Supporting Statement for Paperwork Reduction Act Submissions
Medicare Part D Reporting Requirements and Supporting
Regulations in MMA Title I, Part 423, §423.514
CMS-10185 (OMB 0938-0992)

Background

Section 1860D–12(b)(3)(D) of the Act provides broad authority for the Secretary to add terms to the contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary with information as the Secretary may find necessary and appropriate. Pursuant to our statutory authority, we codified these information collection requirements for Part D sponsors in regulation at 42 CFR §423.514(a).

The Center for Medicare (CM) has identified the appropriate data needed to effectively monitor the Medicare Prescription Drug Benefit through these Part D reporting requirements. Changes to the currently approved data collection instrument reflect new executive orders, legislation, as well as recent changes to Agency policy and guidance. One example is the reporting section, Medicare Prescription Payment Plan, which will support the Inflation Reduction Act's (Section 1860D-2(b)(2)(E) of the Social Security Act, as added by section 11202 of the IRA) provision that all Medicare Part D sponsors offer their Part D enrollees the option to pay their out-of-pocket (OOP) Part D drug costs through monthly payments over the course of the plan year.

A. Justification

1. Need and Legal Basis

42 CFR §423.514(a) requires each Part D sponsor to have a procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public at the times and in the manner that CMS requires statistics indicating the following:

(1) The cost of its operations.
(2) The patterns of utilization of its services.
(3) The availability, accessibility, and acceptability of its services.
(4) Information demonstrating that the Part D sponsor has a fiscally sound operation.
(5) Pharmacy performance measures.
(6) Other matters that CMS may require.

42 CFR §423.505 establishes contract provisions that Part D sponsors must comply with the disclosure and reporting requirements in §423.514.

2. Information Users

Data collected via the Medicare Part D reporting requirements will be an integral resource for oversight, monitoring, compliance, and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. For all reporting sections (Enrollment and Disenrollment, Medication Therapy Management (MTM) Programs, Grievances, Improving Drug Utilization Review Controls, Coverage Determinations and Redeterminations, Employer/Union Sponsored Sponsors, and Medicare Prescription Payment Plan), data are reported electronically to CMS. The data collected via the MTM and Grievances reporting sections are used in the Medicare Part C and D Star Ratings and Display Measures. The other reporting sections' data are analyzed for program oversight to ensure the availability, accessibility, and acceptability of sponsors'

services, such as coverage determinations and appeals processes, and opioid safety edits at the time of dispensing.

Each reporting section is reported at one of the following levels: Contract (data should be entered at the H#, S#, R#, or E# level) or Plan (data should be entered at the Plan Benefit Package (PBP level, e.g. Plan 001 for contract H#, R#, S#, or E). In accordance with 42 CFR §423.505(d), sponsors should retain documentation and data records related to their data submissions. Data will be validated, analyzed, and utilized for trend reporting by the Division of Clinical and Operational Performance (DCOP) within the Medicare Drug Benefit and C & D Data Group. If outliers or other data anomalies are detected, DCOP will work in collaboration with other Divisions within CMS for follow-up and resolution.

3. Use of Information Technology

Part D sponsors will utilize the Health Plan Management Systems (HPMS) system to submit data for 100% of data elements listed within these reporting requirements. The reporting periods vary for each section of the reporting requirements, on a biannual or annual basis. HPMS is the current conduit by which Part D sponsors submit many materials (e.g. formulary, transition, exceptions, and bids) and other information to CMS. CMS and its subcontractors, in turn, communicate to sponsors regarding this information, including approval and denial notices and other related communications. HPMS is a familiar tool for Part D sponsors to navigate through the Part D reporting requirements. Additionally, access to HPMS must be granted to each user, and is protected by individual login and password, electronic signatures are unnecessary.

4. Duplication of Efforts

This collection does not contain duplication of similar information.

5. Small Businesses

This collection does not impose a significant impact on small businesses and other entities.

