Supporting Statement – Part A

Information Collection Request (ICR) for the Medicare Prescription Drug Inflation Rebate Program under Sections 11101 and 11102 of the Inflation Reduction Act (IRA) (CMS-10930, OMB 0938-TBD)

Introduction

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. These statutory provisions were codified at 42 CFR Part 427 and 42 CFR Part 428.

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. 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)). 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). 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 drug 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.

The purpose of this ICR is for the Centers for Medicare & Medicaid Services (CMS) to collect information to implement the Medicare Part D Drug Inflation Rebate Program as proposed in CY 2026 Physician Fee Schedule (PFS) proposed rule. Specifically, section 1860D-14B(b)(1)(B) of

[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); or (3) a biological licensed under section 351 of the Public Health Service (PHS) Act.

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 provides a discount under the 340B Program. Because this requirement starts after the first quarter of the applicable period that begins on October 1, 2025, the exclusion of 340B units in Part D will only apply for the last three quarters of this applicable period. That is, CMS will exclude 340B units starting on January 1, 2026. In the CY 2026 PFS proposed rule, CMS proposed to establish a 340B repository to receive voluntary submissions from covered entities of certain data elements from 340B-identified Part D claims to allow CMS to assess such data for use in identifying units of Part D rebatable drugs for which a manufacturer provides a discount under the 340B Program in a future applicable period. CMS proposed to allow covered entities to submit data on units of Part D rebatable drugs for which a manufacturer provides a discount under the 340B Program beginning in 2026 to begin testing the usability of the 340B repository. This ICR will enable CMS to collect information to implement this voluntary collection.

A. Background

In the CY 2026 PFS proposed rule, CMS proposed to establish a 340B repository and allow 340B covered entities (hereinafter "covered entities") to optionally begin submitting to the 340B repository data elements from all claims with dates of service during the relevant period which the covered entity determined utilized a drug for which the manufacturer provides a discount under the 340B program (hereinafter "340B Part D claims ") for covered Part D drugs billed to Medicare Part D. CMS proposed to allow covered entities to begin submitting the fields specified by CMS to the 340B repository during the testing period beginning in 2026 for Part D claims with dates of service on or after January 1, 2026. This testing period would provide data for CMS to conduct usability testing for the 340B repository and allow covered entities to develop and test processes for submitting data elements to the 340B repository. CMS would not use the data submitted for user testing to remove units from Part D inflation rebates unless and until a policy to do so is proposed and finalized.

Covered entities would voluntarily submit this data directly to CMS (or a contractor) to be included in the 340B repository. CMS would consider all data elements received by the 340B repository to be associated with 340B Part D claims; that is, the 340B repository would not further verify the 340B status of a claim but rather would serve solely to store these data. Under this process, CMS intends to require a certification from covered entities that choose to submit data to the 340B repository that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the covered entity's knowledge, their submission includes all Part D 340B-identified claims for the covered entity at the time of submission for with dates of service during the relevant period. 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. During the testing period, CMS would assess the usability of this data to remove 340B units from the total number of units used to calculate the total rebate amount in a future applicable period.

