August 3, 2023

Dr. Meena Seshamani
Deputy Administrator and Director, Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-10453–Medicare Advantage and Prescription Drug Programs; Part C and Part D Explanation of Benefits
88 Fed. Reg. 37066 (June 6, 2023)

Dear Deputy Administrator Seshamani:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the collection request related to the Medicare Advantage (MA) and Prescription Drug Programs (PDP): Part C and Part D Explanation of Benefits. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is more determined than ever to end cancer as we know it, for everyone.

As Congress debated the *Inflation Reduction Act* (IRA) we strongly advocated for both an annual cap on total Part D out-of-pocket costs and a mechanism that would allow an enrollee the option to pay the required cost-sharing in capped monthly installments. We are pleased the proposed changes to the Part D EOBs reflect the imposition of the Part D cap, beginning in plan year (PY) 2024. As CMS begins to implement the provision of the IRA that allows beneficiaries the option to smooth their cost sharing over the course of the plan year, we strongly encourage CMS to conduct robust education and outreach to inform beneficiaries of this new and important consumer benefit.

To that end, we strongly encourage CMS to include in the Part D EOB information related to the maximum monthly cap described in section 1860D-2(b)(2)(E)(iv). We appreciate CMS noting that it will "conduct extensive stakeholder engagement and consumer testing for communications"[1] related to the maximum monthly cap. We encourage CMS to focus group test whether the term "maximum monthly cap" resonates with consumers or whether a better descriptive term should be used in enrollee educational materials. Once an appropriate descriptive term has been identified, we would encourage CMS to conduct education and outreach to ensure that all stakeholders are using the same term so as to avoid enrollee confusion.

We recognize that the option to elect a maximum monthly cap has never before been implemented in the Medicare program. Enrollees will need clear and concise information educating them about their option to elect a maximum monthly cap. We strongly encourage CMS to use the EOB (1) as a mechanism to inform Part D enrollees about their opportunity to elect to have their monthly prescription drug costs capped, and (2) to inform beneficiaries who have already elected to have their monthly prescription drug costs capped of their remaining financial obligations.

[1] Centers for Medicare & Medicaid Services. Supporting Statement A: The Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits (CMS-10452, OMB 0938-1228), available at https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/1719218337/cms-10453.

EOB as an information tool: We encourage CMS to require Part D plans to include information on the first page of the EOB regarding the availability of enrolling in the maximum monthly cap. This could be done by inserting a new (fourth) bullet under the "Your Medicare Part D Explanation of Benefits (EOB)" which reads:

- **You have the option to cap your monthly prescription drug costs.**
  You have the option to spread the cost of your prescription drugs out through a monthly cap. If you have questions, or would like more information, please call us at the number below.

EOB for those who have elected to enroll in a maximum monthly cap: Enrollees who elect the maximum monthly cap but who are under the annual out-of-pocket cap will need a notice to remind them of their cost sharing obligations and provide notice these costs could increase if the enrollee fills subsequent prescriptions. We recommend that CMS require Part D plans to issue an EOB with information providing the enrollee information regarding their monthly payment amounts. This chart will be different depending on whether or not the enrollee has met their maximum monthly cap within the first month.

Enrollees who hit their Maximum Monthly Cap in first month/initial prescription: Enrollees who meet their annual out-of-pocket cap with their initial prescription drug(s)[2] should receive a notice regarding their remaining cost sharing obligations for the remainder of the year with specific information that their cost sharing obligations will not increase over the course of the year. We recommend that CMS require Part D plans include the following in the EOB:

> **You have elected to cap your prescription drug costs.**
>
> You have elected to enroll in a program that allows you to pay a maximum monthly cap for your prescription drug costs. You will pay [maximum monthly amount] for the rest of the plan year. This amount will not change regardless of whether you continue to take the same prescription drugs or even if you take new prescription drugs. Your monthly prescription drug costs will not exceed [maximum monthly cap amount].

Enrollees who do not hit their Maximum Monthly Cap in the first month/initial prescription: Enrollees who elect the maximum monthly cap but who are under the annual out-of-pocket cap will need a notice to remind them of their cost sharing obligations and provide notice these costs could increase if the enrollee fills subsequent prescriptions. We recommend that CMS require Part D plans to include the following in the EOB:

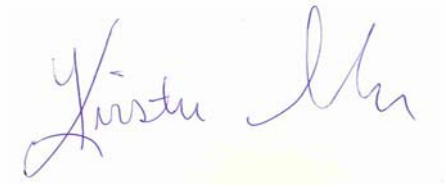
> **You have elected to cap your monthly prescription drug costs.**
>
> You have elected to enroll in a program that caps your prescription drug costs per month. If you take no other prescription drugs, you will pay [maximum monthly cap amount] monthly for the rest of the plan year, regardless of whether you continue to take the same prescription drugs. If you take additional prescription drugs, this amount may increase.

[2] Enrollees may hit the annual out-of-pocket cap with one prescription drug or they may hit the cap as a result of multiple prescription drugs filled at the same time.

CONCLUSION

Thank you for the opportunity to comment on the collection request related to the Medicare Advantage (MA) and Prescription Drug Programs (PDP): Part C and Part D Explanation of Benefits. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at Anna.Howard@cancer.org.

Sincerely,



Kirsten Sloan
Managing Director, Public Policy
American Cancer Society Cancer Action Network

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August 3, 2023

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Agency Information Collection Activities: Proposed Collection; Comment Request for Explanation of Benefits for Medicare Advantage and Medicare Part D [CMS-10453]

Dear Administrator Brooks-LaSure,

On behalf of the Alliance for Aging Research, thank you for the opportunity to provide feedback on the information collection request related to explanation of benefits for Medicare Advantage (MA) and Medicare Part D. Specifically, we want to call your attention to the opportunity for the Centers for Medicare and Medicaid Services (CMS) to utilize both the MA and Part D Explanation of Benefits (EOB) to educate and inform beneficiaries about the Part D annual $2,000 out-of-pocket (OOP) cap in 2025 and the beneficiary option to utilize the new maximum monthly cap flexibility to "smooth" out OOP prescription drug costs over the plan year. On behalf of beneficiaries who will benefit from these provisions created by the Inflation Reduction Act (IRA), it is crucial for beneficiaries to have clear and accessible information to better understand their prescription drug costs and plan accordingly.

The successful implementation of these two provisions is critical. For many beneficiaries, the annual and maximum monthly caps will be among the most directly "felt" impacts of the IRA. Effectively communicating how beneficiaries will interact with these provisions should be one of CMS's top priorities. The opt-in enrollment dynamic of maximum monthly caps increases the difficulty and the essential need for day one operational readiness. If a knowledge gap occurs due to the lack of patient education, it will undoubtedly lead to confusion, financial strain, and underutilization of the program benefits. Beneficiaries' EOBs represent one of many venues for information delivery that CMS should utilize to mitigate and provide education around these new benefits and flexibilities.

In addition to informing beneficiaries about the maximum monthly caps and the need to opt into the program, the EOB will be critical in keeping Medicare beneficiaries that smooth

medication OOP expenses informed as to what they owe and when. The IRA statute expressly enables Medicare Prescription Drug Plans (PDP) and Medicare Advantage Prescription Drug Plans (MA-PD) to disqualify beneficiaries from future use of smoothing due to nonpayment. The statute is particularly direct in allowing enrollees to be disqualified in cases of non-payment. The EOB can serve as a venue to communicate clear information and expectations of enrollees in terms of their participation in the maximum monthly caps program. As such, the EOB serves an important "patient notification" role in keeping beneficiaries apprised of their financial options and obligations to plans.

We strongly urge the CMS to include comprehensive information about the annual and maximum monthly caps programs within the EOBs received by Medicare Part D beneficiaries. We recommend that the information provided should clearly outline the eligibility criteria, coverage limits, and the process for beneficiaries to opt into the maximum monthly cap program. It would also be beneficial to include examples or scenarios that illustrate how the cap and smoothing program can alleviate the financial burden of high prescription drug costs. By doing so, beneficiaries will have a better understanding of how these programs work, the cost-saving and cost-management benefits they offer, and how they can utilize these coverage benefits to afford prescribed medications. Communication through the EOB and other venues will be key in helping beneficiaries to effectively utilize these benefits, and hopefully minimize non-compliance with care plans that can lead to harm and related additional costs to the beneficiary and to the health plan.

Thank you for the opportunity to comment on this important issue. We believe that beneficiaries should be empowered to make more informed decisions about their healthcare and financial well-being. Please do not hesitate to contact me at mward@agingresearch.org with any questions or concerns.

Sincerely,

Michael Ward
Vice President of Public Policy and Government Relations

CVSHealth

1275 Pennsylvania Ave NW, Suite 700
Washington, D.C., 20004

August 7, 2023

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator & Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Part D Explanation of Benefits (EOB) Request for Comment

Dear. Dr. Seshamani:

CVS Health appreciates the opportunity to provide comments on Paperwork Reduction Act (PRA) document identifier CMS-10453 soliciting additional comments for a revised Part D Explanation of Benefits (EOB) issued by the Centers for Medicare & Medicaid Services (CMS) on June 6, 2023.[1]

CVS Health is the leading health solutions company, delivering care like no one else can. We reach more people and improve the health of communities across America through our local presence, digital channels and approximately 300,000 dedicated colleagues — including more than 40,000 physicians, pharmacists, nurses, and nurse practitioners. Wherever and whenever people need us, we help them with their health — whether that's managing chronic diseases, staying compliant with their medications, or accessing affordable health and wellness services in the most convenient ways. We help people navigate the health care system — and their personal health care — by improving access, lowering costs and being a trusted partner for every meaningful moment of health. And we do it all with heart, every day.

We thank CMS for giving the public and stakeholders an opportunity to provide input on various aspects of the revised EOB document. Given our role as a health plan, health care provider, pharmacy, and pharmacy benefits manager, we are well-positioned to comment from different perspectives to help facilitate the smooth implementation of the new EOB.

