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, OMB 0938-1051

Introduction

On March 12, 2014, 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.

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).

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, as well as changes to workforce assigned to the project, and the maturity of the project and documents.

Revisions to the nine (9) templates were non-substantive in nature and did not impact the burden estimates for the 2018 ANOC/EOC documents.

In revising the standardized ANOC/EOCs for contract year 2018, we did not add to or remove any section from the prior contract year ANOC/EOC models**.** 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, 2017, for the 2018 enrollment season, based on 42 CFR 422.111(a)(3) and 423.128(a)(3).

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 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(b) 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 (MAO) 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 requires MAOs and Part D sponsors to use the approved standardized documents to ensure that correct information is disclosed to current and potential enrollees. New and current enrollees can review plan benefits, premiums and cost sharing for the coming year to be in a better position to make informed and educated plan selections.

3. Use of Information Technology

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(h)(2)(ii) 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(d)(2) 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

The collection of information will have a minimal impact on small business since MA organizations and Part D sponsors must possess an insurance license and be able to accept substantial financial risk. Generally, state statutory requirements effectively prelude small businesses from being licensed to bear risk needed to serve Medicare enrollees.

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

There are no special circumstances. More specifically, this information collection does not do any of the following:

- Require respondents to report information to the agency more often than quarterly;
- Require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Require respondents to submit more than an original and two copies of any document;
- Require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Is connected with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Require the use of a statistical data classification that has not been reviewed and approved by OMB;
- Includes a pledge of confidentiality that is not supported by authority established in statue or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Require respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect die information's confidentiality to the extent permitted by law.

MA organizations and Part D sponsors are required to maintain documentation related to their CMS contracts for 10 years pursuant to statutory and regulatory requirements.

8. Federal Register/Outside Consultation

The 60-day notice published in the Federal Register on June 30, 2016 (81 FR 42710). There were a total of 49 public comments.

The 30-day notice published in the Federal Register on February 21, 2017 (82 FR 11222). There were a total of 30 public comments.

There were a total of 79 public comments from the two Federal Register notices. Please refer to **Attachment A**: Crosswalk and **Attachment B**: Comments and Responses to Federal

Register Notice #1 and #2 for detailed comments and responses.

We also had revisions that were based on internal review.

All revisions are noted in the Crosswalk (Attachment A) and reflected in the ANOC/EOC models (**Attachment C**). The revisions to the nine (9) templates were non-substantive in nature and did not impact the burden estimates for the 2018 ANOC/EOC documents.

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 associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates (Hours & Wages)

12.1 Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Table 1: Occupation Titles and Wage Rates

Occupation Title	Occupation Code	Mean Hourly Wage($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage($/hr)
Business Operations Specialist	13-1000	34.54	34.54	69.08

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

12.2 Burden Estimates

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 eachcontract, we estimate that it will take an average of 12 hours to develop and submit the required information. This includes 1 hour to read CMS' accompanying memo and instructions to plans in the standardized document, 6 hours to generate the standardized document, 1 hour to submit the materials, 4 hours to print and disclose to the beneficiaries. We estimate 725 MA organization and 80 Part D sponsor contracts would be affected by this requirement. CMS estimates the cost/wage associated with this requirement is $69.08, multiplied by the number of annual burden hours, for MA organizations and Part D sponsors to review. The total average annual burden associated with this requirement is 9,660 hours, as reflected on Table 2: *Time & Cost Burden*.

Table 2*: Time & Cost Burden*

Organization Type	Number of Contracts	Estimated Hours	Estimated Total Hours	Estimated wage/hour	Estimated Cost	Total Burden Hours
MA-PD	725	12	8,700	$69.08	$600,996	8,700

PD sponsors	80	12	960	$69.08	$66,317	960
Total	805	12	9,660	$69.08	$667,313	9,660

12.3 Information Collection Instruments and Associated Instructions

CMS provides nine (9) standardized ANOC/EOC templates to MA organization and Part D sponsors that reflect recent policy changes. MA organizations and Part D sponsors populate the templates with updated MA, PD or both plan product offerings/options. CMS issues a yearly HPMS memo to MA organizations and Part D sponsors to announce the release of the ANOC/EOC materials. CMS highlights the changes, if applicable, and posts the templates on the CMS' Marketing Models, Standard Documents, and Educational Material website, located at (https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial.html)including specific ANOC/EOC Standardized Model Instructions. CMS requires that all documents are compliant with CMS requirements.

The nine (9) templates consists of the following:

Health Maintenance Organization (HMO) - a type of Medicare managed care plan where a group of doctors, hospitals, and other health care providers agree to give health care to Medicare beneficiaries for a set amount of money from Medicare every month. Members usually get care from the providers of the plan.

Cost Plan - is a plan which is similar to a Medicare HMO in that enrollees have access to a network of doctors and hospitals approved by Medicare. Enrollees can join a Medicare cost plan when it's accepting new members, but may decide to return to original Medicare at any time.

Dual Eligible Special Needs (DSNP) – is a plan that is offered to enrollees who are entitled to Medicare and Medical Assistance from a State plan. These plans are designed for people with specific conditions or financial needs.

Medical Savings Account (MSA) – is a plan that deposits money into a special savings account at the beginning of each calendar year. Only the plan can make deposits into the MSA account; plan enrollees cannot deposit their own money.

Private Fee For Service (PFFS) Plan – is a plan that offers coverage by a private insurance company. PFFS plans are not the same as Original Medicare or Medigap. The plan determines how much it will pay doctors, other health care providers, and hospitals, and how much you must pay when you get care.

Preferred Provider Organization (PPO) - is a type of Medicare Advantage Plan (Part C) offered by a private insurance company. In a PPO Plan, you pay less if you use doctors, hospitals, and other health care **providers** that belong to the plan's network

Preferred Provider Organizations with Prescription Drugs (PPO) – is a PPO that provides prescription drug coverage.

Health Maintenance Organization with Prescription Drugs (HMO MA-PD) – is an HMO that provides prescription drug coverage.

Prescription Drug Plan (PDP) – is a plan that provides prescription drug coverage, which subsidizes the costs of prescription drugs for enrollees. Enrollees pay a co-pay for each prescription, a monthly premium and an annual deductible.

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: **$306,671.64,** as reflected on Table 3**.** The calculations for CMS employees' hourly salary were obtained from the Office of Personnel Management 2017 General Schedule Pay Table for the Washington DC Metro area (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2017/general-schedule/).

Table 3: *Cost to Federal Government*:

9 Versions of the standardized ANOC/EOC	$261,800.00
Medicare MA and Part D Program Subject Manner Experts and staff Help/Review:	
12 GS-13 step 5: 12 x $51.48 x 20 hours	$12,355.20
2 GS -13 step 5: 2 x $51.48 x 304 hours	31,299.84
2 GS -14 step 5: 2 x $60.83 x 10 hours	1,216.60
Total Cost to the Government:	**$306,671.64**

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, as well as changes to workforce assigned to the project, and the maturity of the project and documents.

Currently, OMB has authorized CMS to collect 770 responses with an estimated time of 9,240 hours. Through this iteration, CMS seeks approval for the use of the 2018 versions of the standardized ANOC/EOC documents. 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 805) and corresponding increase in the total burden hours (9,660).

These standardized documents will be used by MA organizations and Part D sponsors for the 2018 contract year.

In revising the standardized ANOC/EOCs for contract year 2018, we did not add to or remove any section from the prior contract year ANOC/EOC models**.** 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, 2017 for the 2018 enrollment season, based on 42 CFR §§ 422.111(a) (3) and 423.128(a)(3).

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.