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

CMS received 11 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 June 6, 2023 for a 60-day public comment period (88 FR 37066). This document provides summaries of the comments received and CMS' responses.

Section/Subject	Comment	CMS Response
Part D, Medicare Prescription Payment Plan (MPPP)	Several commenters provided input on the inclusion of MPPP language in the EOB. Some commenters recommended that CMS not include any information about the MPPP on EOBs since EOBs are only required following months in which the Part D benefit is used and are therefore not a dependable mechanism for conveying monthly information required for MPPP participants. Commenters noted that including MPPP information on EOBs could confuse enrollees and would be contrary to CMS' efforts to maintain streamlined EOB processes and minimize duplicative administrative work.	We agree with the commenters that enrollee-specific financial information related to the MPPP should not be included on the EOB. Under 42 CFR 423.128(e), EOBs must include claims information in relation to how the enrollee moves through the phases of the Part D benefit, including information about incurred costs, and reflecting the enrollee's position as of that month in relation to the annual deductible, initial coverage limit, and out-of-pocket threshold. As such, CMS believes the EOB must continue to reflect what the enrollee, the Part D plan, and others would have paid toward that month's claims under their plan benefit versus what an enrollee who participates in MPPP actually paid. Pursuant to MPPP Part 1 Draft Guidance,[1] the latter information will be provided to such enrollees in a monthly billing statement and therefore would be duplicative if reflected in the EOB, as the commenters suggest. Additionally, the statute and CMS regulations require that the EOB be provided following months in which the Part D benefit is used, making it an insufficient method for conveying monthly MPPP invoice information. Considering the aforementioned, we intend to include only high-level references to the MPPP on EOBs to clarify that amounts shown in the EOB may differ from what an MPPP participant paid and how enrollees can learn more about the MPPP payments and program. See the PRA attachments for the proposed text.

[1] CMS' "Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments" was published August 21, 2023 and is available at https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf

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Part D, MPPP	Two commenters recommended waiting until CMS releases final MPPP guidance to incorporate MPPP information into the CY2026 EOB model or later.	We thank the commenters for this input. Though the 2025 EOB will not be final until after the 2025 MPPP final guidance is issued, Paperwork Reduction Act timelines required us to request stakeholder feedback prior to the final MPPP guidance being released. We believe that including MPPP information in EOBs beginning in 2025, instead of waiting until 2026, will provide the most clarity for enrollees regarding how amounts reflected on EOBs may differ from what enrollees paid at point of sale. We refer the commenters to the previous response and the PRA attachments for more detail about the high-level information we're proposing to add to the 2025 EOB.
Part D, MPPP	Multiple commenters recommended that CMS use the EOB to inform Part D enrollees about the MPPP, including through examples or scenarios that illustrate how the program can alleviate high prescription drug cost burdens. Some commenters recommended that the EOB include an enrollee's history of MPPP payments, future costs owed, and information as to whether an enrollee has met their out-of-pocket cap.	The purpose of the Part D EOB is to communicate to enrollees when their Part D benefits are used and how those benefits align with the enrollee's annual deductible, initial coverage limit, and out-of-pocket threshold. EOBs are not billing statements, are retrospective, and are required following months in which the Part D benefit is used. Including information about the MPPP, such as the process for opting in and examples of payment structures, is likely to detract from the important information the EOB is intended to provide and could confuse enrollees. It would also be duplicative as this type of information about the MPPP will be provided in multiple other enrollee materials, some of which are discussed in the MPPP Draft Part 1 Guidance. We refer the commenters to the previous responses and the PRA attachments for more detail about the high-level information we're proposing to add to the 2025 EOB.
Part D, MPPP	One commenter noted that because the statute requires disenrollment from MPPP for non-payment of amounts billed, this would coincide with existing premium billing processes and should be incorporated therein.	This comment is out of scope. We refer the commenter to the MPPP Draft Part 1 Guidance, which was released on August 21, 2023.
Part D, MPPP	One commenter recommended that CMS conduct robust education and outreach to inform enrollees about MPPP.	This comment is out of scope. We refer the commenter to the MPPP Draft Part 1 Guidance, which was released on August 21, 2023.

