

Supporting Statement – Part A
Medicare Part D Manufacturer Discount Program
CMS-10846 (OMB 0938-1451)

Background

On August 16, 2022, Congress enacted the Inflation Reduction Act of 2022, Public L. 117-169 (IRA). Section 11201 of the IRA eliminates the coverage gap phase of the Part D benefit. It also sunsets the coverage gap discount program (CGDP) after December 31, 2024, and amends the Social Security Act (the Act) to add section 1860D-14C, requiring the Secretary to establish a new Medicare Part D manufacturer discount program (Discount Program) beginning January 1, 2025. Under the Discount Program, participating manufacturers are required to provide discounts on their “applicable drugs” (brand drugs, biologics, and biosimilars) both in the initial coverage phase and in the catastrophic coverage phase of the Part D benefit.

Pursuant to section 11201(g) of the IRA, CMS implemented the Discount Program through program instruction, and issued the Discount Program final guidance on November 17, 2023.¹ Section 1860D-14C(a) of the Act requires participating manufacturers to enter into agreements with CMS. Agreements are valid for not less than one year and automatically renew unless terminated by CMS or the manufacturer, as described at section 1860D-14C(b)(4).

Section 1860D-14C(d)(1) of the Act requires CMS to implement and administer the Discount Program, which includes the determination of discounted amounts, procedures to ensure that discounts are applied appropriately, discount payments (reimbursements) are timely made, and to provide a reasonable dispute resolution mechanism to resolve disputes between manufacturers, Part D plan sponsors, and CMS. However, section 1860D-14C(d)(2) of the Act prohibits CMS from directly receiving or distributing any funds of a manufacturer under the Discount Program. As such, CMS uses a third party administrator (TPA) to facilitate program operations in the same manner as had been done for the CGDP. The TPA, a CMS contractor, is an accredited Automated Clearing House (ACH) vendor that uses data from other CMS sources to invoice manufacturers and plan sponsors, processes ACH transactions, and reports ACH activity to CMS.

Discounts are phased in for “specified manufacturers,” defined at section 1860D-14C(g)(4)(B) of the Act, and “specified small manufacturers,” defined at section 1860D-14C(g)(4)(C) of the Act. In order to accurately determine manufacturer discount amounts under the Discount Program, CMS must identify which participating manufacturers qualify for the phased-in discounts using Medicare claims data and ownership information submitted by manufacturers as part of this information collection, pursuant to the requirements at section 1860D-14C(g)(4) of the Act. As discussed in section 50.1 of the final guidance, all manufacturers that enter into a Discount Program agreement in time to participate in any year of the phase-in will be considered for eligibility, and do not need to submit a separate application.

In addition to the information included in this collection, administration of the Discount

¹ The Discount Program final guidance, which was revised on December 20, 2024, can be accessed here: <https://www.cms.gov/files/document/revise-manufacturer-discount-program-final-guidance-12-2024.pdf>.

Program requires plan sponsors to provide data to CMS for discounts the sponsor or its PBM advanced at the point-of-sale for applicable drugs. This data is submitted as part of the Prescription Drug Event (PDE) file for each relevant paid claim, and is accounted for in a separate information collection, CMS-10174 (OMB control number 0938-0982), currently approved through April 30, 2027.

To fulfill the statutory requirements for information collection and program burden, we are submitting this collection for approval as a revision with minor change. CMS revised the burden for manufacturers to remove the one-time burden associated with program implementation, which took place in 2024.

A. Justification

1. Need and Legal Basis

Information in this collection is needed to set up agreements between manufacturers and CMS. Under section 1860D-14C(a) of the Act, such agreements are required for manufacturers in order to participate in the Discount Program and, under section 1860D43(a) of the Act, for their applicable drugs to be covered under Part D beginning in 2025. The information collected from manufacturers in HPMS (Appendix A) is needed to create and execute Discount Program agreements and to determine which manufacturers qualify as a specified manufacturer or specified small manufacturer for phased-in discounts under section 1860D-14C(g)(4) of the Act. Banking information collected by the TPA from manufacturers and plan sponsors (Appendix B) is needed to prepare invoices and process financial transactions (deposits and payments) through the ACH.

2. Information Users

Pursuant to section 1860D-14C(a) of the Act, manufacturers that wish to participate in the Discount Program must enter into agreements with CMS. CMS or its contractor uses the information collected from manufacturers to create and execute the required agreements, determine which drugs are applicable drugs under section 1860D-14C(g)(2) of the Act, identify which manufacturers qualify for phased-in discounts, prepare invoices, and facilitate payments under the program. Manufacturers are also able to update their information and terminate agreements. CMS or its contractor also collects information from Part D plan sponsors to enable sponsors to receive reimbursement for discounts advanced by sponsors at the point-of-sale. Information is collected from respondents electronically, through HPMS or through a secure electronic portal maintained by the TPA.

