

## Response to Public Comments Received – CMS-10453 (OMB 0938-1228)

CMS received 3 comments regarding the Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits information collection request (ICR), which was posted in the Federal Register on December 8, 2023 for a 30-day public comment period (88 FR 85622).<sup>1</sup> This document provides summaries of the comments received and CMS' responses.

Section/Subject	Comment	CMS Response
Part D, Instructions	One commenter requested clarification as to whether the revised instructions regarding the drug price column imply that drug cost should be calculated differently.	Revisions to instructions regarding the drug price column on the EOB were implemented for clarity and accuracy. The drug price column should continue to reflect the negotiated price, and different calculations are not required. Note that CMS revised the definition of “negotiated price” at § 423.100, which became effective January 1, 2024, as a part of the May 9, 2022 final rule “Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency”. <sup>2</sup>
Part D, Instructions	One commenter requested clarification regarding whether the Inflation Reduction Act (IRA) updates to the Maximum Out-of-Pocket cap will require an additional field on the EOB.	No additional field is required. As described under the “Important things to know” section of the EOB instructions, both “Out-of-Pocket Costs” and “TrOOP” refer to the enrollee’s incurred costs, as defined at 1860D-2(b)(4)(C). “TrOOP” is the term used in the EOB instructions to plans, and “Out-of-Pocket Costs” is the term used in the enrollee-facing text of the EOB.
Part D, Cover page, Chart 1A, Chart 2	One commenter recommended that references to Total Drug	References to Total Drug Costs were minimized in Charts 1A and 2. Because regulations at 423.128(e) continue to require that the EOB

<sup>1</sup> Supporting documents are available at <https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing/cms-10453>.

<sup>2</sup> <https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf>.

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	Cost be minimized.	include the cumulative, year-to-date total of incurred costs to the extent practicable, references to the total drug cost cannot be eliminated entirely.
Part D, Chart 1, Lower Cost Alternative Drug	One commenter requested clarification as to whether the lower-cost alternative drug column can be left blank, or what to include, if no lower-cost alternative exists.	As noted in our response to comments received during the 60-day ICR comment period, <sup>3</sup> we have clarified the EOB instructions to include that if no lower-cost therapeutically equivalent drug is available, plans should enter: “No lower-cost alternative drug is available.” The column should not be left blank. Including this information, as opposed to leaving the column blank, will communicate the information to an enrollee in a manner that is easy to understand, in conformance with requirements at § 423.128(e).
Part D, Chart 1A, Chart 2	One commenter recommended that CMS resolve conflicting language regarding supplemental drug coverage in Charts 1A and 2.	We decline to revise the text further because the charts are referring to different types of coverage. References to supplemental drug benefits in Chart 2 apply to such benefits for covered Part D drugs, whereas references to supplemental drug coverage in Chart 1A refer to non-Part D drugs that are covered by the plan as a supplemental benefit.
Part D, Charts 1 and 2	One commenter recommended CMS not include definitions of “You Paid” and “Plan Paid” in both Charts 1 and 2 because the information is duplicative.	We decline to make this change. As described in our responses to comments received during the 60-day ICR comment period, during the EOB redesign process and user testing, CMS determined that including definitions beneath the corresponding charts was the most helpful for enrollees.
Part D, Chart 3	For plans without a deductible, Chart 3 instructions should include, “Not Applicable,” under Stage 1 (Yearly Deductible) and should include	We have incorporated this change.

<sup>3</sup> [https://www.reginfo.gov/public/do/PRAViewDocument?ref\\_nbr=202312-0938-004](https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202312-0938-004).