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Part D, MPPP	One commenter recommended that CMS conduct focus group testing regarding whether the term “maximum monthly cap” resonates with consumers or whether a different term should be used in enrollee educational materials.	This comment is out of scope. We refer the commenter to the MPPP Draft Part 1 Guidance, which was released on August 21, 2023.
Part D, General support	One commenter expressed strong support for the Part C and Part D EOBs.	We thank this commenter for the feedback.
Part D, Timing	One commenter urged CMS to issue a final model as soon as possible and no later than September 2023.	We appreciate that plans need these model documents with sufficient time to update their systems. However, we cannot finalize the 2025 EOB until we finalize 2025 policies that may affect the content of the EOB. The final version of the 2025 Part C and Part D EOBs will be published in spring 2024.
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, and note that doing so 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, Languages	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. 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 meaningful program access for individuals with limited English proficiency.
Part D, Format	Two commenters requested that CMS offer plans the option to include or remove the decimal points and cents (”.00”) in chart amounts to alleviate formatting burden.	We have incorporated this change.

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Part D, Format	Two commenters requested that CMS give plans the option to print the EOB in landscape or portrait orientation to alleviate formatting burden.	We have incorporated this change.
Part D, Format	One commenter requested clarification as to the placement of the footer and whether the information in the footer must be on every page of the EOB.	Plans are required to include a small footer on every page regarding how enrollees can call the plan if they have questions. Enrollees shared during EOB user testing that they found this footer information helpful. Hours of operation are not required footer content.
Part D, Format	One commenter requested that CMS allow plans to spread text boxes and columns across the page to save space.	These are model documents, and plans are permitted to spread text boxes and text columns across the page to eliminate empty space. We have clarified this in the Part D EOB instructions.
Part D, Format	One commenter requested that CMS provide a large print sample of the EOB.	We thank the commenter for the suggestion and take it into consideration for future updates. While CMS does not provide large print versions of all required Part D materials, under § 423.2267(a)(3), plans must provide accessible formats upon receiving such a request or when otherwise learning of an enrollee's need for an accessible format.
Part D, Definitions	One commenter recommended adding a definitions page or section.	We thank the commenter for this suggestion. 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, Terminology	One commenter recommended that the terms “stage” and “phase” not be used interchangeably, and that “phase” be used in all instances.	The EOB instructions and models contain no use of the word “phase.” We will continue to refer to stages throughout the EOB.
Part D, Terminology	One commenter requested that Out-of-Pocket Costs and Total Drug Costs be capitalized and requested general consistency between exhibits and instructions.	We have capitalized Out-of-Pocket Costs and Total Drug Costs throughout the instructions and models.
Part D, Terminology	One commenter recommended that EOB changes be mostly based on statutory changes and that the term Total Drug Costs be removed throughout the document.	We will not remove the term Total Drug Costs because it refers to gross covered prescription drug costs, as defined at section 1860D-15(b)(3) of the Act.

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Part D, Cover Page, Return Address	One commenter recommended adding a return-to-sender address placeholder.	In the return mailing address field, plans should use the return address that meets the plan's business needs.
Part D, Chart 1, Tier Number	One commenter suggested adding tier numbers to Chart 1 because it may help enrollees understand their costs.	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.	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 1, Lower Cost Alternative Drug	One commenter recommended that CMS clarify what happens when the current drug is already the lowest cost drug.	We thank the commenter for this suggestion. We have clarified the instructions to include that if no lower-cost therapeutically equivalent drug is available, plans may enter: "No lower-cost alternative drug is available."
Part D, Chart 2	One commenter recommended that CMS explain the types of financial assistance that Part D enrollees may receive and whether the assistance counts toward TrOOP.	We thank the commenter for this suggestion. The EOB provides the information required under 42 CFR § 423.128(e), which specifies that it must be provided in a manner that can be easily understood by Part D enrollees. The EOB clearly indicates in the charts and text boxes the enrollee's out-of-pocket costs (TrOOP), and explanations for terminology written in a beneficiary-friendly manner. CMS does not expect to release final guidance related to the Part D redesign until Spring 2024.
Part D, Chart 2 and throughout	One commenter requested that CMS reference Extra Help in a bullet separate from other payment examples, because Extra Help is a component of the Medicare Part D program, unlike the other examples.	In the interest of conserving space, we will not reference Extra Help as a separate bullet.
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. 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 enrollees may have cost	We thank the commenter for this comment. Chart 1A identifies drugs excluded from Part D that are covered under an enhanced benefit.