A more detailed discussion of our recommendations is provided in the attached Appendix.

[1] Available at https://www.federalregister.gov/documents/2023/06/06/2023-11996/agency-information-collection-activities-proposed-collection-comment-request.

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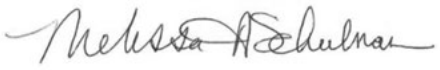
Washington, D.C., 20004

Thank you for considering our recommendations and comments. CVS Health is committed to working with CMS as it formulates rules and policies that advance affordable, cost-effective care that provides beneficiaries with innovative choices of coverage that meets consumer needs. We welcome any follow-up questions you may have.

Sincerely,



Melissa Schulman
Senior Vice President, Government & Public Affairs
CVS Health

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Appendix

Specific Comments on a revised Part D Explanation of Benefits (EOB)

CY2025 Proposed EOB Opportunity: Cost Smoothing Addition to EOB

Because CMS has not yet released its full guidance for the implementation of the cost-smoothing program, CVS Health believes it is premature to include monthly cost sharing payment information on the CY2025 EOB. We recommend waiting until CMS releases complete guidance for the CY2026 EOB model or later. Without full knowledge of the program, we offer recommendations below for CMS' consideration in the recommendations sections below.

CVS Health appreciates that CMS included many of our CY2024 EOB model recommendations into the final CY2024 EOB model. Because CVS Health produces Part D EOBs on behalf of Medicare Part D Plans and mails approximately 149 million annually, we appreciate that CMS has accounted for industry and beneficiary feedback in the proposed 2025 Part D EOB model. We welcome the chance to engage with CMS on the EOB and all beneficiary communication efforts to help them better understand their Medicare drug prescription use and costs.

As stated in CMS' solicitation of comments regarding inclusion of cost-smoothing information in the CY2025 EOB, EOBs are not billing statements and are therefore not designed to provide invoice amounts and premium payments. CVS Health agrees with this statement, and we believe that including member-specific financial information related to cost-smoothing on the EOB would be contradictory to the CMS' intent for the EOB.

CVS Health believes that adding complexity to the EOB model to reflect cost-smoothing payments would negate CMS' ongoing efforts to maintain streamlined processes and minimize duplicative administrative work and burden in the EOB for plan sponsors.

In addition, introducing cost-smoothing information in the EOB could increase member confusion around appropriately interpreting this new information. Further, since EOBs are only required following months in which the Part D benefit is used, depending on an enrollee's use of their Part D Benefit, they may not receive a monthly accounting of premiums or payments due which may include smoothing. Including cost-smoothing information on the EOB would not necessarily provide a dependable system to account

for expenditures and balances which could further hinder cost-transparency for members which we believe is not CMS' intent in creating this program.

Recommendations:

- **The Supporting Statement attached to the PRA announcement includes a request to comment on what information should be included in an EOB related to the maximum monthly payment cap on cost sharing payments under Part D.**
- **Based on the information made available on the cost-smoothing requirement, CVS Health does not recommend including the information in the EOB.**
- **CVS Health recommends either including the cost-smoothing requirement in an invoice statement or incorporate it in the premium bill. Because the statute requires disenrollment for non-payment of the cost-smoothing payment amounts, this would coincide with existing premium billing processes and requirements. In the event that CMS decides to proceed with including cost-smoothing information on the EOB, we recommend to only include a high-level statement that a beneficiary has elected to enroll in the program, therefore the costs outlined in the EOB may not accurately reflect what occurred at the point-of-sale. CMS should not require inclusion of any cost-smoothing financial details on a per-claim basis for the reasons outlined above.**

CY2025 Proposed EOB Model – Model Formatting Comments

In the finalized CY2024 and CY2025 EOB Model and Exhibit, decimal points, and cents when dollar amounts ended in ".00" were removed throughout the model. Operationally, this change introduced system complexity where it is not always feasible to remove only certain decimals throughout the document. Not including the full amounts with dollars and cents may result in incorrect summations throughout the EOB.

CMS updated the CY2024 and CY2025 models to portrait orientation, which is beneficial for the cover page; however, when populated, the charts are more difficult to read in portrait orientation as opposed to landscape throughout the rest of the document.

On Page 1 of the CY2025 model, the section titled, "Need large print or another format?" the part of the sentence, "and translation into other languages," does not apply to plans that do not have another language requirement.

Recommendations:

- **CVS Health recommends that CMS offers plans the option to include or remove the decimal points and cents (".00"). The EOB model and plan instruction document should both be updated.**
- **To improve readability for a beneficiary, CVS Health recommends giving plans the option to print the entire model, aside from the cover page, in landscape orientation. This recommendation requires that plan instructions be updated accordingly.**
- **Where "other languages" is noted in the model (i.e., page 1), the part of the sentence offering, "and translation into other languages," should be variable language because not all plans have language requirements other than English.**
- **For consistency's sake and a positive member experience, the following terminology and section language should be aligned throughout the document:**
  - Out-of-Pocket Costs naming convention should be used throughout the document (Capital O and P and no quotation marks)
  - Total Drug Costs naming convention should be used throughout the document (Capital T, D and C and no quotation marks)
  - Consistency between model and Exhibits language and formatting, for example, all language in Chart 3 scenarios should be aligned (see attached screenshots*).

Expansion of Electronic Delivery of Materials:

Although comments recommending CMS allows plans to deliver an EOB electronically, without prior authorization, is not part of this comment period, CVS Health encourages CMS to consider expanding the materials that may be electronically delivered to beneficiaries without prior authorization to include the EOB.

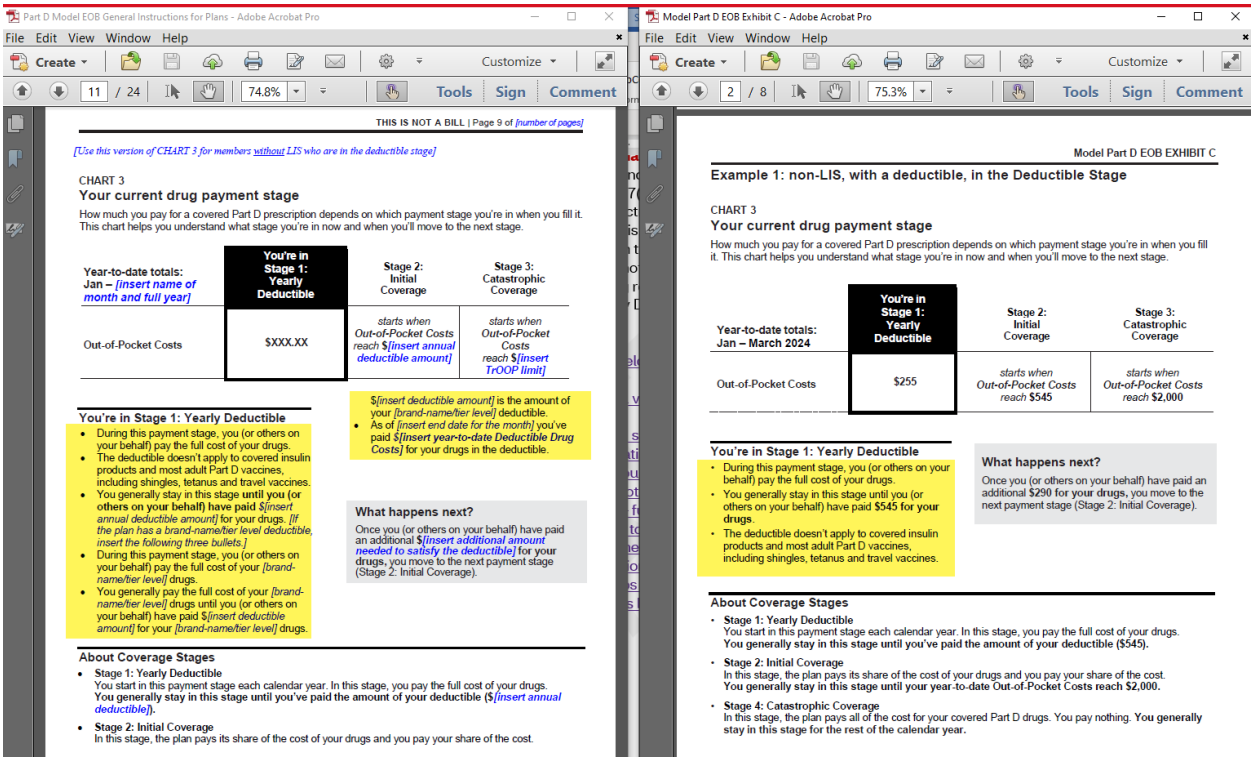
Not only does electronic delivery of beneficiary communications allow for easier access to current and previous documentation, it opens opportunities for caregivers to manage important health information which leads to an improved experience for everyone in our increasingly virtual world.

Recommendations:

- **CVS Health recommends CMS expands electronic delivery opportunity to include the EOB in the following: 42 CFR 423.2267(d):**
  - (2) Materials may be delivered electronically following the requirements in paragraphs (d)(2)(i) and (ii) of this section.

- (1) Without prior authorization from an enrollee, Part D sponsors may mail new and current enrollees a notice that explains how to electronically access the following required materials: Evidence of Coverage, Provider and Pharmacy Directories, and Formulary.

*Screenshots of Chart 3 Scenarios:



Part D Model EOB General Instructions for Plans - Adobe Acrobat Pro

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[Use this version of CHART 3 for members without LIS who are in the deductible stage]

CHART 3

Your current drug payment stage

How much you pay for a covered Part D prescription depends on which payment stage you're in when you fill it. This chart helps you understand what stage you're in now and when you'll move to the next stage.