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	a bullet in the notes stating, “Because there is no deductible for the plan, this payment stage does not apply to you.”	
Part D, Chart 3 and Instructions	One commenter recommended we align text and formatting in EOB models and instructions.	We have clarified instructions for Chart 3 to improve text and formatting alignment between Part D EOB models and instructions.
Part D, Delivery	One commenter requested that CMS expand the opportunity for electronic delivery of the EOB to include electronic delivery without prior authorization.	We disagree with the commenter’s suggestion to permit electronic delivery of EOBs without approval by the enrollee. As explained in our response to comments received during the 60-day comment period, altering electronic delivery requirements would require a change to the regulations at § 423.2267(d)(2) and create an inconsistency between the policy for electronic delivery of the EOB and the policy for electronic delivery of other required materials containing individualized information.
Part D, Throughout	One commenter recommended that the terms “stage” and “phase” not be used interchangeably, and that “phase” be used in all instances.	As noted in our response to comments received during the 60-day ICR comment period, the EOB instructions and models contain no use of the word “phase.” We will continue to refer to stages throughout the EOB.
Part D, Cover Page	One commenter requested approval to remove information regarding language translations from the EOB cover page.	We disagree with the commenter’s suggestion to eliminate text regarding translating the EOB into other languages. As described in our responses to comments received during the 60-day ICR comment period, under § 423.2267(a)(3), plans are required to provide EOBs in any non-English language upon receiving a request or when otherwise learning of the enrollee’s need for materials in a non-English language. Further, under regulations implementing Section 1557 of the Affordable Care Act, specifically 45 CFR § 92.101, Part D sponsors must take reasonable steps to ensure

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		meaningful program access for individuals with limited English proficiency.
Part D, Chart 1, Tier Number	One commenter suggested adding tier numbers to Chart 1 because it may help enrollees understand their costs.	As noted in our response to comments received during the 60-day ICR comment period, we thank the commenter for this comment and will consider it for future years.
Part D, Chart 1, Price Change	One commenter recommended that CMS remove the Price Change column because the information may be confusing to enrollees.	As noted in our response to comments received during the 60-day ICR comment period, under 42 CFR 423.128(e)(4), EOBs must include any cumulative percentage increase in the negotiated price since the first claim of the current benefit year. For this reason, we do not intend to remove the “Price Change” term or column.
Part D, Chart 3	One commenter suggested that CMS clarify that Chart 3 identifies the stage an enrollee was in at the end of a reporting month.	Thank you for this feedback. As noted in our responses to comments received during the 60-day ICR comment period, we have clarified text in Chart 3 to say: “This chart helps you understand what stage you were in at the end of [insert name of month and full year] and when you’ll move to the next stage.”
Part D, Chart 3	One commenter requested that CMS clarify that the deductible does not apply to the preventative tetanus vaccines, or not reference tetanus at all.	We thank the reader for this suggestion. As noted in our responses to comments received during the 60-day ICR comment period, we specify on the EOB that the deductible doesn’t apply to most adult Part D vaccines, which includes the preventative tetanus vaccine. We note that the tetanus vaccine, when administered because of an injury or wound, is covered under Part B and is, therefore, not a Part D vaccine.
Part D, Chart 3	One commenter requested that CMS clarify that enrollees may have cost sharing for drugs that are covered under an enhanced benefit during the Catastrophic stage.	The IRA requires that enrollees pay no cost sharing for covered Part D drugs during the catastrophic stage. As noted in our responses to comments received during the 60-day ICR comment period, Chart 1A identifies drugs excluded from Part D that are covered under an enhanced benefit. Because excluded drugs are not included in Chart 3, we decline to add such language.

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Part C	Option for the member to opt out of receiving the Part C Explanation of Benefits (EOB).	MA organizations are required to send the EOB to all enrollees except enrollees who are dual eligible. An enrollee cannot opt out of receiving the EOB, but can opt to receive the EOB in an electronic format.
Part C	Part C models include the text “You have the right to make an appeal or complaint,” but do not explain how to file an appeal or complaint. The commenter requests that this information be added.	We note that there is a bullet point beneath the quoted text that directs enrollees to the plan’s telephone number for the purposes of appeals and complaints. An enrollee can use this phone number to begin the appeals process or make a complaint. In the event that a claim has been denied, the enrollee will also receive a denial notice from the plan that will contain additional details about the appeals process and enrollee rights. Instructions for the integrated denial notice are detailed separate from the EOB, and can be found at <a href="https://www.cms.gov/medicare/forms-notices/beneficiary-notices-initiative/ma-denial-notice">https://www.cms.gov/medicare/forms-notices/beneficiary-notices-initiative/ma-denial-notice</a> .