CMS Response to Public Comments Received for CMS-10716 30-Day Notice

The Centers for Medicare & Medicaid Services (CMS) received comments from seven Medicare Advantage (MA) health plans, two advocacy organizations, and two individuals on the 30-Day Notice for CMS-10716, the Applicable Integrated Plan Coverage Decision Letter. The following is a summary of their comments.

Comment: Serena Macarelli included a quote from the "Form Instructions for the Applicable Integrated Plan Coverage Decision Letter" stating that "this letter must be used in place of the Notice of Denial of Medical Coverage (or Payment) form (CMS-10003-NDMCP)" and questioned whether this means that the IDN letter will still be used for Medicare-only line of business.

Response: Medicare health plans that are not defined as applicable integrated plans under 42 CFR 422.629(a) continue to be required to issue the Notice of Denial of Medical Coverage (or Payment) (Form CMS-10003-NDMCP), also known as the Integrated Denial Notice (IDN), upon denial, in whole or in part, of an enrollee's request for coverage and upon discontinuation or reduction of a previously authorized course of treatment.

Comment: CVS Health recommended that CMS require CMS-10716 be used without changes or additions by states. The commenter stated that changes or additions by states would complicate the letter and create administrative burden for plans to use different versions of the letter in different states.

Response: We acknowledge the commenter's concern, and we support the goal of reducing complexity and administrative burden whenever possible. However, we decline to make additional edits. We note that there is very limited flexibility for state-by-state specificity within CMS-10716, and we believe the letter presents a reasonable balance between standardized language and state flexibilities. Further, we note that the Bipartisan Budget Act of 2018 directed CMS to establish unified appeals and grievance procedures most protective to the enrollee and that take into account differences under state Medicaid plans. As provided in 42 CFR 422.629(c), states may set standards that are more protective of enrollees in connection with timeframes and notices. CMS-10716, therefore, provides applicable integrated plans with flexibility to add state-specific timelines as documented in their state Medicaid agency contracts required under 42 CFR 422.107. We also note that, because applicable integrated plans also operate Medicaid managed care organizations in these states, they already should have familiarity with state variation.

Comment: CCA recommended consistency in language and wording between similar sections in the "Applicable Integrated Plan Coverage Decision Letter" and the "MMP Integrated Denial Notice." The commenter generally noted that there are portions of each letter that are similar in content but include slightly different wording, but the commenter did not identify inconsistencies or make any specific language recommendations.

Response: We appreciate the commenter's feedback but decline to make any additional changes at this time. Whenever possible, we have made every effort to use consistent font, formatting,

and language to align with other notices developed for Medicare-Medicaid Plans under the Financial Alignment Initiative capitated model demonstrations and to incorporate best practices informed, in part, by consumer research.

Comment: CCA requested that the "Form Instructions for the Applicable Integrated Plan Coverage Decision Letter" clarify that the standard font size is 12. The commenter noted that the form instructions state, "The letter must be provided in 12-point Times New Roman font equivalent or larger," but the font used in the proposed Applicable Integrated Plan Coverage Decision Letter is 11-point Arial font. In addition, an individual commenter, Serena Macarelli, stated that all Medicare letters are 12-point Times New Roman font and recommended consistency across the board.

Response: We acknowledge the commenters' requests but decline to make these changes. The form instructions are consistent with 42 CFR 422.2264(a) and 423.2264(a) and Section 100, Required Materials, of the Medicare Communications and Marketing Guidelines, which states, "Materials must be in 12-point Times New Roman font or equivalent." We clarify that 11-point Arial font is equivalent to or slightly larger than 12-point Times New Roman font. In addition, during consumer testing of model materials, participants have indicated that 11-point Arial font is easier to read than 12-point Times New Roman font.

Comment: CCA questioned whether plans have the flexibility to include additional identifying information below the section heading titled "Service/item this letter is about" if the information is not required by the state.

Response: We clarify that plans have the flexibility to include additional identifying information that is not required by the state. Please see the revised form, form instructions, and Exhibit A, the Change Crosswalk.

