Responses to Comments Received
Federal Register Notice on (CMS-10717)
Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols

CMS received 29 public submissions, which included 192 comments on the June 4, 2020, (CMS-10717) Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols proposed information collection. We then combined the 192 comments into 121 unique comments and provided responses in the document below. Comments are categorized first, by those that are general in nature, next, those that pertain to more than one program area and, finally, those that apply to each individual collection tool and program area.

GENERAL COMMENTS

Comment 1: One commenter cautioned CMS in moving forward with audits in calendar year (CY) 2020 given the data accuracy challenges resulting from the COVID-19 Public Health Emergency (PHE) and recommended that CMS only resume program audits when data is accurate. The commenter encouraged CMS to leverage two-way virtual platforms if in-person interactions are not possible due to COVID-19. The commenter suggested that auditors could review Special Needs Plan Model of Care and Medicare-Medicaid Plan samples through a virtual webinar that enables two-way interaction. The commenter also expressed concern that conducting the audit strictly as a desk review and sending snapshots of information without a virtual webinar would limit auditors' ability to collect complete information in real time thus requiring the Sponsoring organization to provide additional explanation.

Response 1: This comment is beyond the scope of this collection request.

CMS Action 1: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 2:

Three commenters expressed appreciation for the simplified data collection tools stating that the updated protocols found in CMS-10717 provide appropriate improvements. Two of these commenters plus three more, provided recommendations regarding the protocols' implementation timeline. The theme among these comments was that if sufficient lead time could not be provided between finalizing the protocols and their use in the 2021 audit year, CMS should delay implementation until CY 2022. Three of these commenters stated that they would consider sufficient lead time to be having finalized protocols by July or August 2020, or at least six months prior to use. The commenters identified numerous challenges that Sponsoring organizations would need to address in implementing protocols including significant operational updates, dealing with the current COVID-19 PHE, and the upcoming fall Annual Open Enrollment and Welcome season. Commenters stated that these issues are putting an added demand on plans' resources. Two of the commenters concluded by referring to the recent three-year approval of protocols found in CMS-10191, stating their belief that the extension of that expiration date would afford CMS flexibility to delay implementation of the CMS-10717 protocols until 2022.

Response 2: We appreciate the commenters' concerns, particularly about having enough time to implement data collection updates. We will take these comments into consideration prior to implementation and upon final approval of CMS-10717 by the Office of Management and Budget (OMB).

CMS Action 2: No changes were made to the protocols in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 3: One commenter referred to the protocols found in CMS-10191, noting the June 30, 2023, OMB expiration date and asked when the 2021 program audit cycle is expected to start. This commenter also asked for CMS to explicitly state the expected start date for using the protocols found in CMS-10717 in lieu of the CMS-10191 protocols. Another commenter stated CMS should only resume program audits when there is data accuracy and clarity for stakeholders around when audits will occur and which protocols will apply.

Response 3: We anticipate following an annual audit cycle that mirrors that of prior years. Specifically, we anticipate that the 2021 audit cycle will begin in the spring of 2021. As noted above, the timing for implementation of this collection request is dependent upon final approval of CMS-10717 by the OMB, and will be announced via an HPMS memorandum.

CMS Action 3: No changes were made to the protocols in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 4: One commenter stated that the COVID-19 pandemic has placed a strain on health plans, making it especially challenging to allocate staff and other resources towards audits. The commenter requested that CMS coordinate program audits, financial audits, and risk adjustment data validation audits to avoid redundancies.

Response 4: This comment is beyond the scope of this collection request.

CMS Action 4: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 5: One commenter suggested that CMS provide training for MA and Part D plans that would help stakeholders prepare for the upcoming audit cycle. The commenter suggested that the training cover key changes to the audit protocols, best practices, common findings from audits, and enforcement consequences for noncompliance.

Response 5: We agree with the importance of providing stakeholders with training on key changes and will take the commenter's suggestions into consideration.

CMS Action 5: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 6: One commenter stated that while CMS has reduced the scope for many universes, plans with sizeable enrollments have historically faced time-consuming challenges uploading universes to the HPMS audit module due to file size constraints. The commenter asked for CMS to confirm that this file size limitation has been addressed.

Response 6: We increased the HPMS universe file size from 1 gigabyte to 2 gigabytes effective January 31, 2020.

CMS Action 6: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 7: One commenter noted that CMS typically provides the audit samples one hour prior to the start of the audit webinar. To assist the organization in preparing the sample presentation for the live audit, the commenter suggested that CMS consider adding a new column within the record layouts that would allow plans to indicate which business area will present the case during audit field work.

Response 7: We decline the suggested request but note that nothing would preclude the Sponsoring organization from inserting and populating an additional column to the list of sample cases that we provide prior to the live audit.

CMS Action 7: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 8: One commenter requested that CMS provide the program area record layouts in an Excel format as well as the current Adobe PDF format.

Response 8: Because the instructions in the data collection documents allow for universes to be submitted in formats other than Excel, we do not believe a standard template is needed and decline the commenter's suggestion.

CMS Action 8: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 9: One commenter requested that CMS clarify the due date by which Sponsoring organizations would be required to have completed the remediation of any potential noncompliance identified during the live audit. Specifically, the commenter asked whether the remediation is to occur during the 10 business day impact analysis submission timeframe.

Response 9: While impact analyses are generally due within 10 business days of the request, we do not expect that all remediation would necessarily be completed during that timeframe. Remediation plans of varying durations are often outlined by the Sponsoring organization in their corrective action plans and approved by CMS.

CMS Action 9: No changes were made to the protocols in response to this comment. No changes were made to the burden estimate in response to this comment.

MULTIPLE PROGRAM AREAS

Comment 10: One commenter stated that in previous years, during the universe integrity testing portion of the audit, auditors would consider a universe to have passed CMS review if 4 out of the 5 samples were approved. The commenter requested that CMS clarify whether all 10 universe integrity samples will be reviewed under this collection request or if CMS would consider a universe to pass after auditors have approved 8 samples.

Response 10: We will review all cases selected or documentation received for universe integrity testing, as identified in the Method of Evaluation section of each program area protocol. The integrity of the universe will be questioned if the sample case(s) or documentation reviewed during the audit do not match the data provided in the universe.

