CMS Response to Public Comments Received for CMS-10716

The Centers for Medicare & Medicaid Services (CMS) received 16 comments from Medicare Advantage health plans, trade organizations, and advocacy organizations on CMS-10716, the Applicable Integrated Plan Coverage Decision Letter. The following is a summary of these comments.

Comment: Several commenters expressed support for the formatting and clear language CMS used in drafting CMS-10716 and the accompanying form instructions.

Response: We thank these commenters for their support of CMS-10716 form.

Comment: Some commenters requested clarification on when to send this notification. One commenter requested clarification on whether form CMS-10716 should be used for Part D coverage determinations as well as for Part C organization determinations. Another commenter noted that the form instructions do not indicate whether a denial letter must be issued when a benefit is covered under one program, Medicare or Medicaid, but not the other and recommended that CMS clarify whether applicable integrated plans are required to issue a denial if a benefit is covered under Medicaid but not Medicare or vice versa. One commenter requested CMS include language in the form to communicate situations where there is a Medicare denial but a Medicaid approval.

Response: Under 42 CFR 422.629(a), applicable integrated plans must use the integrated organization determination process described in 42 CFR 422.631 in lieu of the Part C organization determination process at 42 CFR 422.566 and the Medicaid adverse benefit determination requirements at 42 CFR 438.404. As provided in 42 CFR 422.631(d)(1), applicable integrated plans must send a notice of an integrated organization determination in cases where a service or item is being denied under Medicare Part C and Medicaid criteria. Part D coverage determinations are not included in the integrated organization determination process under 42 CFR 422.629(a). Therefore, applicable integrated plans will continue to use form CMS-10146, Notice of Denial of Medicare Prescription Drug Coverage, for Part D coverage determination denials.

We clarify that this form should not be sent in instances where the item or service requested is covered in full, regardless of Medicare or Medicaid coverage for the item or service. Communicating whether the decision to cover the item or service is based on Medicare or Medicaid criteria would not be an appropriate use for this notice. We have made updates to the supporting statement and plan instructions to better communicate these requirements. Please see the revised form and Exhibit A, the Change Crosswalk.

Comment: Some commenters expressed concern that a separate notice for a subset of dual eligible special needs plans (D-SNPs) could lead to increased confusion and opportunity for error. The commenters noted that there is an increased risk of confusion when several types of D-SNPs exist in one market or a plan has D-SNPs operating in multiple states.

A few commenters recommended that all states and all D-SNPs use same format to alleviate administrative burden for plans that operate in multiple states. One commenter requested CMS find a balance between standardized language and flexibilities for states.

Response: While we acknowledge the potential for increased complexity for parent organizations with applicable integrated plans and other D-SNPs, we also note that applicable integrated plans are subject to unified appeals and grievance procedures under 42 CFR 422.629-634. As required under the Bipartisan Budget Act of 2018, this unified process must include a single written notice with all grievance and appeals rights and notices written in plain English and available in languages and formats that are accessible to enrollees. Therefore, one format that works for both applicable integrated plans and other D-SNPs is not possible.

Regarding variation by state, we note that there is very limited flexibility for state-by-state specificity within CMS-10716 because the form applies to plan-level appeals processes and includes limited information about Medicaid appeals procedures. However, we note that the Bipartisan Budget Act 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 as required under 42 CFR 422.107. We also note that because applicable integrated plans also operate Medicaid managed care organizations in these states, they should already have familiarity with state variation.

Comment: One commenter requested CMS provide the option for plans to use the form as soon as an integrated process is in place rather than waiting until calendar year 2021. Another commenter recommended that the final version of this form be released no later than February 2020 to allow time for plans and the states in which they operate to customize the form for their market.

Response: We thank the commenters and agree that timely finalization of this form is important for plans implementing the new notice requirements. We do not believe it is necessary for plans to use this form prior to calendar year 2021, as the unified appeals processes are not required under 42 CFR 422.629-634 until January 1, 2021.Other than a provision in New York's state Medicaid agency contract addressing integration of grievance and appeals procedures for a limited subset of plans, CMS is not aware of any other states that have implemented unified appeals and grievance procedures via a requirement in their state Medicaid agency contract for 2020.

Comment: One commenter recommended that CMS use different font types for the form's section headers so they stand out and mirror those in form CMS-10003.

Response: We thank the commenter for this perspective. We changed the font and formatting of the form to more closely align with other CMS notices developed for Medicare-Medicaid Plans under the Financial Alignment Initiative capitated model demonstrations to incorporate best practices informed in part by consumer research. Using one font or typeface consistently and

adding contrast through increased size and emphasis can improve readability for those with and without visual limitations. Rather than using mixed fonts, we accented headings in bold and increased the font size, and we emphasized additional areas of text in bold.

