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

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 will implement the Discount Program through program instruction. On May 12, 2023, CMS issued Discount Program draft guidance[1] through a Health Plan Management System (HPMS) memorandum, giving interested parties an opportunity to review and comment. Comments on the draft guidance were due to CMS on June 12, 2023, and CMS expects to issue final guidance later in 2023. While there are notable differences, the IRA includes many requirements for the Discount Program that largely mirror requirements for the existing CGDP; therefore, CMS intends to implement the Discount Program in a similar manner. Section 1860D-14C(a) of the Act requires participating manufacturers to enter into agreements with CMS no later than March 1, 2024 in order to participate in the Discount Program in 2025. Agreements will be 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 intends to continue using a third party administrator (TPA) to facilitate program operations in the same manner as has 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 implement the Discount Program, CMS will 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

[1] https://www.cms.gov/files/document/part-d-manufacturer-discount-program-draft-guidance-may-2023.pdf

requirements at section 1860D-14C(g)(4) of the Act. When submitting comments on this collection, CMS requests that interested parties give particular attention to the new data fields included in Appendix A that are being added for this purpose.

As discussed in section 50.1 of the draft 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. For the first year of the Discount Program, CMS intends to provide manufacturers that submit and attest to the required ownership information by a certain date (to be announced later this year) with information regarding their eligibility for the phase-ins prior to the statutory deadline of March 1, 2024 to enter into a Discount Program agreement for 2025.

In addition to the information included in this collection, administration of the Discount Program will require 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 February 28, 2025.

To fulfill the statutory requirements for information collection and program burden, we are submitting this collection for approval as a new collection.

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 will use 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 will also be able to update their information and terminate agreements. CMS or its contractor will also collect information from Part D plan sponsors to enable sponsors to receive reimbursement for discounts advanced by sponsors at the point-of-sale. Information will be collected from respondents electronically, through HPMS or through a secure electronic portal maintained by the TPA, in a manner similar to how such information is collected under the existing CGDP.

3. Use of Information Technology

HPMS is currently used to collect the information necessary to create and execute manufacturer and TPA agreements for the CGDP. CMS is enhancing the existing HPMS functionality to support the new requirements for the Discount Program. Changes include 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 are expected to be released in late 2023.

The TPA that administers the CGDP maintains an electronic portal through which participating manufacturers and Part D plan sponsors register, provide banking information, and execute EFT transactions. This portal will be used in the same manner to support the Discount Program.

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 February 7, 2023 (88 FR 7976) for the public to submit written comment on this information collection. We received 2 public comment submissions following the 60-day comment period. A summary of the comments received and CMS' responses can be found in the *Response to Public Comments Received* document included with this posting.

In developing the burden estimates for this collection, CMS considered the burden associated with the CGDP, which has been in place for over 10 years and operates in a similar manner to the Discount Program.

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 2022 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	$45.55	$45.55	$91.10
Top Executive	11-1011	$96.53	$96.53	$193.06
Lawyer	23-1011	$102.37	$102.37	$204.74

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. We estimate that 659 manufacturers will participate in the Discount Program in 2025. This estimate is based on the number of manufacturers expected to participate in the CGDP in 2024, including 621 manufacturers with active agreements in 2023 and 38 additional manufacturers with agreements that will become effective in 2024. 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*. However, most of the information has already been collected in HPMS under the CGDP and CMS does not intend to require manufacturers to resubmit existing information outside of any needed updates (e.g., updating the manufacturer's address, phone number, or point of contact). For the new data fields identified in Appendix A, we estimate it will take 659 manufacturers 1 hour for a business operations specialist to gather the required

information and submit in HPMS for a one-time burden of **659 hours** (659 x 1 hr) and an estimated one-time cost of **$60,035** ($91.10/hr x 659 hrs).

To execute Discount Program agreements, we estimate that it will take 659 manufacturers 5 hours for a lawyer to review the agreement language for a one-time burden of **3,295 hours** (659 x 5 hrs) and an estimated one-time cost of **$674,618** ($204.74/hr x 3,295 hrs). After the relevant legal review, we estimate it will take 659 manufacturers 1 hour for a top executive to review the agreement and attestations and electronically sign in HPMS for a one-time burden of **659 hours** (659 x 1 hr) and an estimated one-time cost of **$127,227** ($193.06/hr x 659 hrs).

