

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

## **Background**

An employer having at least one employee age 65 and older that currently 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 that they offer is creditable (expected to pay at least as much, on average, as the standard prescription drug plan under Medicare). The disclosure is required annually and upon any change that affects whether the coverage is creditable prescription drug coverage. CMS released a Creditable Coverage Disclosure to CMS online form and guidance in January 2006. The form remains active as the only form the employer must submit to CMS under this control number.

### **A. Justification**

#### **1. Need and 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 requires 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' informing us whether such coverage meets the actuarial requirements specified in guidelines provided by CMS in May 2005. 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) for more information.

As outlined in the Disclosure to CMS Guidance paper, the initial disclosure to CMS was due no later than March 31, 2006 for any plan year that ends in 2006. For all subsequent plan years, the entity must disclose to CMS the creditable coverage status of the prescription drug benefit options being provided to Medicare Part D eligible individuals no later than sixty (60 days) following the beginning date of the entities plan year. As outlined under 42 CFR 423.56(f)(2), the entity must also provide a disclosure to CMS upon any change that affects whether the coverage is creditable prescription drug coverage. In an effort to reduce the paperwork burden associated with providing the annual disclosure to CMS, the Disclosure to CMS guidance paper outlines that entities are required to provide the disclosure to CMS via the on-line Disclosure to CMS webpage found at [https://www.cms.hhs.gov/CreditableCoverage/45\\_CCDisclosureForm.asp](https://www.cms.hhs.gov/CreditableCoverage/45_CCDisclosureForm.asp).

#### **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 comparison tool, to ensure that entities are offering prescription drug coverage

equal to or greater than the benefit offered under Medicare Part D. benefit for those who are eligible for the Medicare benefit. The benefit described by the submitter is compared to what is available under Medicare Part D. to determine if it is creditable.

The regulation at 42 CFR 423.46 outlines a late enrollment penalty (LEP) for Part D eligible individuals who go without creditable prescription drug coverage for any continuous period of sixty-three (63) days or longer after the end of their initial enrollment period for Part D coverage, and then subsequently enroll in Medicare prescription drug coverage.

Medicare eligible individuals who delay enrolling in Part D coverage may be required to provide copies of any disclosure notices provided to them by the entity that sponsors the prescription drug coverage in which they were enrolled as proof that they have maintained creditable prescription drug coverage since the end of their Medicare initial enrollment period. Otherwise, the beneficiary may be subject to the late enrollment penalty (LEP) outlined under 42 CFR 423.46 and 423.286(c)(3) and in 70 Federal Register 13397, 13399 (March 21, 2005).

Upon notifying a beneficiary of any LEP determination, plans will advise the beneficiary of the right to ask for a review of CMS' LEP decision. Plans must assist beneficiaries, for example, by making relevant documentation available to support the individual's case, such as notices or other materials related to the initial decision. If an enrollee disagrees with a LEP decision made by CMS (including the determination of the number of months the individual was eligible to enroll in a Part D plan and did not have creditable prescription drug coverage) and the amount of the penalty based on an adverse creditable coverage determination, the enrollee may request reconsideration of that decision under a process described in Medicare Prescription Drug Benefit Manual, Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals, [http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/11\\_Guidance.asp#TopOfPage](http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/11_Guidance.asp#TopOfPage).

Additionally, as set forth under §423.56(g), CMS, upon review, may treat non-creditable coverage as creditable coverage for purposes of applying the late enrollment penalty if:

- an individual establishes that he/ she was not adequately informed that his/ her prescription drug coverage was not creditable prescription drug coverage,
- the individual has made a request in writing to obtain a copy of the creditable coverage disclosure from the entity sponsoring their prior plan, and
- the individual has not received a reply from the entity within a reasonable time. CMS uses the database information collected in the disclosure to assist beneficiaries during the appeals phase by providing the insuring entity's contact information so that the individual may request a copy of the previously issued disclosure notices that entity provided its members.

### 3. Use of Information Technology

CMS issued and posted the on-line Disclosure to CMS form in January 2006 on the CMS website for all entities to complete. The initial disclosure to CMS for plan years ending in 2006 was required to be completed no later than March 31, 2006.

For all subsequent plan years that end in 2007 and beyond, entities must provide their disclosure to CMS via the on-line disclosure to CMS form no later than sixty (60) days following the beginning date of the entity's plan year.

4. Duplication of Efforts

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

5. Small Businesses

There is no significant impact on small businesses who comply with these ICRs. Some entities are small businesses and will have to comply with all the information requirements described in this supporting statement.