Year-to-date totals: Jan – *[insert name of month and full year]*	You're in Stage 1: Yearly Deductible	Stage 2: Initial Coverage	Stage 3: Catastrophic Coverage
Out-of-Pocket Costs	$XXX.XX	*starts when Out-of-Pocket Costs reach $[insert annual deductible amount]*	*starts when Out-of-Pocket Costs reach $[insert TrOOP limit]*

You're in Stage 1: Yearly Deductible

- During this payment stage, you (or others on your behalf) pay the full cost of your drugs.
- The deductible doesn't apply to covered insulin products and most adult Part D vaccines, including shingles, tetanus and travel vaccines.
- You generally stay in this stage **until you (or others on your behalf) have paid** *$[insert annual deductible amount]* for your drugs. *[If the plan has a brand-name/tier level deductible, insert the following three bullets.]*
- During this payment stage, you (or others on your behalf) pay the full cost of your *[brand-name/tier level]* drugs.
- You generally pay the full cost of your *[brand-name/tier level]* drugs until you (or others on your behalf) have paid $*[insert deductible amount]* for your *[brand-name/tier level]* drugs.

- *$[insert deductible amount]* is the amount of your *[brand-name/tier level]* deductible.
- As of *[insert end date for the month]* you've paid *$[insert year-to-date Deductible Drug Costs]* for your drugs in the deductible.

What happens next?

Once you (or others on your behalf) have paid an additional *$[insert additional amount needed to satisfy the deductible]* for your drugs, you move to the next payment stage (Stage 2: Initial Coverage).

About Coverage Stages

- **Stage 1: Yearly Deductible**
  You start in this payment stage each calendar year. In this stage, you pay the full cost of your drugs. **You generally stay in this stage until you've paid the amount of your deductible ($*[insert annual deductible]*).**
- **Stage 2: Initial Coverage**
  In this stage, the plan pays its share of the cost of your drugs and you pay your share of the cost.

Model Part D EOB Exhibit C - Adobe Acrobat Pro

Model Part D EOB EXHIBIT C

Example 1: non-LIS, with a deductible, in the Deductible Stage

CHART 3

Your current drug payment stage

How much you pay for a covered Part D prescription depends on which payment stage you're in when you fill it. This chart helps you understand what stage you're in now and when you'll move to the next stage.

Year-to-date totals: Jan – March 2024	You're in Stage 1: Yearly Deductible	Stage 2: Initial Coverage	Stage 3: Catastrophic Coverage
Out-of-Pocket Costs	$255	*starts when Out-of-Pocket Costs reach* $545	*starts when Out-of-Pocket Costs reach* $2,000

You're in Stage 1: Yearly Deductible

- During this payment stage, you (or others on your behalf) pay the full cost of your drugs.
- You generally stay in this stage until you (or others on your behalf) have paid **$545 for your drugs**.
- The deductible doesn't apply to covered insulin products and most adult Part D vaccines, including shingles, tetanus and travel vaccines.

What happens next?

Once you (or others on your behalf) have paid an additional **$290 for your drugs**, you move to the next payment stage (Stage 2: Initial Coverage).

About Coverage Stages

- **Stage 1: Yearly Deductible**
  You start in this payment stage each calendar year. In this stage, you pay the full cost of your drugs. **You generally stay in this stage until you've paid the amount of your deductible ($545).**
- **Stage 2: Initial Coverage**
  In this stage, the plan pays its share of the cost of your drugs and you pay your share of the cost. **You generally stay in this stage until your year-to-date Out-of-Pocket Costs reach $2,000.**
- **Stage 4: Catastrophic Coverage**
  In this stage, the plan pays all of the cost for your covered Part D drugs. You pay nothing. **You generally stay in this stage for the rest of the calendar year.**

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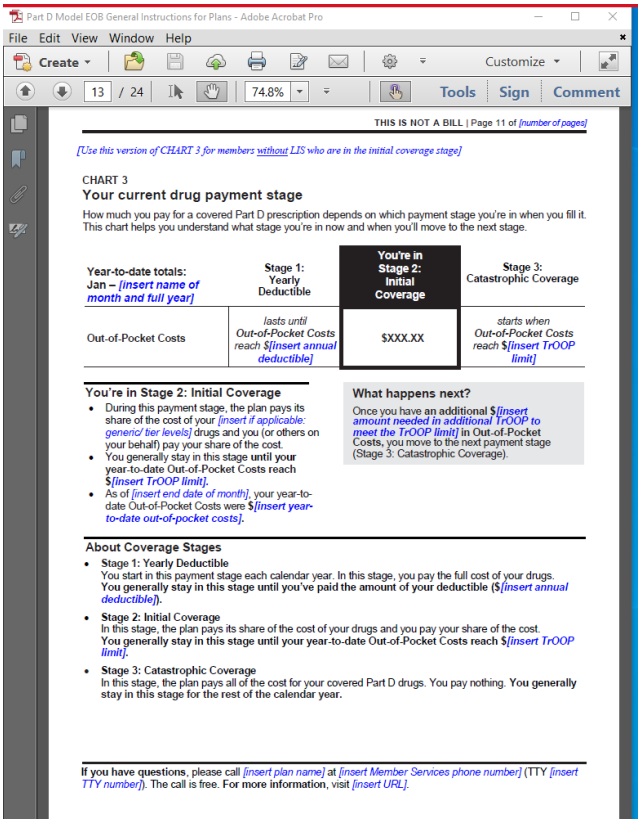

Part D Model EOB General Instructions for Plans - Adobe Acrobat Pro

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[Use this version of CHART 3 for members without LIS who are in the initial coverage stage]

CHART 3

Your current drug payment stage

How much you pay for a covered Part D prescription depends on which payment stage you're in when you fill it. This chart helps you understand what stage you're in now and when you'll move to the next stage.

Year-to-date totals: Jan – *[insert name of month and full year]*	Stage 1: Yearly Deductible	You're in Stage 2: Initial Coverage	Stage 3: Catastrophic Coverage
Out-of-Pocket Costs	*lasts until Out-of-Pocket Costs reach $[insert annual deductible]*	$XXX.XX	*starts when Out-of-Pocket Costs reach $[insert TrOOP limit]*

You're in Stage 2: Initial Coverage

- During this payment stage, the plan pays its share of the cost of your *[insert if applicable: generic/ tier levels]* drugs and you (or others on your behalf) pay your share of the cost.
- You generally stay in this stage **until your year-to-date Out-of-Pocket Costs reach $*[insert TrOOP limit]*.**
- As of *[insert end date of month]*, your year-to-date Out-of-Pocket Costs were **$*[insert year-to-date out-of-pocket costs]*.**

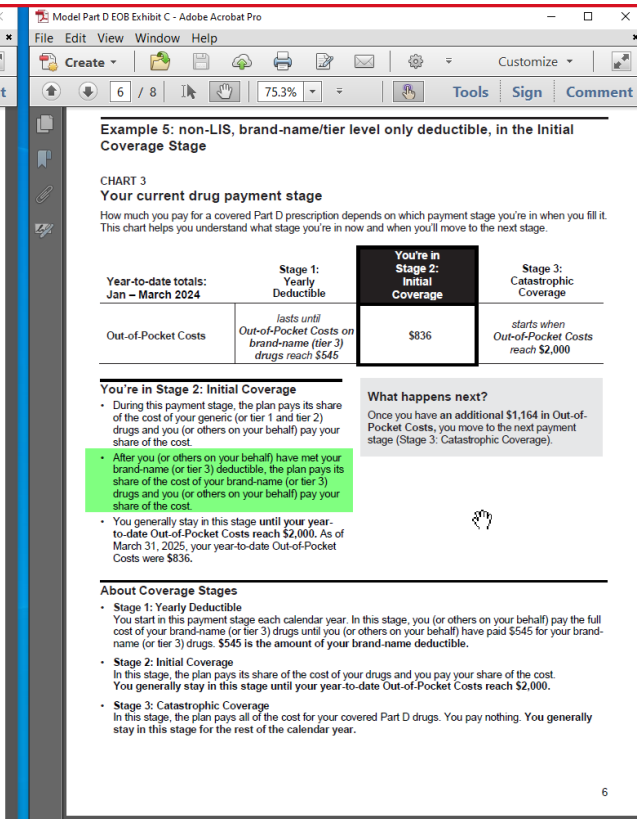
What happens next?

Once you have **an additional $*[insert amount needed in additional TrOOP to meet the TrOOP limit]*** in Out-of-Pocket Costs, you move to the next payment stage (Stage 3: Catastrophic Coverage).

About Coverage Stages

- **Stage 1: Yearly Deductible**
  You start in this payment stage each calendar year. In this stage, you pay the full cost of your drugs. **You generally stay in this stage until you've paid the amount of your deductible ($*[insert annual deductible]*).**
- **Stage 2: Initial Coverage**
  In this stage, the plan pays its share of the cost of your drugs and you pay your share of the cost. **You generally stay in this stage until your year-to-date Out-of-Pocket Costs reach $*[insert TrOOP limit]*.**
- **Stage 3: Catastrophic Coverage**
  In this stage, the plan pays all of the cost for your covered Part D drugs. You pay nothing. **You generally stay in this stage for the rest of the calendar year.**

If you have questions, please call *[insert plan name]* at *[insert Member Services phone number]* (TTY *[insert TTY number]*). The call is free. **For more information**, visit *[insert URL]*.



Model Part D EOB Exhibit C - Adobe Acrobat Pro

Example 5: non-LIS, brand-name/tier level only deductible, in the Initial Coverage Stage

CHART 3

Your current drug payment stage

How much you pay for a covered Part D prescription depends on which payment stage you're in when you fill it. This chart helps you understand what stage you're in now and when you'll move to the next stage.