CMS Action 10: We added the following language to the Part D Coverage Determinations, Appeals, and Grievances (CDAG), Part D Formulary and Benefit Administration (FA), Part C Organization Determinations, Appeals, and Grievances (ODAG), and Special Needs Plans Care Coordination (SNPCC)

protocols: "Review all cases selected for universe integrity testing. The integrity of the universe will be questioned if data points specific to the sample case(s) are incomplete, do not match, or cannot be verified by viewing the Sponsoring organization's systems and/or other supporting documentation." In addition, we clarified the Medicare Part C and Part D Compliance Program Effectiveness (CPE) protocol by removing the following language: "Compare the data in Universe Table 1 to the information in the supplemental documentation via desk review. Determine any variance in oversight activities." We replaced this language in the CPE protocol with: "Review all supplemental documentation submitted with Universe Table 1. The integrity of the universe and supplemental documents will be questioned if the submissions are incomplete, were not prepared in accordance with Program Audit Data Request instructions, or a variance is discovered in oversight activities." No changes were made to the burden estimate in response to this comment.

Comment 11: Two commenters identified an inconsistency between the Parts C and D Compliance Program Effectiveness (CPE) protocol found in CMS-10191 and the Medicare Part C and Part D CPE protocol in CMS-10717. Specifically, the commenters noted that the former protocol allows Sponsoring organizations to enter 'Y' for yes and 'N' for no within the record layouts, whereas within this collection request, Sponsoring organizations are required to enter the entire word 'Yes' or 'No.'. The commenters also noted that other protocols, including CDAG and ODAG, continue to allow Sponsoring organizations to enter 'Y' or 'N' as responses. The commenters recommended that CMS ensure consistency in its approach for collecting this information and concluded by recommending that Sponsoring organizations should be permitted to enter 'Y' and 'N' as acceptable responses in the CPE record layout.

Response 11: We thank the commenters for noting this inconsistency and believe that adopting the suggested change will bring the CPE protocol into alignment with the other program areas in this collection request. In reviewing the remaining program area data requests for these terms, we also identified and corrected one additional instance, within the *Was an Interdisciplinary Care Team (ICT) created/identified?* field of the SNPE record layout, where the field description column provided instructions to enter 'Yes' or 'No' instead of 'Y' or 'N.'

CMS Action 11: We updated the *Corrective Action Required* and *Activity Results Shared?* field descriptions in the CPE COA record layout by changing 'Yes' to 'Y' (for Yes) and 'No' to 'N' (for No). Within the SNPE record layout, we updated the *Was an Interdisciplinary Care Team (ICT) created/identified?* field description to read: "Enter Y (for Yes) if the enrollee has an ICT assigned. Enter N (for No) if the enrollee does not have an assigned ICT." We also updated the field length from 3 characters to 1 character. No changes were made to the burden estimate in response to these comments.

Comment 12: One commenter, referring to the instructions in the *NDC* field description within the applicable FA record layouts, asked CMS to clarify how plans should populate this field for multi-ingredient compound claims given that Prescription Drug Event (PDE) records are only generated for paid claims and these universes contain rejected claims. The commenter further noted that, for claims that never end up in a paid status, there would be no PDE to reference and that not all subsequent paid claim sequences contain the same ingredients, meaning the PDE associated with the NDC may not even be in the rejected claim sequence.

Response 12: We updated the *NDC* and *Related Drug NDC* field descriptions in the applicable FA and CDAG record layouts to clarify that, for multi-ingredient compound claims, Sponsoring organizations should populate the field with the NDC as would be submitted on a paid claim's PDE.

CMS Action 12: We updated the *NDC* and *Related Drug NDC* field descriptions throughout the FA and CDAG record layouts to provide the following clarification: "For multi-ingredient compound claims

populate the field with the NDC as would be submitted on a paid claim's PDE." No changes were made to the burden estimate in response to this comment.

Comment 13: For a redetermination or reconsideration requiring an Appointment of Representative (AOR), several commenters asked if the *Date the request was received field* in the PYMT_D, PYMT_C and RECON record layouts should be populated with the date the request was received by the Sponsoring organization or the date the AOR form or equivalent written notice was received by the Sponsoring organization. For the GRV_D and GRV_C record layouts, commenters also asked how to populate the *Date the grievance was received* field if the grievance required an AOR, and asked whether it would be the date the request came into the Sponsoring organization or the date the AOR was received. Another commenter asked if the *Date the request was received* field should include an AOR receipt date or the date the case was received without the AOR. This commenter noted that there is a separate *AOR/Equivalent notice Receipt Date* field. A commenter also asked how to populate the *AOR/Equivalent notice Receipt Date* field in the CDAG and ODAG record layouts if the Sponsoring organization has a valid AOR/Equivalent form on file for the enrollee prior to submission of the request. This commenter also asked if this field should be populated with the date that the AOR was received (i.e. prior to submission of the request) or the date the request was submitted.

Response 13: The *Date the request was received* and *Date the grievance was received* fields within the CDAG and ODAG record layouts should be populated as stated in the field descriptions with the date the request or grievance was received. The *AOR/Equivalent notice Receipt Date* field within the CDAG and ODAG record layouts should be populated per the field description with the date the AOR form or equivalent written notice was received by the Sponsoring organization, regardless of whether the representative documentation was received prior to the date of the request or grievance.

CMS Action 13: No changes were made to the protocols in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 14: Two commenters asked how to populate the *AOR/Equivalent notice Receipt Date* and *AOR/Equivalent notice Receipt Time* fields in the CDAG and ODAG record layouts if a dismissed case has an AOR date but was dismissed for another reason (e.g., late filing). One of the commenters recommended updating the field descriptions to read: "Enter None if no AOR or equivalent written notice was received or required."

Response 14: Sponsoring organizations should enter the date and time they received the AOR form, or equivalent written notice, if available. We agree with commenters that the *AOR/Equivalent notice Receipt Date* and *AOR/Equivalent notice Receipt Time* fields require an update to account for instances where a case was dismissed for reasons other than a lack of AOR form or equivalent written notice.

CMS Action 14: We updated the *AOR/Equivalent notice Receipt Date* and *AOR/Equivalent notice Receipt Time* field descriptions in the CDAG and ODAG record layouts to remove: "Enter None for dismissed cases." No changes were made to the burden estimate in response to these comments.

Comment 15: One commenter noted that CMS added a *Who made the request?* field to several record layouts after the sixty-day comment period and requested that this field also be added to the CDAG GRV_D and ODAG GRV_C record layouts. The commenter stated that without this information it is difficult to assess record layouts and to determine which records should or should not have AOR field data populated.

Response 15: We agree with the commenter that adding the *Who made the request?* field to the GRV_D and GRV_C record layouts promotes consistency and have adopted the suggestion.

CMS Action 15: We added a *Who made the request?* field to the GRV_D and GRV_C record layouts. No changes were made to the burden estimate in response to this comment.

