Supporting Statement, Part A
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 CY 2016/2017 Reporting Requirements, the following 7 reporting sections will be reported and collected at the Contract-level or Plan-level:

- Enrollment and Disenrollment
- Retail, Home Infusion, and Long-Term Care Pharmacy Access
- Medication Therapy Management (MTM) Programs
- Grievances
- Coverage Determinations and Redeterminations
- Employer/Union Sponsored Sponsors
- Sponsor Oversight of Agents

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. Access to HPMS and Gentran must be granted to each user, and requires individual login and password.

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 data collection is on an annual or bi-annual basis.

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.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on May 1, 2015 (80 FR 24934). Comments were received. A summary of the comments along with our response has been added to this PRA package. The original comments are also attached.

9. Payments/Gifts to Respondents

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

10. Confidentiality

Consistent with federal government and CMS policies, CMS will protect the confidentiality of the requested information. Specifically, only information within a submitted application (or attachments thereto) that constitutes a trade secret, privileged or confidential information, (as such terms are interpreted under the Freedom of Information Act and applicable case law), and is clearly labeled as such by the Applicant, and which includes an explanation of how it meets one of the exceptions specified in 45 CFR Part 5, will be protected from release by CMS under 5 U.S.C. 552(b) (4). Information not labeled as trade secret, privileged, or confidential or not including an explanation of why it meets one of the FOIA exceptions in 45 CFR part 5 will not be withheld from release under 5 U.S.C. 552(b) (4).

11. Sensitive Questions

CMS will adhere to all statutes, regulations, and agency policies. 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' 2014 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes151121.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	$41.98	$41.98	$83.96

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 following table illustrates the estimated hours and costs associated with each reporting section of the CY 2016/2017 Medicare Part D Reporting Requirements.

CY 2016/2017 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	1.5	694	2	1,388	2,082
Retail, Home Infusion, and Long-Term Care Pharmacy Access	Contract	1	694	1	694	694
Medication Therapy Management Programs	Contract	2.5	694	1	694	1,735
Grievances	Contract	2	694	1	694	1,388
Coverage Determinations and Redeterminations	Contract	3	694	1	694	2,082
Employer/ Union Sponsored Sponsors	Plan	0.5	1,253	1	1,253	626.5
Sponsor Oversight of Agents	Contract	2.5	70	1	70	175
				Total	**5,487**	**8,782.5**

No. of Respondents	694
Annual Responses=No.	5,487

Respondents*Reporting Frequency	
Total Hour Burden	8,782.5
Avg. cost/hr	$83.96
Annualized hours/respondent = Total Hour Burden/No. of Respondents	12.65
Annualized wage hours = Avg. cost/hr*Annualized hours/respondent	1,062
Total Annual Cost = Total Hour Burden*Avg. cost/hr	$ 737,378.70

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.

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 $83.96 was used to calculate estimated wages. Please refer to tables under section 12 of this Supporting Statement for details on estimated hours and costs.

There was an overall decrease in responses and hour estimates associated with this reporting due to a smaller number of Part D sponsors required to report.

For CY 2016/2017, to determine the total number of annual responses, we summed the number of responses for each reporting section. This is indicated in the Supporting Statement in the chart under section 12 of this Supporting Statement.

We added four data elements to the Enrollment and Disenrollment reporting section; however, this revision did not result in a change in hours for this section. Additionally, we removed Prompt Payment to Part D Sponsors and Fraud, Waste, and Abuse reporting sections and decreased hour estimates associated with these sections because these data are no longer necessary for monitoring through these reporting requirements. Similarly, we removed the Long-Term Care (LTC) Utilization reporting section and decreased hour estimates associated with the section because information can be obtained via other data already reported to CMS. Lastly, we renamed Plan Oversight of Agents to Sponsor

Oversight of Agents and increased the number of hours associated with this reporting section. We made this change based on technical questions received from sponsors which indicated that the collection had a higher burden that we initially estimated.

This is a revised data collection in comparison to the CY 2014/2015 Medicare Part D Reporting requirements. The following table illustrates the change in burden hours per reporting section from CY 2014/2015 to CY 2016/2017:

Reporting Section	No. of Hours for CY 2014/2015 Reporting	No. of Hours for CY 2016/2017 Reporting	Increase/(Decrease)
Enrollment and Disenrollment	1.5	1.5	-
Retail, Home Infusion, and Long-Term Care Pharmacy Access	1	1	-
Medication Therapy Management Programs	2.5	2.5	-
Prompt Payment by Part D Sponsors	1	0	(1)
Grievances	2	2	-
Coverage Determinations and Redeterminations	3	3	-
LTC Utilization	1.5	0	(1.5)
FWA Compliance Programs	1	0	(1)
Employer/Union Sponsored Sponsors	0.5	0.5	-
Sponsor Oversight of Agents	0.5	2.5	2

Overall, there was a decrease in responses, burden hours, and the annualized burden per respondent associated with this revised data collection. These changes are reflected in the revised Reporting Requirements document. The following table illustrates the changes in burden from CY 2014/2015 to CY 2016/2017:

	CY 2014/2015	CY 2016/2017	Differential
Annual Responses	8,067	5,487	(2,580)
Annual Hour Burden	12,658	8,782.5	(3,875.5)

Annualized Burden per Respondent	18	15	(3)

Additionally, MTM-Element X, within the Medicare Therapy Management section, is suspended. The utility of these free-text data are limited. There is work in the industry to develop standardized fields for this information. We will suspend collection of this type of information until a more standardized set of data can be collected.

16. Publication/Tabulation Dates

Collection of these data will commence in January 1, 2016, and the first reporting deadline will be May 2, 2016 and the last will be February 28, 2017. These data undergo data validation which is completed June 30, 2017. The validated data are analyzed and a summary report and public use file are developed for public release. Since this is a coverage benefit for Medicare beneficiaries, the collection of these data from PDPs and MA-PDs will continue indefinitely.

17. Expiration Date

OMB's expiration date will be displayed on the cover page of the Medicare Part D Reporting Requirements document.

18. Certification Statement

There are no exceptions.

B. Collections of Information Employing Statistical Methods

This information collection does not employ any statistical analyses.