6. Less Frequent Collection

Less frequent collection is not applicable. This information is collected as required by statute and regulation as outlined in 42 CFR 423.56(f). By regulation, entities must provide disclosure to CMS in accordance with the ICRs.

7. Special Circumstances

The creditable coverage disclosure information will occur annually from entities as they renew their prescription drug programs. Entities who make mid-year changes to their prescription drug programs are also required under 42 CFR 423.56(f)(2) to provide a disclosure to CMS of any change in the creditable coverage status.

8. Federal Register/Outside Consultation

*Federal Register Notice*

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.

*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, as necessary, 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 2009, CMS consulted with our contractor, to revise the estimated burden hours to more accurately reflect the number of possible respondents.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

The information collected regarding Medicare eligible individuals and contained in enrollment information 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 2016 National Occupational Employment and Wage Estimates for all salary estimates ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)). In this regard, the following table presents the mean hourly wage, the cost of overhead and fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Overhead and Fringe Benefits (\$/hr)	Adjusted Hourly Wage (\$/hr)
Computer and Information Systems Manager	11-3021	70.07	70.07	140.14
Software Developer	15-1130	48.11	48.11	96.22

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. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

*Burden Estimates*

Procedures to document creditable status of prescription drug coverage.

Each entity that offers prescription drug coverage under any of the types described in 42 CFR 423.56(b) must disclose to CMS whether such coverage meets the actuarial requirements specified in guidelines provided by CMS. These notices must be provided at minimum, at the following times: (1) annually as described under 42 CFR 423.56(e) and in guidance issued in January 2006, no later than sixty (60) days after the beginning date of the entity's plan year; and (2) upon any change in creditable status. In an effort to reduce the burden associated with providing the disclosure to CMS, CMS developed an on-line disclosure web page for an entity to provide the required disclosure information to CMS annually, [https://www.cms.hhs.gov/CreditableCoverage/45\\_CCDisclosureForm.asp](https://www.cms.hhs.gov/CreditableCoverage/45_CCDisclosureForm.asp).

The burden associated with this requirement is the time and effort necessary for each of these entities to provide a disclosure to CMS (including annual notices and notices of changes in creditable coverage status) regarding the creditable coverage status of the prescription drug coverage being offered by the entity to Medicare Part D eligible individuals. We estimate that a total of 85,636 entities will be required to provide their disclosure to CMS via the Disclosure to CMS webpage using the on-line 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 on-line via the Disclosure to CMS web page will be negligible.

CMS estimates that it will take each entity approximately 5 minutes to complete their disclosure to CMS via the on-line Disclosure to CMS web page form for the annual disclosure to CMS notice of creditable coverage and notices of changes in creditable coverage status to CMS.

It is estimated that the burden per entity will be as follows:

- The estimated annual burden on each of the 75,860 health plans' Software Developers to complete the on-line Disclosure to CMS web page form will be 5 minutes at \$96.22/hr for a total burden of 6,321.7 hours at a cost of \$608,273.97.

We also estimate that, on average, 1,500 of these health plans will experience changes in creditable coverage status during the year. They will be required to provide an additional notice regarding their new creditable coverage status to CMS via the on-line Disclosure to CMS web page, which will take a Software Developer 5 minutes at \$96.22/hr for an annual burden of 125.0 hours and \$12,027.50.

We estimate a subtotal of 6,446.70 hours at a cost of \$620,301.47.

- On average, for the sponsors of retiree drug coverage (with the exception of benefit options offered by sponsors that have applied and been accepted for the Retiree Drug Subsidy), we estimate that it will take 9,521 entities approximately 5 minutes (each) at \$96.22/hr for a Software Developer to complete the on-line Disclosure to CMS web page form for a total burden of 793.4 hours and \$76,340.95.

We also estimate that 130 of these sponsors of retiree coverage will experience changes in

creditable coverage status during the year. They will be required to provide an additional notice regarding their new creditable coverage status to CMS via the on-line Disclosure to CMS web page, which will take a Software Developer 5 minutes (per plan) at \$96.22/hr, for an annual burden of 10.8 hours and \$1,039.18.

In aggregate, we estimate an annual burden of 804.2 hours at a cost of \$77,380.13.

