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 0938-1444)

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). As required by §§422.2267(e) and 423.2267(e), all Medicare Advantage and Part D plans must provide the EOC to current enrollees by October 15 and to prospective enrollees within 10 calendar days from receipt of the confirmation of enrollment or by the last day of the month prior to the effective date, whichever is later. They must send the ANOC for enrollee receipt no later than September 30 of each year and enrollees with an October 1, November 1, or December 1 effective date must receive within 10 calendar days from receipt of the CMS confirmation of enrollment or by the last day of the month prior to the effective date, whichever is later. Per §§ 422.2265(c) and 423.2265(c) they must also post the ANOC and EOC to their websites by October 15 prior to the beginning of the plan year. 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 information collection maintains 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 reflect revisions to the D-SNP models under CMS10260 to include information on Medicaid benefits that State Medicaid agencies can customize.

Accompanying this supporting statement is a crosswalk illuminating the changes between the previous package and this proposed package. These modifications have not affected burden, as many are non-substantive, and others are changes made on account of regulatory or administrative decisions for which the burden has been accounted for in different areas. There are no changes to burden aside from what is noted below. An example of this is the sunsetting of the value based insurance design, or VBID, which is requiring updates to language in the models. However, this change has no effect on the burden of this package, as it does not require a substantive lift for the provision of this package.

There are some updates to burden throughout this package that are not connected to the updated materials. Some elements of burden have increased, especially in accounting for the number of plans that will be required to distribute these materials, and some elements of burden have decreased, as we now have more accurate estimates of enrollment in such plans.

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. <u>Use of Information Technology</u>

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. <u>Duplication of Efforts</u>

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. <u>Less Frequent Collection</u>

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 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 the
 information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day notice published in the Federal Register (90 FR 36058) on 7/31/2025.

We received several comments on this package with regard to the overall package and the ANOC and specific chapters of the EOC. We made amendments to several of the chapters of the EOC and the ANOC in response to the comments we received as well as other updates that were needed since we published the 60-day notice. These changes are further discussed in section 15 below, and are described in detail in the crosswalk document in this package. We thank the commenters for their input.

The 30-day Federal Notice (90 FR 58248) published in the Federal Register on 12/16/2025.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. <u>Confidentiality</u>

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 2024 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	Mean Hourly	Fringe Benefits and	Adjusted Hourly
	Code	Wage(\$/hr.)	Overhead (\$/hr.)	Wage(\$/hr.)
Business Operation Specialists, All Other	13-1199	44.41	44.41	88.82

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 109 AIPs will be in States that require these integrated documents. CMS estimates the cost/wage associated with this requirement is \$88.82, 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 1,308 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	Cost per Hour	Estimated Cost
Reporting Information	109	8	872	\$88.82	\$77,451
Disclosing Information	109	4	436	\$88.82	\$38,726
Total	109	12		\$88.82	\$116,117

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 230 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 \$3.50 for a ream of 500 sheets. Since each ANOC/EOC document has approximately 245 pages (230 pages for the EOC + 15 pages for the ANOC) we are estimating a paper cost of 3.50/(500/245) = 1.71 per ANOC/EOC document.

- <u>ii)</u> 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 \$70 for 10,000 pages. Therefore, each ANOC would have a toner cost of \$1.72 (245 pages per ANOC/10000 pages per toner * \$70 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 2.45 pounds (245 pages per ANOC/EOC/2000 pages per ream * 20 pounds per ream). Therefore the postage cost per ANOC/EOC equals \$0.00931 (2.45 pounds per ANOC/EOC / 50 pounds * 0.19 per 50 pounds). It follows that the total cost per ANOC/EOC is \$3.43 (\$1.71, cost of paper + \$1.71 cost per ANOC/EOC + \$0.00931 cost of postage). As of January 2025, the number of individuals enrolled in a HIDE SNP or FIDE SNP in a state that required the use of integrated ANOC/EOC was approximately 911,576. In our estimate, we are also including enrollment numbers for individuals who are enrolled in a Medicare-Medicaid Plan (MMP) in January 2025, as the majority of these MMPs are converting to HIDE or FIDE SNPs in January, 2026. In January 2025, enrollment in MMPs was approximately 237,772. The total enrollee estimate that we are using for this package is 1,149,348 (911,576 + 237,772). Therefore the total cost of producing and mailing ANOC/EOCs to these enrollees is \$3,942,264 (1,149,348 enrollees * \$3.43 cost per ANOC/EOC).

Thus, for total impact, we are estimating \$3,942,264 in non-labor costs and \$116,117 for labor-related costs.