Comment: We received some comments on the language in the opening section of the form. One commenter expressed concern that this language does not include the purpose of the form. Two commenters noted that the language in the opening section applied only to fully integrated D-SNP (FIDE SNPs), which operate from a single legal entity, and not to highly integrated D-SNP (HIDE SNPs), which can operate Medicare and Medicaid plans under different legal entities.

Response: We believe the purpose of the form is clearly communicated in the bolded text below this opening paragraph. We included language in the first paragraph of the form to better describe the entity that is sending this notice but agree based on these comments that some technical edits to the language were warranted to ensure the language worked equally well for FIDE SNPs and HIDE SNPs. Please see the revised form and Exhibit A, the Change Crosswalk.

Comment: One commenter requested that CMS clarify if plans are able to substitute the state-specific term for Medicaid for the word “Medicaid”.

Response: Our intent is for plans to substitute the state-specific term for Medicaid for “Medicaid” in this form. We have made edits in the form and Exhibit A, the Change Crosswalk to better communicate this flexibility.

Comment: One commenter noted that the form does not include language for circumstances where the plan partially denies a service or item.

Response: We thank the commenter for identifying this omission and have added this language in the revised form and Exhibit A, the Change Crosswalk.

Comment: Some commenters made recommendations regarding the section titled "Our plan <denied or reduced or stopped or suspended> [Insert if applicable: payment for] the <service or item> listed below:” One commenter noted that the plan instructions on the information that should be inserted in this section are duplicative and suggested alternative language. Another commenter recommended that CMS provide model language for common reasons for denials and to monitor plans' denial language to ensure readability.

Response: We appreciate the comments on this section. We have made changes to the form and form instructions to clarify that the intent of the first paragraph of this section is to briefly name the service or item that the form concerns and that the second paragraph should be used to more fully describe the reason the plan denied coverage of the service or item. We are also unable to provide model language for common reasons for denials at this time and 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: Two commenters noted an inconsistency between the form and the form instructions regarding the rationale plans should provide for their decisions.

Response: We thank commenters for noting this inconsistency. We have revised the form instructions to match the plan instruction in the form. Please see the revised form instructions and Exhibit A, the Change Crosswalk.

Comment: Some commenters suggested that the form should direct plans to be explicit about the source of coverage, either under the Medicare or Medicaid benefit, for the service or item referenced in the form. One commenter stated that coverage under different benefits can impact payment rates and, therefore, beneficiary access to the service or item. Commenters noted that specificity about coverage empowers beneficiaries or their advocates in the appeal process.

Response: We agree with commenters 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. To address the concerns of the commenters, we have 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. Please see the revised form instructions and Exhibit A, the Change Crosswalk.

Comment: One commenter stated 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 suggests 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: 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 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 include an offer of help in seeking coverage for a Medicaid-covered service or item, as required of all D-SNPs under 42 CFR 422.562. Directing the beneficiary to contact the care manager for help is one way of providing this required assistance.

Comment: One commenter questioned whether plans have the option to add peer-to-peer or reconsideration language to the plan decision language.

Response: We understand that this 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 with the form in such a way that it does not appear as an additional step the beneficiary must take before appealing.

Comment: Two commenters requested that CMS hard code the language choices in the form, such as "doctor or health care provider" and "service or item." The commenters suggested that

limiting customized language would reduce unnecessary variation across states and make the form less burdensome for plans.

Response: We thank the commenters for their input; however, we disagree with the recommendation to limit customization of the form. We believe these language choices reduce complexity and improve readability for the beneficiary. We also clarify that these language choices are not determined by the state but, rather, are at the plan's discretion, and we have added language in the form instructions to clarify this point. Please see the revised form instructions and Exhibit A, the Change Crosswalk.

Comment: One commenter requested clarification on whether to use the Medicare or Medicaid timeframe when communicating a denial.

Response: As provided in 42 CFR 422.629(c), states may set standards that are more protective of enrollees in connection with timeframes and notices. We have therefore revised the form and form instructions to accommodate shorter state-specific time frames that are specified in the state Medicaid Agency contract with the plan.

Comment: Some commenters recommended that CMS explain the terminology "Part B drugs" in the form because of concerns it would not be understood by beneficiaries.

Response: We agree with these commenters that the terminology "Part B drugs" is not meaningful information for beneficiaries. We clarify that references to Part B drugs appear in plan instructions identified as blue italicized text and within brackets. We have added additional language to the form instructions to note that the plan should remove all blue italicized text from the form before sending to the beneficiary. Please see the revised form instructions and Exhibit A, the Change Crosswalk.

Comment: In the section titled "There are two kinds of appeals," a few commenters requested that CMS clarify that the fast appeals process does not apply to payment denials. One commenter noted that the extension language under the description of standard appeals in this section is not included under the description of fast appeals.

Response: We thank the commenters and have made edits in the form in response to these comments. Please see the revised form and Exhibit A, the Change Crosswalk.

