Supporting Statement Part A
Retiree Drug Subsidy (RDS) Payment Request and Instructions
CMS-10170, OMB 0938-0977

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% subsidy for allowable drug costs, through the Retiree Drug Subsidy (RDS) Program. Section 423.886 describes the payment methods, including the provision of necessary information. The information provided in the payment request provides CMS with the information needed to pay RDS sponsors the subsidy.

A. 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% subsidy for allowable drug costs.

Requirements of the RDS Program

- Actuaries act on behalf of Plan Sponsors and complete a two-part Actuarial Equivalence Test indicating that the Prescription Drug Plan offered by the Plan Sponsor is as generous as, or more generous than the defined standard coverage under the Medicare Part D Prescription Drug Benefit.
- Retirees must not be currently enrolled in Medicare Part D.
- Plan Sponsors must use the RDS Secure Website to participate in the RDS Program and submit a timely application prior to the expiration of the Application Deadline, which includes a list of retirees for whom the Plan Sponsor is seeking subsidy.

Qualifications for the RDS Program

To participate in the RDS Program, an organization must:

- Have a valid Employer Identification Number (EIN)
- Fall under one of the following categories:
    - Commercial
    - Government
    - Nonprofit
    - Religious
    - Union
- Demonstrate that the coverage is as generous as, or more generous than the defined standard coverage under the Medicare Part D Prescription Drug Benefit.

Section 423.886 indicates that plan sponsors must submit required prescription drug cost data and other information in order to receive the subsidy. The sponsor provides the estimated premium costs, gross retiree costs, threshold reductions, limit reduction, and the estimated/actual cost adjustment in the payment request form. All of this information is evaluated when determining the subsidy payment.

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. This center's RDS system programmatically processes requests to determine whether the 28% subsidy payment for allowable drug costs should be made, and the amount of the subsidy payment, by evaluating:

- The program eligibility for each Qualifying Covered Retiree (QCR) submitted by the Plan Sponsor. A QCR must be (1) a retiree of the Plan Sponsor or a retiree's spouse/dependents; (2) a person covered under the Plan Sponsor's Qualified Retiree Prescription Drug Plan, and (3) a person eligible for but not enrolled in a Medicare Part D plan;
- The Plan Sponsor-reported drug costs for each Qualified Covered Retiree (QCR) that are eligible for subsidy, defined as drug costs: covered under Medicare Part D, incurred within the Subsidy Period Effective and Termination Dates for the retiree, and must have been paid. The subsidy payment is derived from the Gross Retiree Costs (the non-administrative costs incurred under the plan for Medicare Part D drugs as defined in 42 C.F.R. §423.100, whether paid by the Plan Sponsor or retiree or a combination) between the Federally-defined Cost Threshold and the Cost Limit for each Qualifying Covered Retiree (QCR), their corresponding Subsidy Periods, and the Benefit Options in which each QCR is enrolled. The Cost Threshold is a Federally-defined amount of out-of-pocket expenses paid by, or on behalf of, the beneficiary. The amount up to the Cost Threshold is not eligible for subsidy. The Cost Limit is a Federally-defined amount of out-of-pocket expenses paid by, or on behalf of, the beneficiary. The amount exceeding the Cost Limit is not eligible for subsidy; and
- The cost adjustments reported by the Plan Sponsor that are attributable to Gross Retiree Costs between the Cost Threshold and Cost Limit. Cost adjustments are any discounts, chargebacks, rebates, and/or other price concessions given by the manufacturer or pharmacy to the Plan Sponsor. Cost Adjustments are not eligible for subsidy.

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 https://www.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 https://www.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, 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 that are approved to receive RDS payments are required to submit updated retiree lists on a monthly basis. However, a Monthly Retiree List is not required if no information has changed for a given month.

Additionally, Plan Sponsors are required to retain records (excluding: other than health, medical, government contract, grant-in-aid, or tax records) for more than three years. More specifically, 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.

Otherwise, there are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;

- Submit more than an original and two copies of any document;
- Collect data 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,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include 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; or
- 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.

8. Federal Register/Outside Consultation

The 60-day notice published in the Federal Register on December 16, 2016 (81 FR 91175). No comments were received.

The 30-day notice published in the Federal Register on February 17, 2017 (82 FR 11037). No comments were received.

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.

A System of Records Notice (SORN), SORN System No 09-70-0550, was filed and published on

July 15, 2005. The authority for the maintenance of this system is given under section 1860D–22 of the Act (Title 42 United States Code (U.S.C.) 1302, 1395w–101 through 1395w–152, and 1395hh). These provisions of the Act are amended by section 101 of the MMA and its implementing regulations, codified at Title 42 Code of Federal Regulations (CFR) Part 423, Subpart R.

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)

Wage Estimates

The following costs are based on the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm).

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Financial Analyst	13-2051	45.83	45.83	91.66
Computer and Information Systems Managers	11-3021	67.79	67.79	135.58
Software Developers and Programmers	15-1130	47.08	47.08	94.16
Computer and Information Analyst	15-1120	43.56	43.56	87.12

RDS sponsors utilize a mix of the occupational titles provided in this table to complete the payment request form. We are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that increasing the hourly wage by 100% to estimate total cost is a reasonably accurate estimation method.

Burden Estimates

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. An average wage was calculated using the occupation titles and wages listed in the table above given the fact that sponsors use a mix of these labor categories to complete the payment request form. The average wage is $102.13

2,228 respondents (or responses) x 151 hr/response = 336,428 total hr.

$102.13 average wage x 151 hours = $15,421.63 per respondent

$15,421.63 x 2,228 respondents = $34,359,391.64 total amount for all respondents

Based on current data, there were 2,228 entities applying for the subsidy for plan years ending in 2015. This number includes private, public and union plan sponsors. The total number of hours for all plan sponsors, using the 2,228 number as the outer limit, is 336,428 hr.

The reporting instrument and instructions are attached.

13. Capital Costs

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.

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 approximately 3% of the value of the subsidy for vendor costs for 2015. (Approximately .4 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 2.6% percent of the value of the subsidy will be associated with submitting drug cost data and enrollment data. The average subsidy payment for each qualifying covered retiree in 2015 is around $455.35. There were a total of 2.5 million qualifying covered retirees. The total estimated operation costs for 2015 is $34,151,250 (2.5 million x $455.35 x 3%).

14. Cost to Federal Government

The cost to the Federal Government is estimated to be $9.2 million annually. This amount includes approximately $9 million that is being paid to the contractor who won the award to administer the RDS Program.

In addition, there are two CMS full time employees (FTEs) dedicated to the RDS Program with an estimated cost to the Federal Government of $207,278 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: $207,278/yr = ($103,639/yr x 2 FTEs) @ GS-12 step 10 for the Washington-Baltimore-Arlington locality (effective January 2017). See https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB.pdf.

$9.2 million 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. Program and Burden Changes

The URL to the program website has been updated.

The total burden is adjusted from 679,500 hr to 336,428 hr due to a reduction in RDS sponsor enrollment. (See the above calculation for burden estimate that is determined by the number of respondents.)

The chart below shows the enrollment trends in the RDS program since 2010.

Benefit Year	RDS Enrollment
2010	7,316,951
2011	6,918,581
2012	6,217,640
2013	4,161,090
2014	3,039,813
2015	2,502,325

16. Publication/Tabulation Dates

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

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.

B. Collections of Information Employing Statistical Methods

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