6. Less Frequent Collection

In an effort to reduce the burden for Part D sponsors, each reporting section varies its reporting timeline to capture data as frequently as necessary without increasing undue burden for Part D sponsors. All reporting sections are collected on an annual basis, with the exception of one - Enrollment and Disenrollment data are collected bi-annually so that data analysis may be completed, and any issues resolved before enrollment/disenrollment activities begin for the following contract year.

7. Special Circumstances

Part D records must be retained for 10 years. CMS could require clarification around submitted data and need to contact Part D sponsors within 30 days of data submission. Otherwise, there are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

(1) Report information to the agency more often than quarterly;

(2) Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
(3) Submit more than an original and two copies of any document;
(4) Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
(5) 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;
(6) Use a statistical data classification that has not been reviewed and approved by OMB;
(7) 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
(8) 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

(1) CM requested the Part D reporting requirements document be posted in the Federal Register on February 2, 2024, and the 60-day comment period ended on April 2, 2024.
(2) From April 3, 2024 to May 3, 2024 CM staff reviewed all received comments and questions, and revised the document appropriately. Also, CM staff prepared a document summarizing responses to comments and questions and a revised Part D reporting requirement document.
(3) CM requested the Part D reporting requirements be posted in the Federal Register on May 24, 2024 and the 30-day comment period ended on June 24, 2024.
(4) From June 26, 2024 to July 19, 2024 CM staff reviewed all received comments and questions and revised the document appropriately. CM staff has prepared a document summarizing responses to comments and questions.
(5) CM is providing a final Part D reporting requirements document for OMB review on July 22, 2024, and requests OMB approval by August 15, 2024.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents associated with this information collection request.

10. Confidentiality

CMS will adhere to all statutes, regulations, and agency policies.

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

For contract year (CY) 2025 Medicare Part D reporting requirements, the following 7 reporting sections will be reported and collected at the Contract-level or Plan-level:

(1) Enrollment and Disenrollment – to evaluate sponsors' processing of enrollment, disenrollment, and reinstatement requests in accordance with CMS requirements.
(2) Medication Therapy Management (MTM) Programs – to evaluate Part D MTM programs, and sponsors' adherence to CMS requirements.
(3) Grievances – to assess sponsors' compliance with timely and appropriate resolution of grievances filed by their enrollees.
(4) Improving Drug Utilization Review Controls – to determine the impact of formulary-level safety edits at point of sale in sponsors' processing of opioid prescriptions.
(5) Coverage Determinations and Redeterminations - to assess sponsors' compliance with appropriate resolution of coverage determinations and redeterminations requested by their enrollees.
(6) Employer/Union Sponsored Sponsors - to ensure PDPs and the employer groups that contract with the PDPs properly utilize appropriate waivers and modifications.
(7) Medicare Prescription Payment Plan – to assess pharmacy benefits and compliance of Part D sponsors relating to program's requirements.

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2022 National Occupational Employment and Wage Estimates (bls.gov) for all salary estimates.

In this regard, the following table presents the median hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Median Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Computer Systems Analyst	15-1211	$49.15	$49.15	$98.30

As indicated, 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 overhead 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 total cost is a reasonably accurate estimation method.

Burden Estimates

The tables below illustrate the estimated hours and costs associated with each reporting section of the CY 2025 Medicare Part D reporting requirements. Please note that the level of each section's reporting (contract or plan level) determines the number of respondents used to base the reporting section's burden estimate.

Level of Reporting	Reporting Section	No. of Hours for Reporting	No. of Respondents	Reporting Freq	No. of Responses (No. of Respondents * Reporting Freq)	Total Part D Hour Burden (No. of Hours for Reporting * No. of Responses)
Contract	Enrollment and Disenrollment	2	1,019	2	2,038	4,076
Contract	Medication Therapy Management Programs	3	1,019	1	1,019	3,057
Contract	Grievances	0.5	1,019	1	1,019	509.5
Contract	Improving Drug Utilization Review Controls	2.0	1,019	1	1,019	2,038
Contract	Coverage Determinations and Redeterminations	6	1,019	1	1,019	6,114
Plan	Employer/Union Sponsored Sponsors	0.5	1,823	1	1,823	911.5
Plan	Medicare Prescription Payment Plan	1	6,388	1	6,388	6,388

