

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)

**Background**

Pursuant to disclosure requirements set out in sections 1851(d)(2)(A) and 1860D-1(c) of the Social Security Act (the Act), and cited in §§422.111(a)(3) and 423.128(a)(3), Medicare Advantage (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) using the Annual Notice of Change (ANOC) and before the first day of the AEP for the Evidence of Coverage (EOC). MA organizations and Part D sponsors must notify plan members of the coming year changes using the standardized ANOC. Plans must disseminate the EOC at the time of enrollment and at least annually thereafter.

CMS has implemented this requirement to ensure that people with Medicare receive timely information so that they may make confident, informed decisions about their healthcare options.

We maintain two (2) templates for each of the nine (9) plan types for a total of eighteen (18) templates, see Attachment A.

This 2021 information collection request includes revisions to one standardized Dual Eligible Special Needs Plans (D-SNPs) EOC model. The model will reflect revisions that will provide enrollees with simpler, more straightforward grievance and unified grievance and appeals procedures. Specifically, Section 9 of the D-SNP EOC model reflects the revisions.

The revisions to Section 9 does not impact the total number of pages of the D-SNP EOC model. However, this package does reflect an increase in burden due to adjustment associated with the number of respondents, changes in wages and time spent uploading materials to a CMS platform by MA organizations and Part D sponsors. The total cost is also adjusted to reflect bulk postage rates, a decrease from approximately \$8 billion (prior submission) to \$42 million.

**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 section 1851 (d)(3)(A) of the Act and §422.111 for MA organizations and section 1860D-1(c) of the Act and §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. MA organizations and sponsors may send the ANOC separately from the EOC, but must send the ANOC for enrollee receipt by September 30. The required due date for the EOC is 15 days prior to the start of the AEP.

CMS requires MA organization and Part D sponsors to submit marketing materials to CMS for review prior to the MA organization or sponsor distributing those materials to the public. In section 1851(h), paragraphs (1), (2), and (3) establish this requirement for MA organizations. Section 1860D-1(b)(1)(B)(vi) directs Part D sponsors to follow the same requirements in section 1851(h) that MA organizations must follow for this purpose.

The regulatory provisions at §§ 422.2262 and 423.2262 require MA organizations and Part D sponsors respectively to submit all marketing materials (as defined in §§ 422.2260 and 423.2260) to CMS for review and approval.

Due to statute and regulatory changes of final rule (CMS-4185F), CMS implemented certain provisions of the Bipartisan Budget Act of 2018 (BBA) (Public Law 115-123). BBA Section 50311 requires increased integration of Medicare & Medicaid benefits and appeal processes for MA D-SNPs. These revisions are reflected in D-SNP EOC model, Section 9 and highlighted on both Attachment A, Models and Attachment B, Crosswalk.

## 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 requires MA organizations and Part D sponsors to use the approved standardized documents to ensure that correct information is disclosed to current and potential enrollees. Additionally, CMS requires MA organizations and Part D sponsors to submit the completed ANOC and EOC documents to CMS. CMS stores the completed templates. New and current enrollees can review the ANOC and EOC upon receipt to find plan benefits, premiums and cost sharing for the coming year to be in a better position to make informed and educated plan selections. CMS does not require new and current enrollees to review the documents or use them in any way.

MA organizations and Part D sponsors will use Subpart V of 42 CFR §422 and may use the information discussed in the Medicare Communication and Marketing Guidelines (MCMG) to comply with the requirements to seek CMS approval as required on marketing materials under MA and Part D law and regulations, as described above. Sections 1851(h)(1) and (2) of the Act require MA organizations and Part D sponsors to obtain CMS approval of marketing materials to ensure that MA organizations and Part D sponsors disclose correct information to current and potential enrollees. CMS collects and retains the MA organization and Part D plan marketing materials via the Health Plan Management System (HPMS). MA organizations and Part D plans submit marketing materials to the CMS marketing material review process using HPMS. Both current and potential enrollees can

review other marketing materials to find plan benefits, premiums, and cost sharing for the coming year (after October 1) and the current 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 ANOC and EOC documents into the Health Plan Management System (HPMS) to ensure accuracy and regulatory compliance. Section 422.111(h)(2)(ii) requires that, the ANOC/EOC be available on the website and 422.111(d)(2) requires that the plan send the ANOC to the enrollee in hard copy format, upon request. Section 423.128(d)(2) requires that Part D sponsors post the ANOC and EOC documents on their website and send the ANOC only to enrollees electronically or in hard copy.