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	sharing for drugs that are covered under an enhanced benefit.	Because excluded drugs are not included in Chart 3, we decline to add such language.
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. 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 allow plans with no enrollee cost sharing to suppress the coverage phase details section, regardless of the low-income cost sharing level.	This section can be suppressed for full benefit dual-eligible enrollees who are either institutionalized or receiving home and community-based waiver services (low-income cost sharing (LICS) level 3), but because LICS levels have not changed for 2025, the information should not otherwise be suppressed.
Part D, Chart 3	One commenter requested that CMS provide examples for a plan that does not have a deductible and a plan that has a brand-only or tier-level deductible.	We refer the commenter to Part D Model Materials EOB Exhibit C, which includes examples of Chart 3 for plans with no deductible, as well as plans with a brand name/tier-level only deductible.
Part D, Chart 3	One commenter requested that CMS clarify that the annual deductible is not applicable to low-income subsidy (LIS) enrollees.	We have incorporated this change.
Part D, Chart 4	One commenter recommended that, in an effort to conserve paper, CMS allow plans to suppress Chart 4 when there are no drug updates for the member.	We thank the commenter for this comment. Considering the requirements at 42 CFR § 423.128(e)(5), we will not suppress Chart 4, including when there are no drug updates for enrollees. The information on Chart 4 does not need to be presented on a separate sheet of paper.
Part D, Chart 3	One commenter requested that CMS provide additional clarification on drug payment stages for LIS enrollees, given the differences in their coverage and cost sharing compared to non-LIS enrollees. Examples 6 and 7 in Exhibit C should be updated to clarify which costs would be paid by the LIS enrollee directly and which	We thank the commenter for this comment. We include separate examples of Chart 3 for LIS and non-LIS enrollees. The notes under the chart explain the various parts of the chart and benefit stages. We specify in Charts 1 and 2 that Extra Help counts toward TrOOP. The purpose of the examples of Chart 3 in Exhibit C is to display how a completed EOB might look, and the numbers contained within the examples, while realistic, are fictional. The EOC provides information

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	costs would be covered on their behalf by the low-income cost share subsidy (LICS).	regarding how an enrollee moves through the Part D benefit stages, and we do not duplicate this information in the EOB.
Part D, Instructions and Exhibit F	One commenter suggested that language regarding the LIS rider should be removed when EOBs are sent to non-LIS enrollees, to minimize the risk of enrollee confusion.	We thank the commenter for this comment. Under the current instructions, the LIS Rider language is only included for LIS enrollees.
Part C, MSA and PPO Monthly	A commenter recommended CMS include, for clarity to enrollees, a section in the Part C EOB for plans to include denial reasons when there is no member liability. The commenter also expressed concern with a CMS Program Audit.	We thank the commenter for this feedback; however, at this time, we will not be adding a new section for denial reasons that is solely designated for denials that have no corresponding member liability. Issues that pertain to CMS Program Audits are outside the scope of this ICR and should be sent to part_c_part_d_audit@cms.hhs.gov for response.
Part C	A commenter recommended that CMS integrate the information in the FAQ document into the EOB instructions.	In order to ensure that the instructions in the EOB remain as concise as possible, CMS will not be adding to the instructions at this time. However, we appreciate this feedback and will consider ways to include clarifying information in future updates to the EOB templates in a way that is practical for users.
Part C, Monthly HMO and PPO	A commenter inquired about a portion of the Part C EOB which states that an enrollee can make an appeal if a claim is approved and the enrollee disagrees with the amount they were charged. The commenter asked whether or not this type of dispute qualifies as an appeal, or if it is considered to be a grievance. The commenter pointed out that an enrollee would not receive an integrated denial notice (IDN) in such a case, because the claim was approved.	If an enrollee believes they were charged an incorrect cost-sharing amount for an approved item or service as reflected on the EOB, the plan should process the request as an organization determination. If the plan determines the cost-sharing amount was correct, it must issue an IDN which would provide the enrollee information about how to file an appeal. For more information about organization determinations and appeals, see the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance available on cms.gov.