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.

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 (Enrollment and Disenrollment, Medication Therapy Management Programs (MTM), Grievances, Improving Drug Utilization Review Controls, Coverage Determinations and Redeterminations, and Employer/Union Sponsored Sponsors), data are reported electronically to CMS. The data collected via the MTM and Grievances reporting sections are used in the 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 or enter data for 100% of data elements listed within these reporting requirements. The reporting time 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 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. 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

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 notice published in the Federal Register on February 26, 2020 (85 FR 11087). Four public comments were received. They are attached to this package along with our responses.

- CM has requested the Part D reporting requirement document be posted in the Federal Registry on February 26, 2020 and the 60-day comment period will end April 27, 2020.
- From April 28, 2020 to May 28, 2020 CM staff will review all received comments and questions, and revise the document appropriately. Also, CM staff will prepare a response document summarizing all received comments and questions, and their responses. A revised Part D reporting requirement document will be provided.

The 30-day notice published in the Federal Register on May 29, 2020 (85 FR 32399). CMS received various comments from Part D Sponsors, PBMs, and other associations. We received 35 comments regarding the following reporting sections: Enrollment and Disenrollment, Improving Drug Utilization Review Controls, Coverage Determinations and Redeterminations, Grievances and Medication Therapy Management. They are attached to this package along with our responses.

- CM has requested the Part D reporting requirements be posted in the Federal Registry (85 FR 32399) on May 29, 2020 and the 30-day comment period will end June 28, 2020. From July 1, 2020 to August 1, 2020 CM staff will review all received comments and questions, and revise the document appropriately. Also, CM staff will prepare a response document summarizing all received comments and questions, and their responses. The response document and the final Part D reporting requirement document will be delivered for OMB review by July 23, 2020.

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 CY2021 Reporting Requirements, the following 6 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.
- 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 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.

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' 2018 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	45.01	45.01	90.02

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 table below illustrates the estimated hours and costs associated with each reporting section of the CY2021 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.

CY2021 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	744	2	1,488	2,976
Medication Therapy Management Programs	Contract	3	744	1	744	2,232
Grievances	Contract	0.5	744	1	744	372
Improving Drug Utilization Review Controls	Plan	2.0	6,680	1	6,680	13,360
Coverage Determinations and Redeterminations	Contract	4	744	1	774	2,976
Employer/Union Sponsored Sponsors	Plan	0.5	6,680	1	6,680	3,340
				Total	**17,080**	**25,256.0**

No. of Respondents	744
Annual Responses=No. Respondents*Reporting Frequency	17,080
Total Hour Burden	25,256
Avg. cost/hr	$90.02hr

Total Annual Cost = Total Hour Burden*Avg. cost/hr	$2,273,545.12
Cost Per Response = Total Annual Cost / No. Responses	$133.11
Cost Per Respondent = Total Annual Cost / No. Respondents	$3,055.84

Information Collection Instruments/Instructions

- Medicare Part D Reporting Requirements (Effective January 1, 2021)

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

There was an overall increase in contract respondents (from 627 to 744) and plan respondents (from 5,234 to 6,680) due to an increase in the total number of Part D contracts.

We are not changing any of our frequency of reporting requirements.

For CY2021, to determine the total number of annual responses, we summed the number of responses for each reporting section.

With regard to the CY 2021 Medicare Part D Reporting Requirements, we added data elements to the MTM reporting section. In accordance with February 2020 proposed rule (85 FR 9002), specifically proposing to implement sections 6064 and 6103 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act , CMS added two new data elements to the MTM reporting section to oversee implementation of the new requirements of the SUPPORT Act if applicable. Due to the addition of the two new elements, as well as an increase in the number of respondents from 627 in CY 2019 to a 744 in CY 2021, CMS increased our response estimate. Consequently, we increased our per response estimate for MTM from 2.5 hr/response to 3.0 hr/response. The new data elements added to the Improving Drug Utilization Review Controls reporting section provide CMS with more detail about beneficiaries who are subject to the recommended opioid safety edits. For the care coordination edit, hard morphine milligram equivalents (MME) edit, and opioid naïve hard edit, CMS added elements to capture the total number of claims rejected for these edits that subsequently process successfully at point of sale (POS), as well as whether the paid claim is the result of a POS override, partial fill, approved coverage determination or appeal, etc. CMS also added an element to capture the total number of beneficiaries whose claims processed at POS for the opioid naïve and the hard MME edits. These revisions make review and analysis of the data more comprehensive and assist with monitoring the impact

of the opioid safety edit policies. Consequently, we increased our per response estimate for Improving Drug Utilization Review Controls from 1.5 hr/response to 2.0 hr/response.

The following table illustrates the section changes in burden hours per response from CY2019 to CY2021:

Reporting Section	Hours Per Response for CY2019 Reporting	Hours Per Response for CY2021 Reporting	Increase/(Decrease)
Enrollment and Disenrollment	2	2	No change
Medication Therapy Management Programs	2.5	3.0	0.5
Grievances	0.5	0.5	No change
Improving Drug Utilization Review Controls	1.5	2	0.5
Coverage Determinations and Redeterminations	4	4	No change
Employer/Union Sponsored Sponsors	0.5	0.5	No change

*Removed in its entirety.

The following table illustrates the change in burden hours per reporting section from CY2019 to CY2021:

Reporting Section	No. of Hours for CY2019Reporting*	No. of Hours for CY2021Reporting**	Increase/(Decrease)
Enrollment and Disenrollment	2,508	2,976	168
Medication Therapy Management Programs	1,567.5	2,232	664.5
Grievances	313.5	372	58.5
Improving Drug Utilization Review Controls	7,851	13,360	5,509
Coverage Determinations and Redeterminations	2,508	2,976	468
Employer/Union Sponsored Sponsors	2,617	3,340	723
TOTAL	**17,365**	**25,256**	**7,591**

*Based on the per response changes cited in the preceding table and 627 contract respondents and 5,234 plan respondents.

**Based on the per response changes cited in the preceding table and 744 contract respondents and 6,680 plan respondents.

Overall, there was an increase in responses and burden hours associated with this revised data collection; however, annualized burden per respondent increased by 1. These changes are reflected in the revised Reporting Requirements document. The following table illustrates the changes in burden from CY2019 to CY2021:

	CY2019	CY2021	Differential
Annual Responses	13,603	17,080	3,477
Annual Hour Burden	17,365	25,256	7,891
Annualized Burden per Respondent	13	14	1

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 adjusted hourly wage of $90.02/hr for a Computer Systems Analyst was used to calculate our cost estimates. The previous hourly wage rate was $89.18/hr for the same position.

16. Publication/Tabulation Dates

Following final submission of these data in the spring 2022, and independent data validation in summer 2022, 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.