CMS proposed that covered entities that choose to submit data to the 340B repository during the testing period beginning in 2026 would submit the fields specified by CMS on a quarterly basis to the 340B repository by a date announced in the future, which would be no sooner than 3 months after the date on which the 340B repository is available to receive submissions from covered entities. CMS proposed that covered entities that choose to submit data would report data elements related to all 340B Part D claims with dates of service on or after January 1, 2026. At a point in the future, if the CY 2026 PFS proposed rule is finalized, CMS would provide a deadline that CMS believes would be necessary to allow sufficient time for covered entities to gather, validate, and submit the specified data to the 340B repository and would provide the submission deadline(s) once the Medicare Prescription Drug Inflation Rebate ICR is finalized. During the rest of the testing period, CMS anticipates that covered entities will be expected to report data within 3 months of the end of a given calendar quarter. 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 covered entities that choose to participate, to arrange for their TPAs or other vendors to submit certain data elements to the 340B repository on their behalf. Covered entities would certify and would ultimately be responsible for the accuracy of the data submitted to the 340B repository, even if a covered entity has an arrangement with a vendor to submit on its behalf. The data from these quarterly submissions would be used to assess the usability of such data to remove 340B units from the total number of units and total rebate amount specified in the Preliminary Rebate Report and Rebate Report detailed at § 428.401(b) and (c), respectively. CMS proposed that covered entities participating in the 340B repository during the testing period beginning in 2026 provide information identifying the covered entity, specifically the covered entity's 340B ID and name as designated in the 340B Office of Pharmacy Affairs Information System (OPAIS), when submitting claim information to the 340B repository. CMS would use the collected identifying information to (1) perform analyses to assess suitability of the data for future use in removing 340B units, and (2) provide a means to follow up with the covered entity on questions related to claims data submission.

In addition to this identifying information, CMS proposed that covered entities participating in the 340B repository during the testing period beginning in 2026 submit the following data elements from Part D claims for covered Part D drugs that are purchased under the 340B Program and dispensed to Medicare Part D beneficiaries: (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 proposed to use these data elements to match claims to PDE transactions and perform further analyses to assess the suitability of the data for future use in removing 340B units from Part D drug inflation rebate calculations.

This ICR includes the following form:

- 340B Repository Data Elements Instructions and Collection Form (Appendix A)

To fulfill the statutory requirements for information collection and program burden, CMS is requesting OMB approval for this new collection that focuses on information covered entities may voluntarily submit to CMS for the agency to assess use of a 340B repository to identify 340B units.

B. 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 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.

Data on which units dispensed under Part D and covered by Part D plan sponsors were purchased under the 340B Program is unavailable under 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. As discussed in the CY 2026 PFS proposed rule, CMS proposed to establish a 340B repository and allow covered entities to report Medicare Part D 340B claims data for CMS to assess the suitability 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 provided a discount under the 340B Program.

2. Information Users

The information collected by CMS from covered entities 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) excludes from the total Part D drug inflation rebate amount. CMS understands covered entities typically contract with vendors, such as 340B TPAs, to determine 340B eligibility of claims using data submitted by covered entities and their contract pharmacies. CMS would allow covered entities that choose to participate to arrange for their TPAs or other vendors to submit certain data elements to the 340B repository on their behalf. Covered entities would ultimately certify and be responsible for the accuracy of the submission of data elements to the 340B repository, even if a covered entity has an arrangement with a vendor to submit on its behalf. The data collected from covered entities, or TPAs on their behalf, would then be matched to PDE transactions from the Drug Data Processing System (DDPS) for Part D rebatable drugs dispensed with dates 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.

3. Use of Information Technology

Covered entities that choose to submit data to the 340B repository would submit data elements from claims for covered Part D drugs billed to Medicare Part D and verified by the covered entity as 340B-eligible to the 340B repository on at least a quarterly basis. Covered entities that choose to submit data to the 340B repository are required to submit data using the 340B Repository Data Elements Collection ICR Form. CMS would receive and intake the claims data elements provided from the covered entities. CMS would match submitted claims data from covered entities to PDE transactions from the DDPS system. During the testing period, CMS would assess the usability of this data to identify units associated with PDE transactions that match data elements stored in the 340B repository and that would be considered those for which the manufacturer provided a discount under the 340B Program.

4. Duplication of Efforts

This information collection does not duplicate any other effort, and CMS and covered entities do not otherwise exchange dispensed Part D claim information confirming the 340B status for a Part D rebatable drug.

5. Small Businesses

The impact of this collection on a covered entity is estimated to be the same regardless of the size of the covered entity. The requirements for covered entities that choose to submit data to the 340B repository during the testing period beginning in 2026 do 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 will need to initially establish processes to produce the ongoing data elements submissions. The collection instrument includes the minimum necessary information in a standardized format to ease reporting burden among all covered entities.

