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 five years of experience with oversight and monitoring of the Reporting Requirements, 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: Sponsor (data should be submitted from an organization that is associated with more than one CMS-issued Part D contract), 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 CY2012 Reporting Requirements, the following 14 reporting sections will be reported and collected at the Sponsor-level, Contract-level, or Plan-level:

- Enrollment and Disenrollment
- Retail, Home Infusion, and Long-Term Care Pharmacy Access
- Access to Extended Day Supplies at Retail Pharmacies
- Medication Therapy Management Programs
- Prompt Payment by Part D Sponsors
- Pharmacy Support of E-prescribing
- 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) 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. HPMS, therefore, is already a familiar tool for Part D Sponsors to navigate through the Part D reporting requirements. Additionally, as 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 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 less 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

   CPC's proposed timeframe for Federal Register/outside consultation is as follows:
   - CPC has requested the Part D reporting requirement document be posted in the Federal Registry on December 17, 2010, and the 60-day comment period will end February 15, 2011.
   - From February 15, 2011 to March 16, 2011 CPC staff will review all received comments and questions, and revise the document appropriately. Also, CPC 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. CPC has requested the Part D reporting requirements be posted in the Federal Registry on April 8, 2011, and the 30-day comment period will end May 9, 2011.
   - From May 9, 2011 to May 31, 2011, CPC staff will review all received comments and questions, and revise the document appropriately. Also, CPC 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 August 12, 2011 for OMB review.

Final reporting requirements will be posted on www.cms.gov by November 2011.

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 CY2012 Medicare Part D Reporting Requirements.

CY2012 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	589	4	2,356	3,534
Retail, Home Infusion, and Long-Term Care Pharmacy Access	Contract	1	589	1	589	589
Access to Extended Day Supplies at Retail Pharmacies	Contract	0.5	589	1	589	294.5
Medication Therapy Management Programs	Contract	2	589	1	589	1,178
Prompt Payment by Part D Sponsors	Contract	1	589	2	1,178	1,178
Pharmacy Support of E-prescribing	Contract	1	589	1	589	589
Grievances	Plan	2	2,993	4	11,972	23,944
Pharmacy & Therapeutics (P&T) Committees/Provision of Part D Functions	Contract	1	589	4	2,356	2,356
Coverage Determinations and Exceptions	Plan	1.5	2,993	4	11,972	17,958
Redeterminations	Plan	1	2,993	4	11,972	11,972
LTC Utilization	Contract	1.5	589	2	1,178	1,767
FWA Compliance Programs	Contract	1	589	1	589	589
Employer/Union Sponsored Sponsors	Plan	0.5	1,034	1	1,034	517

CY2012 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)**
Plan Oversight of Agents	Contract	0.5	65	1	65	32.5
				Total	**47,028**	**66,498**

No. of Respondents	2,993
Annual Responses=No. Respondents*Reporting Freq	47,028
Total Hour Burden	66,498
Avg. cost/hr	$46.73
Annualized hours/respondent = Total Hour Burden/No. of Respondents	22.22
Annualized wage hours = Avg. cost/hr*Annualized hours/respondent	1,038.24
Total Annual Cost = Total Hour Burden*Avg. cost/hr	$ 3,107,451.54

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 reduction in respondents and burden estimates associated with this reporting.

For CY2010, to determine the total number of annual responses, we multiplied the total number of reporting sections (21) by the most common reporting frequency (4) and by the most common number of respondents per section (4,526). This resulted in total annual responses of 380,184 (21*4*4,526=380,184). For CY2012, 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. The method used for CY2010 was based on our previous OSORA contact's guidance, where we were advised that the system could not accommodate the different reporting frequencies and levels; therefore we had to apply the most frequent of both these factors. We believe the method used for CY2012 provides a more accurate estimate of the annual responses associated with this package.

In addition to the changes in the methodology used to determine the total number of annual responses, we revised the Enrollment section to include additional enrollment and disenrollment data element which resulted in an increase in burden hours for this section. We removed Retail pharmacy access data elements from the Retail, Home Infusion, and Long-Term Care Pharmacy Access section and included a Retail file upload which resulted to no change in burden hours. We removed all data elements from the Medication Therapy Management (MTM) Programs section and retained the file upload already included for this reporting section which resulted in a decrease in burden hours for this section. We added data elements to the Coverage Determinations and Exceptions section which resulted in an increase in burden hours for this section. We made a slight increase in the reporting burden for the section, Pharmacy Support of E-prescribing, as the original estimate was only 0.5 hr per respondent. In contrast, we decreased slightly the reporting burden associated with the section, Plan Oversight of Agents. We felt these adjustments were better estimates for the burden placed on those organizations required to report. Lastly, we removed the following reporting sections and decreased burden estimates associated with these sections because this data are now being reported through other mechanisms:

- Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions section
- Licensure and Solvency, Business Transactions and Financial Requirements.

This is a revised data collection in comparison to the CY2010 Medicare Part D Reporting requirements. The following table illustrates the change in burden hours per reporting section from CY2010 to CY2012:

Section	No. of Hours for CY2010 Reporting	No. of Hours for CY2012 Reporting	Increase/(Decrease)
Enrollment and Disenrollment	1	1.5	.5
Retail, Home Infusion, and Long-Term Care Pharmacy Access	1	1	-
Access to Extended Day Supplies at Retail Pharmacies	0.5	0.5	-
Medication Therapy Management Programs	2.5	2	(.5)
Prompt Payment by Part D Sponsors	1	1	-
Pharmacy Support of E-prescribing	0.5	1	.5
Grievances	2	2	-
Pharmacy & Therapeutics (P&T) Committees/Provision of Part D Functions	1	1	-
Coverage Determinations and Exceptions	1.25	1.5	.25
Redeterminations	1	1	-
LTC Utilization	1.5	1.5	-
FWA Compliance Programs	1	1	-
Employer/Union Sponsored Sponsors	0.5	0.5	-
Plan Oversight of Agents	1	0.5	(.5)
Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions	2	-	(2)
Licensure and Solvency, Business Transactions and Financial	1.5	-	(1.5)

Section	No. of Hours for CY2010 Reporting	No. of Hours for CY2012 Reporting	Increase/(Decrease)
Requirements			

There was an overall decrease of 333,156 responses, and an overall decrease of 90,952 burden hours associated with this revised data collection. In addition, there was a decrease in the annualized burden per respondent, from 34 hours to 22 hours. This decrease is a result of the deletion of reporting sections or data elements that were not necessary for CMS's monitoring.

These changes are reflected in the revised Reporting Requirement document. The following table illustrates the changes in burden from CY2010 to CY2012:

	CY2010	CY2012	Differential
Annual Responses	380,184	47,028	333,156
Annual Hour Burden	157,450	66,498	90,952
Annualized Burden per Respondent	34	22	12

16. Publication/Tabulation Dates
Collection of these data will commence in January 1, 2012, and the first reporting deadline will be May 31, 2012. 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.