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Submitted electronically via www.regulations.gov

September 15, 2021

William N. Parham, III
Director, Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS Notice of Proposed Collection [CMS–10141 and CMS–R–43] Agency Information Collection

Dear Director Parham,

Thank you for the opportunity to submit comments in response to the Center for Medicare & Medicaid Services' (CMS) information collection request, specifically the agency's collection of information related to the Medicare Prescription Drug Benefit Program published at 86 *Federal Register* 38,485 on July 21, 2021.

CVS Health serves an estimated 39 million people through our local presence, digital channels, and our nearly 300,000 dedicated colleagues – including more than 40,000 physicians, pharmacists, nurses, and nurse practitioners. Our unique health care model gives us an unparalleled perspective on how systems can be better designed to help consumers 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, each and every day.

We would like to submit the following comments and clarifying questions regarding the new model Drug Management Program notifications and the Medicare Part D Explanation of Benefits (EOB) requirements for this year.

I. Delay Enforcement of the Beneficiary Notifications by Six Months

In general, the late approval of these required notifications makes it extremely difficult to implement them by January 1, 2022. The revised beneficiary notifications include new variable fields (e.g., name and credential of clinical staff) that require system updates at a time of year when most companies have a code freeze.

Recommendation:
We recommend that CMS delay enforcement of the new beneficiary notifications until July 1, 2022, in order to allow time for plans to program and sufficiently test the new letters and data fields.

II. Make Optional the Email Address Fields in the Beneficiary Notifications

The updated initial and secondary beneficiary notification letters include new fields for inclusion of the plan's email address. Since the plan will be including both their web portal and mailing address, it is not clear what email address CMS is expecting to be added. Please clarify that an

email address is optional. If it is not optional, please provide more clarity regarding CMS's expectation for an email address.

Recommendation:
We recommend that CMS expressly state that the addition of an email address to the beneficiary notifications is optional. The beneficiary will already have access to request an appeal of their At-Risk Beneficiary status via the plan's toll-free customer service number and website for submitting an appeal request.

III. Confirm that the Provided "Sample Prescriber Inquiry" and "Sponsor Information Transfer" Letters are Optional Model Letters Only

In the instructions for these two sample letters, CMS notes that these models "could be used" to notify prescribers about their patients' frequently abused drug utilization patterns; or to respond to a new sponsor's request for information regarding an At-Risk Beneficiary from a former sponsor. However, both of these new letters have OMB numbers, implying that they must be used verbatim. Most plans already have communication templates for both of these scenarios and may wish to adapt their letters with certain verbiage from these sample letters. Please confirm that the use of these two new model letters are optional and that plans may continue to utilize their current communications if they wish.

Recommendation*:*
The new sample Prescriber Inquiry and Sponsor Information Transfer letters are optional for sponsors to use. Sponsors may modify these letters or continue to use their existing letters.

IV. Update the Language for the Cancer Exemption

The model initial notice letter includes a note about exemptions on page three. The "cancer" exemption should be updated and expanded upon to clarify that a prior history of cancer does not necessarily qualify as an automatic exemption but, rather, what qualifies is a current diagnosis of cancer-related pain.

Recommendation:
Update the "cancer" exemption to read "active, cancer-related pain."

V. Move PRA Disclosure

The PRA disclosure is now at the end of the Provider/Pharmacy Selection form in both the initial and second notice letter. By placing it at the end of the selection form, there is a chance it won't be sent to the member. This is because the selection form is not required to be sent when only medications are limited.

Recommendation:
Move the PRA disclosure up; before the selection form.

VI. Redesign the Part D EOB

Through the "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses" final rule (CMS-4180-F), CMS required plans to add three new data fields to the Medicare Part D Explanation of Benefits (EOB): Drug Price, Price Change Percentage, and Lower Cost Therapeutic Alternative. The addition of these new fields has

increased the EOB's complexity and page count, making it more difficult for beneficiaries to follow and creating confusion by providing after-the-fact pricing information about drugs they have already purchased.

A. The New Additions Have Led to Increased Consumer Complaints and Administrative Burden

In the "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses" (the 2020 Notice of Proposed Rule Making (NPRM) - Part 2), CMS estimated that the cost for plans to implement the changes would be around $200,000. The three new 2021 Medicare Part D EOB data fields required significant changes to CVS Health systems and processes, in addition to print vendor(s) enhancements. As such, CVS Health's actual setup costs alone were far greater than the CMS estimate. CVS Health produces Part D EOBs on behalf of many Medicare Part D Plans, and mails approximately 11.5 million EOBs every month (138 million annually). In addition, we estimate that the additional information increased the length of the EOB by an average of two pages per EOB which, at a cost of approximately $0.05 per page increased our printing costs alone by approximately $6 million or more per year.

