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Submitted electronically via www.reginfo.gov/public/do/ PRAMain

January 8, 2024

Mr. William N. Parham, III
Director, Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs

Centers for Medicare & Medicaid Services
Department of Health and Human Services

Re: Proposed information collection requirements associated with the MA and Part D Programs, Part C and Part D CY 2025 Explanation of Benefits

Dear Director Parham:

Thank you for the opportunity to comment on the Department of Health and Human Services (Department or HHS), Centers for Medicare & Medicaid Services (CMS), proposed collection of information under the Paper Reduction Act, published in the Federal Register on December 8, 2023.

CVS Health serves millions of people through our local presence, digital channels, and our nearly 300,000 dedicated colleagues, which includes more than 40,000 physicians, pharmacists, nurses, and nurse practitioners. Our unique healthcare model gives us an unparalleled perspective on how the Medicare and Medicaid programs can be built upon and integrated to help consumers navigate the healthcare system – and their personal healthcare – by being a trusted partner for every meaningful moment of health. And we do it all with heart, each and every day.

We appreciate CMS' efforts to ensure the Medicare programs are accessible for all beneficiaries and meet beneficiaries' needs equitably. Medicare Advantage Organizations (MAOs) and Medicare Part D (Part D) plan sponsors are dedicated to combining population-level health management with person-centered care coordination, helping make care more affordable, and helping design innovative supplemental benefits and other programs to address medical and social risk factors and gaps in care.

To help CMS better understand the cost and staffing impact to plan sponsors, we describe how CMS' proposals, if finalized as proposed, may impact on current industry processes. With any change in CMS policy, CVS Health is committed to ensuring that we have the right staffing, expertise, processes, and infrastructure in place to enable compliance with the new or changed requirements.

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We have included an appendix with comments about CMS' proposals and focus our recommendations on lessening beneficiary confusion, clarifying definitions, and cohesion across models.

Thank you for considering our comments and recommendations. CVS Health is committed to working with CMS to ensure that Medicare and Medicaid beneficiaries receive the equitable and meaningful benefits to which they are entitled. We appreciate CMS' willingness to continue engaging with our industry, and encourage the Department to continue working with MAOs, Part D plan sponsors, and other stakeholders to focus on the policies that will definitively strengthen the MA plans and Part D plans for the millions of beneficiaries they serve. We are happy to collaborate with HHS on any efforts to improve quality and delivery of care. Please do not hesitate to contact us with any questions about these comments.

Sincerely,

Melissa Schulman
Senior Vice President
Government & Public Affairs
CVS Health

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Appendix
Specific Comments on the proposed information collection requirements associated with the MA and Part D Programs, Part C and Part D CY 2025 Explanation of Benefits.

Proposed EOB Model Plan Instructions

There are several updates in the CY2025 Part D EOB Plan Instructions document that we respectfully request CMS to clarify:

- **The Drug Price column was changed to use the negotiated price, as defined at 423.100. It is not clear if this is a change to the previous definition ("total cost of each drug (including member, plan, and other payments paid) from when the prescription was first filled during the benefit year.'), or if this should be calculated differently.**
- **The new model allows plan sponsors to enter, "No lower-cost alternative drug is available," if no lower-cost therapeutically equivalent drug is available. Please clarify whether this may be left blank, per the current format. Adding this statement will incur IT project costs and resources for plan sponsors.**
- **With the Inflation Reduction Act updates to the Maximum Out-of-Pocket, could CMS please clarify, "Out-of-Pocket Costs" and TrOOP in the Part D EOB Plan Instructions document so that it is clear if it is a replacement of the current TrOOP, YTD TrOOP, or if an additional field is required. There will be IT project costs and resources associated with adding this statement to the model.**

On Page 1 of the CY2025 model, the section titled, "Need large print or another format?", we would like to highlight that, "and translation into other languages," does not apply to plan sponsors that do not have another language requirement.