3. Use of Information Technology

HPMS is used to collect the information necessary to create and execute manufacturer and TPA agreements for the CGDP. Prior to the start of the Discount Program in 2025, CMS enhanced HPMS functionality to support the requirements for the Discount Program. Changes included additional data fields required to operate the Discount Program and other programming

improvements to enable more streamlined data collection. HPMS updates supporting the Discount Program were released in late 2023 and 2024.

The TPA maintains an electronic portal through which participating manufacturers and Part D plan sponsors register, provide banking information, and execute EFT transactions.

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

Small businesses that choose to participate in the Discount Program are required to enter into agreements and to submit the same data specified by the Secretary, pursuant to statutory requirements. As such, there are no discrepancies regarding the burden associated with this collection for small versus large businesses. Software is designed to provide all users with a straightforward and efficient method for providing needed information to CMS to administer the program.

6. Less Frequent Collection

This information cannot be collected less frequently because it is only collected once and is necessary to ensure the statutory requirements for the Discount Program are met.

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

A 60-day notice was published in the Federal Register on June 20, 2025 (90 FR 26301) for the public to submit written comment on this information collection. No comments were received during the 60-day comment period.

A 30-day notice was published in the Federal Register on TBD.

9. Payments/Gifts to Respondents

Respondents will not receive any payments or gifts for responding to this information collection. In order for their applicable drugs to be covered under Part D, manufacturers are required to enter into agreements with CMS and must submit this information.

10. Confidentiality

All information collected will be kept private to the extent allowed by applicable laws and regulations.

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. Collection of Information Requirements and Annual Burden Estimates

Wage Estimates

To derive average costs, we are using data from the May 2024 U.S. Bureau of Labor Statistics' (BLS) National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm). Table 1 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage. The adjusted wages are used to derive our cost estimates.

TABLE 1: National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Business Operations Specialist	13-1000	\$49.08	\$49.08	\$98.16
Top Executive	11-1011	\$145.48	\$145.48	\$290.96
Lawyer	23-1011	\$129.51	\$129.51	\$259.02

We are adjusting the hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Requirements and Associated Burden Estimates

The manufacturer burden associated with the Discount Program requirements is the time and effort for the manufacturer to submit required information, attest to its accuracy and completeness, and electronically sign the agreement. The Discount Program agreement automatically renews after the initial effective period, and CMS will determine specified manufacturers and specified small manufacturers only once when the manufacturer first joins the program. As such, the burden described below is a one-time burden for each manufacturer when that manufacturer commences participation in the program. However, because new manufacturers join the program each year, there is an ongoing annual burden at the program level.

Based on program experience, we estimate that, on average, 40 manufacturers will enter into the Discount Program each year, and use this estimate to annualize the burden. In order to enter into the required agreement with CMS, manufacturers must submit the information described in Appendix A, *Part D Manufacturer Discount Program Data Entry Fields in HPMS*. For the data fields identified in Appendix A, we estimate it will take 40 manufacturers 1 hour for a business operations specialist to gather the required information and submit in HPMS for an annual burden of **40 hours** (40 x 1 hr) and an estimated annual cost of **\$3,926** (\$98.16/hr x 40 hrs).

To execute Discount Program agreements, we estimate that it will take 40 manufacturers 5 hours for a lawyer to review the agreement language for an annual burden of **200 hours** (40 x 5 hrs) and an estimated annual cost of **\$51,804** (\$259.02/hr x 200 hrs). After the relevant legal review, we estimate it will take 40 manufacturers 1 hour for a top executive to review the agreement and attestations and electronically sign in HPMS for an annual burden of **40 hours** (40 x 1 hr) and an estimated annual cost of **\$11,638** (\$290.96/hr x 40 hrs).

Participating manufacturers and Part D plan sponsors are required to submit the information in Appendix B, *Part D Manufacturer Discount Program Third Party Administrator (TPA) Data Entry Fields*. As above, manufacturers that are already participating in the Discount Program and plans with existing Part D contracts have already submitted this information and CMS does not require resubmission outside of any needed updates. We estimate 40 manufacturers will commence participation each year. Based on an April 2025 HPMS extract, we estimate there will be, on average, 40 new Part D plan contracts each year. For the data in Appendix B, we estimate that it will take 40 manufacturers and 40 Part D plan contracts 0.5 hours for a business operations specialist to gather the required information and submit in HPMS for an annual burden of **40 hours** (80 x 0.5 hr) and an estimated annual cost of **\$3,926** (\$98.16 x 40 hrs).

As reflected in Table 2, we estimate the total annual burden for this information collection at **320 hours** with an estimated cost of **\$71,294**.

