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)

We have locked the collection's data elements and do not expect the collection tool to change. Therefore, we are requesting a three-year approval period.

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.

For the CY2019 Reporting Requirements, we removed the Retail, Home Infusion and Long-Term Care Pharmacy Access section since the data are no longer necessary to collect through these reporting requirements. Consequently, the remaining 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.

There was an overall increase in contract respondents (from 561 to 627) and plan respondents (from 4,036 to 5,234) due to an increase in the total number of Part D contracts. Overall, there was an increase in responses (from 11,438 to 13,603) and total time (from 14,750 hours to 17,365 hours). See section 15 of this Supporting Statement for details.

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.

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 notice published in the Federal Register on February 28, 2018 (83 FR 8679). Public comments were received. They are attached to this package along with our responses.

This package has been revised subsequent to the publication of the 60-day notice. There have been changes/updates made to the following two reporting sections based on public comments and internal review: Improving Drug Utilization Review Controls and Medication Therapy Management Programs. We revised burden estimates to the Improving Drug Utilization Controls section as a result of the changes/additional elements to this section. These updates were largely necessary to accurately reflect guidance finalized in the final 2019 Call Letter, especially related to the Medicare Part D opioid overutilization policy, which was released after CMS released the 60-day PRA package for this data collection tool. Final reporting requirements will be posted on www.cms.gov by January 2019.

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)

We have locked the collection's data elements and do not expect the collection tool to change. Therefore, we are requesting a three-year approval period.

For CY2019 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' 2017 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	44.59	44.59	89.18

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 CY2019 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.

CY2019 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	627	2	1,254	2,508.0
Medication Therapy Management Programs	Contract	2.5	627	1	627	1,567.5
Grievances	Contract	0.5	627	1	627	313.5
Improving Drug Utilization Review Controls	Plan	1.5	5,234	1	5,234	7,851.0
Coverage Determinations and Redeterminations	Contract	4	627	1	627	2508.0
Employer/ Union Sponsored Sponsors	Plan	0.5	5,234	1	5,234	2,617.0
				Total	**13,603**	**17,365**

No. of Respondents	627
Annual Responses=No. Respondents*Reporting Frequency	13,603

Total Hour Burden	17,365
Avg. cost/hr	$89.18/hr
Total Annual Cost = Total Hour Burden*Avg. cost/hr	$1,548,610.70
Cost Per Response = Total Annual Cost / No. Responses	$113.84
Cost Per Respondent = Total Annual Cost / No. Respondents	$2,469.87

Information Collection Instruments/Instructions

- Medicare Part D Reporting Requirements (Effective January 1, 2019)

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

We have locked the collection's data elements and do not expect the collection tool to change. Therefore, we are requesting a three-year approval period.

There was an overall increase in contract respondents (from 561 to 627) and plan respondents (from 4,036 to 5,234) due to an increase in the total number of Part D contracts.

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

For CY2019, to determine the total number of annual responses, we summed the number of responses for each reporting section.

With regard to the CY 2019 Medicare Part D Reporting Requirements, we added new data elements to the Improving Drug Utilization Review Controls reporting section to fully capture the means by which beneficiaries who were subject to the opioid safety edits received an opioid fill. For example, a favorable coverage determination does not necessarily mean that a beneficiary received a processed claim for an opioid medication. Therefore, we added elements to differentiate the number of beneficiaries who received a favorable coverage determination or appeal and the number that subsequently had a processed claim, or the number of beneficiaries that had a processed claim at point-of sale due to an override (other than through the coverage determination process). We also finalized a new hard opioid naïve days supply safety edit for initial opioid prescription fills that exceed 7 days for the treatment of acute pain, which accounts for the majority of the additional elements. Consequently, we increased our per response

estimate from 1.0 hr/response to 1.5 hr/response.

We removed Retail, Home Infusion and Long-Term Care Pharmacy Access section and thereby decreased our time estimate by -561 hours (total) since these data are no longer necessary for data collection through these reporting requirements. These data are now captured through the Medicare Plan Finder pharmacy files (approved by OMB under control number 0938- 0951). This source allows monitoring at the plan level quarterly, versus at the contract level annually. In the interest of reducing provider burden, we removed specific grievances fields that were not utilized by CMS for data analysis. The number of hours associated with reporting the Grievances (-1.5 hr/response) and Coverage Determinations and Redeterminations (-2.0 hr/response) section decreased to account for a less detailed data collection about the types of grievances and coverage determinations processed. We removed the timeliness data elements from the Coverage Determinations and Redeterminations section because the plans were not providing accurate data.

The following table illustrates the section changes in burden hours per response from CY2017 to CY2019:

Reporting Section	**Hours Per Response for CY2017 Reporting**	**Hours Per Response for CY2019 Reporting**	**Increase/(Decrease)**
Enrollment and Disenrollment	2	2	No change
Retail, Home Infusion, and Long-Term Care Pharmacy Access	1	0	(1)*
Medication Therapy Management Programs	2.5	2.5	No change
Grievances	2	0.5	(1.5)
Improving Drug Utilization Review Controls	1	1.5	0.5
Coverage Determinations and Redeterminations	6	4	(2)
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 CY2017 to CY2019:

Reporting Section	**No. of Hours for CY2017 Reporting***	**No. of Hours for CY2019 Reporting****	**Increase/(Decrease)**
Enrollment and Disenrollment	2,244	2,508	264
Retail, Home Infusion, and	561	0	(561)

Reporting Section	No. of Hours for CY2017 Reporting*	No. of Hours for CY2019 Reporting**	Increase/(Decrease)
Long-Term Care Pharmacy Access			
Medication Therapy Management Programs	1,402.5	1,567.5	165
Grievances	1,122	313.5	(809)
Improving Drug Utilization Review Controls	4,036	7,851	3,815
Coverage Determinations and Redeterminations	3,366	2,508	(858)
Employer/Union Sponsored Sponsors	2,018	2,617	599
TOTAL	**14,750**	**17,365**	**2,616**

*Based on the per response changes cited in the preceding table and 561 contract respondents and 4,036 plan respondents.
**Based on the per response changes cited in the preceding table and 627 contract respondents and 5,234 plan respondents.

Overall, there was an increase in responses and burden hours associated with this revised data collection; however, annualized burden per respondent has decreased. These changes are reflected in the revised Reporting Requirements document. The following table illustrates the changes in burden from CY2017 to CY2019:

	CY2017	CY2019	Differential
Annual Responses	11,438	13,603	2,170
Annual Hour Burden	14,750	17,365	2,615
Annualized Burden per Respondent	17	13	(4)

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 $89.18/hour for a Computer Systems Analyst was used to calculate our cost estimates. The previous hourly wage rate was $86.72/hour for the same position.

16. Publication/Tabulation Dates

Following final submission of these data in the spring 2020, and independent data validation in summer 2020, CMS will publish a summary report by December 2020 of select reporting areas. The reporting areas that will be included in the 2020 summary report are: Enrollment and Disenrollment, Medication Therapy Management Programs, Grievances, Improving Drug Utilization Review Controls, Coverage Determinations and Redeterminations and Employer/Union Sponsored Sponsors. 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.