Comment 16: A commenter noted the *Who made the request?* field description in the CDAG and ODAG record layouts includes options for enrollees, enrollee's representatives, and prescribing physician or other prescriber (CDAG), contract providers/facilities, and non-contract providers/facilities (ODAG). However, the field descriptions do not include an option for requests submitted by inappropriate submitters which are dismissed when appropriate representative documentation is not obtained. The commenter asked if CMS could provide an additional option to address this scenario.

Response 16: We agree with the commenter and have added the phrase "or purported representative" to the *Who made the request?* field description in the CD, CDER, PYMT_D, RD and GRV_D CDAG record layouts and in the OD, RECON, PYMT_C, GRV_C, and AIP ODAG record layouts. The 'ER' option now reads, "ER for enrollee's representative or purported representative."

CMS Action 16: We updated the *Who made the request?* field description in the CDAG and ODAG record layouts to read: "ER for enrollee's representative or purported representative." No changes were made to the burden estimate in response to this comment.

Comment 17: A commenter asked if the CDAG universes should be based on the Sponsoring organization's date of decision rendered or the date a decision should have been rendered and recommended adding this level of guidance to the record layout instructions. Two commenters asked if the "should have been language" was intentionally removed from the CDAG and ODAG record layout instructions.

Response 17: We believe the commenters are referring to language contained in a different collection request (CMS-10191). The referenced language was intentionally excluded from the CDAG and ODAG record layout instructions within this collection request (CMS-10717).

CMS Action 17: No changes were made to the protocols in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 18: For the GRV_D record layout, a commenter asked whether CMS expects to see a separate row for each issue involved in a grievance. The commenter recommended that, for grievances involving multiple issues, each issue be entered as a separate row.

Response 18: We do not expect Sponsoring organizations to separate out each issue involved in a grievance as a separate line item in the universe and believe it would be more burdensome for all Sponsoring organizations to implement this change at this time. Grievances with multiple issues should be listed as a single line item within the respective CDAG and ODAG grievance universes, unless the Sponsoring organization is treating the issues individually and is issuing separate notifications.

CMS Action 18: We added the following clarifying instruction to the GRV_D and GRV_C record layouts: "Grievances with multiple issues must be entered as a single line item, unless the Sponsoring organization issued separate notifications." No changes were made to the burden estimate in response to this comment.

Comment 19: A commenter asked if plans should provide the time if available or enter 'None' for standard cases if a plan's system captures the time for a field (for example, *Time the request was received*). The commenter also asked if the *Time oral notification provided to enrollee* field should be

populated in the RD universe if oral notification is provided for a standard redetermination since the time is not required for standard appeals.

Response 19: Sponsoring organizations always have the option to enter the time even if it is not required per the record layout field descriptions. We have added this language into the CDAG and ODAG protocols.

CMS Action 19: Within the Universe Submissions section of the CDAG and ODAG protocols we added the following language: "Sponsoring organizations may however enter the time within universes instead of 'None' if the time is not required per the field description." No changes were made to the burden estimate in response to this comment.

MEDICARE PART C AND PART D COMPLIANCE PROGRAM EFFECTIVENESS (CPE)

Comment 20: One commenter noted that CMS intends to conduct integrity testing of submitted information for all audited program areas and asked whether CPE will undergo the same type of integrity testing as ODAG, CDAG, FA and SNPCC or if the CPE integrity testing will be more of a desk review.

Response 20: We will conduct integrity testing of the CPE documentation captured in the Method of Evaluation column of the protocol via desk review. The COA record layout and supporting documents will be evaluated and cross-referenced for accuracy and completeness. If the audit team finds the record layout or supporting documentation is incomplete or missing data, they may ask for resubmission.

CMS Action 20: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 21: One commenter referred to the Method of Evaluation section for integrity testing and asked why CMS will no longer collect the Corporate Compliance/Medicare Compliance/FWA Plan (or similar document in effect at any time during the audit review period).

Response 21: We believe this document is no longer necessary for program audit purposes.

CMS Action 21: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 22: One commenter requested confirmation that CMS will no longer be evaluating the OIG/GSA exclusion list as part of the CPE audit and requested clarification of the way in which CMS will evaluate the OIG/GSA exclusion list.

Response 22: Although we will no longer evaluate Sponsoring organizations' processes for screening individuals against the OIG/GSA exclusion lists as part of the Medicare Part C and Part D program audit, we clarify that we are not removing requirements under which this audit test was previously conducted. Rather, the compliance standards related to GSA/OIG exclusion list screening were removed from the program audit protocol to avoid overlap with other oversight activities currently conducted within CMS.

CMS Action 22: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 23: One commenter requested that CMS confirm whether a list of all active employees during the review period will still be required as has been provided in prior collection requests or if that list is being modified to include new hires within the audit period or audit participants specifically.

Response 23: We clarify that Sponsoring organizations will no longer provide auditors with a full list of employees who are active during the review period.

CMS Action 23: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 24: One commenter requested that CMS clarify the type of documentation that CMS would expect to see for the 2 First Tier Entities (FTEs), as mentioned in the Audit Field Work Phase section of the protocol.

Response 24: In accordance with compliance standard 1.1, during the live review, auditors will look for evidence that Standards of Conduct and Policies & Procedures are accessible to employees and FTEs. Examples may include, but are not limited to, demonstrating accessibility of these documents on an intranet or an attestation from the FTE that these documents were received from the Sponsoring organization.

CMS Action 24: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 25: One commenter requested additional detail pertaining to the timeline by which auditors would complete the live review of the samples of 20 audit participants and 2 FTEs and the deadline for Sponsoring organizations to provide supporting documentation. The commenter stated that with previous audits, samples were due within 48 hours and then a live walk through was conducted to show the various systems. The commenter asked whether CMS would continue to follow this process.

Response 25: We will provide the Sponsoring organization with the list of 20 employees and 2 FTEs on the first day of the CPE audit. We usually conduct the live review of these samples on day 2 or day 3 of the CPE audit, however, scheduling is flexible based on the Sponsoring organization's needs. As noted in the protocol, if not previously provided, the Sponsoring organization is expected to submit supporting documentation within 2 business days of the request.

CMS Action 25: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 26: One commenter asked if CMS would provide the attendance log template that CMS will use to identify its samples of employees and FTEs.

Response 26: The template for attendance logs is available in the Submission Materials section of the HPMS audit module. We have also added it to this collection request.

CMS Action 26: We have included the attendance log template in this collection request. No changes were made to the burden estimate in response to this comment.