Comment: The Medicare Rights Center recommended that CMS consider ensuring that "your Medicare and Medicaid [Insert state-specific term for Medicaid, if applicable] services" identifies both that it is Medicaid and uses a state-specific term (rather than allowing the option for plans to remove the word "Medicaid" and substitute the state-specific term). In addition, an anonymous commenter recommended using "Medicare" and "Medicaid" instead of using state-specific terms that could be confusing to members.

Response: We appreciate the commenters' feedback and will include an instruction to plans to add "(Medicaid)" after the first reference of the state-specific name if the state-specific name does not include the word "Medicaid." We decline to remove the instruction to include a state-specific term for "Medicaid," if applicable, as we believe the state-specific term for "Medicaid" is generally more recognizable to beneficiaries and caregivers than the broader term "Medicaid." Please see the revised form instructions and Exhibit A, the Change Crosswalk.

Comment: PrimeWest Health proposed to add the phrase "coverage of" a service or item in several locations to more accurately reflect the action of the plan.

Response: We acknowledge the validity of the commenter's statement; however, we decline to make this change. We believe the suggested change adds complexity to the language without adding meaningful information for the beneficiary.

Comment: Health Partners recommended updating "<service *or* item>" to "<medical services/items *or* Part B drug *or* Medicaid drug>" throughout the letter, stating that it would provide more specificity in the communication to enrollees.

Response: We support the commenter's desire to improve clarity and specificity for beneficiaries; however, we decline to make this change. There are two sections within the notice that allow the plan to insert more specific language to provide clarity: the section titled "Service/item this letter is about:" and the second paragraph of the notice. Additionally, we believe the terms "service" and "item" are easier to understand than the recommended language.

Comment: The Medicare Rights Center stated that there is currently no identification of a denial of service under Medicare when the service is covered under Medicaid and noted that coverage under different benefits can impact payment rates and, therefore, create access issues. The commenter encouraged CMS to explore ways to communicate this information in a way that is understandable to beneficiaries.

Response: We appreciate the commenter's concern, and we agree that information on how a service or item is covered by either Medicare or Medicaid can be helpful to beneficiaries and their providers or representatives when appealing. In response to similar comments received during the 60-day notice comment period, we added language to the form instructions to more clearly direct plans to communicate the Medicare and Medicaid criteria the plan has considered when making the decision and to describe how both coverage rules were applied to the beneficiary's specific case. We believe these changes are sufficient to address the commenter's concern and decline to make additional edits.

Comment: The Medicare Rights Center acknowledged and expressed appreciation for CMS revisions to the language regarding the plan's reason for the denial. The commenter also expressed appreciation for CMS edits to the "Form Instructions for the Applicable Integrated Plan Coverage Decision Letter" that included guidelines for plain language and instructions for plans to take steps to ensure that members can understand the letter, including conducting routine consumer testing of plan language. However, the commenter reiterated a request previously submitted during the 60-day notice comment period that CMS provide model language for common reasons for denials and monitor plans' denial language to ensure readability.

Response: We appreciate the comments on this section but decline to make additional changes. We are unable to provide model language for common reasons for denials at this time. As we move forward with implementation, we will consider CMS' capacity to conduct retrospective reviews of specific denial language plans use to inform future revisions to the form and accompanying instructions.

Comment: CVS Health reiterated a comment previously submitted during the 60-day notice comment period, stating that plans may not be able to include the contact information for another payer when a Medicaid service or item is not covered by the plan, as stated in the form instructions, because plans do not receive timely information about the responsible payer. To address this issue and reduce the beneficiary's confusion about the responsible payer, the commenter suggested that CMS clarify that plans are only required to provide contact information for the beneficiary's care manger, who can help the beneficiary get coverage for the service or item.

Response: As indicated in our response to 60-day notice public comments, we acknowledge the validity of the commenter's concerns about timely information exchange regarding a beneficiary's Medicaid coverage for the services or items not covered by the plan and the potential for beneficiary confusion. However, we continue to believe that including available contact information for the responsible payer in the form allows the beneficiary to obtain coverage for the denied service or item as quickly as possible. Moreover, inclusion of such information is consistent with the requirement that plans offer their members help in seeking coverage for a Medicaid-covered service or item, consistent with the requirements for all D-SNPs under 42 CFR 422.562. In addition to contact information for the responsible payer, directing the beneficiary to contact the care manager for help is another way of providing this required assistance.

