Supporting Statement Part A
Retiree Drug Subsidy Payment Request and Instructions

(CMS-10170, OMB 0938-0977)

Background

CMS is requesting a revision approval change request for collection CMS-10170.

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR part 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.

Changes have been made to the instrument to increase clarity and readability, to include programmatic changes to the RDS Program, and to modify estimates based on updated data from the RDS Program, the U.S. Office of Personnel Management (OPM), and the U.S. Bureau of Labor Statistics

A. 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 part 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% 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 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 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 efficiency. 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 Secure Web Site, which is accessed at https://www.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. A VDSA authorizes CMS and an employer, or agent on behalf of an employer, to electronically exchange health insurance benefit entitlement information. Plan Sponsors who do not currently have a VDSA with CMS are 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 Secure Web Site, which is accessed at https://www.rds.cms.hhs.gov. In addition, CMS encourages 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 423 Subpart R stipulates that plan sponsors may elect to submit RDS payment requests on a monthly, quarterly, or annual basis. 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

Plan Sponsors approved to receive the RDS payments are required to submit updates to submitted retiree information monthly.

Plan Sponsors must retain records (other than health, medical, government contract, grant-in-aid, or tax records) for more than three years. 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 made in accordance with §423.886, including the underlying claims data.
3. Any other records specified by CMS.

Otherwise, there are no special circumstances that would cause an information collection to be conducted which would require Plan Sponsors 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.
- 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.
- Cause an information collection requiring the use of 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.
- Require respondents 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.

8. Federal Register/Outside Consultation

The 60-day Federal Register Notice was published in the Federal Register on 7/8/2024 (89 FR 55948).
No comments were received during the 60-day comment period.

The 30-day Federal Register Notice was published in the Federal Register on 09/23/2024 (89 FR 77514).

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 groups to continue to improve the operations of the RDS Program.

9. Payments/Gifts to Respondents

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR part 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% subsidy for allowable drug costs.

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.

Regarding the retiree list, a System of Records Notice (SORN), SORN System No 09-70-0550, was filed and published on October 8, 2019. 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)

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2023 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Median Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Financial Analyst	13-2051	47.60	47.60	95.20
Computer and Information Systems Managers	11-3021	81.50	81.50	163.00
Software Developers and Programmers	15-1252	63.59	63.59	127.18
Computer and Information Analyst	15-1210	50.88	50.88	101.76

As indicated, 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. We believe that doubling the hourly wage 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 $121.79.

1,245 respondents (or responses) x 151 hr/response = **187,995 total hr.**

$121.79 average wage x 151 hours = $18,390.29 per respondent

$18,390.29 x 1,245 respondents = $22,895,911.05 total amount for all respondents

Based on current data, there were 1,245 entities applying for the subsidy for plan years ending in 2022. This number includes private, public, and union plan sponsors. The total number of hours for all plan sponsors, using the 1,245 number as the outer limit, is 187,995 hr.

The reporting instrument and instructions are attached.

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 $10.1 million annually. In addition, there are three CMS full time employees (FTEs) dedicated to the RDS Program with an estimated cost to the Federal Government of $386,868 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: $386,868/yr = ($128,956, /yr x 3 FTEs) @ GS-12 step 10 for the Washington-Baltimore-Arlington locality (effective January 2024). See www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/DCB.pdf

15. Program and Burden Changes

The URL to the program website is https://www.rds.cms.hhs.gov.

Changes have been made to this section to include updated RDS Plan Sponsor enrollment values, as well as to include current data for plans that have completed Reconciliation. Additional changes have been made to this instrument to increase clarity and readability, to account for changes to the default value set for all RDS applications in regard to Payment Frequency, and to include updated values from the U.S. Office of Personnel Management (OPM) and the U.S. Bureau of Labor Statistics.

The total burden is adjusted from 326,009 hr to 187,995 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 retiree 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
2016	2,250,295
2017	1,941,506
2018	1,686,225
2019	1,535,715
2020	1,250,204
2021	1,268,380
2022	1,190,819

16. Publication/Tabulation Dates

Pursuant with 42 CFR §423.884(c)(3)(ii), a very limited portion of the collection of information on the RDS application will be published and posted on CMS' website: Plan Payment Data | CMS within the file name "RDS PUF YYYY data". This file contains data elements that include a list of the names of the Plan Sponsor identified on the applications, i.e. "Business Name", the "Total Paid" amount paid in RDS subsidy and retiree eligibility count, "ELGBL Count", per plan year. CMS does not intend to publish any additional information provided by Plan Sponsors. The purpose of this posting is to make payment data for Medicare Part C and Part D, along with the RDS program payment data, publicly available.

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.