Supporting Statement For Collection Requirements pertaining to the Creditable Coverage Disclosure to CMS OnLine Form and Instructions CMS-10198 (OMB 0938-1013)

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 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 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/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 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 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.

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 uses 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 (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 needed. 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

A 60-day Federal Register notice was published on August 21, 2009.

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 (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 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, Fu Associates, to revise the

estimated burden hours.

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 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 Estimates (Hours & Wages)

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.

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 87,500 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 76,905 health plans to complete the on-line Disclosure to CMS web page form will be 5 minutes per plan for a total burden of 6,408.8 hours. 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 5 minutes per plan, for an annual burden of 125.0 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 8,905 entities approximately 5 minutes each to complete the on-line Disclosure to CMS web page form for a total burden of 742.1 hours. 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 5 minutes per plan, for an annual burden of 10.8 hours.

- On average, an estimated 30 Medigap issuers will provide a disclosure to CMS annually for a burden of 5 minute per notice (2.5 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 5 State Pharmacy Plus programs will provide a disclosure notice to CMS for an annual burden of 5 minutes per program (.4 hours annually). 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 25 State Pharmaceutical Assistance Programs will provide the disclosure to CMS notice for an annual burden of 5 minutes per State (2.1 hours annually).

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	76,905	76,905	5	6,408.8

	An Additional Change in Creditable Coverage Status	n/a	1,500	5	125.0
Retiree Drug Plan Sponsors	Annual and Initial Notices	8,905	8,905	5	742.1
	An Additional Change in Creditable Coverage Status	n/a	130	5	10.8
Medigap Issuers	Annual and Initial Notices	30	30	5	2.5
	An Additional Change in Creditable Coverage Status	0	0	0	0
State Pharmacy Plus Programs	Annual and Initial Notices	5	5	5	.4
	An Additional Change in Creditable Coverage Status	0	0	0	0
State Pharmaceutical Assistance Programs	Annual and Initial Notices	25	25	5	2.1
	An Additional Change in Creditable Coverage Status	0	0	0	0
Totals		**85,870**	**87,500**	**35**	**7,291.7**

13. Capital Costs

There are no additional capital costs associated with these ICRs..

14. Cost to Federal Government

The cost to the Federal Government is $100,000. CMS contracted with Fu to provide a system so entities could report whether their prescription drug coverage was creditable. Fu was responsible for the following: creating an online system in accordance with CMS specifications; developing, testing and implementing release/enhancement packages on servers; trouble shooting; maintain technical help line to support the system; as well as maintain and update support services.

15. Changes to Burden

The previous PRA package was a new submission and the responses were estimated at 450,660 annually. CMS revised the annual estimated number of responses based on actual contractor data. The annual revised number is 87,500. The change to the annual burden is a

mathematical calculation. There are no program changes.

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.

C. Collections of Information Employing Statistical Methods

Not Applicable