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 individual 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, upon request by the individual and at other times as outlined in the final MMA regulations. CMS issued a Model Notice of Creditable Coverage and a Model Notice of Non-Creditable Coverage in May 2005 that entities could use for providing the required disclosure. However, entities are not required to use the Model disclosure notices or any specific language to provide the disclosure of creditable coverage status. They are only required to use the data elements outlined in the final MMA regulation and in the General Creditable Coverage guidance issued by CMS in May 2005.

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 status to all Medicare Part D eligible individuals covered under the entity's plan 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.

These disclosure notices must be provided to Part D eligible individuals, at minimum, at the following times: (1) prior to an individual's initial enrollment period for Part D, as described under §423.38 (a); (2) prior to the effective date of enrollment in the entity's coverage, and upon any change in creditable status; (3) prior to the commencement of the Part D Annual Coordinated Election Period (ACEP) which begins on November 15 of each year, as defined in 423.38 (b); and (4) upon request by the individual. In an effort to reduce the burden associated with providing these notices, our final regulations allow most entities to provide notices of creditable and non-creditable status with other information materials that these entities distribute to beneficiaries (rather than separately) and CMS also provided the language for both types of notices.

2. Information Users

Disclosure of whether prescription drug coverage is creditable provides Medicare eligible individuals with important information relating to their Medicare Part D enrollment. Beneficiaries who are not covered under creditable prescription drug coverage and who choose not to enroll before the end of their initial enrollment period for Part D likely will pay a late enrollment penalty on a permanent basis if they subsequently enroll in 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. The higher premium charge (penalty) is based on the number of months that the individual did not have creditable coverage. The premium that would otherwise apply is increased by at least 1% of the national benchmark beneficiary premium for each month that the beneficiary was without creditable coverage. While this percentage will apply for as long as the individual remains enrolled in Part D, the higher premium charge will actually increase each year because the percentage increase will be applied to each subsequent year's base premium.

Medicare eligible individuals that delay enrolling in Part D coverage will be required to provide copies of any disclosure notices provided to them by the entity(s) 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 outlined under 42 CFR §423.46 and §423.286 (c)(3) and in 70 Federal Register 13397, 13399 (March 21, 2005).

Part D Plans ("Plans") will be required to review creditable coverage documentation and report to CMS information upon which CMS will use to determine whether a late enrollment penalty applies, and if so, the penalty amount. Using data provided by CMS systems, Plans must determine if a beneficiary had any gaps of 63 days or longer from the end of his Part D IEP to the proposed effective date in which the beneficiary did not have Medicare prescription drug coverage or other creditable prescription drug coverage. If at least one gap exists, the Plan must review the creditable coverage section of the Plan enrollment form, including any evidence of creditable coverage the beneficiary provides. Part D Plans are required to receive and review all evidence of creditable coverage (EOCC) at the time of enrollment.

Part D Plans are required to receive and review:

- Generic disclosure notice from the entity that provided the coverage with proof of beneficiary coverage during that period (see below for more information regarding proof of coverage items), or
- Personalized disclosure statement from the entity offering the coverage.

Individuals presenting this information are considered to have had creditable coverage for the period(s) attested to by the beneficiary on the Part D plan enrollment form.

As required under 42 CFR 423.56(f), in the event a beneficiary fails to retain evidence of creditable coverage, entities are required, upon request by the individual, to provide either copies of previous disclosure notices provided to the individual back to their initial enrollment period for Medicare and/or provide a personalized disclosure notice with periods of creditable coverage to the Medicare eligible individual.

Generic Disclosure Notice. The generic disclosure notices will likely be in various formats. For example, it might appear inside the coverage handbook or be a separate letter. The individual must provide a copy of the disclosure notice to the Part D plan at the time of enrollment and proof of coverage indicating that the individual was actually enrolled in the plan during the applicable time period and/or elected coverage. The purpose of the beneficiary's proof of coverage is to verify that the beneficiary was enrolled in coverage during the timeframe that was indicated on the Part D enrollment form. This proof of coverage must include the beneficiary name, the entity name, a date the card or bill was issued and/or the coverage timeframes, and it must have an indication that the beneficiary was covered. For example, a copy of the beneficiary identification card, a bill for the coverage, a payroll statement, or some related type of documentation would be acceptable.

Personalized Disclosure Notice. As an alternative, a personalized disclosure notice/statement can be provided by the entity to the individual in addition to or in lieu of generic disclosure notice(s). CMS has included a model alternative disclosure statement in this collection. Beneficiaries may submit a copy of this as the only form of proof of coverage, if it contains all of the required information. If the personalized notice does not have an indication of the timeframe of coverage, the beneficiary must produce additional proof of this.