Year-to-date totals: Jan – March 2024	Stage 1: Yearly Deductible	You're in Stage 2: Initial Coverage	Stage 3: Catastrophic Coverage
Out-of-Pocket Costs	*lasts until Out-of-Pocket Costs on brand-name (tier 3) drugs reach $545*	$836	*starts when Out-of-Pocket Costs reach $2,000*

You're in Stage 2: Initial Coverage

- During this payment stage, the plan pays its share of the cost of your generic (or tier 1 and tier 2) drugs and you (or others on your behalf) pay your share of the cost.
- After you (or others on your behalf) have met your brand-name (or tier 3) deductible, the plan pays its share of the cost of your brand-name (or tier 3) drugs and you (or others on your behalf) pay your share of the cost.
- You generally stay in this stage **until your year-to-date Out-of-Pocket Costs reach $2,000.** As of March 31, 2025, your year-to-date Out-of-Pocket Costs were $836.

What happens next?

Once you have **an additional $1,164 in Out-of-Pocket Costs,** you move to the next payment stage (Stage 3: Catastrophic Coverage).

About Coverage Stages

- **Stage 1: Yearly Deductible**
  You start in this payment stage each calendar year. In this stage, you (or others on your behalf) pay the full cost of your brand-name (or tier 3) drugs until you (or others on your behalf) have paid $545 for your brand-name (or tier 3) drugs. **$545 is the amount of your brand-name deductible.**
- **Stage 2: Initial Coverage**
  In this stage, the plan pays its share of the cost of your drugs and you pay your share of the cost. **You generally stay in this stage until your year-to-date Out-of-Pocket Costs reach $2,000.**
- **Stage 3: Catastrophic Coverage**
  In this stage, the plan pays all of the cost for your covered Part D drugs. You pay nothing. **You generally stay in this stage for the rest of the calendar year.**

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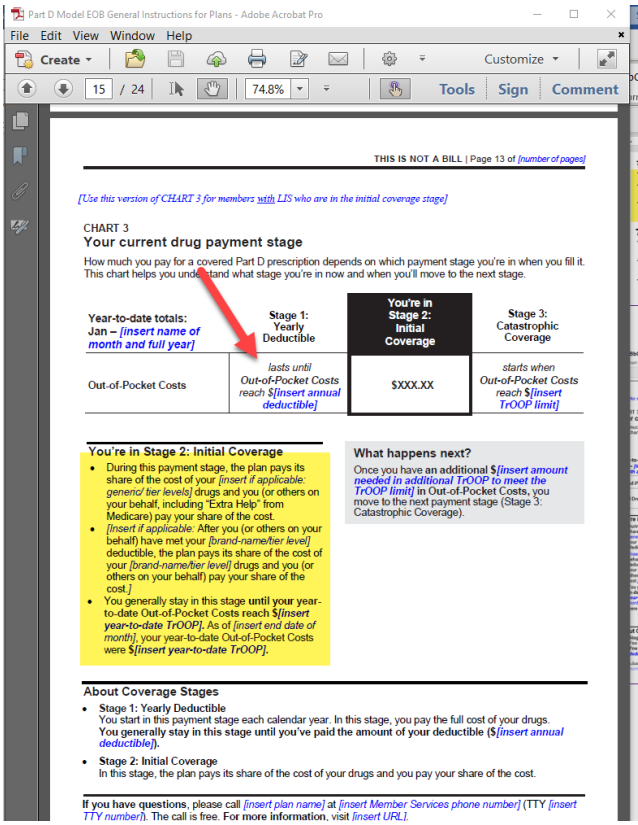


Part D Model EOB General Instructions for Plans - Adobe Acrobat Pro

THIS IS NOT A BILL | Page 13 of *[number of pages]*

[Use this version of CHART 3 for members with LIS who are in the initial coverage stage]

CHART 3

Your current drug payment stage

How much you pay for a covered Part D prescription depends on which payment stage you're in when you fill it. This chart helps you understand what stage you're in now and when you'll move to the next stage.

Year-to-date totals: Jan – *[insert name of month and full year]*	Stage 1: Yearly Deductible	You're in Stage 2: Initial Coverage	Stage 3: Catastrophic Coverage
Out-of-Pocket Costs	*lasts until Out-of-Pocket Costs reach $[insert annual deductible]*	$XXX.XX	*starts when Out-of-Pocket Costs reach $[insert TrOOP limit]*

You're in Stage 2: Initial Coverage

- During this payment stage, the plan pays its share of the cost of your *[insert if applicable: generic/ tier levels]* drugs and you (or others on your behalf, including "Extra Help" from Medicare) pay your share of the cost.
- *[Insert if applicable:* After you (or others on your behalf) have met your *[brand-name/tier level]* deductible, the plan pays its share of the cost of your *[brand-name/tier level]* drugs and you (or others on your behalf) pay your share of the cost.*]*
- You generally stay in this stage **until your year-to-date Out-of-Pocket Costs reach $*[insert year-to-date TrOOP]*.** As of *[insert end date of month]*, your year-to-date Out-of-Pocket Costs were **$*[insert year-to-date TrOOP]*.**

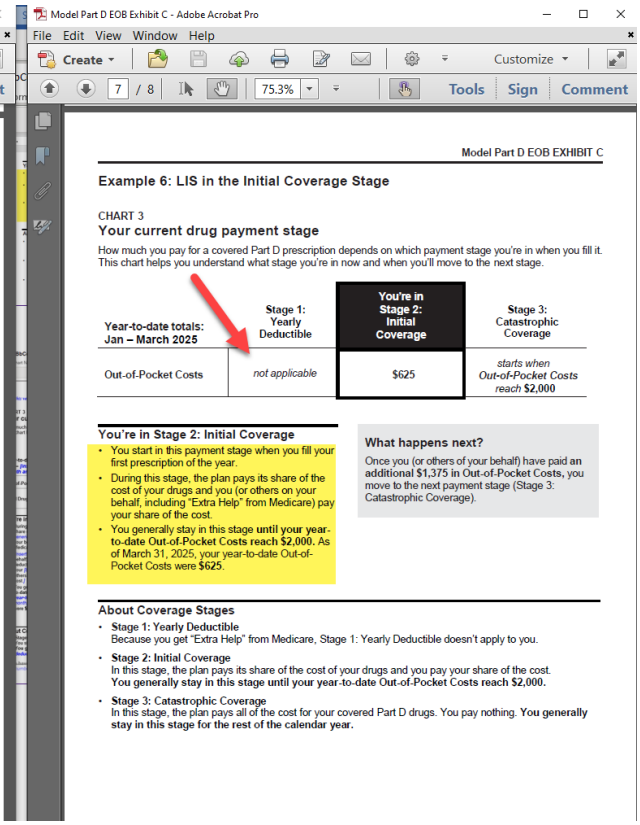
What happens next?

Once you have **an additional $*[insert amount needed in additional TrOOP to meet the TrOOP limit]*** in Out-of-Pocket Costs, you move to the next payment stage (Stage 3: Catastrophic Coverage).

About Coverage Stages

- **Stage 1: Yearly Deductible**
  You start in this payment stage each calendar year. In this stage, you pay the full cost of your drugs. **You generally stay in this stage until you've paid the amount of your deductible ($*[insert annual deductible]*).**
- **Stage 2: Initial Coverage**
  In this stage, the plan pays its share of the cost of your drugs and you pay your share of the cost.

If you have questions, please call *[insert plan name]* at *[insert Member Services phone number]* (TTY *[insert TTY number]*). The call is free. **For more information**, visit *[insert URL]*.



Model Part D EOB Exhibit C - Adobe Acrobat Pro

Model Part D EOB EXHIBIT C

Example 6: LIS in the Initial Coverage Stage

CHART 3

Your current drug payment stage

How much you pay for a covered Part D prescription depends on which payment stage you're in when you fill it. This chart helps you understand what stage you're in now and when you'll move to the next stage.

Year-to-date totals: Jan – March 2025	Stage 1: Yearly Deductible	You're in Stage 2: Initial Coverage	Stage 3: Catastrophic Coverage
Out-of-Pocket Costs	*not applicable*	$625	*starts when Out-of-Pocket Costs reach $2,000*

You're in Stage 2: Initial Coverage

- You start in this payment stage when you fill your first prescription of the year.
- During this stage, the plan pays its share of the cost of your drugs and you (or others on your behalf, including "Extra Help" from Medicare) pay your share of the cost.
- You generally stay in this stage **until your year-to-date Out-of-Pocket Costs reach $2,000.** As of March 31, 2025, your year-to-date Out-of-Pocket Costs were **$625**.

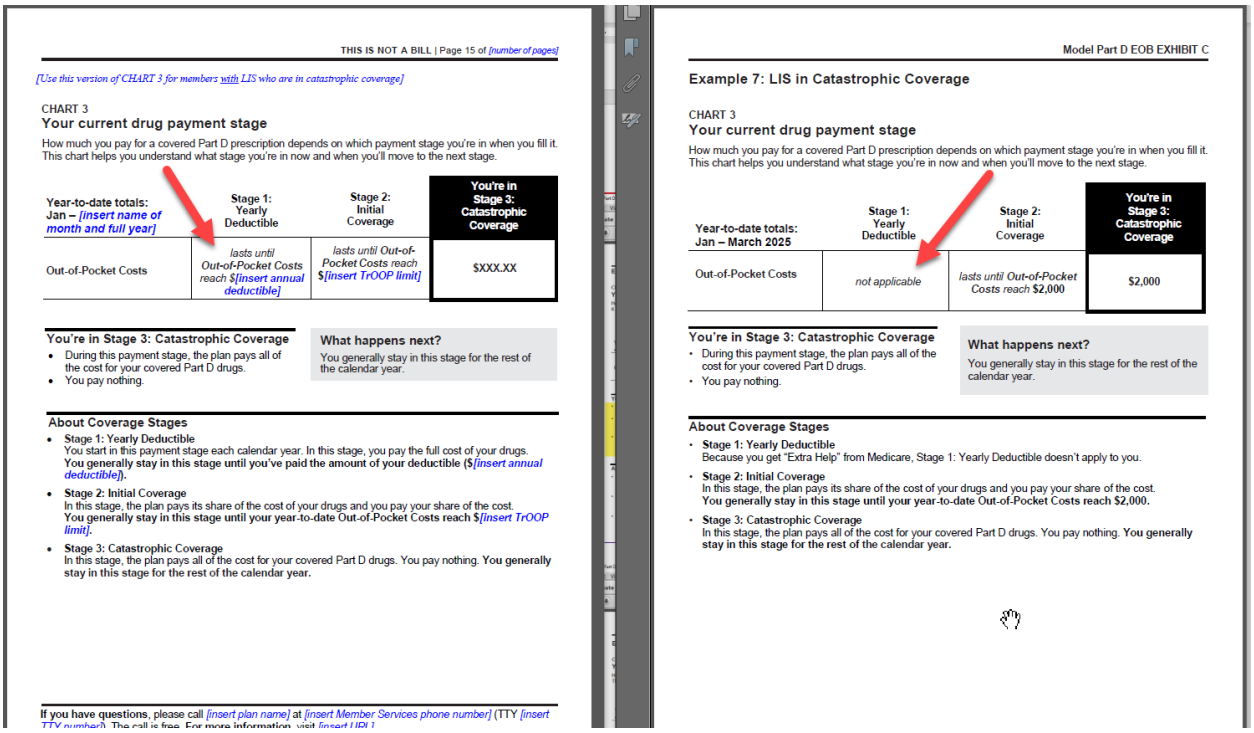
What happens next?