The Discount Program agreement automatically renews after the initial effective period, and CMS will determine specified manufacturers and specified small manufacturers only once at the start of the program. As such, the burden described above will be a one-time burden on manufacturers.

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*. We estimate 659 manufacturers will participate in 2025. Based on a January 2023 HPMS extract, we estimate there will be 1065 Part D plan contracts. However, manufacturers and plans have already submitted this information under the CGDP and CMS does not intend to require them to resubmit existing information outside of any needed updates. Based on CGDP program experience, we estimate any ongoing burden on manufacturers and sponsors to be negligible. Therefore, as reflected in Table 2, we estimate the total one-time burden for this information collection at **4,613 hours** with an estimated cost of **$861,880**.

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

Information Collection	Respondents	Responses (per Respondent)	Total Responses	Total One-Time Burden for Respondents (hrs)	Labor Cost ($/hr)	Total One-Time Cost ($)
Gather and submit new required information	659	1	659	659	$91.10	$60,035
Legal review of agreement	659	1	659	3,295	$204.74	$674,618
Attestation and agreement signature	659	1	659	659	$193.06	$127,227
Total	659	1	659	4,613	Varies	$861,880

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 has a highly similar operational structure.

14. Cost to Federal Government

The costs to the federal government associated with the Discount Program include one-time costs to build systems functionality necessary to implement the Discount Program, as well as annual costs to administer the program.

To generate the salary estimates in the tables below, we used the 2023 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 $53.67/hr for a GS-13 (step 1) by a factor of 100% to account for fringe benefits, for an adjusted hourly wage of $107.34/hr.

One-Time Costs

Implementing the Discount Program involves one-time costs to redesign the existing CGDP module in HPMS to accommodate Discount Program, including new data fields (see Appendix A) and enhancing functionality to support multiple programs and minimize information collection burden on respondents, where appropriate. The TPA that will administer the Discount Program will also need to redesign its existing CGDP portal to improve functionality for the new program and produce revised support documentation. These efforts will be undertaken by CMS employees and contractors.

Based on information provided by CMS contractors, the cost of the HPMS redesign is estimated to be $500,000, and the one-time cost to the TPA is estimated to be $1,778,215. Both of these tasks will be overseen by a CMS employee. We estimate that one GS-13 employee will spend approximately 200 hours to oversee each of these tasks, at an adjusted hourly wage of $107.34/hr, for a total cost of $21,468 for each task. These estimates are reflected in Table 3. Annualized over the 3 year approval period, the one-time costs are $773,717 per year ($2,321,151 / 3).

[2] https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/DCB_h.pdf

TABLE 3: One-Time Cost to Government

Category	Cost
HPMS Redesign	$500,000
1 GS-13 (step 1): $107.34/hr x 200 hrs	$21,468
Discount Program Implementation (TPA)	$1,778,215
1 GS-13 (step 1): $107.34/hr x 200 hrs	$21,468
Total One-Time Cost to Federal Government	**$2,321,151**
Total Annualized One-Time Cost to Federal Government	**$773,717**

Annual Costs

We estimated the annual costs to the government for administering the Discount Program based on CGDP 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 $2,103,177. 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 $107.34/hr, for a total cost of $5,367 for each task. These estimates are reflected in Table 4.

TABLE 4: Annual Cost to Government

Category	Cost
HPMS Discount Program Module - Maintenance and Enhancements	$300,000
1 GS-13 (step 1): $107.34/hr x 50 hrs	$5,367
Discount Program – Program Administration	$2,103,177
1 GS-13 (step 1): $107.34/hr x 50 hrs	$5,367
Annualized One-Time Cost to Government (from Table 3)	$773,717
Total Annual Cost to Government	**$3,187,628**

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

This is a new information collection request; however, we have revised the estimates for one-time costs for manufacturers from the 60-day posting based on updates to the mean hourly wage from the BLS' National Occupational Employment and Wage Estimates (updated data released April 2023). We also updated the burden associated with the attestation and signature from a general operations manager (occupation code 11-1021) to a top executive (occupation code 11-1011), because, as discussed in Appendix A, CMS will require this individual to be (1) the chief executive officer (CEO), (2) the chief financial officer (CFO), (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly

delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

16. Publication/Tabulation Dates

The results of this information collection will not be published for statistical use or analysis. As is currently done for the CGDP, CMS will publish 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 in 2025, manufacturers must provide the required information and enter into agreements with CMS no later than March 1, 2024.

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.