The Personalized statement of creditable coverage from the entity must contain all of the following elements:

- beneficiary's first and last name;
- date of birth or member identification number
- entity name and contact information;
- statement that the entity's plan was determined by the entity to be creditable or non-creditable coverage;
- the date ranges of creditable coverage

While Plans are required to review the disclosure notices and standard types of proof of coverage items, if a beneficiary has other types of evidence of creditable coverage, the Plan may choose to review these other types of creditable coverage documentation as well. A Plan may accept other types of evidence as long as the evidence satisfactorily demonstrates that a beneficiary had creditable coverage during the period(s) in question.

If the beneficiary provides insufficient documentation of creditable coverage with the enrollment form, the Plan will be required to notify the beneficiary. The notice must explain the LEP, the type(s) of creditable coverage evidence needed to avoid a penalty, and the deadline, currently 60 days from the beneficiary's effective date, for providing such evidence to the Plan. Upon receipt of acceptable creditable coverage evidence by the deadline, and in conjunction with data from CMS systems, the Plan will be required to assess the total number of uncovered months. Plans are responsible for sending the number of uncovered months to CMS.

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. 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 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.

Completion of the above set of activities will not delay enrollment of the beneficiary into the Part D Plan. Plans will have a certain amount of time to complete this process post-enrollment. In some instances, therefore, beneficiaries may have to pay retroactive LEP amounts.

3. Use of Information Technology

CMS issued Model disclosure of creditable and non-creditable coverage notices in May 2005 on the CMS website for all entities to download and use. The initial model notices were to be

used until May 15, 2006.[1] The final MMA regulation gave entities the flexibility to include these notices in other communication materials that they distribute to plan participants and did not require that they use the Model disclosure notices published on the CMS website. Entities are not required to sign the notices but were required to inform all Medicare eligible individuals of the following information: whether the coverage offered was creditable or not; information regarding the definition of creditable coverage; and information regarding the late enrollment penalty provisions. CMS will issue model disclosure creditable coverage and non-creditable coverage disclosure notices electronically as well as a model personalized disclosure notice that entities can use after May 15, 2006 and upon request by the Medicare Part D eligible individual.

After May 15, 2006, Part D plans will use the creditable coverage disclosure notice information provided by an individual at the time of enrollment to comply with the eligibility and the associated Part D late enrollment penalty provisions. The Part D plan will determine whether the individual went without any creditable prescription drug coverage for any continuous period of sixty-three (63) days or longer after the end of his initial enrollment period in Part D and determine the number of months without creditable coverage. CMS will use the information submitted by the Part D plan to determine the amount of the late enrollment penalty premium amount each year.

CMS anticipates that the vast majority of new Part D plan applications in the future will be a beneficiary switching from one Part D plan to another. CMS will be retaining all historical information related to all prior Part D enrollment and Retiree Drug Subsidy participation indicators and Part D plans will have a process to query a CMS database at the time of enrollment to check for prior creditable coverage periods, thus reducing the need to verify prior creditable coverage periods with the beneficiary. This will reduce the burden on entities as well as on beneficiaries.

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

1 Medigap issuers were subject to a separate requirement under section 104 of the MMA to provide information about whether their prescription drug coverage was creditable, along with other Medigap-specific information. Medigap issuers were required to send that notice during the period of September 15, 2005 through November 14, 2005. CMS fulfilled its statutory obligation to work with the National Association of Insurance Commissioners to prepare mandatory language for this notice. Medigap issuers that timely provided the notice under section 104 of the MMA were considered to have fulfilled their beneficiary notice requirements under 42 CFR 423.56. Additionally, Medigap issuers were permitted to use those notices through May 15, 2006, to satisfy their beneficiary notice obligations under 42 CFR 423.56.

all the information requirements described in this supporting statement.

6. Less Frequent Collection

This information is collected as needed. If it were to be collected less frequently, CMS and Part D plans would not be able to obtain this data for determining the late enrollment penalty. Some of the consequences would be improper Part D premium calculations thus impacting the cost of the Part D program to the Federal Government.

7. Special Circumstances

Generally, creditable coverage information collections in the Part D drug program occur annually during the Annual Coordinated Election Period. Special circumstances such as an individual being granted a Special Enrollment Period may require information to be submitted to the Part D plan and CMS more often than annually.

8. Federal Register/Outside Consultation

A 60-day Federal Register notice published on May 12, 2006.

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 and late enrollment penalty 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 all Part D eligible individuals whether such coverage meets the actuarial requirements specified in guidelines provided by CMS. These notices must be provided to Part D eligible individuals, at minimum, at the following times: (1) prior to an individual's initial enrollment period for Part D, as described under §423.38 (a); (2) prior to the effective date of enrollment in the coverage, and upon any change in creditable status; (3) prior to the commencement of the Annual Coordinated Election Period (ACEP) which begins on November 15 of each year, as defined in 423.38 (b); and (4) upon request by the individual. In an effort to reduce the burden associated with providing these notices, our final regulations allow most entities to include notices of creditable and non-creditable status with other information materials that these entities distribute to beneficiaries (rather than separately). CMS also provided language for both types of notices.

