Supporting Statement for Retiree Drug Subsidy (RDS) Payment Request and Instructions

OMB #0938-0977
CMS-10170

A. Background

Under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 and implementing regulations at 42 CFR 423 Subpart R, plan sponsors (e.g., employers, unions) who offer prescription drug coverage meeting specified criteria to their qualified covered retirees are eligible to receive a 28% tax-free subsidy for allowable drug costs, through the Retiree Drug Subsidy (RDS) Program..

B. Justification

1 . Need and Legal Basis

Under §1860D-22 of the Social Security Act (Act), added by the MMA of 2003 and implementing regulations at 42 CFR 423 Subpart R, plan sponsors (e.g., employers, unions) who offer prescription drug coverage meeting specified criteria to their qualified covered retirees are eligible to receive a 28% tax-free subsidy for allowable drug costs. Plan sponsors must submit required prescription drug cost data and other information in order to receive the subsidy.

2. Information Users

CMS has contracted with an outside vendor to assist in the administration of the RDS program; this effort is called the RDS Center. Plan sponsors will request subsidy payments on-line by logging on to the RDS Secure Web Site. Plan sponsors may choose whether to submit a maximum of one, three, or twelve interim payment requests that must be supported by cost data the sponsor submits. Plan sponsors that have received at least one interim payment request, or that have not, but would like to receive subsidy, must submit final prescription cost data and a reconciliation or final payment request, as the case may be, within 15 months of the end of the plan year. Cost data required for each payment request may be entered into the RDS Secure Web Site, or be uploaded to the RDS Center mainframe. Once the Plan Sponsor submits a payment request, the RDS Center will process the request to determine whether payment should be made, and the amount of the payment.

3. Use of Information Technology

The payment request process for the RDS is a completely electronic process (100%). The only instances when hard copy/paper payments request can be submitted are when the RDS Center is experiencing technical difficulties or other emergency situations. The Plan Sponsor completes and submits the RDS payment request on-line via the RDS Center secure Web Site, which is accessed at http://rds.cms.hhs.gov.

4. Duplication of Efforts

The data collected for subsidy payment request are not currently being collected through any other mechanism. Therefore, this information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

CMS has made efforts to minimize the burden that this collection of information will have on all submitting entities including small businesses. Towards this end, CMS has made the entire payment request process completely electronic. The Plan Sponsor completes and submits the RDS payment request (including the Payment requestor's electronic signature) on-line via the RDS Center's Secure Web Site, which is accessed at http://rds.cms.hhs.gov. The benefits of receiving the subsidy payments will far exceed the cost associated with submitting subsidy payment requests.

6. Less Frequent Collection

42 CFR 423 Subpart R stipulates that plan sponsors may elect to submit RDS payment requests on a monthly, quarterly, interim annual, or annual basis; once selected, the payment frequency may not be changed during the plan year. Additionally, 42 CFR 423 Subpart R establishes the required timeline for RDS payment reconciliation. Required RDS prescription drug cost data must be submitted for reconciliation within 15 months of the end of the benefit plan year.

Deviation from these requirements would result in noncompliance.

7. Special Circumstances

42 CFR 423 Subpart R requires Plan Sponsors to submit payment requests to receive payments from the RDS program.

- Plan sponsors approved to receive RDS payments will be required to submit updated retiree lists on

a monthly basis.

- There are no special circumstances where plan sponsors would be required to prepare a written response to a collection of information in fewer than 30 days after receipt of it.
- There are no special circumstances where plan sponsors would be required to submit more than an original and two copies of any document.
- There are no special circumstances that would cause an information collection in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study.
- There are no special circumstances that would cause an information collection requiring the use of a statistical data classification that has not been reviewed and approved by OMB.
- There are no special circumstance that includes a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use.
- There are no special circumstances where plan sponsors would be required to submit proprietary trade secret or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.
- There <u>are</u> special circumstances that would cause an information collection to be conducted, which would require Plan Sponsors to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years. 42 CFR 423.888(d)(1) through (3) requires that Plan Sponsors maintain the following records for 6 years after the expiration of the plan year in which costs were incurred:
    1. Reports and working documents of the actuaries who wrote the attestation submitted in accordance with 42 CFR 423.884(a).
    2. All documentation of costs incurred and other relevant information utilized for calculating the amount of the subsidy payment including the underlying claims data.
    3. Any other records specified in additional CMS guidance.

8. Federal Register/Outside Consultation

We are requesting a 60-day Federal Register comment period.

We have consulted on an ongoing basis with business groups, industry groups, union groups, health benefit administrators, and private actuaries to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, reporting format, and on the data elements to be recorded, disclosed, or reported. In addition, CMS may periodically conduct industry focus groups with the aforementioned groups to continue to improve the operations of the RDS Program.

9. Payments/Gifts to Respondents

There are no payments or gifts to respondents.

10. Confidentiality

We have assured potential applicants to the RDS program that laws, regulations, and guidance associated with the Health Insurance Portability and Accountability Act (HIPAA) of 1996, and the Privacy Act of 1974 (as amended) will apply to any information collected by CMS for purposes of this program.