For simplicity, like Chart 3, in which Total Drug Cost was removed, references to Total Drug Cost in other areas of the model can be minimized. For example, Chart 1A states "The amounts paid for these drugs *do not* count toward your Out-of-Pocket Costs or **Total Drug Costs."** Additionally, in Chart 2, there is an entire column for Total Drug Cost that is also described in a note for specific cases where Total Drug Cost is applicable.

There is conflicting language in the notes for Chart 2, where is it optional for plans to add "Out-of-Pocket Costs include": "Supplemental drug benefits paid by your plan." The model (see page 7) explanation says that Supplemental Drug benefits do not include payments made for "Drugs covered by our plan's Supplemental Drug Coverage listed in Chart 1A)."

The "You Paid" and "Plan Paid" definitions added to Chart 2 duplicates the information already provided in Chart 1.

For plans without a deductible, Chart 3 instructions should include, "Not Applicable," under Stage 1 (Yearly Deductible) and should include a bullet in the notes stating, "Because there is no deductible for the plan, this payment stage does not apply to you."

- **Recommendations:**
  - **Clarify the definitions of Drug Price and Out-of-Pocket Costs/TrOOP and confirmation on optional inclusion of added languages when no lower-cost alternative drug is available in the plan instructions.**
  - **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.**
  - **Remove unnecessary references to "Total Drug Cost" like the updates made to Chart 3.**
  - **Align languages regarding whether Out-of-Pocket Costs include supplemental drug benefits paid by the plan.**
  - **Reconsider adding You Paid and Plan Paid information at the end of Chart 2 as it is duplicative of information provided in Chart 1A.**
  - **Add instructions in Chart 3 for plans without a deductible to clarify Stage 1.**
  - **For consistency's sake and a positive member experience, align model and Exhibits language and formatting, for example, all languages in Chart 3 scenarios should be the same (see attached screenshots*).**

Expansion of Electronic Delivery of Materials

Although a request for comments about recommending CMS to allow plan sponsors 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, but it also opens opportunities for caregivers to manage important health information, which leads to an improved experience for everyone in our increasingly virtual world.

- **Recommendations:**
  - **Expand electronic delivery opportunities 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.**

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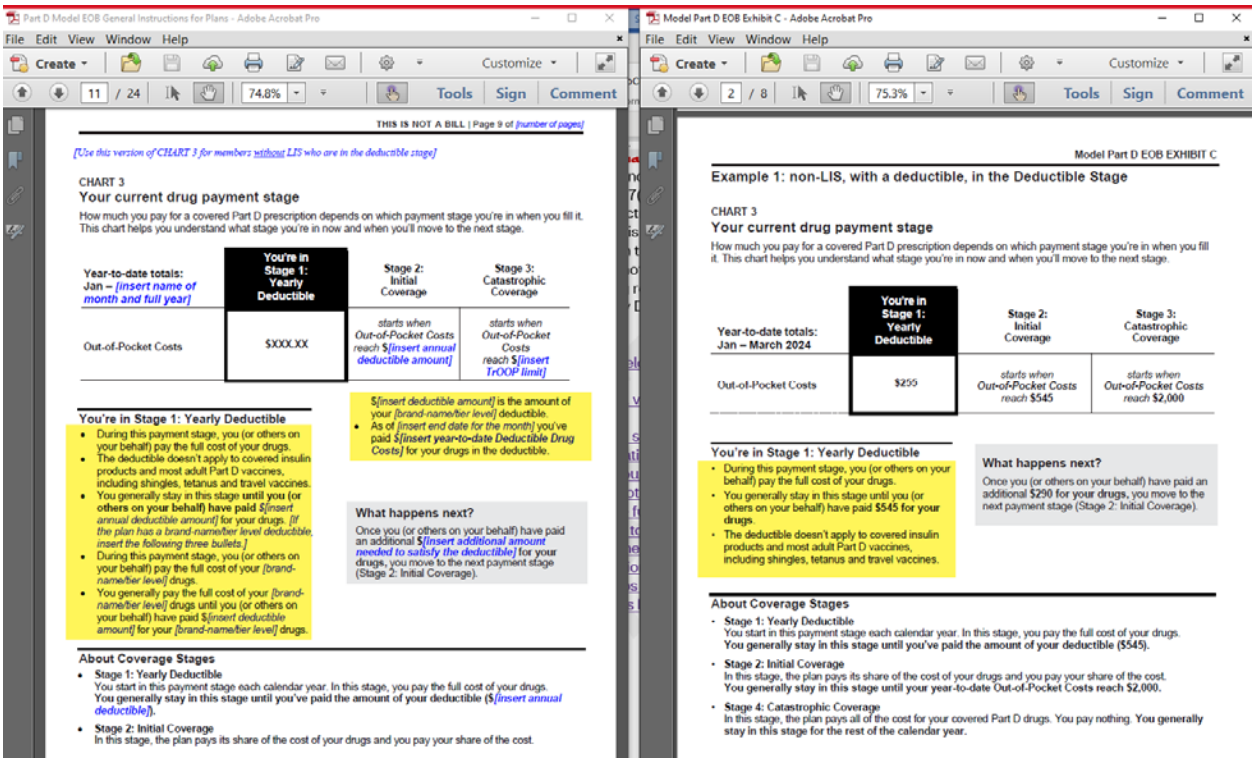
- **(1) Without prior authorization from an enrollee, Part D sponsors may mail new and current enrollees a notice that explains how to electronically access the following required materials: Evidence of Coverage, Provider and Pharmacy Directories, and Formulary.**