Once you (or others of your behalf) have paid **an additional $1,375 in Out-of-Pocket Costs,** you move to the next payment stage (Stage 3: Catastrophic Coverage).

About Coverage Stages

- **Stage 1: Yearly Deductible**
  Because you get "Extra Help" from Medicare, Stage 1: Yearly Deductible doesn't apply to you.
- **Stage 2: Initial Coverage**
  In this stage, the plan pays its share of the cost of your drugs and you pay your share of the cost. **You generally stay in this stage until your year-to-date Out-of-Pocket Costs reach $2,000.**
- **Stage 3: Catastrophic Coverage**
  In this stage, the plan pays all of the cost for your covered Part D drugs. You pay nothing. **You generally stay in this stage for the rest of the calendar year.**

1275 Pennsylvania Ave NW, Suite 700
Washington, D.C., 20004



THIS IS NOT A BILL | Page 15 of *[number of pages]*

[Use this version of CHART 3 for members with LIS who are in catastrophic coverage]

CHART 3

Your current drug payment stage

How much you pay for a covered Part D prescription depends on which payment stage you're in when you fill it. This chart helps you understand what stage you're in now and when you'll move to the next stage.

Year-to-date totals: Jan – *[insert name of month and full year]*	Stage 1: Yearly Deductible	Stage 2: Initial Coverage	You're in Stage 3: Catastrophic Coverage
Out-of-Pocket Costs	*lasts until Out-of-Pocket Costs reach $[insert annual deductible]*	*lasts until Out-of-Pocket Costs reach $[insert TrOOP limit]*	$XXX.XX

You're in Stage 3: Catastrophic Coverage

- During this payment stage, the plan pays all of the cost for your covered Part D drugs.
- You pay nothing.

What happens next?

You generally stay in this stage for the rest of the calendar year.

About Coverage Stages

- **Stage 1: Yearly Deductible**
  You start in this payment stage each calendar year. In this stage, you pay the full cost of your drugs. **You generally stay in this stage until you've paid the amount of your deductible ($*[insert annual deductible]*).**
- **Stage 2: Initial Coverage**
  In this stage, the plan pays its share of the cost of your drugs and you pay your share of the cost. **You generally stay in this stage until your year-to-date Out-of-Pocket Costs reach $*[insert TrOOP limit]*.**
- **Stage 3: Catastrophic Coverage**
  In this stage, the plan pays all of the cost for your covered Part D drugs. You pay nothing. **You generally stay in this stage for the rest of the calendar year.**

If you have questions, please call *[insert plan name]* at *[insert Member Services phone number]* (TTY *[insert TTY number]*). The call is free. For more information, visit *[insert URL]*

Model Part D EOB EXHIBIT C

Example 7: LIS in Catastrophic Coverage

CHART 3

Your current drug payment stage

How much you pay for a covered Part D prescription depends on which payment stage you're in when you fill it. This chart helps you understand what stage you're in now and when you'll move to the next stage.

Year-to-date totals: Jan – March 2025	Stage 1: Yearly Deductible	Stage 2: Initial Coverage	You're in Stage 3: Catastrophic Coverage
Out-of-Pocket Costs	*not applicable*	*lasts until Out-of-Pocket Costs reach* **$2,000**	**$2,000**

You're in Stage 3: Catastrophic Coverage

- During this payment stage, the plan pays all of the cost for your covered Part D drugs.
- You pay nothing.

What happens next?

You generally stay in this stage for the rest of the calendar year.

About Coverage Stages

- **Stage 1: Yearly Deductible**
  Because you get "Extra Help" from Medicare, Stage 1: Yearly Deductible doesn't apply to you.
- **Stage 2: Initial Coverage**
  In this stage, the plan pays its share of the cost of your drugs and you pay your share of the cost. **You generally stay in this stage until your year-to-date Out-of-Pocket Costs reach $2,000.**
- **Stage 3: Catastrophic Coverage**
  In this stage, the plan pays all of the cost for your covered Part D drugs. You pay nothing. **You generally stay in this stage for the rest of the calendar year.**

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Washington, D.C., 20004

IV. Specific EOB Section Comments and Recommendations:

1. **Crosswalk Document**
   - **Throughout**
     The terms "stage" and "phase" should not be intermingled in the document.
     Suggested language: **Phase** should be used.
   - **Chart 3**
     Tetanus when given due to an injury or wound is Part B. Either revise to state preventative vaccines or take out tetanus.

2. **Exhibits A, D, E, F** – No comments.

3. **Exhibit B**
   - Where the deductible payment "stage" word is listed, it should refer to **phase.**
   - Drug Name, Fill Date, Pharmacy, Rx#, suggest adding t**ier #,** it may be of value to member to understand their costs.
   - Drug Price
     Suggest removing "Price Change" and re-order columns as follows: Drug Price; Plan Paid, You Paid, Other Payments, Lower Cost Alternative Drugs.
     "Price Change" column may be confusing and not a value-add. Information may be confusing to member and no action required.
   - Lower Cost Alternative Drug
     Request to clarify what happens when the current drug is already the lowest cost drug.
   - Definitions below chart
     Suggest removing "**Price Change**" term.

4. **Exhibit C**
   - Your current drug payment "stage" should read "**phase**".

     Suggested change: Update all instances of **"stage" to "phase"** throughout the document.

     By definition, **phase** is more accurate for this use. "Phase" refers to a specific step in a process, while "stage" can refer to a period of time or a step in a process in a more general sense

- This chart helps you understand what stage you're in now and when you'll move to the next stage.

  Suggested language: This chart helps you understand what phase **you were in at the end of <reporting Month>** and when you'll move to the next phase.
  Add end of reporting month so that members are not confused if they have moved to another phase at the time they receive the EOB.

- The deductible doesn't apply to covered insulin products and most adult Part D vaccines, including shingles, tetanus, and travel vaccines.

  Suggested language; The deductible doesn't apply to covered insulin products and most adult **preventative** Part D vaccines, including shingles, tetanus, and travel vaccines.

  Add "**preventative**" to prevent confusion when tetanus is given to treat rather than prevent it becomes Part B-covered.

- Stage 4: Catastrophic Coverage In this stage, the plan pays all of the cost for your covered Part D drugs. You pay nothing. You generally stay in this stage for the rest of the calendar year.

  Suggested language: Stage 4: Catastrophic Coverage In this phase, the plan pays all of the cost for your covered Part D drugs. You pay nothing. <insert for plans that include exclude drug coverage under their enhanced benefit designs> **You may have cost-sharing for drugs that are covered under our enhanced benefit.** You generally stay in this phase for the rest of the calendar year.

  This change would align content for consistency with ANOC and EOC models and add sentence for excluded drugs covered by the plan.

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Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits (CMS-10453)

Comment On: CMS-2023-0097-0001
Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits (CMS-10453)

Document: CMS-2023-0097-DRAFT-0001
Comment on CMS-2023-0097-0001

Submitter Information

Name: Anonymous Anonymous
Email: fazal_ahmed_41@gwmail.gwu.edu

General Comment

I am writing to express my strong support for the proposed regulation CMS-10453, which pertains to the collection of information for Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits (EOBs). As a concerned citizen and advocate for accessible and transparent healthcare, I believe this regulation is a crucial step in providing Medicare beneficiaries with the necessary information to make informed decisions about their healthcare options.

The Medicare Advantage and Prescription Drug Programs play a vital role in providing healthcare coverage to millions of Americans, particularly seniors and individuals with disabilities. However, the complexity of these programs can sometimes lead to confusion and uncertainty among beneficiaries, especially when it comes to understanding the costs associated with their medical claims. The proposed regulation seeks to address this issue by requiring Medicare Advantage Organizations (MAOs) and Part D sponsors to provide clear and comprehensive EOBs to enrollees.

One of the key benefits of the proposed regulation is its emphasis on standardized and user-friendly EOBs. By establishing consistent formats and content requirements, the regulation ensures that beneficiaries receive information in a clear and understandable manner. This standardization will enable beneficiaries to easily compare and evaluate their healthcare options, promoting transparency and informed decision-making. Additionally, the provision of language about denied claims and appeals in the EOBs will empower beneficiaries to navigate the claims process more effectively, understand their rights, and take appropriate action when necessary. It’s also necessary to note that this described process of providing EOBs to the relevant beneficiaries has been occurring for multiple years now, and this regulation is a continuation of an established policy.

The proposed regulation also recognizes the importance of information technology and automation in reducing the information collection burden. By encouraging the use of automated collection techniques and other forms of information technology, CMS demonstrates its commitment to streamlining administrative processes and reducing paperwork for MAOs, Part D sponsors, and beneficiaries alike. The use of technology will not only enhance the efficiency of EOB generation and dissemination but also improve the accuracy and timeliness of the information provided to enrollees.

