Document (specify notice, instructions, burden estimates)	Page #	Comment (commenter and summary of comment)	CMS Response
Notice	1	OptumRx, Josh Van Ginkel Why did we deny your request: The National Committee for Quality Assurance's utilization management (NCQA U M 7.0) requires Optum to provide notification to the treating practitioner regarding the opportunity to discuss a pharmaceutical medical necessity denial. We request that CMS add the following general statement within the body of the letter and/or appeal rights : "Your prescriber may request to discuss the decision with a reviewing physician or other appropriate reviewer by contacting [company name] at [company phone number]."	We disagree with the comment. The notice must include a "specific and detailed explanation of why the prescription drug is being denied, including a description of any applicable Medicare coverage rule or any other application Part D plan policy…" CMS also expects plans that do not have complete information to reach out to requesting prescribers as part of the coverage determination process, including P2P discussions, before issuing the denial. Therefore, we believe that the only post-denial "discussion" that is likely to occur would be a dispute about the denial, which CMS requires plans to process as a redetermination. Part D plans must process requests for P2P review received subsequent to a denial notice as a request for redetermination. The right to a redetermination, including the right of the prescriber to request a redetermination on behalf of the beneficiary, is explained in detail in the denial notice. Please note NCQA requirements are superseded by federal regulations.
		Optum, Josh Van Ginkel Why did we deny your request: NCQA UM 7.E.2 states that the letter must contain a reference to the benefit provision, guideline, protocol or other similar criterion on which the denial decision is based.	We disagree with the comment and have not added the requested statement to the denial rationale. The instructions already describe the requirement that the denial rationale field include a description of any applicable Medicare coverage rule or plan coverage policy, so the suggested text may be added as part of the plan's denial rationale, if appropriate. Please note NCQA requirements are superseded by federal

		We request that CMS add the following general statement within the body of the letter: "Your denial was based on the [drug name] coverage policy."	regulations.
Notice	1	OptumRx, Josh Van Ginkel NCQA UM 7.E.3 requires that the letter contain a statement that members can obtain a copy of the actual benefit provision, guideline, protocol, or other similar criterion on which the denial decision was based upon request. We believe this would be a valuable addition to the Notice of Denial of Medicare Prescription Drug Coverage. Specifically, we request that CMS add the following general section to each letter: How can I obtain the material(s) used to review this request? You may request, free of charge, a copy of the drug coverage policy, actual benefit provision, guideline, protocol or other similar criterion on which the denial decision is based, including the diagnosis code and the treatment code and their corresponding meanings, by calling [Company Name] at [Company phone number], or by writing to [Company Name] at the address below [include Company address].	We disagree with the comment. CMS believes that the denial rationale instructions sufficiently explain the content the commenter has requested be included under the header "How can I obtain the material(s) used to review this request?", and that the inclusion of another section will create unnecessary length to the denial notice.
Notice	1	America's Health Insurance Plans, Mark Hamelburg <u>Why did we deny your request:</u> The second sentence appears to be missing a word. It states, "your prescriber requested coverage on your behalf, we have sent a copy of this decision to your prescriber." AHIP recommends that CMS correct the sentence by starting the sentence with "If." Anonymous We believe the word "If" is missing from the beginning of the second sentence. With this addition the language would read, "You should share a copy of this decision with your prescriber so you and your prescriber can	We agree with commenters and have fixed the formatting error that cut off the word "if", so the notice now states "If your prescriber requested coverage on your behalf, we have sent a copy of this decision to your prescriber".