Comment 27: One commenter requested that CMS clarify whether the audit element of Correction Controls and Activities was inadvertently left out of the Program Audit Protocol table. The commenter stated that Detection Controls and Activities (2.1) is followed by All Audit Elements (4.1) and it appears that the Correction Controls and Activities element is missing.

Response 27: While the Correction Controls Activities were previously captured under the category of All Audit Elements, for greater clarity, we have relabeled each of the 7 compliance standards with the

single heading of Prevention, Detection, or Correction and renumbered them 1.1 through 1.7 instead of breaking out each of the elements into a separate category.

CMS Action 27: We updated the Audit Element field for all 7 compliance standards renaming it with the more generalized heading Prevention, Detection, or Correction. The previous compliance standard 4.1 is now labeled 1.2. The previous compliance standard 1.2 is now labeled 1.3. The previous compliance standard 4.2 is now labeled 1.4. The previous compliance standard 2.1 is now labeled 1.5. The previous compliance standard 4.3 is now labeled 1.6. The previous compliance standard 4.4 is now labeled 1.7. No changes were made to the burden estimate in response to this comment.

Comment 28: One commenter requested that CMS clarify its intent in including compliance actions, such as warning letters or notices of noncompliance, in tracer requests. The commenter stated that depending on the timing between the receipt of compliance action and the onset of the audit period, testing remediation of the issue may result in duplicative discipline to plans.

Response 28: Within the tracer evaluations, we will assess the way in which any compliance actions, warning letters or notices of noncompliance have been addressed by the Sponsoring organization. For example, the Sponsoring organization's response to receiving a warning letter would be assessed by the regulatory requirements found in 42 C.F.R. §§ 422.503(b)(4)(vi)(G) and 423.504(b)(4)(vi)(G), and not those connected to the subject of the warning letter.

CMS Action 28: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 29: One commenter requested that CMS elaborate on the way in which auditors would evaluate a Sponsoring organization's implementation of HPMS memoranda through the tracer process. The commenter also asked whether all HPMS memoranda would be considered in scope for a tracer review or if only certain topics would be considered in scope.

Response 29: We will evaluate the Sponsoring organization's applicable integration of the HPMS memoranda into its Compliance Program. For example, to the extent that auditors were to select an HPMS memo pertaining to appeals, we would not be evaluating the operations of appeals during the CPE review but rather, the actions taken by the Sponsoring organization's compliance team in response to the content of the memo.

CMS Action 29: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 30: One commenter requested that CMS provide examples of what may be reviewed during the CPE review if auditors determine that other related CPE requirements are not being met.

Response 30: The statement to which the commenter referred is located in the Purpose section of all program area protocols. However, because all CPE regulations are being tested per the protocol, we have removed this statement from the CPE protocol.

CMS Action 30: We have removed the following statement from the CPE protocol: "CMS may review factors not specifically addressed below if it is determined that there are other related CPE requirements not being met." No changes were made to the burden estimate in response to this comment.

Comment 31: One commenter requested that CMS clarify whether the COA record layout will now include the oversight, monitoring, audits and investigations of the internal operations and contracted entities.

Response 31: Yes. As indicated in the *Component* field description, Sponsoring organizations are instructed to enter the name of the Sponsoring organization's department, operational area, or First Tier Entity that is the focus of the oversight activity.

CMS Action 31: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 32: One commenter stated that intensive resources are required to prepare for the CMS program audit, noting that compliance departments devote their resources to compiling and reviewing all program area universe submissions and documentation requests, and coordinating and participating in interview sessions. The commenter stated that holding the CPE portion of the audit right after these other activities does not leave a plan's compliance department with enough time to develop their universes, tracers, and other document submissions for the CPE audit. The commenter requested that CMS consider conducting the CPE portion of the audit at a later date to allow compliance departments sufficient time to plan for the CPE audit.

Alternately, the commenter suggested that CMS could require plans to hire an independent consultant to audit the CPE portion of the audit at their own expense, and to report those results to CMS, similar to the annual Medicare Parts C and D data validation audit. The commenter stated that CMS already requires Sponsoring organizations to conduct a CPE audit at least annually and, therefore, those results could be submitted to CMS to satisfy the CPE audit.

Response 32: We previously extended the program audit process from 2 weeks to 3 weeks to afford Sponsoring organizations additional time to respond to audit requests and prepare for the CPE audit that is conducted during the last week of field work. We decline the commenter's suggestion to conduct the CPE portion of the audit at a later date and continue to believe that the current structure allows sufficient time for Sponsoring organizations to prepare for the CPE portion of the program audit. Additionally, in the Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs final rule (80 FR 7911), CMS determined that it would not finalize the proposal to require plan sponsors to hire an independent auditor no less than every 3 years to conduct full or partial program audits. Any further consideration of the commenter's proposal would be subject to comment rulemaking and is beyond the scope of this collection request.

CMS Action 32: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 33: One commenter suggested that CMS consider providing guidance as to the way in which CMS will evaluate call routing, classification, etc., since CMS is not requesting Part C and Part D call logs as part of this collection request. Another commenter referred to question number 17 in the Compliance Officer Questionnaire and asked what CMS's expectations are of the Compliance Officer in regard to oversight of incoming requests to ensure they are handled correctly at the operational level.

Response 33: During interviews, auditors will ask questions related to how the Sponsoring organization establishes and implements its system for routine monitoring and identification of compliance risks. Sponsoring organizations will also have the opportunity to describe their measures to prevent, detect, and correct operational noncompliance related to defining and processing requests according to program requirements.

CMS Action 33: No changes were made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 34: One commenter referred to question number 18 of the Compliance Officer Questionnaire and requested that CMS clarify whether Sponsoring organizations should include all compliance reports received, including those disputed by the Sponsoring organization, or only those that were not disputed.

Response 34: All compliance reports received by the Sponsoring organization must be quantified in question number 18 of the Compliance Officer Questionnaire.

CMS Action 34: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

PART D FORMULARY AND BENEFIT ADMINISTRATION (FA)

Comment 35: One commenter referred to a prior version of the FA protocol in CMS-10191 which specified that 2 sample selections of 15 claims would target 7 non-protected class drugs and 8 protected class drugs. The commenter noted that the protocol in this collection request no longer breaks out the number of protected versus non-protected class drugs that will be sampled and requested that CMS add this detail into the Method of Evaluation descriptions noting that it would assist Sponsoring organizations in targeting samples while preparing for a CMS program audit.

Response 35: We decline the commenter's suggestion to provide this level of detail, preserving auditor discretion in sample selection. In prior program audit experience, we have not encountered a situation where more protected class samples were disproportionally selected. It is possible that we may have more non-protected class samples than protected class due to limited sample selections based on the universe.