Comment: Serena Macarelli questioned whether plans have the option to add peer-to-peer reconsideration language.

Response: We understand that peer-to-peer reconsideration language states that a provider can contact the plan to discuss the reason for the plan's denial. However, this alternative cannot replace or delay the beneficiary's appeal rights under 42 CFR 422.633. We caution plans to only include this information in such a way that it does not appear as an additional step the beneficiary must take before appealing.

Comment: PrimeWest Health questioned whether the hours of operation for the plan phone numbers need to be included in the body of the letter.

Response: We clarify that the hours of operation for the plan phone numbers do not need to be included in the body of the letter, with the exception of the plan's member services number listed in the section titled "Get help and more information."

Comment: Health Partners recommended replacing the specific date by which the enrollees must file an appeal with "60 days of the date of this notice." The commenter also recommended replacing the specific date by which enrollees must ask to continue to receive the service or item with "10 days from the date of this notice or before the service is stopped or reduced, whichever is later." The commenter noted that the requested language is used in the Notice of Denial of Medical Coverage (or Payment) form (CMS-10003-NDMCP) and cited administrative burden for having different requirements in different materials.

Response: We acknowledge the commenter's concerns; however, we believe plans already need to calculate the deadline for receipt of an appeal for their internal record keeping. Therefore, inserting the exact date into the form is the only additional burden for plans to meet this requirement. Additionally, when we consumer tested this form, we found that beneficiaries and their caregivers reacted favorably to inclusion of an exact date rather than a timeframe.

Comment: For the section titled "There are two kinds of appeals," Commonwealth Care Alliance (CCA) requested that some of the bracketed language be standardized for both denial options (i.e., Part B drug and any other service or item) in order to avoid errors.

Response: We appreciate the commenter's concern; however, we decline to make this change. The use of instructions to plans (in blue italicized text and brackets) allows plans to customize this section of the notice. We believe these language choices reduce complexity and improve readability and comprehension for the beneficiary.

Comment: The last paragraph of the section titled "There are two kinds of appeals" discusses the possibility that a plan may take more time to review an appeal. PrimeWest Health noted that this paragraph does not apply to Part B drugs under 42 CFR 422.590(c). The commenter did not make any recommendation for changes to this language.

Response: We acknowledge the accuracy of the commenter's statement. A plan cannot extend the time to make a reconsidered determination for a Part B drug, in accordance with Medicare regulations. We have added an instruction to remove this paragraph when the letter is sent for a denial of a Part B drug. Please see the revised form, form instructions, and Exhibit A, the Change Crosswalk.

Comment: UnitedHealthcare (UHC) recommended that the notice be revised so that the fast appeal language only applies to pre-service/coverage denial notices, allowing plans to suppress the language for post-service/payment denial notices throughout the notice. Specifically, UHC requested that the notice be revised to allow plans to insert or remove the fast appeals language as appropriate.

Response: We appreciate the commenter's recommendation. In response to similar comments received during the 60-day notice comment period, we added language to clarify that the beneficiary cannot get a fast appeal for services they already received. We decline to make additional changes at this time.

Comment: In the section titled "How to appeal," PrimeWest Health suggested adding a request for the beneficiary's phone number. Also in this section, this commenter requested to add "ID" to "Your member number with our plan."

Response: We believe these suggested additions are not necessary for members to file an appeal, and adding them as optional would create possible beneficiary confusion as to whether the information is required. We note that the information in this section is similar to the Notice of Denial of Medical Coverage (or Payment) form (CMS-10003-NDMCP).

Comment: The Medicare Rights Center recommended edits to the section titled "How to keep getting your <service *or* item> during your appeal" to clarify that for services to continue, beneficiaries must both file an appeal and submit a request for the services to continue. The commenter also recommended edits to highlight that beneficiaries are not responsible for the cost of continued services if the appeal decision is unfavorable.