6. Less Frequent Collection

In the CY 2026 PFS proposed rule, CMS proposed to require covered entities that choose to submit data to the 340B repository during the testing period beginning in 2026 to submit the fields specified by CMS to the 340B repository on a quarterly basis within 3 months of the end of a given calendar quarter. For example, for claims with dates of service between October 1, 2026, through December 31, 2026, covered entities that choose to submit data to the 340B repository would submit data elements from 340B Part D claims to CMS no later than March 31, 2027. Quarterly submissions are necessary so CMS has more timely information to assess suitability of the data for future use in removing 340B units to develop processes for the 340B repository. In addition, quarterly submissions minimize the burden on covered entities by reducing the amount of data included in each submission (e.g., compared to an annual submission).

7. Special Circumstances

Information collected through the 340B Repository Data Elements Form may contain proprietary, sensitive, or other confidential information. CMS would keep the information collected through this form confidential, to the extent allowable under law. 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)).[2]

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;
- 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

A 60-day notice was published in the Federal Register for the public to submit written comment on the information collection requirements.

Outside Consultation
In the development of the 340B Repository Data Elements ICR Form, CMS sought input from other federal agencies.

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

9. Payments/Gifts to Respondents

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

10. Confidentiality

CMS will keep confidential, to the extent allowable under law, proprietary information submitted by covered entities via the 340B Repository Data Elements ICR Form. Information provided as part of the 340B Repository Data Elements ICR Form 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), (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.

11. Sensitive Questions

There are no sensitive questions associated with this collection.

12. Burden Estimates (Hours & Wages)

CMS used data from the U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wages Estimates to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with manufacturers and covered entities completing the ICR Form form submission, and recordkeeping. [4] Tables 1 and 2 present the mean hourly wage, the cost of fringe benefits and overhead, the adjusted hourly wage, along with total burden and total cost for the form.

The burden estimates associated with the information collected in the following form and record retention requirements are discussed below:

- 340B Repository Data Elements Instructions and Collection ICR Form (Appendix A)

Estimated Burden for Covered Entity to Complete 340B Repository Data Elements ICR Form (Appendix A)

The 340B Repository Data Elements Form (Appendix A) will support CMS' administration of the Medicare Drug Inflation Rebate Program and allow CMS to collect 340B claim data

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

[4] See May 2024 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at: https://data.bls.gov/oes/#/industry/000000

elements via the 340B repository for Medicare Part D claims. These 340B claim data elements would 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-9. Other information collected would include the covered entity's 340B ID and name as designated in OPAIS. Covered entities that choose to submit data to the 340B repository would be required to transmit the 340B Repository Data Elements Form with claim-level data for 340B Medicare Part D claims.

Claim-level data elements from all 340B Part D claims with dates of service during the relevant period should be transmitted to the 340B repository on a quarterly basis by covered entities that voluntarily submit 340B data to the 340B repository. For purposes of this burden estimate, CMS assumes covered entities or their TPAs would have a dedicated Quality Assurance Analyst or team of analysts reviewing sample claim-level data elements and administering reporting to furnish the required data elements. CMS also assumes if a TPA submits claim-level data on behalf of a covered entity, the covered entity would not also submit this data.

For purposes of the burden estimates, CMS assumes approximately 50% of 13,000 (6,500) covered entities would respond to the 340B Repository Data Elements ICR Form in 2026. This number is representative of the unique 340B ID numbers in the 340B OPAIS database that are active (i.e., not terminated) with at least 1 contract pharmacy association listed.[5] Based on comments received on the CY 2025 PFS proposed rule from interested parties, including covered entities, requesting and expressing support for the establishment of a 340B repository, CMS estimates half of covered entities would participate in the 340B repository during the testing period beginning in 2026. 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 have "in-house" pharmacies that are not registered in the 340B OPAIS database or 340B-eligible Aids Drug Assistance Programs (ADAPs) that collect rebates to receive 340B discounts instead of receiving such discount at the time of purchase from a contract pharmacy registered in the 340B OPAIS database.