CMS Action 35: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 36: One commenter requested that CMS clarify the way in which the RCFA record layout will be used to evaluate Transition. The commenter referred to compliance standard 2.1 that states samples will be selected from the RCT record layout. The commenter also requested that CMS clarify the way in which the RCFA record layout will be analyzed as it is listed as part of the Data Request under compliance standard 2.2.

Response 36: We may identify transition issues in the RCFA record layout, such as those relating to mid-year enrollments.

CMS Action 36: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 37: One commenter requested that CMS clarify the way in which the RCT record layout will be used to evaluate Formulary Administration. The commenter referred to compliance standard 1.4 that states samples will be selected from the RCFA record layout.

Response 37: We believe the commenter is referring to compliance standard 1.5. We may identify Formulary Administration issues in the RCT universe, such as those relating to the start of the new benefit year.

CMS Action 37: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 38: A couple of commenters stated that information included in the Scope of Universe Request table and the PDE Data record layout is inconsistent and requested that CMS clarify the way in which plans should populate the PDE Data record layout. Specifically, commenters stated that the Scope of the Universe Request requires the inclusion of November and December enrollees yet no such wording exists for the PDE Data record layout instructions. One commenter requested clarification as to whether CMS intended to limit the PDE Data record layout to new enrollees in November and December, and if September and October should be excluded from the universe period. Another commenter recommended that CMS update the PDE Data record layout instructions to align with the Scope of Universe instructions for the PDE Data record layout which read, "Submit all final action PDEs accepted by CMS with dates of service September – December of the contract year immediately prior to the audit year for all enrollees in Table 2 and enrollees with effective enrollment dates of November and December of the contract year immediately prior to the audit year."

Response 38: We agree with the suggested clarification to update the PDE Data record layout instructions to better align with the Scope of Universe Request table.

CMS Action 38: We updated the PDE Data record layout instructions to read: "Submit all final action PDEs accepted by CMS with dates of service September – December of the contract year immediately prior to the audit year, for enrollees in Table 2 and enrollees with effective enrollment dates of November and December of the contract year immediately prior to the audit year. Include enrollees in employer plans and Medicare-Medicaid Plans (MMPs)." No changes were made to the burden estimate in response to these comments.

Comment 39: One commenter asked CMS to clarify how samples will be selected if Sponsoring organizations are to now include November and December enrollees in the PDE Data record layout but there are no rejected claims for these enrollees in the RCT record layout.

Response 39: We may sample enrollees with a November or December effective enrollment date from the PDE Data universe to evaluate whether these enrollees were afforded a full continuing enrollee transition benefit, if applicable.

CMS Action 39: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 40: One commenter referred to the IAS record layout that would collect all medications impacted by the issue if there's no associated rejected claim. The commenter stated that an impact analysis for a condition not specific to a medication could result in the listing of an exorbitant number of medications that would easily exceed the proposed 4,000 character limit in the *List of Medication Affected* field. For example, if a condition is identified related to a Sponsoring organization's administration of their Transition of Care program, the resulting list of medications would include every product with eligible utilization management (UM). The commenter requested that CMS clarify whether Sponsoring organizations would be expected to include potentially sizable subsets of all eligible Part D medications by RXCUI in the *List of Medications Affected* field that may not ultimately be representative of the condition identified.

Response 40: We may request impacted medications that may not be associated with a rejected claim in limited circumstances. For example, issues related to inappropriate effectuation of prior authorization records. In these situations, we will specify which medications should be reported in the impact analysis.

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CMS Action 40: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 41: One commenter recommended that CMS remove the requirement that Sponsoring organizations include inaccurate records that are not associated with a rejected claim in the ENR-IA record layout. The commenter stated that enrollees should not be considered "impacted" unless a claim is inappropriately rejected. The commenter disagreed that an enrollee who does not experience a point of sale claim rejection should be considered in the population of "impacted" enrollees used by CMS to issue compliance actions. The commenter stated that the impact analysis should only target instances where a plan error results in a point of sale impact to an enrollee to avoid penalizing plans in situations where steps were taken to prevent impact to enrollees through proactive intervention. The commenter stated that, for purposes of the FA audit, an adjudicated claim is required to demonstrate compliance with a contractual requirement.

Response 41: Inaccurate records that are not associated with a rejected claim would still require remediation by the Sponsoring organization once the error is identified during a program audit because the inaccurate records could result in a point of sale claim rejection. Therefore, CMS would still expect to see these records included in the impact analysis.

CMS Action 41: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 42: One commenter recommended that CMS remove the *Is enrollee currently enrolled?* field from the ENR-IA record layout stating that if the enrollee were not enrolled at the time of the claim submission, then the claim would have encountered an administrative reject and would therefore be unlikely to be part of an impact analysis. The commenter suggested that it would be more valuable to include a field that would capture if an enrollee disenrolled subsequent to the impacted claim submission date.

Response 42: We appreciate the commenter's input and believe that the information that would have been captured in this field is no longer necessary for audit purposes.

CMS Action 42: We have removed the *Is enrollee currently enrolled?* field from the ENR-IA record layout and relettered the remaining fields accordingly within the record layout. We also made the corresponding change to the third bullet of the ENR-IA record layout instructions to read: "Inaccurate records (i.e. authorization, enrollment records) that may not be associated with a rejected claim. In this scenario, Sponsoring organizations should only complete the following fields: Enrollee ID, Contract ID, Plan Benefit Package (PBP), Enrollment Effective Date, and Drug Name and Strength (if applicable)." No changes were made to the burden estimate in response to this comment.

PART D COVERAGE DETERMINATIONS, APPEALS AND GRIEVANCES (CDAG)

Comment 43: Two commenters requested that CMS remove the language "including requests for Part B drugs" from the CDAG table instructions and said the language was confusing and inconsistent with the cases found in CDAG universes (i.e. B versus D) and that requests for Part B-only drugs would be found in ODAG universes. For the PYMT_D record layout, a commenter asked whether the Part B drugs that must be included are Part B drug requests that correspond to the Part D benefit. Another commenter

recommended that CMS not include requests for Part B drugs in CDAG universes and that these continue to be reported in the ODAG universes. Another commenter noted the RD record layout instructions state to include all redeterminations (including requests for Part B drugs) and asked for clarification on when Part B drug requests should be included in Part D universes.

Response 43: Sponsoring organizations must include Part B drug requests based on the way in which the request was processed. For example, if the Sponsoring organization processed the request as a coverage determination and issued a Part D denial notice, then the case should be included in the CD universe. To clarify the instructions, we removed the phrase "(including requests for Part B drugs)" from the CD, CDER, PYMT_D and RD record layouts and added the phrase "for Part D coverage." For example, the CD record layout instructions now read, "Include all coverage determinations the Sponsoring organization approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE or dismissed for Part D coverage during the universe request period."

