Supporting Statement for Paperwork Reduction Act Submissions: Medicare Part D Reporting Requirements and Supporting Regulations in MMA Title I, Part 423, §423.514

A. 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.

B. 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 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 CY2014 Reporting Requirements, the following 10 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
- Prompt Payment by Part D Sponsors
- Grievances
- Coverage Determinations and Redeterminations
- LTC Utilization
- Fraud, Waste, Abuse (FWA) Compliance Programs
- Employer/Union Sponsored Sponsors
- Plan 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. 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 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 March 15, 2013.

Final reporting requirements will be posted on www.cms.gov by December 2013.

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

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

12. Burden Estimates (Hours & Wages)

The table below illustrates the estimated hours and costs associated with each reporting section of the CY2014 Medicare Part D Reporting Requirements.

CY2014 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	690	2	1,380	2,070
Retail, Home Infusion, and Long-Term Care Pharmacy Access	Contract	1	690	1	690	690
Medication Therapy Management Programs	Contract	2.5	690	1	690	1,725
Prompt Payment of Part D Sponsors	Contract	1	690	2	1,380	1,380
Grievances	Contract	2	690	1	690	1,380
Coverage Determinations and Redeterminations	Contract	3	690	1	690	2,070
LTC Utilization	Contract	1.5	690	2	1,380	2,070
FWA Compliance Programs	Contract	1	690	1	690	690
Employer/ Union Sponsored Sponsors	Plan	0.5	455	1	455	227.5
Plan Oversight of Agents	Contract	2.5	22	1	22	55
				Total	**8,067**	**12,358***

- **The total hour burden actually calculates to 12,657.5; however, we rounded the total to the nearest whole hour.**

No. of Respondents	690
Annual Responses=No. Respondents*Reporting Frequency	8,067
Total Hour Burden	12,658*
Avg. cost/hr	$46.73
Annualized hours/respondent = Total Hour Burden/No. of Respondents	17.91
Annualized wage hours = Avg. cost/hr*Annualized hours/respondent	836.91
Total Annual Cost = Total Hour Burden*Avg. cost/hr	$ 577,465.98

- **The total hour burden actually calculates to 12,657.5; however, we rounded the total to the nearest whole hour.**

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 $46.73 was used to calculate estimated wages. Please refer to table listed under #12 for details on estimated burden hours and costs.

There was an overall decrease in responses and burden estimates associated with this reporting.

For CY2014, 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 #12.

We removed and/or added data elements for the Medication Therapy Management Programs reporting section; however, these revisions did not result in a change in burden for

this reporting section. In addition, we combined the Coverage Determinations and Exceptions reporting section with the Redeterminations reporting section and renamed the newly created reporting section "Coverage Determinations and Redeterminations." We added new data elements and/or revised existing data elements in this combined section. The burden for this new combined section is a sum of the burden associated with the previous two separate sections. We also added new data elements and/or revised existing data elements for the Grievances, and Plan Oversight of Agents reporting sections, which resulted in an increase in burden hours. Lastly, we removed Pharmacy & Therapeutics (P&T) Committees/Provisions of Part D reporting section and decreased burden estimates associated with these reporting sections because these data are no longer necessary for monitoring through these reporting requirements and are collected via another mechanism.

This is a revised data collection in comparison to the CY2013 Medicare Part D Reporting requirements. The following table illustrates the change in burden hours per reporting section from CY2013 to CY2014:

Reporting Section	No. of Hours for CY2013 Reporting	No. of Hours for CY2014 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	1	-
Grievances	2	2	-
Coverage Determinations and Exceptions	2	0	(2)
Redeterminations	1	0	(1)
Coverage Determinations and Redeterminations	0	3	3
LTC Utilization	1.5	1.5	-
FWA Compliance Programs	1	1	-
Employer/Union Sponsored Sponsors	0.5	0.5	-
Plan Oversight of Agents	0.5	2.5	2

There was an overall decrease in responses, burden hours, and annualized burden per respondent associated with this revised data collection. The decrease in responses, burden hours, and annualized burden per respondent associated with this data collection is attributed to the removal of one reporting section.

These changes are reflected in the revised Reporting Requirements document. The following table illustrates the changes in burden from CY2013 to CY2014:

	CY2013	CY2014	Differential
Annual Responses	11,269	8,067	3,202
Annual Hour Burden	14,774	12,358	2,416
Annualized Burden per Respondent	23	18	5

16. Publication/Tabulation Dates
    Collection of these data will commence in January 1, 2014, and the first reporting deadline will be May 31, 2014. 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
    This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement
    There are no exceptions.

C. Collections of Information Employing Statistical Methods

This information collection does not employ any statistical analyses.