Response: We appreciate the comments on this section and are adding language to clarify that a beneficiary must file an appeal and submit a request for a service or item to continue. We will consider adding language to clarify that the beneficiary is not responsible for the cost of continued services if the appeal decision is unfavorable in future versions of this notice. Please see the form and Exhibit A, the Change Crosswalk.

Comment: PrimeWest Health recommended edits to the second and third bullets in the section titled "How to keep getting your <service *or* item> during your appeal."

Response: We appreciate the commenter's recommendation. We decline the suggested edits in the second bullet because we believe they do not communicate that a beneficiary's service or item will not increase or decrease during an appeal. We have accepted the edits in the third bullet which we agree improve readability. Please see the revised form and Exhibit A, the Change Crosswalk.

Comment: PrimeWest Health requested that CMS change the term "Fair Hearing" to "State Appeal" to match new terminology in the plan's service area.

Response: We appreciate the commenter's concern and have updated the form to allow plans to insert a state-specific term in parentheses. We are keeping the term "Fair Hearing" because we believe it is more widely understood by beneficiaries, advocates, and other health plans. Please see the revised form, form instructions, and Exhibit A, the Change Crosswalk.

Comment: The Medicare Rights Center reiterated a concern previously submitted during the 60-day notice comment period about the lack of state fair hearing information and recommended that CMS reconsider its inclusion.

Response: In response to comments received during the 60-day notice comment period, we added a short reference to Medicare Level 2 appeals and state fair hearings processes in the section titled "What happens next." We decline to make any additional changes. We intentionally simplified this form by omitting information on state fair hearings because such information is not actionable for beneficiaries until after the plan denies the beneficiary's appeal. Further, when testing this language, beneficiaries and caregivers found including fair hearing instructions to be confusing because it made them uncertain of the first step in the appeal process.

Comment: PrimeWest Health requested that the plan address and fax number in the section titled "What to do if you need help with your appeal" be formatted in a way that is easier to read.

Response: We have made edits and changes to the format of this section to improve readability. Please see the revised form and Exhibit A, the Change Crosswalk.

Comment: In the section titled "Get help and more information," PrimeWest Health requested that CMS include language to identify that calls are toll-free.

Response: We thank the commenter for their suggestion but decline to include this language. We believe that beneficiaries are generally aware that 1-800 numbers are toll-free.

Comment: The Medicare Rights Center reiterated previously submitted comments regarding translation, urging CMS to require that plans provide denial notices in the predominately spoken languages of their service areas and to require the inclusion of a multi-language insert with information about translation services for other languages. Justice in Aging also reiterated a comment submitted during the 60-day notice comment period that CMS follow up with plans on consumer testing of translations and their desire to see routine consumer testing of health plan language for English as well as non-English documents. The commenter also reiterated their previous request that CMS encourage plans to send translated decision letters to known members with limited English proficiency (LEP), even in situations where translation is not required, and to reach out to members to ensure member comprehension in instances where the plan can only send an English-language decision letter.

Response: As indicated in our response to 60-day notice public comments, we appreciate the commenters' perspectives on the translation of plan materials; however, the comments on CMS requirements for MA plan translation of vital beneficiary communication materials at 42 CFR 422.2268(a)(7) are outside the scope of this PRA submission. However, we will consider ways to encourage plans to provide translated material to members with LEP when translation is not required.

Comment: The Medicare Rights Center recommended that CMS explore the creation of a standardized form that beneficiaries can choose to use to initiate their appeal, rather than having to draft an appeal themselves.

Response: We appreciate the commenter's recommendation; however, the comment is outside the scope of this PRA submission.

Comment: SCAN submitted a "comment crosswalk" that described circumstances under which the plan would issue coverage decision letters to beneficiaries.

Response: CMS identified technical issues with these comments and addressed these issues directly with the plan.

Comment: We received comments from Anthem, Inc., regarding the CY 2021 draft model appeals letters for applicable integrated plans: "Letter about Your Right to Make a Fast Complaint" and "Appeal Decision Letter."

Response: These comments are outside of the scope of this PRA submission for the "Applicable Integrated Plans Coverage Decision Letter."