*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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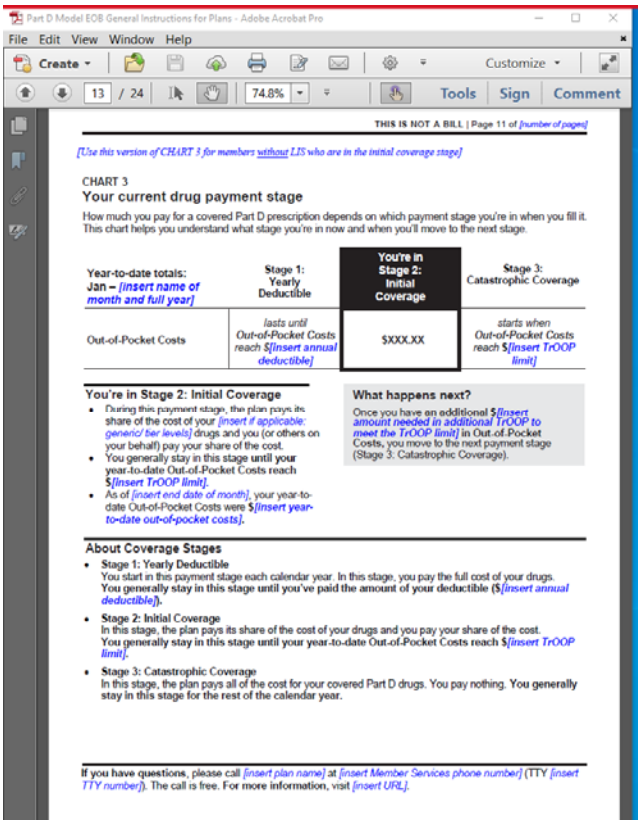

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[Use this version of CHART 3 for members without LIS who are in the initial coverage stage]