The burden associated with this requirement is the time and effort necessary for each of these entities to disclose to an individual a notice of coverage. We estimate that it will require 450,160 entities to provide notices in existing plan materials (including 400,000 total health plans with Medicare-eligible individuals, including group health plans, individual plans, state high risk pools and Indian Health Service plans, 50,000 retiree drug plan sponsors and 38 State Pharmaceutical Assistance Programs and 2 State Pharmacy Plus programs) and 120 Medigap insurers to provide separate notices (including initial notices to new beneficiaries, annual notices prior to the ACEP, and notices of changes in creditable coverage status), as well as additional separate notices to be provided to individuals upon request.

Given that each entity will be creating most of these disclosure notices for inclusion in existing plan materials, we make the following burden estimates. For initial notices of creditable coverage, subsequent notices prior to the commencement of the ACEP, and notices of changes in creditable coverage, we estimate that it will take each entity approximately 1 hour to produce the model disclosure notice. We further estimate that, on average, it will take each entity a negligible amount of time to deliver each notice, since they will be incorporating notices into existing plan materials that are already provided to beneficiaries. We further estimate that each entity will spend approximately 5 minutes per notice for providing separate additional copies of the notices to individual beneficiaries upon request. It is estimated that the burden per entity will be as follows:

- On average, each of the 400,000 health plans will be negligible, since they will be able to include these notices in their existing plan materials with minimal modifications for annual burden of 1 hour per plan. Additionally, on average, we estimated that these 400,000 health plans will provide 100,000 additional separate notices to individuals upon request for an annual burden of 5 minutes per notice. We also estimate that, on average, 4,000 of these health plans will experience changes in creditable coverage status and provide notice of their new creditable coverage status in their plan materials,

for an annual burden of 2 hours per plan.

- On average, for the sponsors of retiree drug coverage, we estimated that it will take 50,000 entities approximately 1 hour each to produce a standardized notice for a total of 50,000 burden hours on an ongoing basis. Since each entity can include initial disclosure notices in existing beneficiary plan materials, which are already being disseminated to their participants, we estimate that this will involve a negligible amount of time. Additionally, on average, we estimate that each entity will provide 13 additional separate notices to individuals upon request for an annual burden of about 5 minutes for each notice. We also estimate that in subsequent years 500 of these sponsors of retiree coverage will provide notices of a change in creditable coverage for an average annual burden of 2 hours for each sponsor.
- On average, each of an estimated 120 Medigap issuers will provide 15,833 separate notices annually for a burden of 1 minute per notice (264 hours annually). Additionally, on average, we estimate that these 120 Medigap issuers will provide 40 additional separate notices to individuals upon request for an annual burden of 5 minutes for each notice. We estimate that the annual burden associated with providing notices prior to the ACEP will be negligible since the regulatory impact analysis assumes that the vast majority of beneficiaries with Medigap drug coverage will enroll in Part D (and upon doing so, can no longer have Medigap drug coverage).
- On average, the 2 State Pharmacy Plus programs will provide notices in existing beneficiary plan materials for an annual burden of 1 hour per program (these notices are required even though, these States may decide to lower their costs while maintaining equivalent benefits by replacing or reforming these programs).
- We estimate that each of the 38 State Pharmaceutical Assistance Programs will provide notices in existing beneficiary plan materials for an annual burden of 1 hour 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 and Initial Notices	400,000	400,000	60	400,000
	Upon Request		100,000	5	8,333
	Change in Creditable Coverage Status		4,000	120	8,000
Retiree Drug Plan Sponsors	Annual and Initial Notices	50,000	50,000	60	50,000
	Upon Request		650,000	5	54,167
	Change in Creditable Coverage Status		500	120	100
Medigap Issuers	Annual and Initial Notices	120	15,833	1	264
	Upon Request		48		

			00	5	400
	Change in Creditable Coverage Status		n/a	n/a	n/a
State Pharmacy Plus Programs	Annual and Initial Notices	2	2	60	2
	Upon Request		0	0	0
	Change in Creditable Coverage Status		0	0	0
State Pharmaceutical Assistance Programs	Annual and Initial Notices	38	38	60	38
	Upon Request		0	0	0
	Change in Creditable Coverage Status		0	0	0
Totals		**450,160**	**1,225,173**	**496**	**522,204**

13. Capital Costs

There are no additional capital or equipment costs to CMS 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.

14. Cost to Federal Government

There are no additional costs 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.

16. Publication/Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

CMS would like an exemption from displaying the expiration date because these forms are used on a continuing basis, and because this collection does not lend itself to the displaying of an expiration date due to the fact that this collection does not utilize any 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