Supporting Statement Part A
Medicare Advantage and Prescription Drug Program:
Final Marketing Provisions in 42 CFR 422.111(a)(3) and 423.128(a)(3)
CMS-10260, OCN 0938-1051

Introduction

On August 3, 2010, the Office of Management and Budget (OMB) approved the Centers for Medicare and Medicaid Services (CMS) the Medicare Advantage (MA) and Prescription Drug Program: Final Marketing Provisions collection. This approval authorized CMS to require MA organizations and Part D sponsors to meet disclosure requirements through the use of standardized Annual Notice of Change/Evidence of Coverage (ANOC/EOC) documents. OMB approved CMS to collect 740 responses, estimated to require 8880 work hours. Through this submission, CMS seeks approval for the use of the 2015 versions of the standardized ANOC/EOC documents. There are nine versions of the standardized ANOC/EOC, to correspond to the different MA organization and Part D sponsor product offerings. Due to changes in the number of MA organizations and Part D sponsors, CMS is anticipating a potential increase in the number of responses (to 770) and corresponding increase in the total burden hours (to 9240).

Background

Pursuant to disclosure requirements set out in §§ 1851(d)(2)(A) and 1860D-1(c) of the Social Security Act (the Act), and cited in 42 CFR §§ 422.111(a) (3) and 423.128(a)(3), MA organizations and Part D sponsors must provide notice to plan members of impending changes to plan benefits, premiums and cost sharing in the coming year. To this effect, 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). MA organizations and Part D sponsors must notify plan members of the coming year changes using a combined standardized document called the Annual Notice of Change/Evidence of Coverage (ANOC/EOC) which must be disseminated at the time of enrollment and at least annually thereafter.

This requirement is designed to ensure that people with Medicare receive timely information so that they may make confident, informed decisions about their healthcare options.

We are requesting OMB approval to reflect the information collection requirements imposed by the Agency's requirement that MA organizations and Part D sponsors use these standardized documents to meet the disclosure requirements contained in §§ 422.111(b) and 423.128(b).

A. Justification

1. Need and Legal Basis

CMS requires MA organizations and Part D sponsors to use the standardized documents being submitted for OMB approval to satisfy disclosure requirements mandated by § 1851 (d)(3)(A) of the Act and 42 CFR § 422.111(b) for MA organizations, and § 1860D-1(c) of the Act and 42 CFR § 423.128(a)(3) for Part D sponsors.

The regulatory provisions at §§ 422.111 and 423.128(b) require MA organizations and Part D sponsors to disclose plan information, including: service area, benefits, access, grievance and appeals procedures, and quality improvement/assurance requirements by September 30 of each year.

2. Information Users

MA organizations and Part D sponsors use the information discussed below to comply with the disclosure requirements under MA and Part D law and regulations, as described above. CMS will use the approved standardized documents to ensure that correct information is disclosed to current and potential enrollees.

3. Use of Information Technology

The collection of information covered by this regulation involves the use of automated, electronic, mechanical, or other technological collection techniques designed to reduce burden and enhance accuracy. MA organizations and Part D sponsors upload these documents into the Health Plan Management System (HPMS) under the File & Use marketing review process to ensure accuracy and regulatory compliance. Section 422.111 requires that, to the extent that an MA organization has a website, the ANOC/EOC be available on the website and sent to the enrollee in hard copy format. Section 423.128 requires that Part D sponsors post the ANOC/EOC on their website and send it to enrollees electronically or in hard copy, based on enrollee's request.

4. Duplication of Efforts

The information collection requirements discussed herein and 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 to ensure compliance with applicable laws and regulations. If it were to be collected less frequently, MA organizations and Part D sponsors would not be providing updated, accurate information to their enrollees. Possible consequences include improper enrollment of beneficiaries in an MA organization or Part D sponsor, the release of misleading information regarding health care coverage through an MA organization or Part D sponsor to potential and/or current members, and inadequate provision

of patients' rights regarding Medicare-covered services.

7. Special Circumstances

These information collections occur annually, as combined standardized ANOC/EOC must be provided to new enrollees at the time of enrollment and existing enrollees annually. These documents are updated annually based on policy changes. The ANOC/EOC must also be submitted to CMS annually through File & Use certification prior to distribution. MA organizations and Part D sponsors must maintain documentation related to their CMS contracts for 10 years pursuant to statutory and regulatory requirements. There are no special circumstances for enrollees to report, prepare written responses or retain records, and no statistical methods are employed.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on October 23, 2013 (78 FR 63208). There was only one public comment. For details, please see the Crosswalk and the Response to Comment attachments.