Comment: Some commenters noted the administrative burden to insert an exact date by which the beneficiary must act rather than the general timeline (e.g., 60 days from the date of the form is mailed) and recommended that CMS eliminate this requirement. One commenter stated that the exact date should not be included because the mailing and beneficiary receipt dates of the form are different. Another commenter suggested that if CMS keeps the requirement to add the date, CMS should release the final form with ample time for plans to implement necessary system changes.

Response: We acknowledge the commenters' 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. We also note that, consistent with 42 CFR 422.633(d), the 60-day timeframe for a beneficiary to appeal begins from the date that the coverage decision form is dated, not when it is received. We have clarified this in the form instructions. Please see the revised form instructions and Exhibit A, the Change Crosswalk.

Comment: One commenter requested clarification on whether plans must insert their customer service call center phone number in each section where the plan's phone number is required.

Response: We thank the commenter and note that we have updated the form and form instructions to clarify which of the plan's phone numbers should be included. We clarify that the number provided may be for the plan's customer service call center or another plan number that is more appropriate for appeals issues. Please see the revised form and form instructions and Exhibit A, the Change Crosswalk.

Comment: One commenter recommended deleting the sentence in the "How to appeal" section that begins "On the first page of this decision form…" as it is duplicative. In this same section, another commenter requested that CMS add the plan contact information to the sentence "You can ask us for a free copy of the information we used to make our decision."

Response: Please see the revised form and Exhibit A, the Change Crosswalk. We have made updates to this section to reduce duplicative language, improve readability, and address the issues raised by these commenters.

Comment: One commenter questioned whether an alternate name for "Evidence of Coverage" could be used if a plan uses a different name for this document. Another commenter recommend that the plan only be required to provide the chapter number in the Evidence of Coverage as the chapter subsections frequently change.

Response: We agree with these commenters and have made updates in the form and form instructions to provide the flexibility the commenters recommended.

Comment: Some commenters suggested alternative language to the first sentence of the "How to Keep Services or Items during Appeal" section of the form. One commenter requested that CMS clarify that this section only applies to authorizations that were stopped or reduced and not to authorizations that were time limited.

Response: We appreciate the commenters' suggestions to this section; however, we are not making these recommended changes. We believe additional detail regarding which types of authorizations could be eligible for continuation of benefits would be confusing to beneficiaries. We also believe the language stating a beneficiary can "ask" to keep getting a service or item during an appeal does not imply that the benefit will always continue in the event an authorization expires, and so additional clarification is not needed.

Comment: A few commenters expressed concern that the information on a state fair hearing was not included because beneficiaries would not be aware of their rights in subsequent levels of the

appeals process. One commenter noted that beneficiaries often asked for a state fair hearing before seeking a plan level appeal.

Response: We appreciate the comments regarding including information for state fair hearings. 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. Additionally, 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. However, in response to the commenters, we have added a short reference to Medicare Level 2 appeals and state fair hearings processes in the section titled "What happens next."

Comment: One commenter recommended moving the section titled "What to do if you need help with your appeal" to follow the section titled "How to appeal."

Response: We disagree with this recommendation. Based on findings from consumer testing of this form with beneficiaries and their caregivers, we have deliberately sequenced the information in the form to align with the sequence of steps in the appeals process.

Comment: We received some comments on the language regarding appointing a representative. Two commenters recommended clarifying language. One commenter noted that the language around identifying a personal representative in this form does not reflect all plans' processes. Another commenter recommended adding a plan instruction to allow the addition of a URL address for members to download the plan's personal representative form.

Response: We appreciate these comments concerning representatives. We have made revisions to the form and form instructions, including allowing plans to insert the web address for the Medicare Appointment of Representative form or the web address for the plan's form. Please see the revised form, form instructions, and Exhibit A, the Change Crosswalk.

Comment: Several commenters made editorial recommendations regarding the "Get help and more information" section of this form. While one commenter appreciated the changes to this section, another commenter requested this section be limited to the plan's contact information to limit beneficiary confusion.

Response: We thank the commenters for their recommendations and have made necessary edits to this section. We decline to limit this section to the plan's contact information as we believe providing beneficiaries with contact information to additional resources, such as the state's Ombudsman program, the State Health Insurance Assistance Program, and the state Medicaid agency, increases their ability to successfully navigate the appeals process. Beneficiaries and their caregivers also responded favorably to inclusion of this information in consumer testing of the form.

Comment: One commenter noted the lack of a Spanish-language version of this form. Two commenters recommended CMS provide or require plans to provide notices in the predominately spoken non-English languages of the plan's service area. Some commenters also requested that CMS encourage plans to improve their processes for beneficiaries with limited English proficiency.

Response: We note that the Spanish language version of this form is included in this 30-day package. 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.

Comment: Some commenters made recommendations for how CMS can successfully implement unified appeals and grievance processes for applicable integrated plans.

Response: We appreciate the commenters' recommendations and will consider them as we move forward with implementation; however, these comments are outside the scope of this PRA submission.