CMS Action 43: We removed the phrase "(including requests for Part B drugs)" from the CD, CDER, PYMT_D and RD record layout instructions and added the phrase "for Part D coverage." No changes were made to the burden estimate in response to these comments.

Comment 44: A commenter asked if the Sponsoring organization should populate the *Date oral notification provided to enrollee* and *Time oral notification provided to enrollee* fields when a good faith attempt is completed, or only when the outreach is successful. Another commenter asked if these fields should be populated in the RD universe for standard redeterminations if oral notification is attempted.

Response 44: We previously removed the phrase "attempted or" from these field descriptions in the CDAG record layouts. See CMS Action 42 in the Responses to Comments Received Federal Register Notice on (CMS-10717) Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols found at: https://www.cms.gov/files/document/cms-responses-60-day-comment-summaries-cms-10717.pdf. Sponsoring organizations are to populate fields as specified in the applicable field descriptions. Refer to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for more information on when a notice is considered delivered.

CMS Action 44: No changes were made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 45: A commenter asked if the *Request Determination* field should be populated as 'Denied' for cases that are partially approved.

Response 45: Yes. As, the table instructions indicate, any request denied in whole or in part should be entered as denied. For this scenario, the *Request Determination* field should be populated with 'Denied.'

CMS Action 45: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 46: A commenter noted that CMS clarified in the sixty-day Responses to Comments Received Federal Register Notice on (CMS-10717) Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols that partially favorable decisions should be populated as denials in CDAG universes. The commenter asked, for such cases, if Sponsoring organizations should include or omit data regarding effectuation of the favorable portion of the decision.

Response 46: Per the CDAG record layout instructions, any request denied in whole or in part is to be entered as denied in the universe. For partially favorable decisions, Sponsoring organizations should include data regarding effectuation of the favorable portion of the decision.

CMS Action 46: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 47: A commenter asked if the *Date written notification provided to enrollee* field in the CD and CDER record layouts should be populated with 'None' for dismissed cases.

Response 47: For dismissed cases, the *Date written notification provided to enrollee* field in the CD, CDER, PYMT_D and RD record layouts should be populated with the date the written notification of the dismissal determination was provided to the enrollee. As the field description indicates, enter 'None' if no written notification was provided.

CMS Action 47: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 48: Three commenters asked how to populate the *Date of Determination* and *Time of Determination* fields for coverage determinations or redeterminations that are auto-forwarded to the Independent Review Entity (IRE) as untimely. The commenters asked if Sponsoring organizations should enter 'None' because they did not make a decision or whether Sponsoring organizations should enter another date and time, such as when the Sponsoring organization closed its case file as untimely and began preparing the case file for the IRE, or when the file was sent to the IRE.

Response 48: As the CDAG record layout instructions indicate, the date of the Sponsoring organization's determination must fall within the universe request period. Because this date determines the universe inclusion timeframe we are not adding a 'None' option to the *Date of Determination* field description. For untimely coverage determinations or redeterminations that are auto-forwarded to the IRE (*Request Determination* of IRE auto-forward), the Sponsoring organization may enter the date and time it closed the case file as untimely and began preparing the case file for the IRE, or when the file was sent to the IRE in the *Date of Determination* and *Time of Determination* fields.

CMS Action 48: No change was made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 49: A commenter recommended that CMS continue to allow each UM criteria and/or exception type to be reported as a single line item in the universe. The commenter asked CMS to clarify how Sponsoring organizations should report coverage determinations and appeals that are reviewed simultaneously against UM and exception criteria. For example, if an enrollee simultaneously tries to satisfy prior authorization (PA) criteria and obtain a quantity limit exception and/or a tiering exception at the coverage determination level. The commenter asked if the Sponsoring organization would report the UM review in the CD universe and the exceptions reviews in the CDER universe. The commenter also asked, at the appeal level, if the Sponsoring organization would report UM and exception appeals as a single line item or would report a UM line item and a separate exception line item in the RD universe.

Response 49: We are retaining the table instructions requiring requests for a single drug involving multiple UM criteria and requests for a single drug involving multiple exception types to be entered as a single line item in the universe in order to test the enrollee experience as it pertains to receiving a single notification. For the first scenario presented, the case would be included as a single line item in the CDER universe. If any part of a single drug request involves an exception, that drug should be entered as a single

line item in the CDER universe. We have added instructions to the CDER record layout that state, "Requests for a single drug involving multiple UM criteria and exception types must be entered as a single line item in Universe Table 2 only." For the second scenario presented, the case would be included as a single line item in the RD universe. We added instructions to the RD record layout that state, "Requests for a single drug involving multiple UM criteria and exception types must be entered as a single line item." We also added instructions to the CDER and RD record layouts to clarify that if a request has multiple exception types and includes a tiering exception, the case should be reported as a tiering exception for program audit purposes.

CMS Action 49: We updated the CDER and RD record layout instructions as mentioned above to address the universe population questions presented by the commenter. No changes were made to the burden estimate in response to this comment.

Comment 50: A commenter asked if the *Authorization or Claim Number* field could be populated with the internal tracking or case number if the Sponsoring organization is unable to look up a case file in its system based on an authorization number. The commenter also asked if by "authorization number" CMS is specifically referring to the override placed in the claims processing (i.e. adjudication) system.

Response 50: Per the *Authorization or Claim Number* field description, the authorization or claim number is the Sponsoring organization's associated authorization or claim number for the request. If a Sponsoring organization is unable to look up a case file in its system based on an authorization number, the *Authorization or Claim Number* field can be populated with the internal tracking or case number.

CMS Action 50: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 51: A commenter asked if the *NDC* field could be left blank if no information was provided for the record.

Response 51: Yes. Per the *NDC* field description, when less than 11 characters or a blank field is submitted by the pharmacy or delegate, or the NDC is not applicable (e.g. for at-risk redeterminations), the field can be populated as submitted.

CMS Action 51: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 52: Two commenters asked how to populate the *Exception Type* field in the CDER universe if the case involves a dual review for 2 exception types. One of the commenters asked if CMS has hierarchy for case types that can be provided to Sponsoring organizations and Pharmacy Benefit Managers (PBMs). The other commenter asked if tolling for the additional information should occur for the second exception type to gain a prescriber supporting statement and to provide a decision for both requests.