Subsequent to the publication of the 60-day notice, we had made revisions based on internal review. All revisions are noted in the Crosswalk and are reflected in the ANOC/EOC models.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

The information collected through these documents from MA organizations and Part D sponsors is intended for public disclosure to current and potential enrollees regarding health care and prescription drug coverage choices, program rules, premiums and cost sharing of the contracting MA organizations and Part D sponsors' plan offerings.

11. Sensitive Questions

There are no sensitive questions included in this collection effort.

12. Burden Estimates (Hours & Wages)

The burden associated with completing these documents is the time and effort associated for a MA organization and Part D sponsor to submit the required information and disclose to the beneficiary. For each entity, we estimate that it will take 12 hours to develop and submit the required information. This includes 1 hour to read CMS' published instructions, 6 hours to generate the standardized document, 1 hour to submit the materials, 4 hours to print and disclose to the beneficiaries. We estimate 687 MA organizations and 83 Part D sponsors would be affected by this requirement. CMS estimates the cost/wage associated with this

requirement is $27.24, based upon an hourly rate of GS-10 step 1, multiplied by the number of annual burden hours, for MA organizations and Part D sponsors to review. The total annual burden associated with this requirement is 9240 hours, as reflected on Table 1: *Time & Cost Burden*.

Table 1: Time & Cost Burden

Organization Type	Number of Organizations	Estimated Hours	Estimated Total Hours	Estimated wage/hour	Estimated Cost	Total Burden Hours
MA-PD	687	12	8244	27.24	$224,566.56	8244
PD sponsors	83	12	996	27.24	$27,131.04	996
Total	770		9240		$251,697.60	9240

13. Capital Costs

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

14. Cost to Federal Government

The burden to the Federal government for this collection and the cost of CMS employees' time are calculated to be: **$323,076.26.** The calculations for CMS employees' hourly salary were obtained from the OPM website: http://archive.opm.gov/oca/12tables/html/dcb_h.asp

Table 2: *Cost to Government*:

9 Versions of the standardized ANOC/EOC	$298,000.00
Medicare MA and Part D Program Subject Manner Experts and staff Help/Review:	
8 GS-13: 8 x $42.66 x 20 hours	$6,825.60
2 GS -13: 2 x $42.66 x 208 hours	17,746.56
2 GS -14: 1 x $50.41 x 10 hours	504.10
Subtotal	$25,076.26
Total Cost to the Government:	**$323,076.26**

15. Changes to Burden

The changes in burden and the number of respondents are adjustments associated with the expected increase in the number of MA organizations and Part D sponsors that will participate for the new contract year. The per response burden estimate has not changed.

For 2014, CMS has a total of nine standardized ANOC/EOC documents:

- Cost Plan
- Dual Eligible Special Needs Plan
- Health Maintenance Organization
- Health Maintenance Organization with Prescription Drugs
- Medicare Medical Savings Account
- Prescription Drug Plan
- Private Fee-for-Service Plan
- Preferred Provider Organization
- Preferred Provider Organization with Prescription Drugs

These standardized documents will be used by MA organizations and Part D sponsors for the 2015 contract year.

In revising the standardized ANOC/EOCs for contract year 2014, we did not add to or remove any section from the prior contract year ANOC/EOC models**.** We developed a separate model for Dual Eligible Special Needs Plans to facilitate the provision of these documents to dual eligible enrollees. These revisions will not create additional burden. MA organizations and Part D sponsors are still required to use the standardized language in the ANOC/EOC models and to send this document to current members at least 15 days prior to the start of the annual enrollment period or by September 30, 2014 for the 2015 enrollment season, based on the statutory change under § 3204 of the Affordable Care Act (ACA), P.L. 111-148.

16. Publication/Tabulation Dates

MA organizations and Part D sponsors must ensure that enrollees receive this information by September 30 of each year, and must therefore submit the populated documents to CMS for marketing review under the File & Use process with sufficient time to allow it to meet this requirement.

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.

B. Collections of Information Employing Statistical Methods

This collection does not employ statistical methods.