Additionally, I appreciate the provision of contact information for member services and instructions for reporting

suspected fraud within the EOBs. This feature is instrumental in promoting beneficiary engagement and ensuring that beneficiaries have access to the necessary resources and support to address any concerns or questions they may have. It fosters a sense of trust and accountability, allowing beneficiaries to actively participate in their healthcare and protect themselves from potentially fraudulent activities.

While the need for such regulation has been described well, it is also established to be legally justified, per CMS' detailed supporting statement on the regulation in its PRA listing (CMS, 2023). The collection of patient information does not include any sensitive, confidential, or privileged information, and the information that does get collected is protected by HIPAA laws. Stakeholders provided input on what kinds of data should be received, and no sensitive questions regarding sexual behaviors, religious beliefs, and other related matters were asked. I believe that the privacy of enrollees is protected well. Additionally, the proposed financial details in the supporting statement also make a convincing case that continuing this process of information collection is not an overly expensive use of taxpayer dollars, as many of the processes described are automated or a one-time burden. As described, the benefits of providing EOBs to these Medicare beneficiaries are likely to yield greater cost-savings on healthcare in the long run.

In conclusion, I wholeheartedly support the proposed regulation CMS-10453 for Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits. The provision of clear, comprehensive, and standardized EOBs, along with the emphasis on user-friendliness and the use of information technology, will empower Medicare beneficiaries to make informed decisions about their healthcare, improve healthcare outcomes, and enhance overall satisfaction with the Medicare program.

Thank you for considering my detailed comments. I trust that you will carefully evaluate the feedback received and take appropriate action to implement this important regulation.

Reference:
CMS. (2023, June 6). CMS-10453. CMS.gov. https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/1719218337/cms-10453

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Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits (CMS-10453)

Comment On: CMS-2023-0097-0001
Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits (CMS-10453)

Document: CMS-2023-0097-DRAFT-0007
Comment on CMS-2023-0097-0001

Submitter Information

Email: jools.x.brandt@healthpartners.com
Organization: HealthPartners

General Comment

Part C
HealthPartners recommends that CMS integrate the information in the FAQ document into the EOB instructions. This approach streamlines the structure of the guidance and ensures consistent application across MAOs.

Part D
HealthPartners strongly encourages CMS to issue a final model as soon as possible and no later than September 2023. The number of changes proposed by CMS to the 2024 Part D EOB will be challenging for Part D sponsors to implement timely. New templates to support Part D benefits need to be built, coded and tested. Delays beyond a September release will jeopardize plan compliance and member experience. In addition, the IRA and re-design of Part D present additional implementation challenges for the CY 2025 Part D EOB. We strongly encourage CMS to issue the final CY 2025 EOB in June 2024.

August 7, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Submitted via http://www.regulations.gov

RE: CMS-10453–Medicare Advantage and Prescription Drug Programs; Part C and Part D Explanation of Benefits

Dear Administrator Brooks-LaSure:

The MAPRx Coalition (MAPRx) appreciates the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments regarding the Explanation of Benefits (EOB) required to provide beneficiaries enrolled in Medicare Part D and Medicare Advantage (MA) plans.[1]

Our group, MAPRx, is a national coalition of beneficiary, caregiver, and healthcare professional organizations committed to improving access to prescription medications and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities. We welcome the opportunity to provide CMS with our comments in response to the information collection request regarding the EOBs offered by Part D and MA plans.

MAPRx appreciates CMS' commitment to ensuring beneficiaries have access to clear documentation about the services incurred within the Medicare program. As a coalition of patient groups, we believe strongly in transparency for beneficiaries, especially related to cost, coverage and beneficiary rights and responsibilities, including appeals and financial obligations. We have consistently advocated that patient-facing materials, such as EOBs and marketing materials, be created and deployed in a manner in which a beneficiary can easily understand the information and make informed decisions that are in the best interest of their own health care.

[1] CMS–10453 Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits. Accessed July 31, 2023. https://www.federalregister.gov/documents/2023/06/06/2023-11996/agency-information-collection-activities-proposed-collection-comment-request.

The Inflation Reduction Act included some of the most significant changes to Medicare Part D since the inception of the benefit in 2006, including the establishment of a $2,000 out-of-pocket cap and a “smoothing” mechanism or monthly maximum that enables beneficiaries to spread costs over the course of the plan year. It is critical beneficiaries are aware of these changes and that CMS develop and deploy a variety of initiatives to educate beneficiaries about these new benefits, and related rights and responsibilities. MAPRx believes that including information about the OOP cap and monthly maximum as part of EOBs is an important way to educate and inform beneficiaries about these new policies. Specifically, we recommend the EOB include:

- Notification, in clear, easy to understand language, of the annual out-of-pocket cap in plan year 2024, how the cap will change in 2025 and subsequent years.
- Notification, in clear, consistent and easy to understand language, on the first page of the EOB, about the option for a beneficiary to select the maximum monthly cap or, alternatively, the term CMS determines to describe the monthly cap. Such notification also should include:
    - Information describing how beneficiaries can learn more about the option and where they can direct questions.
    - Information about how beneficiaries can opt-in to the monthly cap.

- If a beneficiary already has enrolled in the monthly cap, the EOB should include:
    - Financial obligations for the remainder of the plan year.
    - Notice that monthly costs may increase if they have subsequent prescriptions and have not hit the annual cap.
    - Notice that a beneficiary’s monthly costs will not increase if they already have hit the annual cap.
    - A description of penalties that may be imposed if a beneficiary fails to meet their remaining financial obligations and the opportunity to appeal.

Thank you for your consideration of our comments on this information collection request. MAPRx looks forward to continuing to work with you on behalf of the Medicare beneficiaries we represent. If you have any questions, please contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at (202) 540-1070 or bduffy@nvgllc.com.

Sincerely,

MAPRx Coalition

PUBLIC SUBMISSION

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Comment On: CMS-2023-0097-0001
Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits (CMS-10453)

Document: CMS-2023-0097-DRAFT-0011
Comment on CMS-2023-0097-0001

Submitter Information

Email: eroman@medicalcardsystem.com
Organization: MCS Advantage, Inc.

General Comment

MCS Advantage, Inc appreciates the opportunity to submit comments in response to the Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits (CMS-10453).

Our comment regarding Appendix A, CMS Approved Part C Explanation of Benefits Template HMO, Monthly EOB Version (Page 5, Section: Details for Claim Processed in [insert month and year]) and Appendix A, CMS Approved Part C Explanation of Benefits Template PPO, Monthly EOB Version (Page 5, Section: Details for Claim Processed in [insert month and year]) is the following:

• On section title: “You have the right to make an appeal or complaint”, refers to complaint, but on the description does not include the applicable process. It calls our attention, the following part, that read: “You can also make an appeal if we approve a claim but you disagree with how much you are paying for the item or services”. We will appreciate, if CMS can validate that description to determine if is referring to a complaint (grievance) related to a member’s claim processing dispute with the Plan, instead of an appeal. Furthermore, if claim is approved, the member won’t receive a Denied Letter with Appeal rights.

1570 Midway Pl.
Menasha, WI 54952

August 7, 2023

U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
CMS-10453; OMB 0938-1228
Submitted electronically: www.regulations.gov

Re: CMS-10453; OMB 0938-1228; Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits ("EOBs")

To Whom it May Concern:

Network Health ("NH") appreciates the opportunity to provide feedback to the Centers for Medicare and Medicaid Services ("CMS") on the proposed changes to the Part C and Part D EOBs as published on June 6, 2023. in the Federal Register.

CMS requested feedback by August 7, 2023. The following is NH's response.

Part C EOBs

NH Response:

The Part C EOB model document does not include a section/requirement for claim denial reasons when there is no member liability. During our CMS Program Audit this year, the CMS contracted auditors preliminarily cited us for not providing a denial reason for denied claims that have no member liability; however, the Part C EOB does not have a location for the denial reasons in this instance. Additionally, the Integrated Denial Notice ("IDN") requirements in the MA and Part D appeals and grievances guidance, section 40.12.1, states that MA plans are not required to issue an IDN if there is no enrollee liability beyond the applicable cost sharing. An EOB would be issued and indicate any applicable cost sharing. However, the Part C EOB model document does not have a section/requirement for claim denial reasons when there is no member liability.