TABLE 2: Summary of Part D Manufacturer Discount Program Information Collection Burden

Information Collection	Respondents	Responses (per Respondent)	Total Responses	Total Annual Burden for Respondents (hrs)	Labor Cost (\$/hr)	Total Annual Cost (\$)
Gather and submit required information (Appendix A)	40	1	40	40	\$98.16	\$3,926
Legal review of agreement	40	1	40	200	\$259.02	\$51,804
Attestation and agreement signature	40	1	40	40	\$290.96	\$11,638
Gather and submit required information (Appendix B)	80	1	80	40	\$98.16	\$3,926
Total	Varies	1	Varies	320	Varies	\$71,294

13. Capital Costs

There are no capital or start-up costs anticipated for this information collection. Respondents have had data systems in place since 2011 under the CGDP, which had a highly similar operational structure.

14. Cost to Federal Government

The costs to the federal government associated with the Discount Program are the annual costs to administer the program, which is largely routine system maintenance.

To generate the salary estimates in the table below, we used the 2025 General Schedule (GS) Locality Pay Tables published by the Office of Personnel Management (OPM) for the

Washington-Baltimore-Arlington locality.² We adjusted the hourly wage of \$57.78/hr for a GS-13 (step 1) by a factor of 100% to account for fringe benefits, for an adjusted hourly wage of \$115.56/hr.

One-Time Costs

There are no one-time costs to the government.

Annual Costs

We estimated the annual costs to the government for administering the Discount Program based on program experience, including invoices from HPMS and TPA contractors. We estimate the annual cost for maintenance and enhancements to the HPMS module to be \$300,000, and the annual cost to administer the Discount Program to be \$1,738,855. The annual administration cost is reduced from the currently approved ICR as a result of a modification to the contract with the TPA effective in August 2025. These tasks will also be overseen by a CMS employee. We estimate that one GS-13 employee will spend approximately 50 hours to oversee each of these tasks, at an adjusted hourly wage of \$115.56/hr, for a total cost of \$5,778 for each task. As reflected in Table 3, we estimate the total annual cost to the government for the Discount Program to be **\$2,050,411**.

TABLE 3: Annual Cost to Government

Category	Cost
HPMS Discount Program Module - Maintenance and Enhancements	\$300,000
1 GS-13 (step 1): \$115.56/hr x 50 hrs	\$5,778
Discount Program – Program Administration	\$1,738,855
1 GS-13 (step 1): \$115.56/hr x 50 hrs	\$5,778
Total Annual Cost to Government	\$2,050,411

15. Changes to Collection of Information Requirements, Burden, and Collection of Information Instruments

There are no changes to the requirements or to the collection instruments for this collection. Because the Discount Program has already been implemented, we revised the burden for manufacturers to remove the one-time burden associated with program implementation, which took place in 2024. As discussed in more detail in section 12 of this document, we are using an annual burden going forward based on the estimated number of manufacturers that will newly join the Discount Program each year, and the number of new Part D plan contracts that are established each year. While the required information is only collected once from each manufacturer (and for the information in Appendix B, each plan contract), new manufacturers enter into Discount Program agreements and new plan contracts commence every year. We

² https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2025/DCB_h.pdf

updated the estimates for annual costs for manufacturers and Part D plan contracts to reflect the mean hourly wage from the May 2024 BLS' National Occupational Employment and Wage Estimates. Overall, the revisions result in a change in the cost burden associated with this ICR from \$861,880 to \$71,294, which is a decrease of \$790,586.

We also revised section 14 to reflect a decrease in the costs to the government associated with this ICR. Most of the one-time HPMS system changes associated with the Discount Program and included in the currently approved ICR have already been completed and the remaining one-time changes will be completed by July 2025. We also updated the wage estimates to reflect 2025 federal employee wages. Finally, we reduced the annual cost to the government for Discount Program administration, which reflects modifications to the TPA contract beginning in August 2025. The revisions reflect a shift to annual burden and costs for ongoing program administration and routine system maintenance, and result in a change in the costs to the government associated with this ICR from \$3,187,628 to \$2,050,411, which is a decrease of \$1,137,217.

16. Publication/Tabulation Dates

The results of this information collection will not be published for statistical use or analysis. CMS publishes a list of labeler codes associated with applicable drugs for each participating manufacturer, including the date added and the effective date, on a monthly basis through HPMS. This list is used by Part D plan sponsors to identify applicable drugs and advance manufacturer discounts at the point-of-sale. In order to participate in the Discount Program, manufacturers must provide the required information and enter into a Discount Program agreement with CMS.

17. Expiration Date

The expiration date and OMB control number will be displayed in HPMS.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

There are no statistical methods, surveys, or questionnaires.