No. of Respondents	1,019
Annual Responses=No. Respondents*Reporting Frequency	14,325
Total Hour Burden	23,094
Avg. cost/hr	$98.30/hr
Total Annual Cost = Total Hour Burden*Avg. cost/hr	$2,270,140
Cost Per Response = Total Annual Cost / No. Responses	$158
Cost Per Respondent = Total Annual Cost / No. Respondents	$2,228

Information Collection Instruments/Instructions

- Medicare Part D reporting requirements (Effective January 1, 2025)

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to Federal Government

The cost to the Federal Government will be $300,000 to support electronic data collection through HPMS performed by a contractor.

15. Changes to Burden

There was an overall increase in contract respondents (from 814 to 1019) due to an increase in the total number of Part D contracts.

We are not changing the frequency of any reporting requirements.

Based on comments received during the 60-day comment period, we rescind the proposal to remove one data element in the Medication Therapy Management (MTM) reporting section. There was no change in burden associated with the proposal to remove the data element.

We added a new reporting section – Medicare Prescription Payment Program – which supports oversight of this new program under the Inflation Reduction Act. Based on comments received during the 60-day comment period, we added data elements and increased the hours for each response for this reporting section.

The following table illustrates the section changes in burden hours per response.

Reporting Section	Hours Per Response for CY 2022 Reporting	Hours Per Response for CY 2025 Reporting	Increase/(Decrease)
Enrollment and Disenrollment	2	2	No change
Medication Therapy Management Programs	3	3	No change
Grievances	0.5	0.5	No change
Improving Drug Utilization Review Controls	2	2	No change
Coverage Determinations and Redeterminations	6	6	No change
Employer/Union Sponsored Sponsors	0.5	0.5	No change

Medicare Prescription Payment Plan	n/a – new section	1	Increase

The following table illustrates the change in burden hours per reporting section from CY 2022 to CY 2025:

Reporting Section	No. of Hours for CY2022 Reporting*	No. of Hours for CY2025 Reporting**	Increase/(Decrease)
Enrollment and Disenrollment	3,256	4,076	820
Medication Therapy Management Programs	2,442	3,057	615
Grievances	407	509.5	102.5
Improving Drug Utilization Review Controls	1,628	2,038	410
Coverage Determinations and Redeterminations	4,884	6,114	1,230
Employer/Union Sponsored Sponsors	3,845.5	911.5	(2,934)
Medicare Prescription Payment Plan		6,388	6,388
TOTAL	**16,462.5**	**23,094**	**6,631,50**

* Based on the per response changes cited in the preceding table and 814 contract respondents and 7,691 plan respondents.
**Based on the per response changes cited in the preceding table and 1019 contract respondents and 6,388 plan respondents.

Overall, there was an increase in responses and burden hours associated with this revised data collection, and the annualized burden per respondent increased by 7 hours. These changes are reflected in the revised Part D reporting requirements document. The following table illustrates the changes in burden from CY 2022 to CY 2025:

	CY 2022	CY 2025	Differential
Annual Responses	12,575	14,325	1,750
Annual Hour Burden	16,462.5	23,094	6,631.5
Annualized Burden per Respondent	16	23	7

Data included in Part D reporting requirements are already available to Part D sponsors. CMS does not expect compliance with these reporting requirements would result in additional start-up costs.

Anticipated staff performing these data collection would be data analysts, and/or IT analysts. An adjusted hourly wage of $98.30/hr for a Computer Systems Analyst was used to calculate our cost estimates. The previous hourly wage rate was $92.46/hr for the same position.

16. Publication/Tabulation Dates

Following the final submission of these data in spring of 2026 and independent data validation in the summer of 2026, CMS will release a limited data set of plan-reported data.

17. Expiration Date

The expiration date is set out in the reporting requirements document. (Note the effective date is upon approval by OMB).

18. Certification Statement

There are no exceptions.

B. Collections of Information Employing Statistical Methods

This information collection does not employ any statistical analyses.