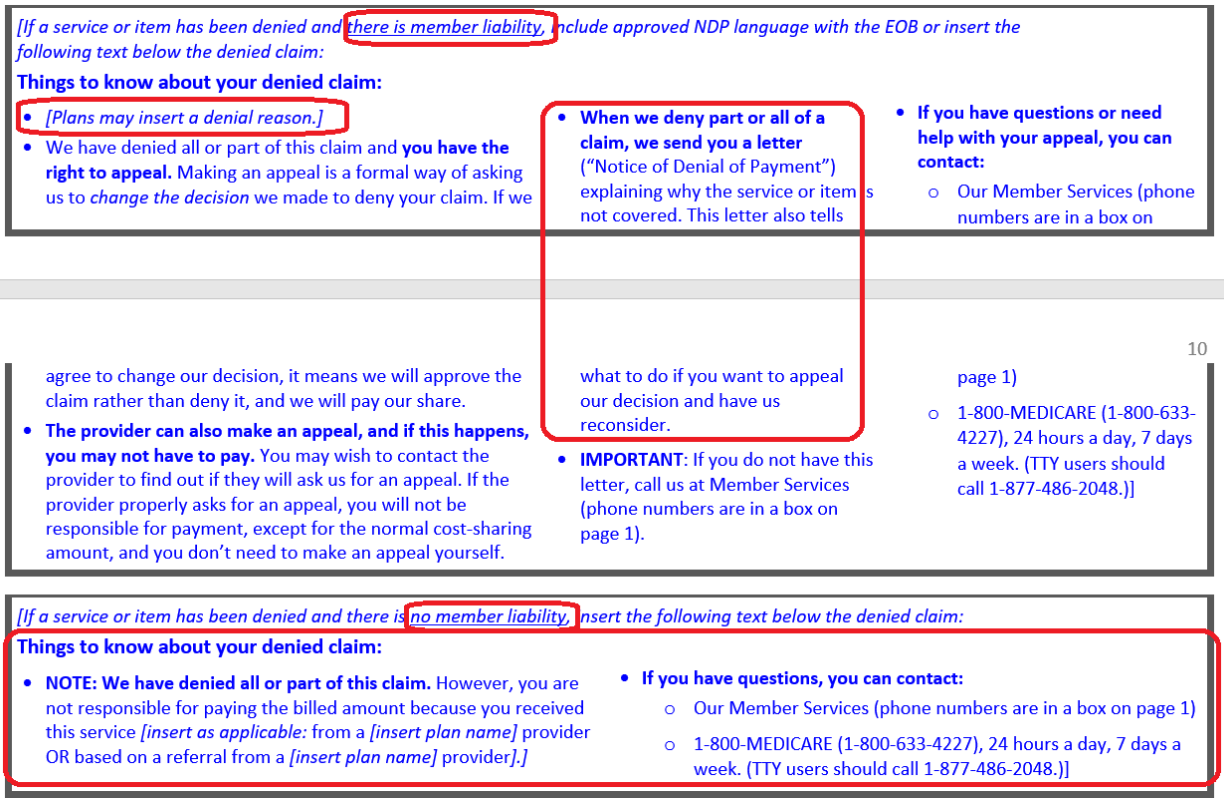
Recommendation: CMS should consider including a location/section in the Part C EOB for plans to include denial reasons for claims in which there is no member liability for clarity to members. Currently the Part C EOBs contain instructions for what to communicate when there is a denied claim and no member liability, yet these instructions do not specifically include providing a denial reason.

These are examples of the locations in the Part C draft EOBs that we're referencing:

MSA Monthly: pg. 11 and 16 have instructions for if a service or item has been denied and there is no member liability, insert the following text below the denied claim: Things to know about your denied claim…

MA PPO Monthly: pg. 12 and 17 have instructions for if a service or item has been denied and there is no member liability, insert the following text below the denied claim: Things to know about your denied claim….

This is a visual of the EOB:



[If a service or item has been denied and there is member liability, include approved NDP language with the EOB or insert the following text below the denied claim:

Things to know about your denied claim:

- *[Plans may insert a denial reason.]*
- We have denied all or part of this claim and **you have the right to appeal.** Making an appeal is a formal way of asking us to *change the decision* we made to deny your claim. If we agree to change our decision, it means we will approve the claim rather than deny it, and we will pay our share.
- **The provider can also make an appeal, and if this happens, you may not have to pay.** You may wish to contact the provider to find out if they will ask us for an appeal. If the provider properly asks for an appeal, you will not be responsible for payment, except for the normal cost-sharing amount, and you don't need to make an appeal yourself.
- **When we deny part or all of a claim, we send you a letter** ("Notice of Denial of Payment") explaining why the service or item is not covered. This letter also tells what to do if you want to appeal our decision and have us reconsider.
- **IMPORTANT:** If you do not have this letter, call us at Member Services (phone numbers are in a box on page 1).
- **If you have questions or need help with your appeal, you can contact:**
  - Our Member Services (phone numbers are in a box on page 1)
  - 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. (TTY users should call 1-877-486-2048.)]

10

[If a service or item has been denied and there is no member liability, insert the following text below the denied claim:

Things to know about your denied claim:

- **NOTE: We have denied all or part of this claim.** However, you are not responsible for paying the billed amount because you received this service *[insert as applicable:* from a *[insert plan name]* provider OR based on a referral from a *[insert plan name]* provider*].]*
- **If you have questions, you can contact:**
  - Our Member Services (phone numbers are in a box on page 1)
  - 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. (TTY users should call 1-877-486-2048.)]

NH appreciates CMS's consideration of our and other stakeholders' feedback to the draft EOBs.

Respectfully submitted,

Shannon Schuster
Director, Regulatory Affairs

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Comment On: CMS-2023-0097-0001
Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits (CMS-10453)

Document: CMS-2023-0097-DRAFT-0002
Comment on CMS-2023-0097-0001

Submitter Information

Name: David Broccoli
Email: dbroccoli@nhpri.org

General Comment

Would CMS consider allowing plans, such as MMPs and D-SNPs, with no member cost share to suppress the coverage phase details section on the Part D EOB (i.e., chart 3) regardless of LICS level? This section can cause confusion for members who have no financial liability even when including language stating this payment stage doesn't apply. Currently, the instructions say this section can be suppressed only for duals with LICS level 3.

August 7, 2023

Filed electronically via federal eRulemaking Portal: http://www.regulations.gov

Mr. William N. Parham, III
Director, Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Agency Information Collection Activities: Submission for OMB Review; Comment Request, [Document Identifier CMS–10453, OMB 0938]

Dear Mr. Parham:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to comment on the information collection request notice with comment period issued by the U.S. Centers for Medicare & Medicaid Services (CMS) titled: "Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits information collection," as published in the *Federal Register* on June 6, 2023.[1]

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 275 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and plans offered for sale on the Exchanges established by the Affordable Care Act.

We appreciate the efforts by CMS to appropriately capture all the Explanation of Benefits (EOBs) changes based the on Inflation Reduction Act's (IRA) related statutory changes and make readability and usability improvements to the Medicare Part D EOB model document. The EOB, though not a financial bill, is an accounting system and a significant communication between Part D plan sponsors and their enrollees and includes critical information to help beneficiaries manage their health care spending.

PCMA appreciates CMS's ongoing efforts in taking industry and beneficiary feedback into account in their proposed, redesigned 2025 model EOB. Industry engagement is crucial to increase beneficiaries' understanding of their Medicare drug prescription use and associated

[1] 86 Fed. Reg. 37066, June 6, 2023.

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

costs. Ultimately, CMS's work should yield an improved and less confusing EOB experience for all beneficiaries.

We have the following comments regarding the proposed CY 2025 model EOB:

1. Formatting

The goal of this section is to highlight concerns regarding layout and formatting of the proposed model CY 2025 EOB. These comments are meant to recommend ways to maximize space and minimize waste while preserving document accessibility and readability.

- **Maximizing space** – Given that printing and mailing long EOBs is a resource intensive effort, we recommend that all empty spaces are utilized. This recommendation includes empty spaces between sections. Overall, this will minimize the number of pages for each EOB and prevent beneficiaries from being overwhelmed by the sheer number of pages.

- **Layout** – This section highlights concerns and suggestions related to how the pages are laid out including margins, text boxes, font size, pagination, and page orientation.

    - *Page orientation*: The proposed portrait orientation of the model EOB is going to create an issue with regards to large print and alternate language prints. As proposed, large print EOBs will require additional pages to be printed and mailed. Please note that the landscape layout allows for space for the data to fit properly. This increased page count will be a cost intensive resource burden for PBMs and overwhelming for beneficiaries. This proposed change in page layout orientation may cause an increase in print page count even for regular print. Given these considerations, we recommend not using portrait orientation for both practical and economical purposes. We recommend that the cover page stays in portrait orientation given that it is a print process restriction for the cover page to be in portrait layout, so the member address block perfectly fits in the envelope window.

    - *Cover page*: We would like to note that the model has no place holder for Return to Sender address, whereas Exhibit A shows it. Instead, the model shows it as part of the Operated By statement. We request clarification and resolution of this discrepancy and suggest that the cover page include the Return to Sender address.

    - *Footer*: We are requesting clarification as to the placement of the footer. Does the information in the footer have to be on every page? It should be noted that the addition of this to every page will create additional page count as some plans have lengthy hours of operation messaging. This increase in pages again will create administrative burdens related to printing and mailing.

- *Text boxes and columns of text*: We request that CMS allow us to spread text boxes and text columns across the page to save lines. For example, see model on page 2, "Totals for the month of" gray box, and on page 8, "Totals for the year-to-date" gray box.[2] In this example, the text flow goes from bottom left to top right and then goes straight down from one page to the next page. This again leads to an increase in pages and, as mentioned before, becomes an administrative and resource burden for PBMs and overwhelming for beneficiaries.

- *Large print sample*: We request that CMS provide us with a large print sample, given that this proposed model does not include one.

- *Statutory necessity and clarity*: New changes should be mostly based on statutory changes and requirements. Any additional changes or modifications, beyond statutory requirements, should include clarifications, and alignment across sections and tables along with a focus on length and complexity of the document. For example, CMS has removed emphasis on the "Total Drug Costs" from Chart 2[3] due to the statutory changes effective in 2025. For the sake of alignment and clarity, we request the removal of the term throughout the document, as this accumulation will no longer move members through the benefit stages. Specifically, if there is no statutory reason to include "Total Drug Costs" in Chart 1, we request exclusion of this language in Chart 1 to align with Chart 2.

2. Charts clarifications request

- **Chart 3** – For the coverage stages section, can CMS also provide an example showing messaging if the plan does not have a deductible and one if the plan has a brand-name/tier-level deductible to clarify? For Low Income Subsidy members in the initial coverage limit, the yearly deductible is waived, so the current language should be replaced with not applicable. These changes will reflect current Medicare program policies and prevent unnecessary beneficiary confusion.

- **Chart 4** – The EOB is meant to reflect and inform beneficiaries of changes to Drug Lists during the year, like adding new drugs, removing drugs, changing coverage restrictions, or moving drugs from one cost-sharing tier to another. The proposed model lists Chart 4 as its own page. When there are no drug updates that pertain to the member, the short message leaves a large majority of the page blank. The Chart 4 messaging when there are no updates may not always fit at the bottom of the previous page, and there is no space to fit the messaging on the last page. To conserve paper, we recommend that CMS allow plans to suppress Chart 4 when there are no drug updates for the member. We also note that the table of contents, which lists each section that was removed from

[2] Appendix B. CY 2025 Part D EOB Exhibit G.pdf
[3] Appendix B. CY 2025 Part D EOB Exhibit G.pdf

the cover page as of 2024, further supports our request to suppress as the member would not be expecting Chart 4 when there are no updates.