Response 52: As the CDER record layout instructions state, "Requests for a single drug involving multiple exception types (e.g. tiering exception, prior authorization exception, quantity limit exception, and step therapy exception) must be entered as a single line item." We do not have a hierarchy of case types for CDAG program audit universes. For a request with multiple exception types, populate the *Exception Type* field based on the approval or denial reason. We have added this language to the *Exception Type* field descriptions within the CDER, PYMT_D, and RD record layouts. Policy questions relating to processing requirements should be directed to the CMS policy mailbox https://appeals.lmi.org.

CMS Action 52: We have added the following language to the *Exception Type* field descriptions within the CDER, PYMT_D, and RD record layouts: "If multiple exception types apply, enter the exception type applicable based on the approval or denial reason." No changes were made to the burden estimate in response to these comments.

Comment 53: A commenter asked what would meet the requirement for dismissing a case as it relates to the *Issue Description* fields in the CDER and PYMT_D record layouts.

Response 53: Policy questions should be directed to the CMS policy mailbox https://appeals.lmi.org.

CMS Action 53: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 54: A commenter noted that withdrawn cases are excluded from universes and asked if there was a reason for this decision and whether these cases will be evaluated in future audits.

Response 54: We excluded withdrawn cases from the universes as we do not plan to review withdrawn cases as part of the protocols included in CMS-10717.

CMS Action 54: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 55: A commenter asked if safety edit exceptions and at-risk determinations should be included in the CD universe. The commenter also asked if at-risk determinations should be included in the CDER universe.

Response 55: Since safety edit requests are exceptions, they should be included in the CDER universe. At-risk determinations should be included in the AR universe.

CMS Action 55: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 56: A commenter asked if the *Expiration date of the approval* fields pertain to clinical approvals. The commenter recommended that CMS allow Sponsoring organizations to populate these fields based on date of service since payment requests are approved based on date of service.

Response 56: The *Expiration date of the approval* field should be populated as stated in the field description with the expiration date of the exception approval. If the exception was not approved, or if the request was not an exception request, Sponsoring organizations should enter 'None' in the universe.

CMS Action 56: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 57: A commenter asked if CMS has a preferred hierarchy for the *Formulary UM Type* field in the CD record layout.

Response 57: As mentioned above, we do not have a hierarchy of case types for CDAG program audit universes. Per the field description, if multiple formulary UM criteria apply, enter the criteria applicable based on the approval or denial reason.

CMS Action 57: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 58: A commenter asked if 'SE' could be entered for the *Formulary UM Type* field in the CD universe. For example, if the safety edit is for an enrollee who appears opioid naïve, but wants to show evidence that s/he meets the criteria as not opioid naïve (so they can fill greater than a 7 day supply). The commenter also noted that coverage requests are submitted at times for formulary drugs which have no criteria and asked how to populate the field for this scenario. Another commenter asked why a safety edit would be within the CD universe when it is considered an exception request and stated that safety edit requests should only be populated within the CDER universe.

Response 58: In Response 159 of the Responses to Comments Received Federal Register Notice on (CMS-10717) Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols, we removed the safety edit option from the *Formulary UM Type* field description in the CD record layout since safety edit requests are exceptions. However, in light of the scenario raised by the first commenter noted above, we are updating the *Formulary UM Type* field description in the CD record layout to allow for an entry of 'SE' for Safety Edit.

CMS Action 58: We added "SE for Safety Edit" to the *Formulary UM Type* field description in the CD record layout. No changes were made to the burden estimate in response to these comments.

Comment 59: A commenter requested that CMS add an 'NA' option for the *Formulary UM Type* field in the CD record layout to address the scenario when an enrollee asks the plan to cover a drug but the drug is covered on the formulary without restriction. Another commenter stated a 'None' option is necessary for the *Formulary UM Type* field in the CD record layout for coverage determinations where formulary UM criteria is not applicable.

Response 59: Per CMS Action 31 in the Responses to Comments Received Federal Register Notice on (CMS-10717) Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols, we simplified the field descriptions within the CDAG record layouts by removing the options to enter 'NA,' 'NF,' and 'NE', allowing Sponsoring organizations to enter 'None.' We agree with the commenters, and in light of the prior updates made from 'NA' to 'None' within the protocol, have added the following language to the *Formulary UM Type* field description in the CD record layout: "Enter None if the enrollee did not satisfy, or was not attempting to satisfy, Prior Authorization and/or Step Therapy criteria."

CMS Action 59: We added, "Enter None if the enrollee did not satisfy, or was not attempting to satisfy, Prior Authorization and/or Step Therapy criteria" to the *Formulary UM Type* field description in the CD record layout and updated the field length to 4. No changes were made to the burden estimate in response to these comments.

Comment 60: A commenter asked how to populate the *Formulary UM Type* field in the CD record layout if there is a PA and step therapy (ST) with different outcomes. For example, the PA is denied and the ST is approved. The commenter asked if each decision should be reported separately in the universe.

Response 60: For this scenario, per the CD record layout instructions, requests for a single drug involving multiple UM criteria (e.g. step therapy and a prior authorization) must be entered as a single line item in the universe. If multiple formulary UM criteria apply, enter the criteria applicable based on the approval or denial reason for the request. For the example provided, 'PA' should be entered in the *Formulary UM Type* field because the overall disposition of the request would be entered as denied per the instruction that partially denied cases be entered as denied.

CMS Action 60: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 61: A commenter requested clarification on acceptable scenarios for receiving information from an enrollee for exceptions requests. The commenter asked, for example, whether it is an acceptable practice for an enrollee to answer the necessary questions for a supporting statement without conducting prescriber outreach.

Response 61: Policy questions should be directed to the CMS policy mailbox https://appeals.lmi.org.

CMS Action 61: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 62: A commenter requested that CMS remove the 'SE' option for the *Formulary UM Exception Type* field in the CDER record layout because it is potentially duplicative of response value 'Safety edit exception' in the *Exception Type* field. The commenter noted the *Formulary UM Exception Type* field seems to only be needed to specify the type of formulary UM exception requested.

Response 62: We decline to remove 'SE' as an option for the *Formulary UM Exception Type* field as we may use this field to sample a non-formulary exception that involves a safety edit. For those reasons we do not see this as a duplicative response value, however we updated the field name to *UM Exception Type* and have also clarified the field description.

CMS Action 62: We renamed the *Formulary UM Exception Type* field to *UM Exception Type* in the CDER, PYMT_D and RD record layouts and also removed the "formulary" references within the field descriptions. No changes were made to the burden estimate in response to this comment.