Our average EOB page count in 2020 was six pages. We've seen an increase in 2021 to an average page count of eight pages. We are concerned the addition of the new fields, coupled with an increased page count, is increasing the complexity of the EOB at the expense of clarity, thus increasing beneficiary confusion. This confusion, in turn, increases beneficiary frustration as well as results in more calls and complaints to Customer Care.

In 2021, we have already received a 70% increase in beneficiary calls to Customer Care regarding the EOB compared to 2020. Some example of beneficiary complaints received are:

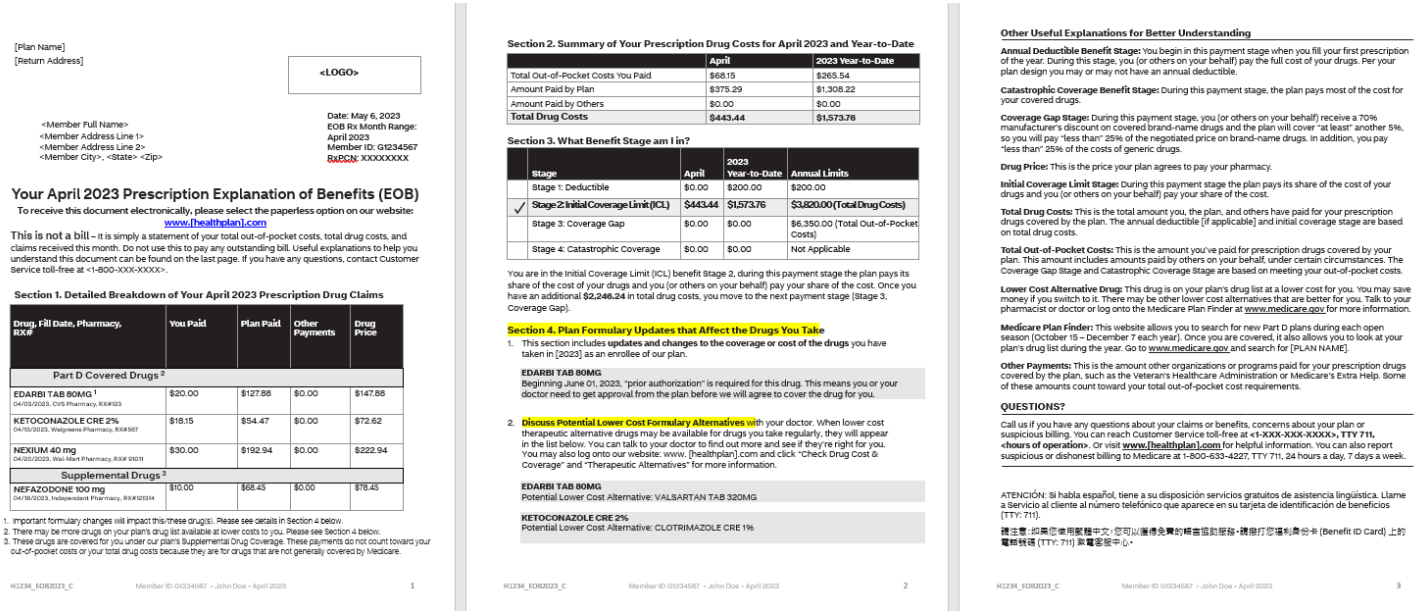
- Beneficiary said she is not happy with the wording of our EOB. She said it's hard for her to understand and she wishes it was clearer.
- Beneficiary is dissatisfied with EOBs. Stated they are very confusing. Beneficiary stated that our EOBs are a joke with a lot of unnecessary things.
- The beneficiary would like to file a complaint about the EOBs and how she thinks that they are poor bookkeeping. The beneficiary stated that the EOBs are confusing and that it is too much for her to try to understand.

***Recommendations*:**
Redesign the 2023 Part D EOB. Since late 2019, CVS Health has had the opportunity to meet several times with CMS, together with the PBM trade association, PCMA, to discuss the EOB. In these meetings, proposals were offered for how the EOB could be re-designed, simplified and made more useful to beneficiaries. We also presented data received from 2019 focus group/online survey where we showed a simulated streamlined 2021 EOB vs. the current design and which showed overwhelmingly positive beneficiary support for the more streamlined version. Representative feedback is below:

- Majority agreed the mock streamlined version had all the information they would need, and the information presented made sense.
- Majority agreed the re-designed version made the important information more visible.
- Many said they wouldn't miss the information that had been removed from the new version.

