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.

After six years of experience with oversight and monitoring of the Reporting Requirements, 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 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 CY2013 Reporting Requirements, the following 12 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
- Pharmacy & Therapeutics (P&T) Committees/Provision of Part D Functions
- Coverage Determinations and Exceptions
- 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 section of the reporting requirements, on a quarterly, semi-annually or yearly 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 requirement section varies its reporting timeline to capture data as frequently as necessary without increasing undue burden for Part D Sponsors. Most data collection are on a biannual or more frequent

basis. Less frequent collection of the reporting requirement data from Part D Sponsors would severely limit CMS' ability to perform accurate and timely oversight, monitoring, compliance and auditing activities around the Part D prescription drug benefit.

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

   CM's proposed timeframe for Federal Register/outside consultation is as follows:
   - CM has requested the Part D reporting requirement document be posted in the Federal Registry on April 20, 2012, and the 60-day comment period will end June 19, 2012.
   - From June 20, 2012 to July 9, 2012 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. CM has requested the Part D reporting requirements be posted in the Federal Registry on July 13, 2012, and the 30-day comment period will end August 12, 2012.
   - From August 13, 2012 to September 12, 2012, 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 final Part D reporting requirement document will be delivered for OMB review by September 17, 2012.

Final reporting requirements will be posted on www.cms.gov by December 2012.

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 section of the CY2013 Medicare Part D Reporting Requirements.

CY2013 Estimated Hours and Costs						
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	637	4	2,548	3,822
Retail, Home Infusion, and Long-Term Care Pharmacy Access	Contract	1	637	1	637	637
Medication Therapy Management Programs	Contract	2.5	637	1	637	1,593
Prompt Payment of Part D Sponsors	Contract	1	637	2	1,274	1,274
Grievances	Plan	2	3,180	4	12,720	25,440
Pharmacy & Therapeutics (P&T) Committees/Provision of Part D functions	Contract	1	637	4	2,548	2,548
Coverage Determinations and Exceptions	Plan	2	3,180	4	12,720	25,440
Redeterminations	Plan	1	3,180	4	12,720	12,720
LTC Utilization	Contract	1.5	637	2	1,274	1,911
FWA Compliance Programs	Contract	1	637	1	637	637
Employer/Union Sponsored Sponsors	Plan	0.5	421	1	421	211
Plan Oversight of Agents	Contract	0.5	16	1	16	8
				Total	**48,152**	**76,240**

No. of Respondents	3,180
Annual Responses=No. Respondents*Reporting Frequency	48,152
Total Hour Burden	76,240
Avg. cost/hr	$46.73
Annualized hours/respondent = Total Hour Burden/No. of Respondents	23.97
Annualized wage hours = Avg. cost/hr*Annualized hours/respondent	1,120..34
Total Annual Cost = Total Hour Burden*Avg. cost/hr	$ 3,562,695.20

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 increase in respondents and burden estimates associated with this reporting.

    For CY2013, to determine the total number of annual responses, we summed the number of

responses for each section. This is indicated in the Supporting Statement in the chart under #12.

We removed and/ or added data elements for the Prompt Payment by Part D Sponsors, Grievances, Fraud, Waste, and Abuse Compliance Programs, and Plan Oversight of Agents reporting sections; however, these changes resulted in no changes to the burden for these sections. In addition, we added data elements and revised data elements for the Medication Therapy Management Programs and the Coverage Determinations and Exceptions reporting sections, which resulted in an increase in burden hours for both sections. Lastly, we removed the following reporting sections and decreased burden estimates associated with these sections because these data are no longer necessary for monitoring through these reporting requirements:

- Access to Extended Day Supplies at Retail Pharmacies
- Pharmacy Support of E-prescribing

This is a revised data collection in comparison to the CY2012 Medicare Part D Reporting requirements. The following table illustrates the change in burden hours per reporting section from CY2012 to CY2013:

Section	No. of Hours for CY2012 Reporting	No. of Hours for CY2013 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	2.5	.5
Prompt Payment by Part D Sponsors	1	1	-
Grievances	2	2	-
Pharmacy & Therapeutics (P&T) Committees/Provision of Part D Functions	1	1	-
Coverage Determinations and Exceptions	1.5	2	.5
Redeterminations	1	1	-
LTC Utilization	1.5	1.5	-

Section	No. of Hours for CY2012 Reporting	No. of Hours for CY2013 Reporting	Increase/(Decrease)
FWA Compliance Programs	1	1	-
Employer/Union Sponsored Sponsors	0.5	0.5	-
Plan Oversight of Agents	0.5	0.5	-

There was an overall increase of 1,124 responses, and an overall increase of 9,742 burden hours associated with this revised data collection. In addition, the annualized burden per respondent increased from 22 hours to 24 hours. The increase in responses, burden hours and annualized burden associated with this data collection is attributed to: (1) an increase in the estimated number of new plans for CY2013, (2) a change in the most common reporting frequency from bi-annual to quarterly, and (3) the addition of data elements included in two reporting sections.

These changes are reflected in the revised Reporting Requirements document. The following table illustrates the changes in burden from CY2012 to CY2013:

	CY2012	CY2013	Differential
Annual Responses	47,028	48,152	1,124
Annual Hour Burden	66,498	76,240	9,742
Annualized Burden per Respondent	22	24	2

16. Publication/Tabulation Dates
    Collection of these data will commence in January 1, 2013, and the first reporting deadline will be May 31, 2013. 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.