

Supporting Statement For Collection Requirements pertaining to the Medicare Prescription Drug Benefit Program (CMS-4068-F)

A. Background

Most entities that currently provide 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 to be provided annually and upon any change that affects whether the coverage is creditable prescription drug coverage. CMS released a Disclosure to CMS Guidance Paper and a disclosure to CMS notification on-line form in January 2006.

B. Justification

1. Need and Legal Basis

Section 1860D-1 of 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 the Centers for Medicare & Medicaid Services informing them 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 Federal Register 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/apps/ccdisclosure/default.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 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 will be required to provide copies of any disclosure notices provided to them by the entity that sponsors the prescription drug coverage that they were covered by as proof that they have maintained creditable prescription drug coverage since the end of their 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's 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 late enrollment penalty 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 to be established by CMS through operational guidance. Final LEP reconsideration procedures are currently under development. Finalized reconsideration instructions will be published as part of Chapter 18 of CMS' Part D Manual which may be accessed at <http://www.cms.hhs.gov> in the near future.

Additionally, as set forth under §423.56(g), if upon review by CMS an individual establishes that he or she was not adequately informed that his or her prescription drug coverage was not creditable prescription drug coverage, and 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 has not received a reply from the entity within a reasonable time, then CMS will treat the coverage as creditable for purposes of applying the late enrollment penalty. CMS is proposing to use the disclosure to CMS database information to assist beneficiaries during the appeals phase by providing the contact information disclosed to CMS by the entity so that the individual may request a copy of the previously issued disclosure notices provided to individuals by the entity.

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 contained in the regulations are not duplicated through any other effort.

5. Small Businesses

Some Entities are small businesses so they may be affected. They will have to comply with all the information requirements described in this supporting statement.

6. Less Frequent Collection

This information is collected as needed. By regulation, entities must provide disclosure to CMS annually.

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

The required Federal Register notice was published on August 3, 2004 (69FR 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 information collection requirements. 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.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

The information collected from Medicare eligible individuals and contained in enrollment information must conform to all requirements at 42 CFR Part §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. (a) Burden Hours

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.

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 446,160 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 estimate the annual burden on each of the 400,000 health plans to complete the on-line Disclosure to CMS web page form will be 5 minutes per plan for a total burden of 33,333 hours. We also estimate that, on average, 4,000 of these health plans will experience changes in creditable coverage status during the year and therefore be required to provide notice of their new creditable coverage status to CMS via the on-line Disclosure to CMS web page, for an annual burden of 333.3 hours.
- 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 46,000 entities approximately 5 minutes each to complete the on-line Disclosure to CMS web page form for a total burden of 3,883 hours. We also estimate that 500 of these sponsors of retiree coverage will need to provide a disclosure to CMS of a change in creditable coverage status for an average annual burden of 5 minutes for each sponsor.
- On average, an estimated 120 Medigap issuers will provide a disclosure to CMS annually for a burden of 5 minute per notice (10 hours annually). 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.
- On average, CMS estimates that 2 State Pharmacy Plus programs will provide a disclosure notice to CMS for an annual burden of 5 minutes per program (the disclosure to CMS notice is required even these States may decide to lower their costs by reforming these programs).
- We estimate that each of the 38 State Pharmaceutical Assistance Programs will provide the disclosure to CMS notice for an annual burden of 5 minutes per State.

Type of Plan/Respondent	Type of Notice	Number of Plans/ Respondents	Annual # Notices/ Responses	Est. Minutes per Response	Annual Burden Hours
Health Plans	Annual Disclosure	400,000	400,000	5	33,333.3
	Change in Creditable Coverage Status		4,000	5	333.3

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-NEW. The time required to complete this information collection is estimated to average 5 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

Retiree Drug Plan Sponsors	Annual and Initial Notices	46,000	46,000	5	3,833.3
	Change in Creditable Coverage Status		500	5	41.7
Medigap Issuers	Annual and Initial Notices	120	120	5	10.0
	Change in Creditable Coverage Status		n/a	0	n/a
State Pharmacy Plus Programs	Annual and Initial Notices	2	2	5	.2
	Change in Creditable Coverage Status		0	0	0
State Pharmaceutical Assistance Programs	Annual and Initial Notices	38	38	5	3.2
	Change in Creditable Coverage Status		0	0	0
Totals		446,160	450,660	35	37,555.0

13. Capital Costs

In 2005, there were no capital or equipment costs to CMS resulting from the collection of information because the on-line disclosure to CMS webpage was created by the CMS website development team. However, in 2006, CMS will need to contract with a vendor to manage the disclosure information so that the database can be used in the late enrollment penalty reconsideration/appeals process to provide Medicare Part D eligible individuals with contact information at the entity in order for the individual to request a copy of the disclosure notices provided by the entity. In the future, CMS is exploring the development of a voluntary data file that could be provided to CMS to capture creditable coverage information by individual to maintain in a system that the Part D plan would have access to when reviewing an enrollment application to assist in determining prior creditable coverage status.

14. Cost to Federal Government

There are no additional costs identified at this time to the Federal Government resulting from the collection of information. Also refer to “Section V” (Impact Analyses) of the preamble of the attached regulation for more information related to capital costs.

15. Changes to Burden

This is a new program.

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16. Publication/Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

CMS would like a three year expiration date because the disclosure web page form is being used on a continuing basis, and because this collection does utilize a standard information collection instrument or instructions.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

Not Applicable