- On average, an estimated 204 Medigap issuers will provide a disclosure to CMS annually for a burden of 5 minute per notice at \$96.22/hr for a Software Developer. Since Medigap policies will not be changed mid-year, we do not estimate that there will be a need to do any additional disclosures to CMS for any mid year changes in creditable coverage status. We estimate an annual burden of 17 hours at a cost of \$1,635.74 (17 hr x \$96.22/hr).
- On average, CMS estimates that 10 State Pharmacy Plus programs will provide a disclosure notice to CMS for an annual burden of 5 minutes per program at a cost of \$140.14/hr for a Computer and Information Systems Manager. The disclosure to CMS notice is required even these States may decide to lower their costs by reforming these programs. We estimate an annual burden of 0.83 hours at a cost of (0.83 hr x \$140.14/hr).
- We estimate that each of the 11 State Pharmaceutical Assistance Programs will provide the disclosure to CMS notice for an annual burden of 5 minutes at \$140.14/hr for a Computer and Information Systems Manager. We estimate an annual burden of 9.2 hours at a cost of \$1,289.29 (9.2 hr x \$140.14/hr).
- On average, we estimate that 29 Indian Health Service entities will provide the annual disclosure to CMS notice for an annual burden of 5 minutes at \$140.14/hr for a Computer and Information Systems Manager.. It is not expected that there will be a need to do any additional disclosures to CMS for any mid-year changes in creditable coverage status. We estimate an annual burden of 2.4 hours at a cost of \$336.34 (2.4 hr x \$140.14/hr)

**Table: Summary of Type of Respondent and Calculated Burden**

Type of Plan/Respondent	Type of Notice	No. of Plans/ Respondent s	Annual No. of Notices / Responses	Minutes per Response	Annual Time	Hourly Wage (\$/hr)	Total Cost (\$)
Health Plans	Annual and Initial Disclosure	87,265	75,860	5	6,321.70	96.22	620,302
	An Additional Change in Creditable Coverage Status	87,265	1,500	5	125	96.22	
Retiree Drug Plan Sponsors	Annual and Initial Notices	9,521	9,521	5	793.4	96.22	77,342

	An Additional Change in Creditable Coverage Status	9,521	130	5	10.8	96.22	
<b>Medigap Issuers</b>	Annual and Initial Notices	204	204	5	17	96.22	1,636
	An Additional Change in Creditable Coverage Status	0	0	0	0	96.22	
<b>State Pharmacy Plus Programs</b>	Annual and Initial Notices	10	10	5	0.83	140.14	116
	An Additional Change in Creditable Coverage Status	0	0	0	0	140.14	
<b>State Pharmaceutical Assistance Programs</b>	Annual and Initial Notices	11	11	5	0.92	140.14	129
	An Additional Change in Creditable Coverage Status	0	0	0	0	140.14	
<b>Indian Health Service</b>	Annual and Initial Notices	29	29	5	2.4	140.14	336
	An Additional Change in Creditable Coverage Status	0	0	0	0	140.14	
<b>TOTAL</b>		<b>97,040</b>	<b>87,265</b>	<b>40</b>	<b>7,272.10</b>	<b>varies</b>	<b>699,861</b>

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 \$4,530.49. The cost/FTE's were obtained from [https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB\\_h.pdf](https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB_h.pdf). The locality is Baltimore, MD, Washington D. C. and Arlington VA area.. The two FTE's are GS-12 Step 4 (at \$42.02/hr) and GS-5 Step 2 (at \$17.96/hr) and two contractor positions (a program manager at \$65.29/hr and a software developer at \$49.17/hr). CMS switched to a contractor already employed by the government, who will provide a system so entities could report whether their prescription drug coverage is creditable or not. The contractor is responsible for the following: continued support of an online system in accordance with CMS specifications; developing, testing and implementing release/enhancement packages on servers; trouble shooting; as well as maintain and update support services.

<b>Role</b>	<b>Hourly Salary (\$/hr)</b>	<b>Hours</b>	<b>Total Cost</b>
Program Manager-Contractor	65.29	6.5	\$424.39
Developer-Contractor	49.17	12.75	\$626.92
GS 12 Step 4	42.02	61	\$2,563.22
GS 5 Step 2	17.96	51	\$915.96
<b>Totals:</b>	<b>174.44</b>	<b>131.25</b>	<b>\$4,530.49</b>

15. Changes to Burden

There are no program changes or any revisions to the instructions and screenshots.

Our 5 min/response estimate is unchanged.

However, we are correcting and adjusting our burden estimates as follows:

The currently approved information collection request inadvertently set out 2,793 states in the ROCIS burden table. This should have been 29 states.

We are adjusting our private sector respondent estimate +3,285.

The net change is +521 responses and -93 hours

We are also correcting our cost estimates by aligning respondents with BLS occupations and by doubling their wage to account for fringe benefits and overhead.



16. Publication/Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

CMS would like to display the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

**B. Collections of Information Employing Statistical Methods**

Not applicable.