

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

Title I, Part 423, §423.514 describes CMS' regulatory authority to establish reporting requirements for Part D sponsors. It is noted that each Part D plan sponsor must have an effective 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 in the following areas:

- (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 plan sponsor has a fiscally sound operation.
- (5) Other matters that CMS may require.

Center for Medicare (CM) has identified the appropriate data needed to effectively monitor plan performance. Changes to the currently approved data collection instrument reflect new executive orders, legislation, as well as recent changes to Agency policy and guidance. We have locked these data elements and do not expect this collection tool to change. Therefore, we are requesting a three-year OMB approval.

A. Justification

1. Need and Legal Basis

In accordance with Title I, Part 423, Subpart K (§ 423.514), the Act requires each Part D Sponsor to have an effective procedure to provide statistics indicating:

- the cost of its operations;
- the patterns of utilization of its services;
- the availability, accessibility, and acceptability of its services;
- information demonstrating it has a fiscally sound operation;
- and other matters as required by CMS

Subsection 423.505 of the MMA regulation establishes as a contract provision that Part D Sponsors must comply with the reporting requirements for submitting drug claims and related information to CMS.

2. Information Users

Data collected via 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, data are reported electronically to CMS. 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). 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.

For CY2017 Reporting Requirements, the following 7 reporting sections will be reported and collected at the Contract-level or Plan-level:

- Enrollment and Disenrollment – to evaluate sponsors’ processing of enrollment, disenrollment, and reinstatement requests in accordance with CMS requirements.
- Retail, Home Infusion, and Long-Term Care Pharmacy Access - to evaluate Part D sponsors’ continued compliance with pharmacy access requirements.
- Medication Therapy Management (MTM) Programs – to evaluate Part D MTM programs, and sponsors’ adherence to CMS requirements.
- Grievances – to assess sponsors’ compliance with timely and appropriate resolution of grievances filed by their enrollees.
- Improving Drug Utilization Review Controls – to determine the impact of formulary-level edits at point of sale in sponsors’ processing of opioid prescriptions.
- Coverage Determinations and Redeterminations - to assess sponsors’ compliance with timely and appropriate resolution of coverage determinations and redeterminations requested by their enrollees.
- Employer/Union Sponsored Sponsors - to ensure PDPs and the employer groups that contract with the PDPs properly utilize appropriate waivers and modifications.

3. Use of Information Technology

Part D Sponsors will utilize the Health Plan Management Systems (HPMS) and the Gentran system to submit or enter data for 100% of data elements listed within these reporting requirements. The reporting time periods vary for each reporting section of the reporting requirements, on a bi-annual or annual basis. HPMS is the current conduit by which Part D Sponsors submit many sources of application materials (e.g. formulary, transition, exceptions, bids) and other ongoing updates to CMS. CMS and its subcontractors, in turn, communicate to Sponsors regarding this information, including approval and denial notices and other related announcements. Gentran is a system used by Part D contracts to submit beneficiary level data that cannot be submitted via HPMS. HPMS and Gentran are both familiar tools for Part D Sponsors to navigate through the Part D reporting requirements. Additionally, as access to HPMS and Gentran 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

- As mandated by MMA, Part D records are to be retained for 10 years.
- CMS could potentially require clarification around submitted data, and therefore CMS may 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:

- 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

The 60-day Federal Register notice published on May 6, 2016 (81 FR 27450). Public comments were received. They are attached to this package along with our response.

This package has been revised subsequent to the publication of the 60-day notice. There have been changes/updates made to the following reporting sections based on public comments: Enrollment/Disenrollment, Improving Drug Utilization Review Controls and Coverage Determinations and Redeterminations. We did not have to revise any burden estimates as a result of the changes/updates made to these sections.

The 30-day Federal Register notice published on September 12, 2016. Public comments were received, and attached to this package with our response. No changes were made as a result of these comments.

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)

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' 2015 National Occupational Employment and Wage Estimates for all salary estimates

(http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
Computer Systems Analyst	15-1121	43.36	43.36	86.72

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. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Burden Estimates

The table below illustrates the estimated hours and costs associated with each reporting section of the CY2017 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.