3. Other

- **Definitions page** – The model EOB is full of terms and acronyms that need to be spelled out and defined for beneficiary comprehension and accessibility. Acknowledging this complexity, we recommend the addition of a definitions page or section. This type of organization of terms and acronyms will allow for the maximization of space. It will also improve readability by placing all terms from various sections and pages in one place.

- **CY 2024 model carryovers to proposed CY 2025 model** – In the CY 2024 model, the cents were removed from even numbers; however, this causes the cents to be removed from all numbers if applied. We recommend this update be optional. We also recommend that language about translation be a variable field based on whether the plan meets any language translation thresholds.

4. Smoothing and maximum out-of-pocket (MOOP) related sections on the EOB

We recognize that policy decisions regarding the smoothing and MOOP programs have not been finalized. Moreover, the model EOB statements related to these programs would be based on actual programmatic specificities. Given the lack of information, we recommend that any smoothing-related information in the EOB simply indicates whether the member is enrolled in the cost-smoothing program. Our recommendation is that since policy precedes EOB, the model CY 2025 document should **only** include an indicator if a beneficiary is enrolled in the smoothing program.

Conclusion

PCMA is pleased with the ongoing stakeholder engagement CMS has undertaken in redesigning its model EOBs for the Part D program. These documents are important, and plans and beneficiaries have learned much over the history of the program to better identify what people need to know and how to convey that information to them. If you have any questions regarding these suggestions and recommendations, please do not hesitate to contact me directly. I can be reached at tdube@pcmanet.org.

Sincerely,

Tim Dube

Tim Dube
Vice President, Regulatory Affairs

August 7, 2023

Submitted via: www.regulations.gov

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier/OMB Control Number: CMS-10453
Room C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1850

Re: Agency Information Collection Activities: Proposed Collection – Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments on the Information Collection Request (ICR): *Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits*, which was published in the *Federal Register* on June 6, 2023.[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $1.2 trillion in the search for new treatments and cures, including $100.8 billion in 2022 alone. Consistent with that mission, PhRMA companies are committed to the continued success of the Medicare Prescription Drug Benefit Program (Part D).

The Centers for Medicare & Medicaid Services (CMS) solicits comments on its request to renew a currently-approved information collection, which includes updates to the Medicare Part D Explanation of Benefits (EOB) to comply with the Inflation Reduction Act's (IRA) Part D benefit redesign provisions. CMS notes that the IRA's significant changes to the Part D benefit design – such as the cap on enrollee cost sharing and Part D out-of-pocket (OOP) cost "smoothing" – require CMS to make conforming revisions to the model Part D EOB.[2] CMS states that the Part D EOB must include the cumulative year-to-date amount of benefits provided in relation to the different benefit phases of the Part D program.[3] CMS requests comment on what information related to the Part D maximum monthly payment cap on cost sharing payments (i.e., OOP smoothing) should be included in the EOB.[4]

For many years, PhRMA has supported and advocated for an OOP cap for outpatient prescription drugs covered under Medicare Part D, along with a program that allows Medicare

[1] 88 Fed. Reg. 37067 (June 6, 2023).
[2] Supporting Statement at 3.
[3] *Id.*
[4] *Id.*

beneficiaries to spread out or "smooth" their Part D cost sharing across the calendar year. Both policies were included in the recently enacted Inflation Reduction Act, and take effect in 2024 and 2025, respectively. PhRMA believes that the revised EOB must highlight these critical improvements in patient affordability and accurately reflect and describe the Part D benefit. PhRMA agrees with CMS on the importance of an enrollee's EOB accurately reflecting OOP costs and the movement of patients through the annual deductible, initial coverage, and catastrophic phases of the benefit.

EOB Content Related to OOP Smoothing

EOB Language on Enrollment in the Smoothing Program

The EOB should be consistent with other Part D materials and serve as a supplemental avenue for education and outreach to beneficiaries about the major changes to the Part benefit under the IRA, in particular the new OOP cap and smoothing benefits in Part D. As such, starting with the 2025 plan year, CMS should include standard language in the EOB related to beneficiary enrollment into the smoothing program and beneficiary costs and payments under the smoothing program. This will help ensure that beneficiaries understand the design changes in Part D and have sufficient information to make informed health care decisions.

If a beneficiary has not yet elected the smoothing option and could potentially benefit from it, the EOB should alert the beneficiary to the option for smoothing and include information on the various ways a beneficiary could learn more and potentially enroll in OOP smoothing, such as references or links to Part D smoothing educational materials and calculator tools that help illustrate the mechanics of smoothing.

Beneficiary OOP Costs under the Smoothing Program in the EOB

In order to meet the needs of beneficiaries who have elected to "smooth" their Part D cost sharing across the calendar year, as appropriate the Part D EOB should display both the beneficiary's incurred OOP costs and the beneficiary's smoothed payments over time to clearly capture incurred liability and smoothing payments, including payments that have been made by the beneficiary to date and future payments owed, to accurately reflect beneficiary OOP costs and movement through the benefit.[5] This could provide beneficiaries with the ability to understand their total OOP expenses (and total liabilities) and track their payments toward the costs they have incurred under the smoothing program. In addition, this could also guard against potential confusion and/or future missed payments that would jeopardize beneficiaries' ongoing enrollment in the program while enabling them to make informed decisions about their health and treatment plans.

Additionally, PhRMA was pleased to see an acknowledgement in the recent technical memorandum on smoothing calculations that CMS will develop tools such as calculators for

[5] Supporting Statement at 3.

beneficiaries[6] and we look forward to additional details in the forthcoming smoothing guidance. PhRMA agrees that these tools will be important in helping beneficiaries and their caregivers understand how smoothing could affect monthly OOP costs and determine whether they could benefit from the program. Regardless of whether a beneficiary has enrolled in the smoothing program, the EOB should include language directing beneficiaries to where they can access additional educational materials on the smoothing program and these CMS-developed tools, including the smoothing calculator, so that beneficiaries can see projected monthly OOP costs with and without smoothing.

EOB Layout and Content Issues

Part D EOB Exhibit B

The Part D EOB should clearly delineate the types of financial assistance that Part D beneficiaries may receive when explaining what OOP costs are included in Exhibit B, including to what extent the other financial assistance counts towards beneficiary TrOOP and help a beneficiary progress through the Part D benefit design. As currently proposed, the EOB combines Medicare's Extra Help program and other types of assistance into one bullet. PhRMA recommends that CMS update the EOB to separate out payments made by "Extra Help from Medicare," as Extra Help is a component of the Medicare Part D program. Other forms of assistance listed are external support that is outside of Medicare itself. The bullets on page 10 of Exhibit B under the "Out-of-Pocket Costs include" section should therefore be updated to read:

- Any payments made for your drugs by Extra Help from Medicare
- Appropriate beneficiary costs in enhanced plans, which beginning in 2025 will count towards TrOOP[7]
- Any other payments made for your drugs by employers or union health plans, TRICARE, the Indian Health Service, AIDS drug assistance programs, charities, and most State Pharmaceutical Assistance Programs (SPAPs)."

Part D EOB Exhibit C

The Part D EOB layout should also provide additional clarification on drug payment stages for low-income subsidy (LIS) enrollees / those enrolled in Extra Help, given the differences in their coverage and cost sharing compared to non-LIS enrollees. The EOB Exhibit C template could confuse and potentially mislead a beneficiary with LIS about what they would pay in OOP costs. For example, in Example 6 and 7, LIS enrollees may understand the displays to mean that they would owe $625 in the initial coverage phase and up to $2,000 in OOP costs. These examples should be updated to clarify which costs would be paid by the LIS enrollee directly and which costs would be covered on their behalf by the low-income cost share subsidy (LICS). Moreover, these pages for LIS enrollees should more clearly explain that costs paid by the LICS count as OOP costs and towards an enrollee's progression through the coverage stages of the Part D benefit.

[6] CMS. Technical Memorandum on the Calculation of the Maximum Monthly Cap on Cost-Sharing Payments under Prescription Drug Plans. July 17, 2023.
[7] SSA 1860D-2(b)(4)(C)(iii)(II)

Part D EOB Exhibit F

CMS should ensure that the EOB can be clearly understood by all Part D beneficiaries (who have varying levels of health insurance literacy), including LIS beneficiaries who comprise about 27 percent of all Part D enrollees.[8] Because EOBs are customized to a beneficiary's unique circumstances, as mentioned above, CMS should establish separate EOB templates for LIS and non-LIS beneficiaries. As LIS beneficiaries may not understand how the LIS rider interacts with the EOB, the EOB for LIS enrollees should clearly articulate what an LIS enrollee would pay (as discussed above) and the LIS rider language in Exhibit F should state how the LIS rider impacts the EOB. In addition, the language on the LIS rider should be removed in the EOB sent to non-LIS enrollees, to minimize the risk of beneficiary confusion for non-LIS enrollees who may not be sure whether they qualify for the LIS.

PhRMA appreciates the opportunity to share our comments and we look forward to continuing to work with CMS regarding these issues. Please contact Rebecca Hunt or Judy Haron at 202-835-3400 if we can provide any further information or if you have any questions about the topics discussed in our comments.

Sincerely,

Rebecca Jones Hunt
Deputy Vice President, Policy & Research

/s/

Judy Haron
Deputy Vice President, Law

Kristin Williams
Manager, Policy & Research

[8] Medicare Payment Advisory Commission (MedPAC). March 2023 Report to Congress. Chapter 12. The Medicare prescription drug program (Part D): Status report.