providers would be expected to report data on a quarterly basis (though they may choose to submit more frequently) to the 340B repository within one calendar quarter following the close of the relevant calendar quarter. For example, for claims with dates of service between October 1, 2027, through December 31, 2027, 340B providers would submit the data elements from Part D 340B claims to the 340B repository no later than March 31, 2028. 340B providers would submit this data directly to CMS to be included in the 340B repository. We propose that we would rely upon the completeness and accuracy of the data submitted by 340B providers to the 340B repository, consistent with the 340B provider requirement to certify the accuracy of such submissions, to consider all data elements received by the 340B repository to be associated with Part D 340B claims. We also propose, as part of every submission to require 340B providers (or an individual or contractor with the delegated authority as an authorized representative of the 340B provider to perform the certification) to certify that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the 340B provider's knowledge, its submissions include all Part D 340B claims for the 340B provider at the time of submission for the relevant period. 340B providers or their authorized representative would be required to certify the completeness and accuracy of the data submitted and to certify that the submitter is authorized to submit on behalf of the 340B provider. We would match the stored data elements in the 340B repository to PDE transactions for each Part D rebatable drug dispensed during the applicable period and would evaluate 340B repository data for: (1) data integrity, and (2) submission frequency and completeness across covered entity types and geographies.

The information collected by CMS from 340B providers would provide CMS with information to assess the usability of the data received and feasibility of CMS removing 340B units from the total number of units used to calculate the total rebate amount in the future based on the data submitted. This data and information are necessary to implement statutory requirements of the Medicare Part D Drug Inflation Rebate Program at section 1860D-14B(b)(1)(B) of the Act, which requires that beginning with plan year 2026, we shall exclude from the total number of units for a Part D rebatable drug, with respect to an applicable period, those units for which a

manufacturer provides a discount under the 340B Program. As stated earlier, we are proposing to require all 340B providers to submit data elements from their Part D 340B claims to the 340B repository for all covered Part D drugs billed to Medicare Part D beginning in 2027 for Part D claims with dates of service on or after January 1, 2027.

Based on internal CMS analyses of the unique 340B ID numbers in the OPAIS database that are active (that is, not terminated) with at least one contract pharmacy association listed, we estimate that approximately 14,000 340B providers would respond by submitting data 4 times per year (quarterly) to the 340B repository in the format and manner specified by CMS.

For a 340B provider or its third-party administrator (TPA), we estimate it would take 6 hours at $107.20/hr for a Software Quality Assurance Analyst and Tester sampling for each submission and 2 hours at $129.74/hr for a General and Operations Manager to review each submission. In addition to the recurring submissions, we estimate it would take a General and Operations Manager one hour at $129.74/hr to complete the one-time registration for the 340B repository.

In aggregate, we estimate an annual burden of 462,000 hours ([56,000 responses x 8 hr/response] + [14,000 340B providers x 1 hr/registration]) at a cost of $52,366,440 [(2 hr x $129.74/hr x 56,000 responses) + (6 hr x $107.20/hr x 56,000 responses) + (1 hr x $129.74/hr x 14,000 registrations)]).

Comparison of Currently Approved Burden vs our Proposed Revisions

Item	Total for Currently Approved ICR	Total for Proposed 60-Day Revisions	Total Difference
Respondents	2,600	14,000	11,400
Total Responses	10,400	70,000	59,600
Total Time (hr)	83,200	462,000	378,800
Total Cost ($)	9,278,048	52,366,440	43,088,392

16. Publication/Tabulation Dates

The results of this information collection will not be published for statistical use or analysis.

17. Expiration Date

When it becomes available, the expiration date will be displayed within the data collection information technology system (see attached PRA Disclosure Statement).

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

This collection does not employ any statistical methods.