CMS assumes a dedicated Software Quality Assurance Analyst or Tester or team of analysts at a covered entity or its TPA would spend 6 hours sampling for each submission and a General and Operations Manager would spend 2 hours for each submission. Therefore, the total burden hours for each respondent for each response is 8 hours, with a total cost per respondent per response of $892.12. Responding quarterly, the total annual burden hours for each respondent would be 32 hours, with a total annual cost per respondent of $3,568.48. For 2026, the total annual burden for 6,500 respondents is $23,195,120.00 and 208,000 hours.

[5] See: https://340bopais.hrsa.gov/reports.

TABLE 1: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR A COVERED ENTITY OR TPA COMPLETING 340B REPOSITORY DATA ELEMENTS FORM IN 2026

Occupation Title	Mean Hourly Wage	Cost per hour	# Of Hours per Response per Occupation	Cost per Occupation per Response
General and Operations Managers (11-1021)	$64.00	$128.00	2	$256.00
Software Quality Assurance Analysts and Testers (15-1253)	$53.01	$106.02	6	$636.12
Total			8	$892.12

TABLE 2: SUMMARY OF TOTAL BURDEN OF INFORMATION COLLECTION REQUEST FOR ALL COVERED ENTITIES OR TPAs TO COMPLETE 340B REPOSITORY DATA ELEMENTS FORM IN 2026

Response Frequency	Number of Respondents	Time per Response (Hours)	Total Annual Burden (Hours)	Total Annual Cost
Quarterly	6,500	8	208,000	$23,195,120.00

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.[6] As a result, CMS expects the number of parties submitting claims data may be less than what is outlined above in Table 2, and that Table 2 is representative of the maximum number of potential respondents.

13. Capital Costs

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 covered entities and TPAs that submit claim-level data to 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 covered entities and TPAs.

[6] See: https://www.oregon.gov/oha/HSD/OHP/Tools/340B%20State%20Policy.doc.

To generate salary estimates reflected in Table 3 below, CMS used the 2025 General Schedule (GS) Locality Pay Tables published by the Office of Personnel Management (OPM) for the Washington-Baltimore-Arlington region.[7] In this regard, Table 3 presents the FTE equivalent of staff required for the task, the hourly wage (adjusted for the cost of fringe benefits, calculated at 100 percent of salary), total burden hours, and the total labor cost of the information collection.

The estimates below in Table 3 show the total labor cost to the government for operationalizing the 340B repository. Staffing estimates are based on CMS duties as follows:

- Covered entities and TPAs send submissions formatted in a standardized file template.
- CMS would perform analyses on the submissions of data into the 340B repository, matching covered entities' 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 drug inflation rebate calculation.
- Review and analyze the information submitted by covered entities and TPAs and perform follow up outreach for incomplete submissions.

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 $1,124,417.84.

TABLE 3: TOTAL LABOR COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE BUILD AND OPERATIONS OF THE 340B REPOSITORY IN THE INITIAL YEAR

	FTE	Hourly Wage	Total Burden Hours	Total Labor Cost
340B Claim-Level Data Elements Review Personnel, Wage, and Hours				
GS-13 (step 1)	8	$115.56	8,060	931,413.60
GS-14 (step 1)	3	$136.54	1,365	186,377.10
GS-15 (step 1)	1	$160.62	26	4,176.12
Senior Executive Service	1	$188.54	13	2,451.02
Total Labor Cost to Government Over One Year			**9,464**	**1,124,417.84**

15. Changes to Burden

This is a new information collection request. Therefore, there are no changes to burden compared

[7] See: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2025/DCB_h.pdf.

to any previous collection.

16. Publication/Tabulation Dates

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

17. Expiration Date

The expiration date and OMB control number will be displayed within the data collection information technology system.

18. Certification Statement

There are no exceptions to the certification statement.