Supporting Statement for Retiree Drug Subsidy (RDS) Application and Instructions
OMB # 0938-0957
CMS-10156

A. Background

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR §423 Subpart R plan sponsors (e.g., employers, unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% tax-free subsidy for allowable drug costs. In order to qualify, plan sponsors must submit a complete application to the Centers for Medicare & Medicaid Services (CMS) with a list of retirees for whom it intends to collect the subsidy. Once CMS reviews and analyzes the information on the application and the retiree list, notification will be sent to the plan sponsor about its eligibility to participate in 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 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implementing regulations at 42 CFR §423 Subpart R, Plan Sponsors (e.g., employers or unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% tax-free subsidy for allowable drug costs. Plan Sponsors must submit a complete application to CMS in order to be considered for the RDS Program.

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 apply on-line for the retiree drug subsidy by logging on to the RDS Secure Web Site. Once the Plan Sponsor submits the RDS application via the RDS Secure Web Site (and a valid initial retiree list) CMS will analyze the application to determine whether the Plan Sponsor qualifies for the RDS.

3. Use of Information Technology

The application process for the RDS is a completely electronic process (100%). The basis for the decision for adopting this means of collection was to maximize efficiencies.The only instance when hard copy/paper applications can be submitted is when the RDS Center is experiencing technical difficulties. The Plan Sponsor completes and submits the RDS application (including the Plan Sponsor's Authorized Representative's electronic signature) on-line, via the secure RDS Center web site, which is accessed at http:\\rds.cms.hhs.gov.

The collection is currently available for completion electronically. It requires the signature of the Plan Sponsor's Authorized Representative.

4. Duplication of Efforts

The data collected on the application 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.

Consideration has been given to the duplication of the submission of the Plan Sponsor retiree list. In an effort to avoid duplication, Plan Sponsors who have an existing Voluntary Data Sharing Agreement (VDSA) can submit their retiree list via the Coordination of Benefits (COB) contractor to CMS. Plan Sponsors who do not currently have a VDSA with CMS are being encouraged to enter into one.

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 application process completely electronic. The Plan Sponsor completes and submits the RDS application (including the Plan Sponsor's Authorized Representative's electronic signature) on line via the RDS Center's Secure Web Site which is accessed at http:\\rds.cms.hhs.gov. In addition, CMS is encouraging Plan Sponsors to utilize existing VDSAs, or enter into new VDSAs for the submission of the Plan Sponsor retiree list. The benefits of receiving the subsidy payments will far exceed the cost associated with applying for the subsidy.

6. Less Frequent Collection

42 CFR Subpart R of the final rule stipulates the required timelines for the submission of the RDS application and retiree list. Presently, an application for the given plan year, including the initial retiree list, must be submitted no later than 90 days prior to the beginning of the plan year. After the application is submitted, Plan Sponsors must submit updated retiree lists on a monthly basis, to the extent there are any updates.

Deviation from those requirements would result in noncompliance.

7. Special Circumstances

42 CFR §423 Subpart R requires Plan Sponsors to submit an application for the RDS on an annual basis.

- Plan Sponsors approved to receive the RDS payments will be required to submit updates to submitted retiree information 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 are 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 to determine whether an individual is Medicare-eligible, and not already enrolled in a Medicare Part D plan.

12. Burden Estimates (Hours & Wages)

For each entity we estimate an average of 16 hours administrative work to read the instructions and complete and submit the application, 40 hours for systems changes to extract identifying information on qualifying covered retirees, and about 8 hours for preparation of the actuarial attestations,. This is a total of approximately 64 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 not attributable to changes made to the collection instrument. Rather, it reflects CMS' better understanding of the burden imposed by the instrument, based on three years of program experience .Based on current data, there are approximately 4,500 entities applying for the subsidy for plan years ending in 2008. This number includes public, private and union sponsors. The total number of hours for all entities applying for the subsidy is (64 x 4,500), or 288,000. This decrease in total burden is attributable to a much lower estimate of the number of participating entities.

13. Capital Costs

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

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.

15. Changes to Burden

The total change to burden is a decrease of 1,737,000 hours. As discussed in Section 12, we calculate an increase of burden per entity of 23.5 hours (64 burden hours per entity, vs. 40.5 hours per entity in the original 2005 PRA submission). However, 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 not attributable to changes made to the collection instrument. Rather, it reflects CMS' better understanding of the burden imposed by the instrument, based on three years of program experience. The increase in burden per entity has been more than offset by the decrease in number of entities, from 50,000 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

A very limited portion of the collection of information on the RDS application will be published. Specifically, a list of the names of the Plan Sponsor identified on the applications, and their self-reported state, will be periodically published and posted on CMS' Web Site. CMS does not intend to publish any additional information provided by Plan Sponsors.

Every year, A Plan Sponsor will submit an application through the Secure Web Site no later than 90 days before the start a new plan year, unless and until CMS specifies a different deadline. In addition to the annual on-line application, Plan Sponsors must submit an initial retiree list to the RDS Center, by that deadline. Plan Sponsors must submit any updates to this list on a monthly basis,

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.