Supporting Statement For Paperwork Reduction Act Submissions

A. Background

1. 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). Beginning 2009, organizations will be required to notify plan members of the coming year changes using a combined standardized document. 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.

2. 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 is 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 new information collection requirements referenced in Title II Final Rule (4069-F) which was published in the Federal Register on January 28, 2005. The collection instrument that requires OMB approval concerns §422.111 (d) (2) disclosure requirements. CFR §422.111 (d) (2) is associated with §422.80 and must therefore follow the review procedures for approval of marketing materials and election forms.

B. Justification

1. Need and Legal Basis

The information collection requirements are mandated by 42 CFR §422. 111 (d)(2) and §422.80. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P. L. 108-173) added the new requirements specified in this statement.

2. Information Users

Medicare Advantage (MA) organizations (formerly M+C organizations) and potential MA organizations (applicants) use the information discussed below to comply with the eligibility requirements and the MA 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.

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 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 annually. Several of the provisions of this rule, however, will minimize burden for all insurers, including small businesses. This includes streamlining the approval of marketing materials (§ 422.80).

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 organization, the release of misleading information regarding health care coverage through an MA plan to potential members, and inadequate provision of patients' rights to Medicare-covered services.

7. Special Circumstances

Generally, information collections contained in the MA program occur annually or quarterly. Under 422.111 (d)(2) disclosure requirements, the combined standardized Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) are reviewed annually. Special circumstances that would require information to be submitted to the agency more often than quarterly include:

Approval of marketing materials and election forms (§422.80) - An MA organization may not distribute any marketing materials, as defined in this section, unless CMS has approved the materials in advance. While the Evidence of Coverage or Annual Notice of Change are reviewed annually, CMS may require revision of these documents if found to be inaccurate, even if the original submission was approved. These materials must be submitted to CMS as approval is requested and thus information may be collected more frequently than quarterly. In addition other materials requiring CMS review and approval, such as official notices pertaining to enrollment, disenrollment, appeals procedures, ect. may be modified my MA organizations at any time during the year and will need to be submitted at that time.

8. Federal Register/Outside Consultation

A 60-day Federal Register notice was published on April 18, 2008

Previously, we published a 60-day Federal Notice in the proposed rule on August 3, 2004 (69 FR 46866). Comments received were responded to in the final rule which published on January 28, 2005. We also held several open door forums and town hall meetings. On July

21, 2004 we held a public meeting in Chicago to discuss the designation of MA-PD regions. We received many comments on both this meeting as well as our discussion of the regions in the proposed rule.

We also published the disclosure requirements for 422.111(d)(2) in the draft combined standardized Annual Notice of Change and Evidence of Coverage on January 16, 2008 on CMS website. Comments received were addressed in the final combined standardized document and released on March 17, 2008.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

The collection of information from the MA applicants and contracting organizations that pertain to their financial records and submission of data to comply with the requirements concerning enrollment, applications, and bids have been determined by CMS's Freedom of Information officer to be proprietary and confidential. The information collected from MA organizations 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. Contracted MA organizations 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 V. Collection of Information Requirements, contained in the preamble of the Final Rule published on January 28, 2005.

§ 422.80: We estimate the notification to the general public and submission of the designated marketing materials to be performed by a plan employee who is the equivalent of the GS 12 Step 10 in 2007 ($35.07 per hour). Thus the hourly wage is $35.07 x 13,400=$469,938.

§ 422.111(d) (2): The cost associated with this requirement is captured in § 422.80.

Approval of Marketing Materials and Election Forms (§ 422.80)

The MA organization must submit any marketing material or election forms to CMS for review at least 45 days (or 10 days if using marketing materials that use without modification, proposed model language as specified by CMS) before distribution. The materials must be in a format and using standard terminology specified by CMS that meets the requirements specified in this section. The burden associated with this requirement is time and effort put forth by the MA organization to submit the material to CMS for review. We estimate it would take on MA organization 12 hours to comply with this requirement. We estimate 670 MA organizations would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 8,040.

§422.80(a)(3) If the MA plan meets the performance requirements established by CMS, the MA plan may distribute the designated marketing materials 5 days following their submission to CMS with a certification that the marketing materials meet the model language guidelines specified by CMS.

The burden associated with this requirement is the time and effort necessary for the plan to submit the designated marketing materials to CMS five days prior to distribution. While this requirement is subject to PRA, we believe the burden associated with this requirement is exempt from the requirements of the Paperwork Reduction Action of 1995 (PRA) as defined in 5 CFR 1320.3 (h) (1).

Disclosure requirements (§ 422.111)

422.111(d) (2) if an MA organization intends to change its rules for an MA plan, it must submit the changes for CMS review under the procedures of § 422.80. For changes that take effect on January 1, the plan must notify all enrollees 15 days before the beginning of the Annual Election Period as defined in section 1851(e)(3)(B) of the Act. CMS is requiring plans to use a combined standardized document to notify enrollees. The burden associated with this requirement is captured in § 422.80.

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

There is no cost to the Federal Government

15. Changes to Burden

The changes in these requirements the program are associated with the Title II MMA

requirements.

This information collection requirement includes changes for this final rule which implements certain provisions relating to the Medicare Advantage (MA) program (formerly Medicare + Choice program) that were enacted in Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P. L. 108-173. Additional collections include disclosure requirements (§422.111(d) (2)). While §422.111(d) (2) is a new collection requirement this specific requirement must be reviewed under the procedures of §422.80.

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 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.

17. Expiration Date

At the current time this collection requirement does not lend itself to an expiration date because there are no forms. Therefore, CMS requests this exception.

18. Certification Statement

There are no exceptions to the certification statement.