

Supporting Statement Part A
Annual Notice of Change and Evidence of Coverage for Applicable
Integrated Plans in States that Require Integrated Materials
(CMS-10824, OMB 0938-XXXX)

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 enrollees of impending changes to plan benefits, premiums, and cost sharing in the coming year. To this effect, enrollees 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 enrollees 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.

CMS maintains EOC and ANOC models for each of the nine (9) plan types for a total of eighteen (18) models under CMS-10260, OMB control number 0938-1051.

This new information collection request creates new standardized EOC and ANOC models for Dual Eligible Special Needs Plan (D-SNP) applicable integrated plans (AIPs), as defined at § 422.561, in certain States that chose to require that plans issue an integrated EOC and ANOC that covers the Medicare and Medicaid benefits. The models will reflect revisions to the D-SNP models under CMS-10260 to include information on Medicaid benefits that State Medicaid agencies can customize.

CMS will submit a non-substantive request package with the Spanish and Chinese translated version of these EOC and ANOC models within two months of the submission of these models.

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.

2. Information Users

MA organizations with AIPs in States that require these integrated documents will use the information discussed below to comply with the disclosure requirements under MA and Part D law and regulations, as described above. CMS requires these AIPs to use the approved standardized documents to ensure that correct information is disclosed to current and potential enrollees. Additionally, CMS requires these AIPs to submit the completed ANOC and EOC documents to CMS. CMS stores the completed models. 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 with AIPs in States that require these integrated documents 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 AIPs to obtain CMS approval of marketing materials to ensure that AIPs 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). AIPs 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 with AIPs in States that require these integrated documents upload ANOC and EOC documents into HPMS to ensure accuracy and regulatory compliance. Sections 422.111(h)(2)(ii) and § 422.2265(c) requires that the ANOC/EOC be available on the website, and § 422.111(h)(2)(ii) requires that the plan send the EOC to the enrollee in hard copy format upon request. Section 423.2265(c) requires that Part D sponsors post the ANOC and EOC documents on their website and § 423.2267(d)(2) allows Part D sponsors to mail enrollees a notice informing enrollees how to access the EOC electronically

without prior consent.

AIPs upload marketing materials into HPMS for CMS review as well.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source. While purpose for this collection of information is substantially similar to form CMS-10260, CMS is not able to combine this information collection with CMS-10260 due to potential confusion for MA organizations with AIPs in States that require these integrated documents.

5. Small Businesses

The collection of information will have a minimal impact on small business since MA organizations with AIPs 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 with AIPs in States that require these integrated documents would not be providing updated, accurate information to their enrollees and potential enrollees. AIPs update their contracts on a yearly cycle. If CMS were to collect the completed models less frequently, it would not be doing its due diligence in maintaining oversight of plans' compliance with the applicable statute and regulation. Possible consequences include improper enrollment of individuals in an AIP, the release of misleading information regarding health care coverage through an AIP to potential and/or current enrollees, and inadequate provision of patients' rights regarding Medicare and Medicaid covered services.

7. Special Circumstances

CMS requires MA organizations with AIPs in States that require these integrated documents 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 (87 FR 54696) on September 7, 2022. CMS received over 250 comments from 12 organizations. CMS has included comments to the responses as well as a crosswalk of the changes that CMS has made as a result of the comments received. Also, in addition to the final version of the models, CMS has included a redline version which shows the updates that CMS made to the models.

9. The 30-day notice published in the Federal Register on XXXX X, 2023. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

The information collected through these documents from MA organizations with integrated D-SNPs 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 with integrated D-SNPs' 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 2021 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 and overhead (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 Benefits and Overhead (\$/hr.)	Adjusted Hourly Wage(\$/hr.)
Business Operation Specialists, All Other	13-1199	38.10	38.10	76.20

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 the 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

Labor Burden: The burden associated with completing the ANOC and EOC documents is the time and effort associated for an MA organization with an AIP in a State that

requires these integrated documents to submit the required information to CMS and disclose the information to the beneficiary in the ANOC and EOC. For each AIP, 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 47 AIPs will be in States that require these integrated documents. CMS estimates the cost/wage associated with this requirement is \$76.20, 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 564 hours, as reflected in Table 2.

