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 two years of experience with oversight and monitoring of the Reporting Requirements, CBC has identified the appropriated data needed to effectively monitor plan performance. We have locked these data elements and do not expect this collection tool to change. Therefore we are requesting a 3 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 Economic

Performance (DCEP) within the Medicare Drug Benefit Group. If outliers or other data anomalies are detected, DCEP 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 94% of data elements listed within these reporting requirements. The other 6% of data elements are submitted via U.S. Postal mail directly to CMS. The reporting time periods vary for each section of the reporting requirements, on a quarterly, semi-annual 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

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

- The 2008 Part D reporting requirement document was posted in the Federal Registry on October 12, 2007, and the 30 day comment period ended on November 13, 2007.
- CBC staff will review all received comments and questions, and revise the document appropriately. Also, CBC staff will prepare a response document summarizing all received comments and questions, and their responses.
- A final 2008 Part D reporting requirement document will be delivered for OMB review.

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 $21.04 was used to calculate estimated wages.

Estimated number of respondents = 4,857 (The number of contracted plans increased from CY2006 to CY2007. The number of respondents is based on the number of plans contracted for CY2007 in HPMS.)

Frequency of data submission = Monthly, quarterly, semi-annually, annually

Estimated per respondent burden:
Annualized hour burden per respondent = Total hours divided by # respondents= 54.117 hours per respondent
Annualized wage burden per respondent = 54.117 hours * $21.04/hour =$1,138.62

Estimated burden across all respondents:
Total annual responses = 4,857 respondents * (4 responses/respondent) * 15 sections =

291,420 responses
Total annual hours requested = 4,857 respondents * 54.12 hours/respondent = 262,847 hours
Total annual wage burden = 262,847 hours * $21.04/hour = $5,530,290.36

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 the CY 2007 Medicare Part D Reporting requirements, as well as in comparison to the version posted in October for a 30-day comment period.

Changes since CY2007 Data collection:

- There was an overall increase of 139,097 hours for the annual hour burden estimate associated with this revised data collection. The factors contributing to this increased burden include the higher number of contracted plans (respondents), the addition of three reporting sections, and the increase in frequency for reporting data in one reporting section.
- The total annual wage burden was also affected by use of a higher hourly wage rate. The wage rate was increased to reflect inflation rates.
- The annualized burden per respondent, however, decreased from 62 hours to 54.12 hours due to the deletion of one reporting section.
- Table 2 of the collection instrument lists changes made from CY2007 to CY2008.

Changes since October 2007 Draft of CY2008 Data collection:
In the October supporting statement, the annualized burden per respondent was listed as 59.12 hours/respondent. Due to decreasing the frequency of reporting data for two reporting sections; decreasing the reporting level from Plan (PBP) level to Contract level for two reporting sections; and deleting two reporting sections, the annualized burden per respondent is now 54.12 hours. Please refer to the document Summary of Revisions- 30 Day Comments to Part D Reporting Requirements for the specific details related to changes made after the 30 day comment period.

16. Publication/Tabulation Dates

Collection of these data will commence in January 1, 2008, and the first reporting deadline will be May 15, 2008. 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.