# 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 four years of experience with oversight and monitoring of the Reporting Requirements, CPC has identified the appropriated 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. 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.

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

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. 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.

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.
- Part D Sponsors will be responsible for reporting multiple data elements related to rebates. These data will be monitored as components of a Part D Sponsor's operational costs. CMS recognizes the importance of maintaining confidentiality of these records. CMS will do everything within its authority to limit access to those who have appropriate use or oversight role and will track those who have accessed these records.

8. Federal Register/Outside Consultation

A 60-day Federal Register notice was published on January 16, 2009; thirteen comments were received.

CPC's proposed timeframe for Federal Register/outside consultation is as follows:

- CPC has requested the Part D reporting requirements document be posted in the Federal Registry on May 22, 2009 for a 30-day comment period.
- 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 OSORA review in July for OMB review.
- Final reporting requirements will be posted on www.cms.gov as soon as OMB approval is received.

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)

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 $21.66 was used to calculate estimated wages.

- Estimated number of respondents = 4,526 Plans (based on the number of plans contracted for CY2009).
- Frequency of data submission = Quarterly, semi-annually, or annually
- Estimated per respondent burden:
  - Annualized hour burden per respondent = Total hours divided by # respondents= 34.79 hours per respondent
  - Annualized wage burden per respondent = 34.79 hours * $21.66/hour =$ 753.55
- Estimated burden across all respondents:
  - Total annual responses = 4,526 respondents * (4 responses/respondent) * 21 sections = 380,184 responses
  - Total annual hours requested = 4,526 respondents * 34.79 hours/respondent = 157,460 hours
  - Total annual wage burden = 157,460 hours * $21.66/hour = $3,410,584

13. Capital Costs

There is no capital costs associated with this collection.

14. Cost to Federal Government

There are no costs to the Federal Government associated with this collection.

15. Changes to Burden

This is a revised data collection in comparison to first draft of the CY2010 Medicare Part D Reporting requirements, and as a result, there are changes to the associated burden.

Changes since 1st draft of the CY2010 Data collection:

- There was a slight net increase in the annualized burden per respondent, from 34.16 hours to 34.79 hours, and the corresponding annualized wage burden per respondent, from $739.94 to $753.55. This increase in burden is a result of allotting hours for Sponsors to prepare auditing materials of reported data for 17 of 21 reporting sections. This revised package also reflects a reduction in burden from several data elements being deleted, some data elements being combined into one, and the revision of one reporting section to allow voluntary reporting of data from Sponsors. The overall net change to the annualized burden per respondent was an increase of 0.63 hours per respondent.
- As a result of the increased annualized burden per respondent, the total annual hours requested and wage burden decreased to 157,460 hours, and $3,410,584, respectively.
- There was an increase in the total annual responses due to the addition of two reporting sections. These sections were included in the OMB-approved Part C reporting requirements to apply to all Part C and Part D sponsors, therefore these sections must be included in the Part D reporting requirements. The total number of annual responses increased to 380,184.

16. Publication/Tabulation Dates

Collection of these data will commence in January 1, 2010, and the first reporting deadline will be May 15, 2010. 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.