Supporting Statement For Paperwork Reduction Act Submissions

A. Background

1. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Pub. L. 110-275 was enacted on July 15, 2008 and amended titles XVIII and XIX of the Social Security Act to make various revisions to the Medicare statute intended to improve the Medicare program. Section 103 established new statutory prohibitions and limitations for Medicare Advantage plans and Medicare prescription drug plans. On September 18, 2009_we published the Final Rule-4131F in the Federal Register (E8-21674) that set forth the provisions that would implement Section 103 of MIPPA. This rule finalized six new marketing provisions and modified the disclosure and dissemination of Part C and D information. Specifically, plans must disclose the information specified in §422.111 (b) and §423.128 (b), as specified in §422.111 (a)(3) and §423.128 (a)(3), at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

2. Medicare Prescription Drug, Improvement, and Modernization Act of 2003

   The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) was enacted on December 8, 2003. Title II of the MMA makes important changes to the current Medicare+Choice (M+C) program by replacing it with a new Medicare Advantage (MA) program under Part C of Medicare. On August 3, 2004, we published a proposed rule in the Federal Register (69 FR 46866) that set forth the provisions that would implement Title II of the MMA. Section 1851 (d)(2)(A) of the Act and 422.111 (d) (2) of the Final Rule published January 28, 2005 established disclosure requirements for changes to rules in a MA plan. Specifically, MA plans must provide notice to plan members of impending changes to plan benefits, premiums and copays in the coming year so that members will be in the best position to make an informed choice on continued enrollment or disenrollment from that plan at least 15 days before the Annual Election Period (AEP). Since 2009, organizations are required to notify plan members of the coming year changes using a combined standardized document at the time of enrollment and annually thereafter. This new requirement is designed to:

   - Ensure that people with Medicare receive timely information so that they may make confident, informed decisions about their healthcare options.

- Streamline and standardize information required annually to Medicare beneficiaries to improve the clarity of material and organize materials to help people with Medicare understand their benefits, rights and obligations.
- Create an efficient process for developing and reviewing annual renewal materials.

3. We are requesting OMB approval to reflect the information collection requirements referenced in the Proposed Rule 0938-AQ00 CY 2012 Medicare Advantage and Prescription Drug Benefit program. The collection instrument that requires OMB approval concerns the proposed disclosure requirements in new proposed paragraphs §422.111(b)(12) and §423.128 (b)(11). The proposed information collection would require MA organizations and Part D sponsors to periodically provide each enrollee with enrollee specific data to use to compare utilization and out-of-pocket costs in the current plan year to projected utilization and out-of-pocket costs for the following plan year. Plans would disclose this information to plan enrollees in each year in which a minimum enrollment period has been met, in conjunction with the annual renewal materials (currently the ANOC and EOC) described in §422.111(b) and 423.128(b).

B. Justification

1. Need and Legal Basis

Section 1852(c) of the Social Security Act requires MA organizations to disclose a detailed plan description in a clear, accurate, and standardized form to each Medicare enrollee in a MA plan offered by the organization. The plan description is to be provided at the time of enrollment and annually thereafter and includes items such as service area, premium, benefits, plan providers and coverage. Additionally, section 1860D-1(c)(3) of the Act requires Part D sponsors to provide comparative information to beneficiaries about their qualified prescription drug benefits, premiums, cost sharing, quality and performance, and results of consumer satisfaction surveys. Specifically, the Part D plan description includes items such as service area, benefits, premium, formulary, network pharmacies, and coverage. These requirements are codified at §422.111 and §423.128 and are implemented through the annual notice of change (ANOC) and evidence of coverage (EOC) documents, which must be furnished to all plan enrollees at least 15 days before the annual open election period.

In accordance with authority cited above, we propose to also require MA organizations and Part D sponsors to periodically provide each enrollee with enrollee specific data to use to compare utilization and out-of-pocket costs in the current plan year to projected utilization and out-of-pocket costs for the following plan year, as reflected in proposed new paragraphs §422.111(b)(12) and §423.128(b)(11). Plans would disclose this information to plan enrollees in each year in which a minimum enrollment period has been met, in conjunction with the annual renewal materials (currently the ANOC and EOC). This customized information would supplement general plan information in the ANOC and EOC documents as well as enhance the currently available information through tools such as Medicare Options Compare (MOC) and the Medicare Prescription Drug Plan Finder (MPDPF), which provide general information about plan costs. We intend for any customized enrollee statement to provide

personal information to beneficiaries that would help them consider using other tools and resources, including MOC and MPDPF, to determine whether to select a new plan.

2. Information Users

Medicare Advantage (MA) organizations (formerly M+C organizations) and prescription drug plan sponsors use the information discussed below to comply with the eligibility requirements and the MA and Part D contract requirements. CMS will use this information to ensure that correct information is disclosed to Medicare beneficiaries.

3. Use of Information Technology

Where feasible the collection of information covered by this regulation does involve the use of automated, electronic, mechanical, or other technological collection techniques designed to reduce burden and enhance accuracy. Specifically, Section §422.111 requires, to the extent that a MA plan has a website, annual notification through the website of written, hard copy notification sent to the beneficiaries. Section 423.128 requires that a Part D plan have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms include an Internet website that includes information about the Part D plan.