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]*.**

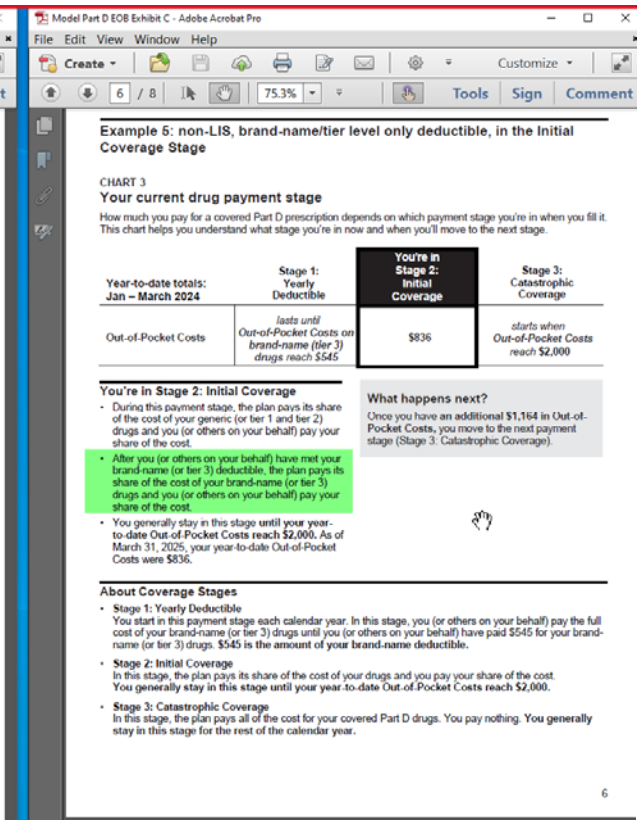
What happens next?

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]*.



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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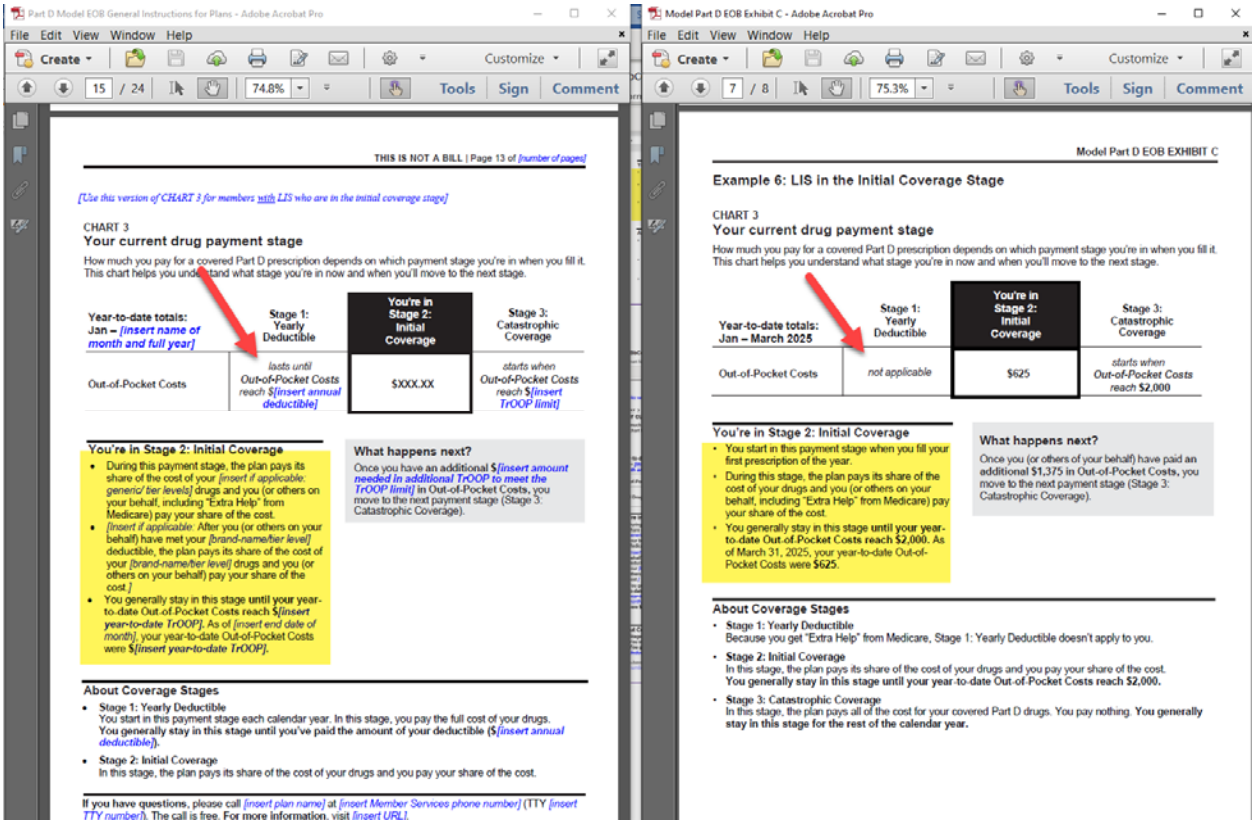