- Like: “This version is simplified and cleaner, still contains all the relevant information and put it up front, easier to read and understand, and it’s not as intimidatingly long.”
- Dislike: “I think the Drug price change % concept is confusing.”

We also recommend that CMS consider moving the Lower Cost Therapeutic Alternatives field to “Section 4. Plan Formulary Updates that Affect the Drugs You Take” and include drug strength and manufacturer information there as well, if applicable. CVS Health prepared the below draft snapshot to illustrate how a redesigned 2023 EOB would look to the beneficiary. We would be happy to share and discuss our full draft mock-up of the 2023 Part D EOB with CMS, as well.



[Plan Name]
[Return Address]

<LOGO>

<Member Full Name>
<Member Address Line 1>
<Member Address Line 2>
<Member City>, <State> <Zip>

Date: May 6, 2023
EOB Rx Month Range: April 2023
Member ID: G1234567
RxPCN: XXXXXXXX

Your April 2023 Prescription Explanation of Benefits (EOB)

To receive this document electronically, please select the paperless option on our website: www.[healthplan].com

This is not a bill – it is simply a statement of your total out-of-pocket costs, total drug costs, and claims received this month. Do not use this to pay any outstanding bill. Useful explanations to help you understand this document can be found on the last page. If you have any questions, contact Customer Service toll-free at <1-800-XXX-XXXX>.

Section 1. Detailed Breakdown of Your April 2023 Prescription Drug Claims

Drug, Fill Date, Pharmacy, RX#	You Paid	Plan Paid	Other Payments	Drug Price
Part D Covered Drugs [2]				
EDARBI TAB 80MG [1] 04/03/2023, CVS Pharmacy, RX#123	$20.00	$127.88	$0.00	$147.88
KETOCONAZOLE CRE 2% 04/13/2023, Walgreens Pharmacy, RX#567	$18.15	$54.47	$0.00	$72.62
NEXIUM 40 mg 04/20/2023, Wal-Mart Pharmacy, RX# 9101	$30.00	$192.94	$0.00	$222.94
Supplemental Drugs [3]				
NEFAZODONE 100 mg 04/18/2023, Independent Pharmacy, RX#121314	$10.00	$68.45	$0.00	$78.45

1. Important formulary changes will impact this/these drug(s). Please see details in Section 4 below.
2. There may be more drugs on your plan's drug list available at lower costs to you. Please see Section 4 below.
3. These drugs are covered for you under our plan's Supplemental Drug Coverage. These payments do not count toward your out-of-pocket costs or your total drug costs because they are for drugs that are not generally covered by Medicare.

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Section 2. Summary of Your Prescription Drug Costs for April 2023 and Year-to-Date

	April	2023 Year-to-Date
Total Out-of-Pocket Costs You Paid	$68.15	$265.54
Amount Paid by Plan	$375.29	$1,308.22
Amount Paid by Others	$0.00	$0.00
Total Drug Costs	**$443.44**	**$1,573.76**

Section 3. What Benefit Stage am I in?

	Stage	April	2023 Year-to-Date	Annual Limits
	Stage 1: Deductible	$0.00	$200.00	$200.00
✓	**Stage 2: Initial Coverage Limit (ICL)**	**$443.44**	**$1,573.76**	**$3,820.00 (Total Drug Costs)**
	Stage 3: Coverage Gap	$0.00	$0.00	$6,350.00 (Total Out-of-Pocket Costs)
	Stage 4: Catastrophic Coverage	$0.00	$0.00	Not Applicable

You are in the Initial Coverage Limit (ICL) benefit Stage 2, during this payment stage the plan pays its share of the cost of your drugs and you (or others on your behalf) pay your share of the cost. Once you have an additional **$2,246.24** in total drug costs, you move to the next payment stage (Stage 3, Coverage Gap).

Section 4. Plan Formulary Updates that Affect the Drugs You Take

1. This section includes **updates and changes to the coverage or cost of the drugs** you have taken in [2023] as an enrollee of our plan.

EDARBI TAB 80MG
Beginning June 01, 2023, "prior authorization" is required for this drug. This means you or your doctor need to get approval from the plan before we will agree to cover the drug for you.

2. **Discuss Potential Lower Cost Formulary Alternatives** with your doctor. When lower cost therapeutic alternative drugs may be available for drugs you take regularly, they will appear in the list below. You can talk to your doctor to find out more and see if they're right for you. You may also log onto our website: www. [healthplan].com and click "Check Drug Cost & Coverage" and "Therapeutic Alternatives" for more information.