		discuss next steps. If your prescriber requested coverage on your behalf, we have sent a copy of this decision to your prescriber." Health Care Service Corporation, Sue Rohan It appears the proposed language includes a typographical error, and we recommend CMS revise the draft as described below to ensure clarity. We note that CMS recently proposed a comparable change to the agency's Notice of Denial of Medical Coverage (MA Denial Notice), and our suggested edit is consistent with that proposed revision. "You should share a copy of this decision with your prescriber so you and your prescriber can discuss next steps. If your prescriber requested coverage on your behalf, we have sent a copy of this decision to your prescriber."	
Notice	1	Anonymous <u>Why did we deny your request:</u> We agree that the new language for standalone PDPs would be helpful to beneficiaries communicating there may be coverage under their medical plan.	CMS agrees and thanks you for your comment.
Notice	1	Anonymous <u>Why did we deny your request:</u> Regarding the language for Medicare Advantage plans under the section "Why did we deny your request?", we recommend adding optional language to address drugs that cannot be covered under D, B, or A.	CMS thanks you for your comment, plans should utilize the free text field in the denial notice to address denials that can't be covered under both B and D.
Notice	1	Anonymous	While discussion of adjudication timeframes are outside the scope of this notice, and the MA-PD

		We recommend keeping the prior language in the current form and not stating approval under Parts A/B. The review for coverage under Parts A/B would fall under Part D turnaround times creating additional internal challenges to review and approve under the short Part D times frames. America's Health Insurance Plans, Mark Hamelburg <u>Why did we deny your request:</u> We have concerns with CMS' proposal as it relates to MA-PD plans. In the calendar year (CY) 2017 Call Letter, CMS indicates that the agency intends to develop and issue sub regulatory guidance that would provide CMS' expectations for MA-PD plans regarding coordination of benefits when a prescription drug may be covered under Parts A, B or D. It might address, for example, the appropriate timeframe that has to be met for a determination about a drug which is not a Part D-covered drug but may be covered under Part B pending the plan's medical review. Since the sub regulatory guidance could directly impact the Notice of Denial language and decision timelines, we believe it is premature for CMS to address the topic through the Notice of Denial. We therefore recommend that CMS not move forward with its proposed language until plans have an opportunity to review and comment on the applicable sub regulatory guidance. We also note that the proposed language and related instructions for MA-PD plans address cases in which a prescription drug is not a Part D-covered drug but is covered by the Medicare Advantage plan as a drug covered under Medicare Part B. However, they do not address cases in which a prescription drug is neither a Part D-covered drug nor eligible for coverage by the Medicare Advantage	instructions for B v. D drugs are not a new addition to the Part D denial notice, we have added language noting that the MA-PD approval language is only inserted "if applicable".

		plan under Medicare Part B. For clarity purposes, we recommend that CMS address this other scenario in the form instructions.	
Notice		Anonymous We still feel strongly that approving and denying coverage in one letter is confusing, especially in cases of denial under Part D but approval under Parts A or B. Given the title of and intent of the letter to notify regarding a denial, we feel a beneficiary would expect a separate approval letter the messaging of an approval could get lost in the letter and raise more questions for beneficiaries expecting an approval letter if a drug is covered.	CMS acknowledges the possible confusion noted by the commenter, but the denial notice is required by regulation for all Part D denials, including when the requested drug is approved under Part B. MAPD's can also send a written Part B approval notice to these beneficiaries to minimize potential confusion.
Notice	1	Anonymous <u>What Do I Include with My Appeal Request:</u> We recommend changing the third sentence to read, "The supporting statement ~~You~~ should include information about why the coverage rule should not apply to you because of your specific medical condition." To emphasize it's the provider that must provide this information in the supporting statement and not the member. America's Health Insurance Plans, Mark Hamelburg <u>What Do I Include with My Appeal Request:</u> We support CMS' proposal to provide additional instructions to the beneficiary to ensure that required documentation is submitted with the beneficiary's appeal request. In order to provide clearer instructions to the beneficiary, we believe that the proposed language should be modified to describe the type of	CMS acknowledges the comments and has changed the language to "The supporting statement should include information about why the coverage rule should not apply to you because of your specific medical condition".