MA organizations and Part D sponsors upload marketing materials into HPMS for CMS review as well.

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 preclude small businesses from being licensed to bear risk needed to serve Medicare enrollees.

6. Less Frequent Collection

The Act/statute requires CMS to collect this information to ensure compliance with applicable laws and regulations. If CMS were to collect the information less frequently, MA organizations and Part D sponsors would not be providing updated, accurate information to their enrollees and potential enrollees. MA and Part D plans update their contracts on a yearly cycle. If we were to collect the completed templates less frequently, we would not be doing our due diligence in maintaining oversight of plans' compliance with the applicable statute and regulation. 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

CMS requires MA organizations and Part D sponsors to maintain documentation related to their CMS contracts for 10 years pursuant to statutory and regulatory requirements. Otherwise, there are no special circumstances. More specifically, this ANOC/EOC and marketing materials 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;
- Make use of 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 statute 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 the information's confidentiality to the extent permitted by law.

## 8. Federal Register/Outside Consultation

The 60-day notice published in the Federal Register on 11/18/2019 (84 FR 63655). There were a total of 48 public comments. Please refer to **Attachment B: Crosswalk** and **Attachment C: Comments and Responses to Federal Register Notice #1** for detailed comments and responses. We also had revisions that were based on internal review. All revisions are noted in the Crosswalk (**Attachment B**) and reflected in the ANOC and EOC models (**Attachment A**). We received and accepted several non-D-SNP comments from both public and SME's and these changes/revisions are also reflected in both **Attachment A: Templates/Models** and **Attachment B: Crosswalk**.

The revisions to the models were non-substantive in nature and did not impact the burden estimates for the 2021 ANOC/EOC documents.

The 30-day notice published in the Federal Register on 04/07/2020 (85 FR 19486).

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 2018 National Occupational Employment and Wage Estimates for all salary estimates ([http://www.bls.gov/oes/current/oes\\_nat.htm](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 and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Table 1: Occupation Titles and Wage Rates

<b>Occupation Title</b>	<b>Occupation Code</b>	<b>Mean Hourly Wage(\$/hr.)</b>	<b>Fringe Benefits and Overhead (\$/hr.)</b>	<b>Adjusted Hourly Wage(\$/hr.)</b>
Business Operations Specialist	13-1000	35.52	35.52	71.04

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.

The requirement to submit marketing materials to CMS for review imposes a burden only in the form of the time required of plan personnel to upload the materials in CMS's Health Plan Management System (HPMS). We have chosen to use the same occupation title for the

purpose of determining the burden estimate for submitting marketing materials to CMS as we used to determine the ANOC and EOC burden estimate as it would be the same category of plan staff that would accomplish this operation.

## 12.2 Annual Requirements and Burden Estimates

### *ANOC/EOC (REVISED)*

Labor Burden (Changes): The burden associated with completing the ANOC and EOC documents is the time and effort associated for a MA organization and Part D sponsor to submit the required information to CMS and disclose the information to the beneficiary in the ANOC and EOC. For each contract, we estimate that it will take an average of 12 hours to develop and submit the required information to CMS. 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 732 MA organization and 63 Part D sponsor contracts are affected by this requirement. CMS estimates the cost/wage associated with this requirement is \$71.04, 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 9540 hours, as reflected in Table 2c.

Table 2a: ANOC/EOC Burden (Reporting Information)

Organization Type	Number of Contracts	Estimated Hours	Estimated Total Hours	Estimated Cost
MA Plans	732	8	5856	\$416,010.24
PD sponsors	63	8	504	35,804.16
<b>Total</b>	<b>795</b>	<b>8</b>	<b>6360</b>	<b>\$451,814.40</b>

Table 2b: ANOC/EOC Burden (Disclosing Information)

Organization Type	Number of Contracts	Estimated Hours	Estimated Total Hours	Estimated Cost
MA Plans	732	4	2928	\$208,005.12
PD sponsors	63	4	252	17,902.08
<b>Total</b>	<b>795</b>	<b>4</b>	<b>3180</b>	<b>\$225,907.20</b>

Table 2c: ANOC/EOC Burden (Total)

Organization Type	Number of Contracts	Estimated Hours	Estimated Total Hours	Estimated Cost
MA Plans	732	12	8784	\$624,015.36
PD sponsors	63	12	756	53,706.24
<b>Total</b>	<b>795</b>	<b>12</b>	<b>9540</b>	<b>\$677,721.60</b>

Non-Labor Burden:

For a plan to meet our requirements regarding what must be in an EOC, we expect the EOC to be an average of 238 pages in length. The length of the EOC has remained consistent over time, and the average length is approximately 238 pages. Per the updated regulatory requirements, we expect MA organizations and Part D sponsors to mail the documents when requested by their members. We expect that approximately one-third of each organization’s members will request paper documents. Finally, we expect MA organizations and Part D sponsors to use commercial bulk rates as measured per pound.