EDARBI TAB 80MG
Potential Lower Cost Alternative: VALSARTAN TAB 320MG

KETOCONAZOLE CRE 2%
Potential Lower Cost Alternative: CLOTRIMAZOLE CRE 1%

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Other Useful Explanations for Better Understanding

Annual Deductible Benefit Stage: You begin in this payment stage when you fill your first prescription of the year. During this stage, you (or others on your behalf) pay the full cost of your drugs. Per your plan design you may or may not have an annual deductible.

Catastrophic Coverage Benefit Stage: During this payment stage, the plan pays most of the cost for your covered drugs.

Coverage Gap Stage: During this payment stage, you (or others on your behalf) receive a 70% manufacturer's discount on covered brand-name drugs and the plan will cover "at least" another 5%, so you will pay "less than" 25% of the negotiated price on brand-name drugs. In addition, you pay "less than" 25% of the costs of generic drugs.

Drug Price: This is the price your plan agrees to pay your pharmacy.

Initial Coverage Limit Stage: During this payment stage the plan pays its share of the cost of your drugs and you (or others on your behalf) pay your share of the cost.

Total Drug Costs: This is the total amount you, the plan, and others have paid for your prescription drugs covered by the plan. The annual deductible [if applicable] and initial coverage stage are based on total drug costs.

Total Out-of-Pocket Costs: This is the amount you've paid for prescription drugs covered by your plan. This amount includes amounts paid by others on your behalf, under certain circumstances. The Coverage Gap Stage and Catastrophic Coverage Stage are based on meeting your out-of-pocket costs.

Lower Cost Alternative Drug: This drug is on your plan's drug list at a lower cost for you. You may save money if you switch to it. There may be other lower cost alternatives that are better for you. Talk to your pharmacist or doctor or log onto the Medicare Plan Finder at www.medicare.gov for more information.

Medicare Plan Finder: This website allows you to search for new Part D plans during each open season (October 15 – December 7 each year). Once you are covered, it also allows you to look at your plan's drug list during the year. Go to www.medicare.gov and search for [PLAN NAME].

Other Payments: This is the amount other organizations or programs paid for your prescription drugs covered by the plan, such as the Veteran's Healthcare Administration or Medicare's Extra Help. Some of these amounts count toward your total out-of-pocket cost requirements.

QUESTIONS?

Call us if you have any questions about your claims or benefits, concerns about your plan or suspicious billing. You can reach Customer Service toll-free at **<1-XXX-XXX-XXXX>, TTY 711, <hours of operation>**. Or visit **www.[healthplan].com** for helpful information. You can also report suspicious or dishonest billing to Medicare at 1-800-633-4227, TTY 711, 24 hours a day, 7 days a week.

ATENCIÓN: Si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame a Servicio al cliente al número telefónico que aparece en su tarjeta de identificación de beneficios (TTY: 711).

請注意：如果您使用繁體中文，您可以獲得免費的輔書協助服務。請撥打您福利身份卡 (Benefit ID Card) 上的電話號碼 (TTY: 711) 聯繫客服中心。

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B. The EOB Should Direct Beneficiaries to Available RTBTs

The “Price Change Percentage” field presents confusing, retrospective pricing information about drugs beneficiaries have already purchased. Instead, we recommend encouraging beneficiaries to use available online Beneficiary Real Time Benefit Tool (RTBTs) to find the most current drug pricing for drugs they are taking or have been prescribed.

Per the 2022 Final Rule, CMS is requiring all Part D plan sponsors to implement a RTBT that includes real-time cost-sharing information for beneficiaries; formulary status and any clinically appropriate formulary alternatives, where appropriate; and any utilization management requirements, such as step therapy, quantity limits, and prior authorization, applicable to each alternative medication. Plans are required to have this tool available electronically and via the plan’s customer service call center by January 1, 2023. CMS expects that a plan’s RTBT will comply with current non-discrimination obligations, including accessibility to individuals with vision or hearing impairments. Information must be understandable to the average patient.