		documentation that would be required in cases concerning a coverage rule exception request. The notice currently states, "You should include information about why the coverage rule should not apply to you because of your specific medical condition." For clarity, AHIP recommends that CMS revise this sentence to read, "The supporting statement provided by your doctor should include information about why the coverage rule should not apply to you because of your specific medical condition." Health Care Service Corporation, Sue Rohan <u>What do I Include with My Appeal Request:</u> CMS is proposing to revise this section of the Notice to include language reminding beneficiaries that their doctor must provide a supporting statement when an exception is requested. While we recognize the value of including information along these lines, we believe the language could be further refined for clarity. To minimize beneficiary confusion, we recommend CMS revise the new proposed language as follows or in a similar manner: "Remember, your doctor must provide us with a supporting statement if you're requesting an exception to a coverage rule. ~~You~~ The supporting statement should include information about why the coverage rule should not apply to you because of your specific medical condition."	
Notice	Title	HealthCare Services Corporation, Sue Rohan <u>Title:</u> We are concerned that the title, "Notice of Denial of Medicare Prescription Drug Coverage," may be misleading to beneficiaries, particularly in the case of MA-PD plan enrollees who may receive a notice from their plan denying	CMS acknowledges the comments and has changed the title to " Notice of Denial of Medicare Part D Prescription Drug Coverage"

		coverage or payment of a drug under Part D, but approving coverage or payment of the drug under Medicare Part A or Part B. We recognize the requirement to include language related to approved coverage or payment of a drug under a benefit other than Part D was not applicable when the standardized denial notice was first developed and implemented, and that recent regulatory changes have necessitated including this information in the notice. To minimize confusion, we believe CMS should at a minimum, revise the title to send a more accurate signal to beneficiaries of the purpose and content of the notice. For example, revising the title to read, "Notice of Denial of Medicare Part D Prescription Drug Coverage," or a comparable change.	
Notice, Summary of Changes	3	Health Care Service Corporation, Sue Rohan <u>Get More Help & Information:</u> CMS is proposing to revise this section of the Notice to include language and contact information directing beneficiaries to call 1-800-MEDICARE or email AltFormat@cms.hhs.gov "to request this publication in an alternative format." The CMS Summary of Changes document that accompanied the draft Notice and instructions indicates that the agency is proposing this revision to assist beneficiaries who need to access the denial notice in another language. Since Part D plan sponsors have principal responsibility to provide assistance to beneficiaries regarding the denial notice, and since the denial is customized in response to the unique coverage determination of the individual enrollee, we believe it would be more appropriate for enrollees to first be directed to their plan in these instances, and subsequently to CMS as an alternative if needed.	We agree that enrollees should first be directed to contact their plan, and the notice continues to direct enrollees to their plan. CMS has also included alternate format language as required by Section 504 of the Rehabilitation Act.
Notice,	2,3	America's Health Insurance Plans, Mark Hamelburg	CMS acknowledges the comments and has changed

Crosswalk		Get help & more information: The agency's Crosswalk for Changes document that summarizes the proposed revisions to the Notice of Denial indicates that this new language is intended to aid beneficiaries who need to access the "denial notice in another language." The new language regarding the alternative format is unclear. For example, it refers to a publication and not the decision notice. Further, it appears to be referring the beneficiary to CMS for a document that the agency does not have. We seek clarification from CMS regarding the agency's intentions.	the Crosswalk language to clarify that the new language is intended for beneficiaries who need access to the denial notice in an alternate format. CMS has included alternate format language as required by Section 504 of the Rehabilitation Act.
Notice	2	Anonymous CMS has numerous declaimers for member materials, but we are unclear for the reason and/or the requirement to use the disclaimer on the last page. It is not in the 2016 or draft 2017 Medicare Marketing Guidelines.	CMS has included alternate format language as required by Section 504 of the Rehabilitation Act. This notice does not constitute marketing material per the definitions in the Medicare Marketing Guidelines.