

Supporting Statement Part A
Creditable Coverage Disclosure to CMS On-Line Form and Instructions
(CMS-10198, OMB 0938-1013)

Background

An entity that provides prescription drug benefits to any Medicare Part D eligible individual must disclose to the Centers for Medicare & Medicaid Services (CMS) whether the prescription drug benefit they offer is creditable (expected to pay at least as much, on average, as the standard prescription drug plan under Medicare). CMS released an online form and guidance in January 2006 for this disclosure. The form is titled “Disclosure to CMS Form” and is found at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/CreditableCoverage/CCDDisclosureForm>. The form is the only form the entity must submit to CMS under this control number. There have been no changes to the requirements or form in this package from the prior PRA approval.

A. Justification

1. Legal Basis

Section 1860D-13 of the Social Security Act, as established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implementing regulations at 42 CFR §423.56(e), require that entities that offer prescription drug benefits under any of the types of coverage described in 42 CFR §423.56(b) provide a disclosure of creditable coverage to CMS. There are other disclosure and notification requirements to Part D eligible individuals in §423.56(c), (d), and (f); this PRA covers the requirement in subsection (e). Entities required to make this disclosure state whether their prescription drug coverage meets the actuarial requirements defined in §423.56(a). In general, this actuarial determination measures whether the expected amount of paid claims under the entity’s prescription drug coverage is at least as much as the expected amount of paid claims under the standard Medicare prescription drug benefit. See 70 FR 4225 (January 28, 2005) at <https://www.govinfo.gov/content/pkg/FR-2005-01-28/pdf/05-1321.pdf> for more information.

Section 423.56(e) states that the disclosure to CMS must occur in a form and manner described by CMS. The entities exempted under 42 CFR §423.56(e) include Medicare prescription drug plans (PDPs), Medicare Advantage plans that offer prescription drug coverage (MA-PDs), and Programs of All-Inclusive Care for the Elderly (PACE) or cost-based HMOs or CMPs that provide “qualified Part D coverage” as defined in 42 CFR §423.100. As further explained in sub-regulatory guidance, a sponsor that has been approved for the Retiree Drug Subsidy (RDS) is exempt from filing the Disclosure to CMS Form with respect to those qualified covered retirees for which the sponsor is claiming the RDS. The reason for this is because the sponsor’s RDS application serves as its Disclosure to CMS under 42 CFR §423.56(e). For example: If a plan option has 100 retired

beneficiaries and the plan claims RDS for 97 of them, the plan must report the 3 non-RDS participants on the Disclosure to CMS form, in addition to the non-RDS participants on other plan options.

Timing of CMS Disclosure

Entities subject to the creditable coverage disclosure to CMS must submit their information at these times:

- No later than sixty (60 days) following the beginning date of the entity's plan year;
- Within 30 days after termination of a prescription drug plan; or
- Within 30 days after any change in creditable coverage status.

2. Information Users

Disclosure of whether prescription drug coverage is creditable provides Medicare with important information relating to whether prescription drug benefits offered by an entity to Medicare Part D eligible individuals is expected to pay at least as much as the standard benefits under Medicare Part D. The form is used as a reporting tool where entities offering prescription drug coverage indicate whether the coverage being provided is considered creditable or non-creditable.

Beneficiaries have appeal rights when assessed a Part D late enrollment penalty (LEP) due to lack of prior creditable coverage. In researching the facts related to the appeal, the Part D Independent Review Entity (IRE) may need to investigate whether the beneficiary had creditable coverage for the time period in question. The disclosures contain this information.

3. Use of Information Technology

CMS is continuing to use a web form titled "Disclosure to CMS Form", available at <https://www.cms.gov/Medicare/Prescription-DrugCoverage/CreditableCoverage/CCDisclosureForm>.

4. Duplication of Efforts

The information collection requirements (ICRs) contained in the regulations are not duplicated through any other effort.

5. Small Businesses

Some entities subject to this disclosure requirement are small businesses and will have to comply with all the information requirements described in this supporting statement. The burden is small for all entities and no more or less burdensome on small businesses.

6. Less Frequent Collection

As defined in §423.56(a), prescription drug coverage is considered creditable only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year. Given that this value can change from year to year, entities are expected to disclose their coverage on an annual basis.

7. Special Circumstances

The creditable coverage disclosure information generally occurs annually from entities as they renew their prescription drug programs.

8. Federal Register/Outside Consultation

Federal Register Notice

The 60-day notice published in the Federal Register on 01/08/2021 (86 FR 1503).
No comments were received.

The 30-day notice published in the Federal Register on 03/18/2021 (86 FR 14753).