12.3 Burden Summary

Regulatory Section(s) in Title 42 of the CFR	Respondents	Response	per	(hours)	Labor Cost	Total Cost (\$)
422.111 and 423.128 (ANOC/EOC completion and disclosure)	AIPs in certain States		12 hr.	1,308	\$88.82	\$116,117
ANOC/EOC (non-labor)	AIPs in certain States		n/a		n/a	\$3,942,264

¹ CMS SNP Comprehensive Report, January 2025 retrieved from: https://www.cms.gov/data-research/statisticstrends-and-reports/medicare-advantagepart-d-contract-and-enrollment-data/special-needs-plan-snp-data

² January 2025 MMP enrollment data retrieved by CMS from MARx.

	and MMPs in certain States			
TOTAL		Varies	\$88.82/h r.	\$4,058,381

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 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/

<u>MarketngModelsStandardDocumentsandEducationalMaterial.htm</u> 1) 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-

<u>Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html</u></u>). 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. <u>Capital Costs</u>

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 2024 General Schedule Pay Table for the Washington DC Metro area) https://www.opm.gov/policy-data-oversight/pay-leave/salarieswages/salary-tables/pdf/2024/DCB_h.pd.

The annual burden to the Federal government including the cost of CMS employees' time is calculated to be: **\$29.558** (\$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 **\$29,311**. 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 Manner Experts and staff Help/Review:	
3 GS-13 step 5:3 x \$65.48/hr. x 20 hours	\$3,929
1 GS -14 step 7: 1 x \$81.93/hr. x 300 hours	\$24,579
1 GS -15 step 0: 1 x \$80.31/hr. x 10 hours	\$803
SUBTOTAL	\$29,311

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: **\$247**, 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

11 (109 material packages x 10%)	
Medicare MA and Part D Program Subject Manner Experts Review:	
1 GS-11 step 5: \$44.94/hr. x 11 material packages x .5 hr.	\$247
SUBTOTAL	\$247

15. Changes to Burden

There are small modifications to the models, however, these modifications have not affected burden, as many are non-substantive, and others are changes made on account of regulatory or administrative decisions for which the burden has been accounted for in different areas.

An example of this is the sunsetting of the value based insurance design, or VBID, which is requiring updating to language in the models. This change has no effect on the burden of this package, as it does not require the plans to make any substantive changes or updates, and the burden on CMS to make updates to the model documents has already been accounted for in the previous package.

However, we note that there are updates to costs and figures throughout section 12, accounting for plan burden, and section 14, accounting for federal burden. Modifications to the cost of the burden have been noted throughout, and are additionally noted and explained here:

- Section 12

- o We have updated wages to account for 2024 BLS wage data, which is an increase over wages in the previous package.
 - O In this package, we estimate that there are 109 AIPs that will employ these models, which more than doubles our previous estimate. The number of AIPs has increased since 2023, when this package was last published.
 - O Because the number of AIPs has increased, the burden for completing the requirements in this package has increased in equal measure, by over 100 percent.
 - O The number of beneficiaries who would receive these materials decreased by almost half from the previous package. In the previous package, as the requirement for integrated ANOCs and EOCs was new, we gave a best estimate as to the number of impacted beneficiaries and included all HIDE and FIDE SNP enrollment. In contrast, for this package, as we have several years of experience issuing integrated materials, and as a result we have a more accurate understanding of who is going to receive these materials. For this package, as we have consistent communication with States that are requiring integrated materials for the AIPs in their State, we limited our burden to AIP SNPs in States that chose to work with us on developing an integrated ANOC and EOC. We also included beneficiaries in States that are transitioning to D-SNPs from MMPs in 2026. This more accurate count resulted in almost half as many impacted beneficiaries.

- Section 14

- o We updated wage data for CMS employees based on OPM's 2024 General Schedule pay table
- O The cost of reviewing and updating materials to the federal government has decreased by almost half from the previous package. This is partially on account of a better understanding of the actual burden, as described above, and partially due to a more efficient review by CMS.
 - O There was an increase in the burden of reviewing marketing materials after they have been completed by plans. This is due to an increase in hourly wage for the CMS employee reviewing the materials, and an increase in the number of AIPs employing these models. The reason for the increase in AIPs is similarly discussed above.

<u>Changes made to this collection of information between the 60-day package published as 90 FR 36058 and the subsequent 30-day package.</u>

We made changes to this package and its instruments as a result of comments we received from the public as well as changes due to CMS policies. All of these changes except for routine changes to the documents adjusting applicable dates, minor grammatical changes, URLs, and other non-substantive word changes are detailed in the attached crosswalk document. Changes made for this 30-day package do not have an effect on the burden associated with this package.

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 does not object to displaying the expiration date on information collection materials.

18. <u>Certification Statement</u>

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

This collection does not employ statistical methods.