Table 2: ANOC/EOC Burden for MA organizations with AIPs in Certain States (Reporting Information)

Activity	Number of Contracts	Estimated Hours	Estimated Total Hours	Estimated Cost
Reporting Information	47	8	376	\$28,651
Disclosing Information	47	4	188	\$14,326
Total	47	12	564	\$42,977

Non-Labor Burden:

For a MA organization with an AIP in a State that requires these integrated documents to meet our requirements regarding what must be in an EOC, we expect the EOC to be an average of 238 pages in length. Per the updated regulatory requirements, we expect for an AIP to mail the documents when requested by their enrollees. We expect that approximately one-third of each AIP's enrollees will request paper documents. Finally, we expect AIPs 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: 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 \$2.59 (\$1.29, cost of paper + \$1.29 cost per ANOC/EOC + \$0.0098 cost of postage). As of July 2022, the number of individuals enrolled in a HIDE SNP or FIDE SNP was approximately 2,200,000.¹ Therefore the total cost of producing and mailing ANOC/EOCs to these enrollees is \$5,698,000 (2,200,000 enrollees * \$2.59 cost per ANOC/EOC).

Thus, for total impact, we are estimating \$5,698,000 in labor-related costs and \$42,977 for non-labor costs.

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)	AIPs in certain States		12 hr.	564	\$76.20	\$42,977
ANOC/EOC (non-labor)	AIPs in certain		n/a		n/a	\$5,698,000
TOTAL			Varies		\$76.20/hr.	\$5,740,977

12.4 Information Collection Instruments and Associated Instructions

ANOC/EOC

CMS provides one standardized ANOC and one EOC model to MA organizations with integrated D-SNPs that reflect recent policy changes (if any). MA organizations with AIPs in States that require these integrated documents populate the models with updated MA-PD product offerings/options. CMS will issue a yearly HPMS memo MA organizations with AIPs in States that require these integrated documents to announce the release of the ANOC and EOC

¹ CMS SNP Comprehensive Report, July 2022 retrieved from: <https://www.cms.gov/httpswwwcmsgovresearch-statistics-data-and-systemsstatistics-trends-and/snp-comprehensive-report-2022-07>

materials. CMS highlights the changes, if applicable, and posts the models on the CMS' Marketing Models, Standard Documents, and Educational Material website, located at (<https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketingModelsStandardDocumentsandEducationalMaterial.html>) including specific ANOC/EOC Standardized Model Instructions. CMS requires that all documents are compliant with CMS requirements.

Marketing Materials

AIPs 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>). AIPs can find instructions for how to submit documents for review by CMS in the HPMS User Guide which is available on the 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

There are no capital costs.

14. Cost to Federal Government

The calculations for CMS employees' hourly salary were obtained from the Office of Personnel Management 2022 General Schedule Pay Table for the Washington DC Metro area) <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2022/general-schedule/>.

The annual burden to the Federal government including the cost of CMS employees' time is calculated to be: **\$50,665** (\$Table 4 total + \$Table 5 total) 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 **\$50,563**. This is reflected in Table 4.

Table 4: Cost to Federal Government – ANOC/EOC

2 Versions of the standardized ANOC and EOC documents	
Medicare MA and Part D Program Subject Matter Experts and staff Help/Review:	
12 GS-13 step 5: 12 x \$58.01/hr. x 20 hours	\$13,922
2 GS -13 step 5: 2 x \$58.01/hr. x 304 hours	\$35,270
2 GS -14 step 5: 2 x \$68.55/hr. x 10 hours	\$1,371
SUBTOTAL	\$50,563

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: **\$102**, 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

5 (47 materials x 10%)	
Medicare MA and Part D Program Subject Matter Experts Review:	
1 GS-11 step 5: \$40.70/hr. x 5 materials x .5 hr.	\$102
SUBTOTAL	\$102

15. Changes to Burden

This is a new submission; there are no changes to burden.

16. Publication/Tabulation Dates

MA organizations with AIPs in States that require these integrated documents 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 will display the expiration date and OMB approval number on the ANOC and EOC.

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.