The major expenses in printing an ANOC/EOC document are i) paper, ii) toner and iii) postage. We are not estimating maintenance costs of printers and computers nor the time involved. We therefore estimate the cost per ANOC/EOC for each of these three items.

i) Cost of paper per ANOC/EOC: The typical ANOC/EOC has 258 pages. Typical wholesale costs of paper are approximately \$2.50 for a ream of 500 sheets. Since each ANOC/EOC document has approximately 258 pages (238 pages for the EOC + 20 pages for the ANOC) we are estimating a paper cost of  $\$2.50 / (500 / 258) = \$1.29$  per ANOC/EOC document

ii) Cost of Toner per ANOC/EOC: Toner costs can range from \$50 to \$200 and each toner can last 4,000 to 10,000 pages. CMS assumes a cost of \$50 for 10,000 pages. Therefore each ANOC would have a toner cost of \$1.29 (258 pages per ANOC/10000 pages per toner \* \$50 per toner)

iii) Cost of Postage per ANOC/EOC: As established in CMS-4180-F, (84 FR 23832), May 23, 2019, we assume a bulk postage rate of 0.19 per 50 pounds. Since a ream of paper with 2000 sheets weighs 20 pounds, each ANOC/EOC weighs 2.58 pounds (258 pages per ANOC/EOC/2000 pages per ream \* 20 pounds per ream). Therefore the postage cost per ANOC/EOC equals  $\$0.0098040$  (2.58 pounds per ANOC/EOC / 50 pounds \* 0.19 per 50 pounds). It follows that the total cost per ANOC/EOC is \$2.5898 (\$1.29, cost of paper + \$1.29 cost per ANOC/EOC + 0.0098 cost of postage). As of August 2019 there are 48.6 million beneficiaries enrolled in Medicare Advantage. As indicated above we expect one-third of these enrollees, or

16.2 million beneficiaries to request ANOC/EOCs. Therefore the total cost of producing and mailing ANOC/EOCs to these enrollees is \$42 million (16.2 million enrollees \* \$2.5898 cost per ANOC/EOC).

Thus for total impact, we are estimating \$677,721.60 in labor-related costs and \$42 million for non-labor costs.

*Marketing Materials*

Labor Burden The burden associated with uploading marketing materials is the time and effort associated for a MA organization and Part D sponsor to submit the required information to CMS. We estimate that it takes a plan 30 minutes at \$71.04/hr. for a business operations specialist to submit each of the marketing materials. As indicated in Table 3 (below) we estimate that CMS reviews a total of 47,167 marketing materials, as of August 2019. The total average annual burden associated with this requirement is 23,583.50 hours (47,167 materials x .5 hour per material) at a cost of \$1,675,371.84 (23,583.5 hr. x \$71.04/hr.), as reflected in Table 3.

The 30 minute time estimate does not include the time to generate, print, and disseminate the materials as MA organizations and Part D sponsors would be performing these activities regardless of any federal requirement. Plans and Part D sponsors that choose to market do so based on their own initiative. It is not mandated by CMS. Moreover, the process for developing generating, and distributing marketing materials (and the scope of the same) differs significantly from plan to plan and from region to region. We also have no basis to establish this estimate. Given the above, we are not estimating such burden without credible public input.