Outside Consultations

In the course of developing the Final Regulations for the Medicare Prescription Drug Benefit Program (CMS-4068-F), the required Federal Register notice was published on August 3, 2004 (69 FR 46632). The Office of Management and Budget (OMB) waived the requirement for a second Federal Register notice. The final rule went on display on January 21, 2005 to announce the new or revised ICRs. The public meetings were held in February at CMS and written comments were received, which were in turn utilized by CMS during the regulations drafting stage. Also, CMS consulted with technical experts and industry and beneficiary advocates to obtain their opinions on the creditable coverage disclosure provisions of the statute. These consultations continued as CMS implemented the final rule. Additionally, in 2020, CMS consulted with our contractor to verify the continued use of this information collection.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

The information disclosed in the “Disclosure to CMS Form” must conform to all requirements at 42 CFR §423.56, and in all Federal and State laws regarding confidentiality and disclosure.

11. Sensitive Questions

There are no sensitive questions included in this collection effort.

12. Burden Estimates (Hours & Wages)

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics’ May 2019 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). Table 1 presents the mean hourly wage plus an estimated cost of overhead and fringe benefits, which sum to the adjusted hourly wage. This is necessarily a rough estimate, 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 our approach to doubling the hourly wage to account for overhead and fringe benefits is a reasonably accurate estimation method.

Table 1. Occupations and Wages for Respondents

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Estimated Overhead and Fringe Benefits (\$/hr)	Total Adjusted Hourly Wage (\$/hr)
Human Resources Managers	11-3121	62.69	62.69	125.38
Compensation and Benefits Managers	11-3111	64.52	51.44	129.04
Average				127.21

Burden Estimates

In this section, we estimate the time and effort burden for entities to complete the “Disclosure to CMS Form”. Based on the prior year’s reporting, we estimate that CMS will receive around 110,000 disclosures via the Disclosure to CMS online form.

Given that each entity will have made their annual determination of the creditable coverage status of their prescription drug plan for disclosure to Medicare Part D eligible individuals, the burden to provide the disclosure to CMS via the Disclosure to CMS online form is modest.

The estimated annual burden on the Human Resources Managers and Compensation and Benefits Managers who typically complete the Disclosure to CMS online form will be about 5 minutes at an

average of \$127.21/hr for a total burden of 9,185 hours at a cost of \$1.2 million. Details of the estimate are provided in Table 2.

Table 2: Summary of Coverage Types and Estimated Burden

Type of Plan/Respondent	Estimated Number of Disclosures (using actual 2019 figures)	Minutes per Response	Annual Time (in hours)	Average Adjusted Hourly Wage (\$/hr; from Table 1)	Total Cost (\$)
Group health plans, including those offered by employers; union/TaftHartley plans; church plans; Federal, State and local government plans; and other group-sponsored plans	102,691	5	8,558	127.21	1,088,610
Government sponsored plans, including Medicaid; State Pharmaceutical Assistance Programs (SPAPs); State High Risk Pools	28	5	2	127.21	297
Military coverage, including the United States Department of Veterans Affairs (VA) coverage and TRICARE	2	5	0	127.21	21
Individual health insurance	121	5	10	127.21	1,283
Indian Health Service; Tribe or other Tribal Organizations; Urban Indian Organizations	49	5	4	127.21	519
Medigap (Medicare Supplement) plans, including standardized plans H, I or J; prestandardized plans; waiver State plans; and plans with innovative benefits	165	5	14	127.21	1,749
Total	103,056	5	8,588	127.21	1,092,479

13. Capital Costs

There is no additional capital costs associated with these ICRs.

14. Cost to Federal Government

The cost to the Federal Government is \$2,693. The costs/FTEs were obtained from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salarytables/pdf/2020/DCB.pdf> and are summarized in Table 3.

Table 3. Government Cost Estimate

Government Employee	Hourly Salary (\$/hr)	Hours	Total Cost
GS 11 Step 2	35.66	5	\$178
GS 12 Step 6	48.26	20	\$965
GS 15 Step 5	77.49	20	\$1,550
Totals:		45	\$2,693

15. Changes to Burden

The information collection requirement, means, number of expected respondents all remain largely the same. There are no program changes or any revisions to the instructions and screenshots for this package. Our 5 min/response estimate is unchanged.

The key revisions have been to update our estimates using the most recent data available. For instance, the estimate for the number of expected forms is based on actual data of the number of forms we received last year: 103,056. At five minutes a form, this totals 8,588 hours. Three years ago, the estimate for the number of forms was slightly lower, at 97,000, which at five minutes a form totaled about \$7,000.

16. Publication/Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

The current expiration date is located under the PRA disclosure statement on the online disclosure form.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

Not applicable.