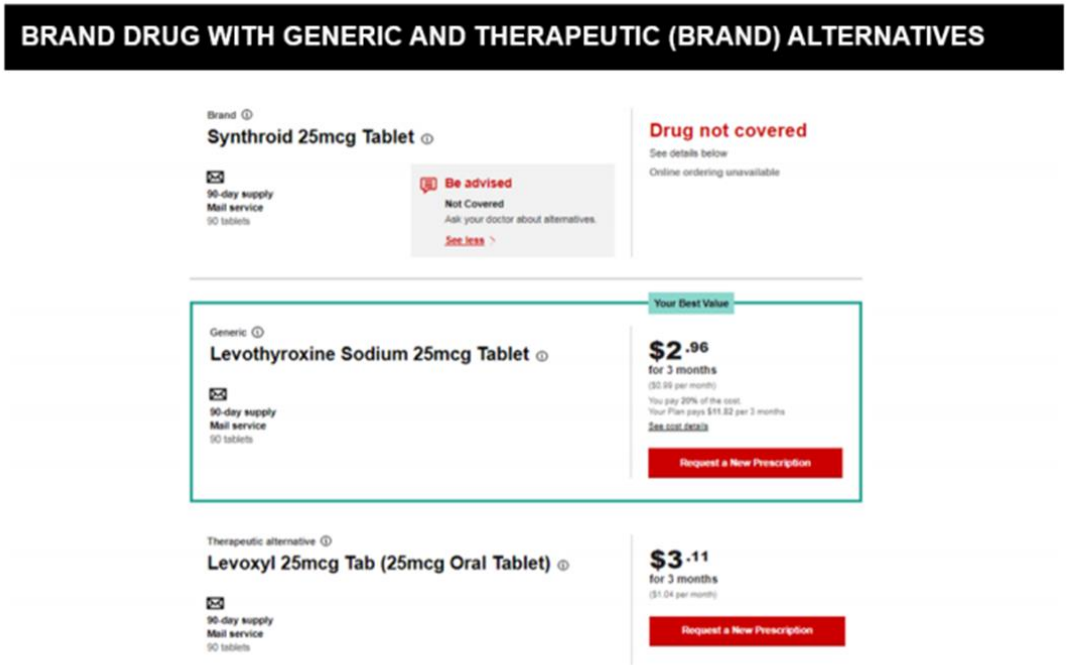
We strongly believe that in addition to the potential use of electronic EOBs as a mechanism for informing and educating beneficiaries about their benefit, beneficiaries should also be using the online tools available to them.

***Recommendation**:*
All plans to remove the "Price Change Percentage" field and include information about how members can access RTBTs.

To illustrate this, Caremark's "Check Drug Cost & Coverage" tool allows beneficiaries to determine the cost of a prescription and see potential drug alternatives. Here are some facts about this tool:

- Pricing will always show both 90-days' supply and 30-days' supply options, if available.
- Provides pricing for Brand (if searched) and Generic equivalent / most prescribed generic alternative automatically.
- If a drug is not covered, it will display with no price. An explanation that the drug is not covered, as well as other coverage notes will be displayed in the gray box labeled "Be advised"
- Along with highlighting the Best Price option in a green box, relevant coverage information will be displayed, such as Prior Authorization, Quantity Limits, or Step Therapy requirements. Clicking on "See Details" under "Drug Cost", will show the breakdown of the Total Cost Details. "Total Cost" is defined as the Negotiated Drug Cost which is the total amount of the prescription in accordance with the beneficiary's applicable benefit plan, which may be a deductible, a percentage of the prescription price, a fixed amount or other charge PLUS the balance, if any, paid by the benefit plan.

Our "Therapeutic Alternatives" tool gives the beneficiary information about lower cost alternatives. Generic alternatives will be shown first, followed by brand alternatives. The following screenshot illustrates the online real-time experience that is available today for CVS Health beneficiaries:



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Washington, DC 20004

C. Remove the Requirement that Beneficiaries Must Affirmatively Opt-In to Electronic Delivery of the EOB

Requiring mailing of EOBs, unless an enrollee opts-in to electronic delivery, was established as a policy in 2005. Sixteen years later, email and electronic delivery has gained widespread acceptance among consumers. Electronic delivery of EOBs allows beneficiaries secure and immediate access to EOBs from anywhere there is an internet connection. We recommend that CMS allow plans to delivery EOBs electronically without prior authorization from the beneficiary in the same way as permitted for documents such as the Evidence of Coverage and formularies. This would significantly reduce administrative costs and would result in a more secure method of delivery than mailing, especially for beneficiaries who do not have a permanent home address.

Recommendation:
Allow for the electronic delivery of EOBs without beneficiary prior authorization.

* * *

CVS Health is committed to working with you to improve beneficiary notifications. We would be happy to respond to any follow-up questions you may have.

Sincerely,

Melissa Schulman
Senior Vice President
Government & Public Affairs