Table 3: Estimated Time & Cost by Marketing Code

Marketing Code	Description	Estimated Number of Materials Submitted	Hours per response	Total Hours	Wage	Total Cost in Dollars
1000	Enrollment and related documents	6292	30 min	3146.	\$71.04	223,491.84
1100	ANOC/EOC/LIS Rider	8809	30 min	4404.5	\$71.04	312,895.68
4000	Advertisements	29627	30 min	14813.5	\$71.04	\$1,052,351.04
6000	Presentations/Scripts/Surveys	2439	30 min	1219.5	71.04	86,633.28
	TOTAL	47,167	30 min	23583.50	71.04	\$1,675,371.84



### 12.3 Burden Summary

Regulatory Section(s) in Title 42 of the CFR	Respondents	Responses	Burden per Response	Total Annual Burden (hours)	Labor Cost	Total Cost (\$)
422.111 and 423.128 (ANOC/EOC completion and disclosure)	795	795	12 hr.	9540	\$71.04	677,721.60
ANOC/EOC (non-labor)	795	n/a	n/a	n/a	n/a	42,000,000.00
422.2260 and 423.2260 marketing materials	795	47,167	30 min	23583.50	71.04	1,675,371.84
<b>TOTAL</b>	<b>795</b>	<b>47,962</b>	<b>Varies</b>	<b>33,123.50</b>	<b>\$71.04/hr.</b>	<b>\$2,353,093.44</b>

### 12.4 Information Collection Instruments and Associated Instructions

#### *ANOC/EOC*

CMS provides nine (9) standardized ANOC and nine (9) standardized EOC templates to MA organizations and Part D sponsors that reflect recent policy changes (if any). 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 and 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.htm>) including specific ANOC/EOC Standardized Model Instructions. CMS requires that all documents are compliant with CMS requirements.

The nine (9) categories of templates consists of the following with two (2) documents (one ANOC and one EOC) in each category. As previously stated, this 2021 iteration has revisions to D-SNP EOC model, Section 9, to include appeals and grievance processes.

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.

### *Marketing Materials*

Plans can find instructions for what CMS looks for when reviewing marketing materials in the Medicare Communications and Marketing Guidelines (MCMG) located on CMS.gov (<https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html>). Plans can find instructions for how to submit documents for review by CMS in the HPMS User Guide which is available on the Health Plan Management System (HPMS) to individuals (i. e., plan staff) who have been approved for HPMS access. The scope of these documents is much greater than the scope by which we address here. Additionally, the HPMS User Guide is a document owned by another component. As such, those documents as a whole are not part of this package.

13. Capital Costs

Not applicable.

14. Cost to Federal Government

The calculations for CMS employees’ hourly salary were obtained from the Office of Personnel Management 2018 General Schedule Pay Table for the Washington DC Metro area) <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2018/generalschedule/>.

The annual burden to the Federal Government including the cost of CMS employees’ time is calculated to be: **\$394,846.86** (\$307,700.28 + \$87,146.58) as reflected in Tables 4 and 5.

*ANOC/EOC*

The burden for this collection and the cost of CMS subject matter experts to review the sections are calculated to be **\$307,700.28**. This is reflected in Table 4.

Table 4: Cost to Federal Government – ANOC/EOC

18 Versions of the standardized ANOC and EOC documents	\$261,800.00
Medicare MA and Part D Program Subject Matter Experts and staff Help/Review:	
12 GS-13 step 5: 12 x \$52.66/hr. x 20 hours	12,638.40
2 GS -13 step 5: 2 x \$52.66/hr. x 304 hours	32,017.28
2 GS -14 step 5: 2 x \$62.23/hr. x 10 hours	1,244.60
SUBTOTAL	\$307,700.28

*Marketing Materials*

The burden to the Federal government for the collection of marketing materials and the cost of CMS employees’ time are calculated to be: **\$87,146.58**, as reflected below in Table 5. CMS prospectively reviews about 10 percent of the marketing materials submitted.

Table 5: Cost to Federal Government – Marketing Materials

4717 (47,167 materials x 10%)	
Medicare MA and Part D Program Subject Matter Experts Review:	
12 GS-11 step 5: \$36.95/hr. x 4717 materials x .5 hr.	\$87,146.58
SUBTOTAL	\$87,146.58

15. Changes to Burden

This 2021 information collection request subsumes revisions to the D-SNP EOC and ANOC and EOC models. The changes in burden are adjustments associated with the number of respondents, changes in wages, and a more accurate estimate in number of marketing materials that MA organizations and Part D sponsors upload into the HPMS. It also includes the changes to non-labor costs based on bulk postage rates.

16. Publication/Tabulation Dates

MA organizations and Part D sponsors must ensure that enrollees receive the ANOC by fifteen days prior to the start of the AEP each year and the EOC by the first day of the AEP of each year, and must therefore submit the populated documents to CMS for review.

MA organizations and Part D sponsors must ensure that they submit each marketing material to CMS for review prior to use.

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.