CY2017 Estimated Hours and Costs						
Reporting Section	Level of Reporting	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)
Enrollment and Disenrollment	Contract	2	561	2	1,122	2,244
Retail, Home Infusion, and Long-Term Care Pharmacy Access	Contract	1	561	1	561	561
Medication Therapy Management Programs	Contract	2.5	561	1	561	1,402.5
Grievances	Contract	2	561	1	561	1,122
Improving Drug Utilization Review Controls	Plan	1	4,036	1	4,036	4,036
Coverage Determinations	Contract	6	561	1	561	3,366

and Redeterminations						
Employer/Union Sponsored Sponsors	Plan	0.5	4,036	1	4,036	2,018
Total					11,438	14,749.5

No. of Respondents	561
Annual Responses=No. Respondents*Reporting Frequency	11,438
Total Hour Burden	14,749.5
Avg. cost/hr	\$86.72/hr
Annualized hours/respondent = Total Hour Burden/No. of Respondents	26.29
Annualized wage hours = Avg. cost/hr*Annualized hours/respondent	2,279.99
Total Annual Cost = Total Hour Burden*Avg. cost/hr	\$1,279,076.64

Information Collection Instruments/Instructions

- Medicare Part D Reporting Requirements (Effective January 1, 2017)

13. Capital Costs

There is 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

Data included in Part D Reporting Requirements are already available to Part D Sponsors. CMS does not expect compliance to 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 average competitive hourly wage rate of \$86.72/hr for a Computer Systems Analyst was used to calculate estimated costs. The previous hourly wage rate was \$83.96/hr for the same position. Please refer to the tables set out above under section 12 for details on estimated burden hours and costs.

There was an overall increase in respondents and burden estimates associated with this reporting due to

an increase in the total number of Part D contracts.

For CY2017, to determine the total number of annual responses, we summed the number of responses for each reporting section.

With regard to the CY 2017 Medicare Part D Reporting Requirements, we added a new section, Improving Drug Utilization Review Controls, due to new CMS expectations in the 2017 Call Letter for Sponsors' processing of opioid prescriptions. We also added data elements to the Enrollment and Disenrollment reporting section to monitor changes in Sponsors' enrollment processes. Additionally, we removed Sponsor Oversight of Agents reporting section and decreased our time estimate since this data are no longer necessary for monitoring through these reporting requirements. Lastly, we increased the number of hours associated with reporting the Coverage Determinations and Redeterminations section to account for a more detailed data collection about the types of coverage determinations processed.

The following table illustrates the change in burden hours per reporting section from CY2016 to CY2017:

Reporting Section	No. of Hours for CY2016 Reporting	No. of Hours for CY2017 Reporting	Increase/(Decrease)
Enrollment and Disenrollment	1.5	2	.5
Retail, Home Infusion, and Long-Term Care Pharmacy Access	1	1	-
Medication Therapy Management Programs	2.5	2.5	-
Grievances	2	2	-
Improving Drug Utilization Review Controls	-	1	1
Coverage Determinations and Redeterminations	3	6	3
Employer/Union Sponsored Sponsors	0.5	0.5	-
Sponsor Oversight of Agents	2.5	0	(2.5)

Overall, there was an increase in

responses and burden hours associated with this revised data collection; however, annualized burden per respondent has increased. These changes are reflected in the revised Reporting Requirements document. The following table illustrates the changes in burden from CY2016 to CY2017:

	CY2016	CY2017	Differential
Annual Responses	5,487	11,438	5,951
Annual Hour Burden	8,783	14,749.5	5,966.5
Annualized Burden per Respondent	15	17	2

16.

Publication/Tabulation Dates

Following final submission of these data in the spring 2018, and independent data validation in summer 2018, CMS will publish a summary report by December 2018 of select reporting areas. The report will provide program-wide averages and identifies historical trends to provide information about beneficiary experience, sponsor performance, and overall program functioning. CMS will also release a public use file (PUF) of validated plan-reported data.

17. Expiration Date

The expiration date is set out in the Reporting Requirement 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.