4. Duplication of Efforts

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

5. Small Businesses

Some MA organizations and Part D sponsors are considered small businesses and will be affected by this rule. They will have to comply with the disclosure requirement in each year in which a minimum enrollment period has been met, in conjunction with the annual renewal materials as specified in 42 CFR §422.111 (b)(12) and §423.128 (b)(11). Several of the provisions of this rule, however, will minimize burden for all insurers, including small businesses.

6. Less Frequent Collection

This information is collected as needed. Some of the consequences would be information provided to enrollees that is too general for enrollees to actively and meaningfully evaluate their plans annually with respect to plan costs, benefits, and overall value, resulting in enrollment in a plan that is not the best value for the enrollee.

7. Special Circumstances

Generally, information collections contained in the MA and Part D program occur annually or quarterly. Under the proposed 42 CFR §422.111(b)(12) and §423.128(b)(11) disclosure requirements, the customized enrollee data must be disclosed to enrollees in each year in which a minimum enrollment period has been met. Whether this disclosure will occur annually, quarterly or with some other frequency will be determined through the receipt of comments to the proposal.

8. Federal Register/Outside Consultation

CMS published a proposed rule on September XX, 2010 for comments.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

Information will be kept private to the extent permitted by law. Contracted MA organizations and Part D sponsors must adhere to the HIPAA privacy rule on sharing patient health information during a change of ownership or a novation agreement.

11. Sensitive Questions

There are no sensitive questions included in this collection effort.

12. Burden Estimates (Hours & Wages)

The following material is from Section VI. Collection of Information Requirements, contained in the preamble of the Proposed Rule published on September XX, 2010.

§ 422.111(b) (12)-Customized Enrollee Data : The estimated cost/wage associated with this requirement in the initial year is $27.24 x 16,920 =$460,900. This is based upon the hourly rate of GS 10 step 1 multiplied by the number hours of annual burden hours (16,920).

The estimated cost/wage associated with this requirement in subsequent years is $27.24 x 11,280 =$307,267. This is based upon the hourly rate of GS 10 step 1 multiplied by the number hours of annual burden hours (11,280).

§ 423.128(b)(11)-Customized Enrollee Data: The estimated cost/wage associated with this requirement in the initial year is $27.24 x 1,700=$46,308. This estimate is based upon the hourly rate of GS 10 step 1 multiplied by the number of annual hours (1,700).

The estimated cost/wage associated with this requirement in subsequent years is $27.24 x 1,275=$34,731. This estimate is based upon the hourly rate of GS 10 step 1 multiplied by the number of annual hours (1,275).

Customized Enrollee Data (§ 422.111(b)(12) and §423.128(b)(11))

Plan sponsors already collect enrollee utilization and cost-sharing information as part of their claims processing operations. Therefore, the burden associated with this proposed requirement is the time and effort necessary for a plan sponsor to complete program development and testing, and to disclose (print and mail) this information to each beneficiary. We anticipate that in the initial year, it would take 30 hours per MA organization and 20 hours per Part D sponsor to develop and submit the required information. This includes 2 hours for reading CMS' published instructions, 20 hours per MA organization and 10 hours per Part D sponsor generating the document or documents, and 8 hours printing and disclosing to beneficiary. We developed this burden estimate using our burden estimates for the ANOC/EOC documents under OCN 0928-1051 as a baseline, then expanding on that baseline, and factoring in expected programming and development costs to provide beneficiary specific information. We estimate 564 MA organizations and 85 Part D sponsors would be affected annually by this requirement. The total annual burden associated with this requirement is 18,620 hours in a fiscal year.

In subsequent years, the burden associated with this proposed requirement is the time and effort necessary for a plan sponsor to disclose (print and mail) this information to each beneficiary. We anticipate that it would take 20 hours per MA organization and 15 hours per Part D sponsor to develop and submit the required information. This includes 1 hour for reading CMS' published instructions, 10 hours per MA organization and 5 hours per Part D sponsor generating the document or documents, and 6 hours printing and disclosing to beneficiary. We estimate 564 MA organizations and 85 Part D sponsors would be affected annually by this requirement. The total annual burden associated with this requirement is 12,555 hours in a fiscal year (20 hours for each of the 564 MA organizations + 15 hours for each of the 85 Part D sponsors).

13. Capital Costs

Not applicable. The entities that will offer coverage are ongoing health organizations and should have no or minimal total capital, startup, operational or maintenance costs resulting from this collection of information

14. Cost to Federal Government

Not applicable.

15. Changes to Burden

The changes in burden and the number of respondents are associated with the number of MA organizations and Part D sponsors that will participate for the new contract year.

16. Publication/Tabulation Dates

Generally there are no publication or tabulation dates. The schedule for the annual notices issued by CMS containing information regarding available choices for Medicare coverage is outlined in §422.64 and §423.48.

17. Expiration Date

CMS does not object to displaying the expiration date on information collection materials.

18. Certification Statement

There are no exceptions to the certification statement.