Medicare Prescription Drug Benefit Program CMS-10141, OMB 0938-0964
60-Day Comments and Responses

Topic	Comment	CMS Response
Precluded Provider	Now that the Precluded Provider letter has a CMS form number and OMB number, can the "Last Updated <Date>" be removed from the bottom.	See response to question #4 in the December 14, 2018 HPMS memo "Preclusion List Requirements Frequently Asked Questions," which states "Plans are not required to use this version for the required beneficiary notice, however, the letters should include the information specified in the sample notice." OMB-approved versions of model (e.g., sample) forms must convey the vital information in the content, but are not required to repeat content verbatim. Flexibilities permitted with respect to model materials are described in regulation at 42 CFR § 423.2267. Sponsors may choose not to include fields they do not find pertinent to the notice. Additional language has been added to the instructions on the letter to emphasize that use of the letter is optional.
DMP	The 2021 version of the Initial DMP Notice, Second Notice, Alternate Second DMP Notice, and Sample Prescriber Inquiry Letter replaces "For More Information and Help with This Notice" with "Sincerely, [NAME AND CREDENTIAL OF CLINICAL STAFF]". Our question is whether this signature is intended to name the specific clinician who reviewed the case or whether a generic signature referencing the drug management program is acceptable? If the intention is to name the specific clinician, we have privacy concerns.	CMS agrees with the recommendation and has updated the initial and second notices accordingly.
DMP	With expected changes to all Drug Management Program templates, there will be a significant work effort required for implementation. To successfully implement these changes and push them into production, we request 4-6 months between final rule and effective date.	CMS acknowledges this concern. Consistent with 42 CFR § 423.153(f)(5)-(7), DMP notices must use language approved by the Secretary. The revised notices are pending OMB approval through the PRA process. The regulatory changes associated with proposed changes to the DMP notices became effective March 22, 2021, applicable to coverage beginning January 1, 2022.

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DMP	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.*	CMS agrees with the recommendation and has updated the initial and second notices accordingly.
DMP	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."*	CMS agrees with the recommendation and has updated the initial notice accordingly.
DMP	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.*	CMS regulations at 42 CFR § 423.153(f)(2)(i)(A) require sponsors to send written information to relevant prescribers as part of required case management for potential at-risk beneficiaries. However, CMS does not have standardized language for such communication. We confirm that the Prescriber Inquiry Letter and Information Transfer Memo are CMS model documents, and use of the specific language or format of these documents is optional. Flexibilities permitted with respect to standardized and model materials are described in regulation at 42 CFR § 423.2267. We believe that the current instructions for the Model Prescriber Inquiry Letter clearly state that plans may use all or part of the language in this model, modify the language, or create their own language. We have revised instructions in the Information Transfer Memo to more clearly state that the language and format of the memo is optional.

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DMP	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.*	CMS agrees with the recommendation and has updated the initial, second, and alternate second notice letters accordingly. Plans will not be required to include an email address.
DMP	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.*	CMS acknowledges this concern. Consistent with 42 CFR § 423.153(f)(5)-(7), DMP notices must use language approved by the Secretary. The revised notices are pending OMB approval through the PRA process. The regulatory changes associated with proposed changes to the DMP notices became effective March 22, 2021, applicable to coverage beginning January 1, 2022.

Topic	Comment	CMS Response
DMP	We encourage CMS to limit date fields contained within the initial notice which lead to member confusion as evidenced by the plan during member engagement. For example; the following language is misleading "your access to these medications will change on [insert date 30 days from the date of this notice]". Per DMP guidance the Implementation Start-date is the effective date of the coverage limitation(s) or the date of the Second Notice. This date must be within 60 days after the Notification Start-date and not later than one day after a Notification End-date. Therefore, inserting a date of "30 days from the date of this notice" is confusing and inaccurate. Furthermore, if additional information is received within the allotted timeframe the beneficiary's coverage may not change. UnitedHealthcare recommends removing the additional date field and changing the language to align with CMS guidance "your access to these medications may change within 60 days from the date of this notice". UHC encourages CMS to limit date fields contained within the initial notice which lead to member confusion as evidenced by the plan during member engagement. UnitedHealthcare recommends removing the additional date field and changing the language to the following: "Based on information available at the time of our review we intend to limit your access in the following ways"	CMS agrees that, depending on the circumstances of the case, a DMP limitation may be implemented up to 60 days from the date of the Initial Notice. However, the limitation could be as soon as 30 days from the date of the Initial Notice, and it’s important that the beneficiary is aware of the shortest potential timeframe. We have modified the text in the initial notice based on this comment, but have retained some of the date fields.

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DMP	We encourage CMS to add a heading to the Alternate Second Notice similar to the initial notice (NOTICE OF INTENT TO LIMIT YOUR ACCESS TO CERTAIN PART D DRUGS) and second notice (YOUR ACCESS TO CERTAIN PART D DRUGS IS LIMITED). UnitedHealthcare recommends the following heading to the Alternate Second Notice "YOUR ACCESS TO CERTAIN PART D DRUGS WILL NOT BE LIMITED". This provides the beneficiary immediate visibility that their access is not limited. Moreover, it will alleviate any anxiety associated with opioid access.	CMS agrees with the recommendation and has updated the alternate second notice accordingly.
DMP	UHC requests Beneficiary's utilization of frequently abused drugs (opioids and benzodiazepines). There are security concerns associated with disclosing this type of information to beneficiaries who may have their access limited based on this type of review. In the alternative, UnitedHealthcare recommends something to the effect of "UnitedHealthcare Case Management Staff" without specifically calling out someone's full name and credentials related to limiting access to frequently abused drugs.	CMS agrees with the recommendation and has updated the initial, second, and alternate second notices accordingly.
Part D EOB	The addition of 3 new data fields per CMS' final rule (4180-F) 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.	CMS did not propose any changes for the Part D EOB; therefore, this comment is outside scope of this renewal. Consistent with 42 CFR § 423.128(e)(5), all plans must include any cumulative percentage increase in the negotiated price beginning with the first claim of the current benefit year.

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Part D EOB	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. ***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.*	CMS did not propose any changes for the Part D EOB; therefore, this comment is outside scope of this renewal. We will consider this feedback for future revisions.

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Part D EOB	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. 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*.	Per 42 CFR § 423.128(e)(5), all plans must include any cumulative percentage increase in the negotiated price beginning with the first claim of the current benefit year. This was established to provide greater transparency on drug prices for the beneficiary and encourage them to speak with their providers if they are seeing increases month over month. We do recognize the benefits of using RTBT for implementing further transparency to the beneficiary and believe that these tools can be used together, rather than a plan using one exclusively over the other.

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Part D 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.*	CMS did not propose any changes to the delivery requirements for the EOB, which are codified at 42 CFR § 423.2267(d). Pursuant to that regulation, a sponsor is only permitted to deliver the Part D EOB electronically with prior authorization from the enrollee. The comment is outside scope of this renewal.
Part D EOB	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.	CMS did not propose any changes for the Part D EOB; therefore, this comment is outside scope of this renewal. We will consider this feedback for future revisions.