The regulations governing the RDS program (42 CFR 423.888(c)) require that officers, employees, and contractors of the U.S. Department of Health & Human Services (DHHS) may use information collected for the RDS program only for the purposes of, and to the extent necessary, to carry out the requirements of the program. We have assured on an ongoing basis that any proprietary information submitted by applicants will not be disclosed.

11. Sensitive Questions

No questions of a sensitive nature, such as sexual behavior and attitudes, and religious beliefs are asked. The data collected is a statement of prescription drug costs paid by the plan sponsor's qualified prescription drug plan and by, or on behalf of, the qualifying covered retiree, as well as related price concession (i.e., rebate) data, which are used to calculate Plan Sponsor's RDS payment.

12. Burden Estimates (Hours & Wages)

The burden associated with the payment requirements is the time and effort for a plan sponsor to submit the required data and information. For each entity we estimate an average of 145 hours to report the required data (this includes reading CMS' published instructions, assembling the data, and transmitting the data), and 6 hours to retain the required documentation on an annual basis. This is a total of approximately 151 hours for each prescription drug plan. This increase in burden per entity from the estimates that were submitted for the original PRA clearance in 2005, is primarily attributable to the fact that the burden estimate now includes an estimate of the time it takes to submit the reconciliation or final payment request by following the 12-step reconciliation process. That process had not been developed at the time the 2005 PRA package was submitted. Based on current data, there are approximately 4,500 entities applying for the subsidy for plan years ending in 2008. This number includes private, public and union plan sponsors. The total number of hours for all plan sponsors, using the 4,500 number as the outer limit, is 679,500 (151 x 4,500).

13. Capital Costs

(a) Total Capital and Start-up Cost

We have determined that there are no new capital outlays required to receive RDS payments. We have assumed that all businesses will own at least one computer and have access to the internet.

(b) Total Operation and Maintenance and Purchase of Services Component

We estimate that there may be expenses associated with hiring of vendors to assist Plan Sponsors in gathering and aggregating prescription cost data for qualifying covered retirees and complying

with ongoing information sharing requirements. We estimate that the cost will equal 4.4% of the value of the subsidy for vendor costs for 2009. (Approximately .8 percent of the expected subsidy payments will be due to the fixed costs associated with developing methodologies and modifying systems to generate the required cost data and allocate rebates. We estimate that 3.6% percent of the value of the subsidy will be associated with submitting drug cost data and enrollment data. We estimate that the average subsidy payment for each qualifying covered retiree in 2009 will be around $ $641. We also estimate that there will be a total of 6.6 million qualifying covered retirees. The total estimated operation costs for 2009 is $186,120,000 (6.6 million x $641 x 4.4%).

14. Cost to Federal Government

The cost to the Federal Government is estimated to be $20.6 million annually. This amount includes approximately $20 million that is being paid to the contractor who won the award to administer the RDS Program. In addition, there are six CMS full time employees (FTEs) dedicated to the RDS Program with an estimated cost to the Federal Government of $600,000 per year. This number is derived multiplying the average employee hourly salary x the number of FTEs assigned to the Program x 40 hours a week x 52 weeks a year. Note that this cost is the entire annual cost to administer the RDS Program. It is not possible to apportion only the amount of costs to administer the payment component of the RDS Program.

15. Changes to Burden

The total change to burden is an increase of 457,500 hours. As discussed in Section 12, we calculate an increase of burden per entity of 124 hours (151 burden hours per entity, vs. 37 burden hours per entity in the original 2005 PRA submission). As discussed in section 12, this increase in burden per entity from the estimates that were submitted for the original PRA clearance in 2005, is primarily attributable to the fact that the burden estimate now includes an estimate of the time it takes to submit the reconciliation or final payment request by following the 12-step reconciliation process. That process had not been developed at the time the 2005 PRA package was submitted. In calculating total burden, this increase in burden per entity has been slightly offset by the decrease in the number of entities, from 6,000 to 4,500. This is attributable to a revision to the estimated number of entities applying for the RDS program based on actual program experience.

16. Publication/Tabulation Dates

The collection of information on the RDS interim, final and reconciliation payment requests will not be published.

Plan Sponsors may submit payment request(s) to the RDS Center at the maximum frequency they selected on the RDS application. Payment frequency choices are monthly, quarterly, interim annual and annual, which means that for each RDS application, a Plan Sponsor can submit a maximum of one, four, or twelve interim payment requests. All Plan Sponsors that have received at least one interim payment request for an application must submit a reconciliation payment request. All Plan

Sponsors that have not submitted any interim payment requests for an application, but that desire subsidy, must submit a final payment request.

Final or reconciliation payment requests must be submitted within 15 months following the end of the RDS plan year specified in the RDS application.

17. Expiration Date

The collection instrument will be displayed on-line as part of a paperless initiative. The new expiration date will be incorporated into the electronic document, after the expiration date is known.

18. Certification Statement

There are no exceptions to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions, " of OMB Form 83-I.

C. Collections of Information Employing Statistical Methods

Not applicable. The information collection does not employ statistical methods.