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.

2007 Reporting requirements received emergency PRA approval in April 2006. An extension PRA package is being submitted to receive 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
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 95% of data elements listed within these reporting requirements. The other 5% 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 a 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 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 2007 Part D reporting requirements document receiving emergency PRA approval to be posted for public comment on www.cms.hhs.gov on June 16, 2006. Notification of posting of the draft data requirements during weekly User Group calls and via listserv notification. Prospective and renewing Part D Sponsors, as well as other outside stakeholders will have the opportunity to provide comment.
- CBC has requested the 2007 Part D reporting requirements document receiving emergency PRA approval be published in the Federal Register on June 16, 2006, and the 60 day comment period end August 15, 2006.
- CBC has requested the revised 2007 Part D reporting requirements document be published in the Federal Register on September 22, 2006, and the 30 day comment period end October 23, 2006.
- Final reporting requirements to be posted on www.cms.hhs.gov by October 31, 2006.

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 $20.43 was used to calculate estimated wages.

Estimated number of respondents = 3,203

Frequency of data submission = Quarterly or semi-annually

Estimated per respondent burden:
Annualized hour burden per respondent = 62 hours
Annualized wage burden per respondent = 62 hours * $20.43/hour =$1,267

Estimated burden across all respondents:
Total annual responses = 179,368 responses
Total annual hours requested = 122,902 hours (179,368 / 122,902 = .6851946) or .685 responses per hour
Total annual wage burden = $2,510,887.86

13. Capital Costs

There are 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 revision includes changes to annualized hour burden per respondent and estimated burden across all respondents. Additionally, changes were made to the data collection instrument as a result of public comments received, and overall experiences from the Part D program since January 2006.

Annualized hour burden per respondent:

- In June we estimated this to be 32 hours. However, based on the fact that we have more experience, we have increased this amount to 62 hours.

Estimated burden across all respondents:

- In the June supporting statement our total annual responses were 12,812. This calculation was the 3,203 respondents times 4 responses/respondent. In the current supporting statement our total annual responses is now 179,368. We have adjusted this calculation to be the 3,203 respondents times 4 responses/respondent times 14 reporting sections. The 14 reporting sections is to account for the number of reporting sections.

16. Publication/Tabulation Dates

Collection of these data will commence in January 1, 2007, and the first reporting deadline will be May 15, 2007. Since this is a new 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.