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. Balanced Budget Act of 1997

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Public Law 105-33) enacted August 5, 1997, added sections 1851 through 1859 to the Social Security Act (the Act) to establish a new Part C of the Medicare program, known as the Medicare+Choice program. The Centers for Medicare & Medicaid Services (CMS) published an interim final rule to establish the Medicare+Choice program on June 26, 1998. A final rule revising these sections was published on February 17, 1999 and again on June 29, 2000. Information supplied by organizations was used to determine eligibility for contracting with CMS, for determining compliance with contract requirements, and for calculating proper payment to the organizations. Information supplied by Medicare beneficiaries was used to determine eligibility to enroll in the M+C organization and to determine proper payment to the organization that enrolled the beneficiary. Separate OMB approval was sought for each form as required.

We are requesting OMB approval to reflect the information collection requirements referenced in the Final Rule 4131 F-Medicare Advantage and Prescription Drug Benefit program: Final Marketing Provisions published September 18, 2008. The collection instrument that requires OMB approval concerns the disclosure requirements in §422.111(b) and §423.128 (b) which requires MA organization and prescription drug plan sponsor information to be disclosed at the time of enrollment and annually thereafter, 15 days before the annual election period as specified in §422.111 (a)(3) and §423.128(a)(3).

B. Justification

1. Need and Legal Basis

The information collection requirements are mandated by 42 CFR §422.111(a)(3) and §423.128(a)(3). The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Pub. L. 110-275, added the new requirements specified in this statement.

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, both potential enrollees and enrollees.

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 requirements at the time of enrollment and 15 days before the annual election period as specified in 42 CFR §422.111 (a)(3) and §423.128 (a)(3). 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. If it were to be collected less frequently, CMS would not be able to obtain this data. Some of the consequences would be improper enrollment of beneficiaries in an MA or prescription drug plan, the release of misleading information regarding health care coverage through an MA plan or Part D plan to potential members, and inadequate provision of patients' rights to Medicare-covered services.

7. Special Circumstances

Generally, information collections contained in the MA and Part D program occur annually or quarterly. Under the 42 CFR §422.111(a)(3) and §423.128(a)(3) disclosure requirements, the combined standardized Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) must be used by plans for both new and current enrollees. These documents are updated annually based on recent policy changes and changes in plan benefits offered year-to-year.

8. Federal Register/Outside Consultation

A 60-day Federal Register notice was published on September 25, 2009. No comments were received.

CMS published a proposed rule on May 16, 2008 for comments. Comments received were responded to in the final rule which was published on September 18, 2008.

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. The information collected from MA organizations and Part D sponsors for the purposes of disclosing to the potential enrollees their health care coverage choices is public information and in fact is being collected for purposes of the National Medicare Education Program, whose purpose is to broadly disseminate to the public objective, comparative information on benefits, program rules, and premiums of the contracting MA organizations and Part D sponsors. 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 Final Rule published on September 18, 2008.

§ 422.111(a) (3)-Disclosure Requirements : The estimated cost/wage associated with this requirement is $21.73 x 7,836=$170,276. This is based upon the hourly rate of GS 10 step 1 multiplied by the number hours of annual burden hours (7,836).

§ 423.128(a)(3)-Disclosure Requirements: The estimated cost/wage associated with this requirement is $21.73 x 1,044=$22,686. This estimate is based upon the hourly rate of GS 10 step 1 multiplied by the number of annual hours (1, 044).

Disclosure requirements (§ 422.111 and §423.128)

MA and Part D sponsors are required as specified in §422.111(a)(3) and §423.128(a)(3) to disclose information specified in §422.111(b) and §423.128(b) at the time of enrollment and annually thereafter, 15 days before the annual coordinated election period. The information required at the time and enrollment and annually, 15 days before the annual coordinated election period, is provided in the standardized ANOC/EOC. Sections 422.111(b) and 423.128(b) require the following information be provided: content of plan description, service area, benefits, access, emergency coverage, supplemental benefits, prior authorization, grievance and appeals, quality improvement and catastrophic caps.

As provided under §422.111(a) (3) and §423.128 (a)(3), MA organizations and Part D sponsors must submit the required disclosure information for CMS review under the procedures of §422.2262 and §423.2262. CMS requires plans to use a combined standardized ANOC/EOC to notify enrollees at the time of enrollment and annually thereafter, 15 days before the annual coordinated election period. While plans are required to have their marketing materials submitted for review and approval under §422.2262 and §423.2262,the ANOC/EOC is a separate requirement.

The burden associated with the disclosure requirements is the time and effort associated for a plan sponsor to submit the required information and disclose to beneficiary. For each entity we anticipate that it would take 12 hours to develop and submit the required information. This includes 1 hour for reading CMS'published instructions, 6 hours generating standardized document, 1 hour submitting materials, 4 hours printing and disclosing to beneficiary. We estimate 653 MA organizations would be affected annually by this requirement and 87 Part D sponsors would be affected annually by this requirement. The total annual burden associated with this requirement is 8,880 hours.

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

The estimated wage / salary cost associated to the Federal Government for developing model marketing notices annually is 480 hours @ $35.62 per hour = $17,098.

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.

The 2009 model document included text variations for all types of Medicare Advantage plans,

using color coding to identify which standardized text to use for which types of plans. For contract year 2010 CMS conducted an assessment of the ANOC/EOC model documents for improvement through listening sessions with plan representatives and advocacy groups. The document was also consumer tested with beneficiaries through in-depth interviews. Based on the feedback, the ANOC/EOC models for contract year 2010 were re-structured and formatted for ease of use and beneficiary understanding. CMS has separated the EOC into six plan specific models (MA plan, MA-PD plan, cost-based plans, PDP, PPO plan, and PFFS plan). The contract year 2010 ANOC/EOC models were used by MA organizations and Part D sponsors for the 2009 annual coordinated election period (November 15 – December 31, 2009) for contract year 2010.

In re-structuring the contract year 2010 ANOC/EOC, no sections from the contract year 2009 ANOC/EOC models were either eliminated or added. The requirements for plan sponsors sending the ANOC/EOC will not create additional burden based on these changes. Plan sponsors are still required to use the standardized language in the ANOC/EOC models and send this document to current members by October 31. The attached table 1 below summarizes the revisions made to the contract year 2010 ANOC/EOC.

16. Publication/Tabulation Dates

Generally there are no publication or tabulation dates. However, as part of the National Medicare Information Program, in connection with the annual election period in November of each year, information collected from MA organizations and Part D sponsors will be published in the Medicare Handbook and on the Internet. 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.