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[Use this version of CHART 3 for members with LIS who are in the initial coverage stage]

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

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

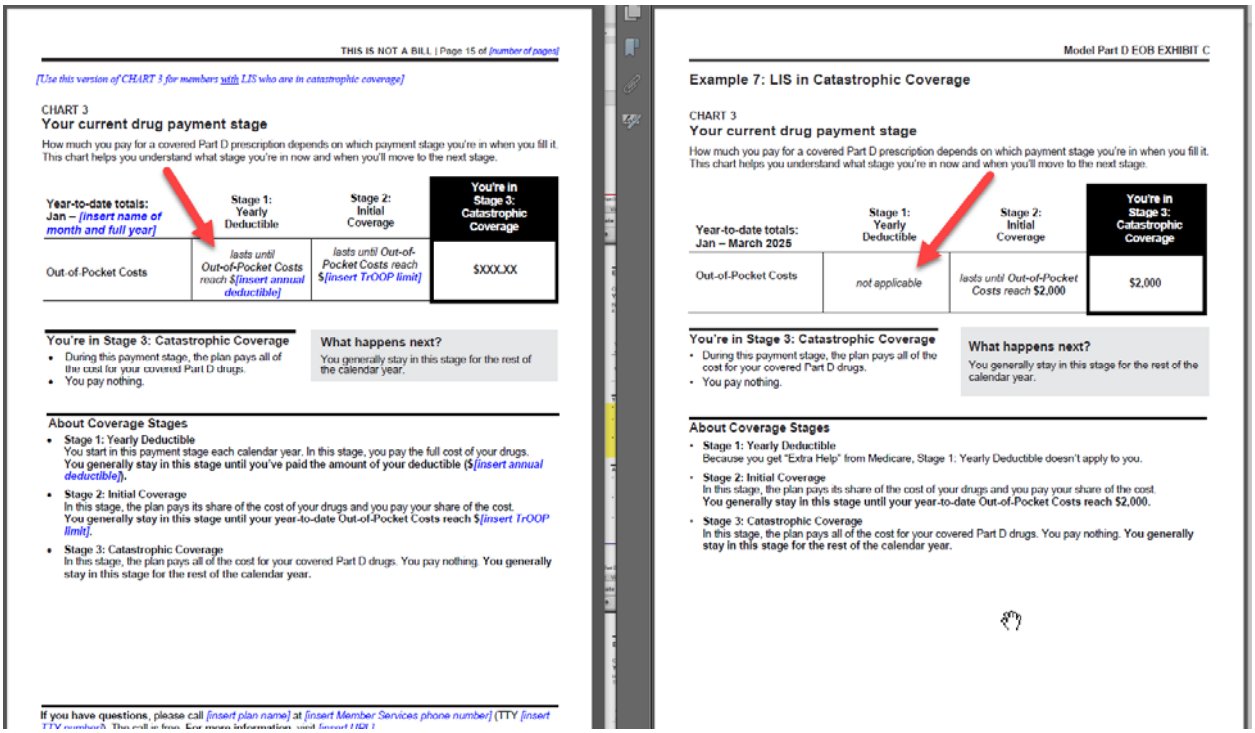
- You start in this payment stage when you fill your first prescription of the year.
- During this stage, the plan pays its share of the cost of your drugs and you (or others on your behalf, including "Extra Help" from Medicare) pay your share of the cost.
- You generally stay in this stage until your 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.



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[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]).

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.

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.

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 tier #, it may be of value to member to understand their costs.**
- **Drug Price**
  Suggest to re-order columns and remove "Price Change" column **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 when 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.