Comment 63: For the *Formulary UM Exception Type* field in the CDER record layout, a commenter asked if 'Hospice' should be an option. If so, the commenter recommended that CMS add the following Hospice FAQ information per Chapter 18 of the Medicare Prescription Drug Benefit Manual: Is tolling allowed for these beneficiary-level hospice PAs? For purposes of the 2014 coordination of benefits processes outlined in this memo, we believe it is appropriate to apply the processing timeframes applicable to exception requests as described in section 30.2 of Chapter 18 of the Medicare Prescription Drug Benefit Manual to coverage determination requests that involve the beneficiary-level hospice PA.

Response 63: We do not believe another option is necessary in the *Formulary UM Exception Type* field, as hospice would be captured in the *Exception Type* field. For this scenario, Sponsoring organizations should adhere to the *Formulary UM Exception Type* field description and enter 'None' if the request was not a formulary UM exception or safety edit exception. Policy questions relating to processing timeframes should be directed to the CMS policy mailbox https://appeals.lmi.org.

CMS Action 63: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 64: A commenter recommended that CMS remove the *Date prescriber supporting statement received* field in the PYMT_D record layout since no clinical exception requests are found in this universe.

Response 64: The PYMT_D record layout includes approved, denied, re-opened approved, re-opened denied, auto-forwarded to the IRE and dismissed case types. We are retaining the *Date prescriber*

supporting statement received field in the PYMT_D record layout since a prescriber supporting statement may be needed to support a formulary UM or an exception request.

CMS Action 64: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 65: A commenter asked if a direct member reimbursement can be requested by a physician.

Response 65: Policy questions should be directed to the CMS policy mailbox https://appeals.lmi.org.

CMS Action 65: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 66: A commenter asked how to populate the *Date prescriber supporting statement received* field in the PYMT_D record layout. Specifically, the commenter asked if Sponsoring organizations should enter the date based on the initial coverage determination, the date of the subsequent redetermination, or both dates. Another commenter asked whether this field should be populated with the date of the redetermination request or the date of the coverage determination request if the prescriber's supporting statement came in with the coverage determination.

Response 66: Populate the *Date prescriber supporting statement received* field in the PYMT_D universe based on the type of the request. For payment coverage determinations, enter the date the prescriber's supporting statement was received for the payment coverage determination. For payment redeterminations, enter the date the prescriber's supporting statement was received for the payment redetermination.

CMS Action 66: No changes were made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 67: A commenter asked why 'None' is an available option for the *Is this a protected class drug?* field in the EFF_D record layout but is not an option for this field in the RD record layout and asked for a scenario when this would apply. Another commenter requested that CMS add 'None' to the *Is this a protected class drug?* field description in the RD record layout for at-risk redeterminations where there is no specific drug under appeal.

Response 67: We agree that the *Is this a protected class drug?* field may not apply for at-risk redeterminations and have added a 'None' option for the field in the RD record layout.

CMS Action 67: We added, "None if not applicable" to the *Is this a protected class drug?* field description in the RD record layout and updated the field length to 4. No changes were made to the burden estimate in response to these comments.

Comment 68: For the *Date forwarded to IRE* and *Time forwarded to IRE* fields in the RD record layout, a commenter asked if these fields should only be populated for untimely cases forwarded to the IRE. Another commenter asked if these fields are to be populated when an untimely case is auto-forwarded to the IRE, and/or for every case that eventually makes it the IRE (if applicable), and/or for denials for at-risk beneficiary status auto-forwarded to the IRE. This commenter recommended that CMS use the language "Provide the date/time the request was forwarded to the IRE" in the field description.

Response 68: These fields should be populated according to the field descriptions in the record layout. If the Sponsoring organization forwarded the request to the IRE, the Sponsoring organization should enter

the date and time the request was forwarded to the IRE in the respective fields. If the request was not forwarded to the IRE, the Sponsoring organization would enter 'None' for these fields. We do not believe an update is necessary as the current field descriptions are the same as the commenter's suggested language.

CMS Action 68: No changes were made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 69: A commenter asked how to identify at-risk determination appeals in the RD record layout and requested that a value be added to differentiate at-risk determination appeals in the RD universe.

Response 69: We agree with adding a field to the RD record layout to identify at-risk determination appeals. We added a field named *Is this an appeal of an at-risk determination?*. The field description reads, "Enter whether it was an appeal of an at-risk determination (e.g. request for a change in pharmacy and/or prescriber limitations, request for a change in the enrollee's at-risk determination status) Y for Yes N for No."

CMS Action 69: We added a field to the RD record layout named *Is this an appeal of an at-risk determination?* and relettered the remaining fields accordingly within the record layout. No changes were made to the burden estimate in response to this comment.

Comment 70: For the RD record layout, a commenter asked if at-risk redeterminations with multiple restrictions (e.g. Provider Lock-In and Pharmacy Lock-In) should be entered as a single line item or treated as separate requests and entered in separate line items. The commenter also asked what to enter in the *Exception Type* field of the RD universe for at-risk redeterminations.

Response 70: Per the RD record layout instructions, each redetermination request must be listed as its own line item in the submitted universe. If the case with multiple restrictions came in as a single redetermination request, we would expect for it to be listed as a single line item in the submitted universe. If an at-risk redetermination with multiple restrictions came in as separate redetermination requests, we would expect for them to be listed as separate line items in the submitted universe. For at-risk redeterminations, Sponsoring organizations should enter 'None' in the *Exception Type* field of the RD universe.

CMS Action 70: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 71: For the *Expiration Date of the Approval* field in the RD record layout, a commenter noted that for at-risk redeterminations (e.g. Pharmacy Lock-In), the result of an approved case may be a removal of a restriction authorization currently in place (e.g. termination of the Pharmacy Lock-In). The commenter stated that an approved exception would be required to have an expiration date entered in the *Expiration Date of the Approval* field. However, there would not be an expiration date for a case that was approved to remove all authorizations restricting pharmacy access. The commenter asked how to populate the *Expiration Date of the Approval* field in the following scenario: Enrollee had Pharmacy-Lock in restriction approved from February 12, 2020 through February 11, 2021. The restrictive authorization was entered in the claims processing system to limit pharmacy access to the approved pharmacy only. The enrollee requests an at-risk redetermination on March 10, 2020, and the provider gives information that the enrollee is newly diagnosed with cancer. The at-risk redetermination is approved to remove the Pharmacy Lock-In due to new cancer diagnosis and the current restrictive authorization entered in the claims processing system is removed and no authorization remains.

Response 71: For this scenario, the Sponsoring organization may enter 'None' in the *Expiration Date of the Approval* field of the RD universe.

CMS Action 71: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 72: A commenter asked if "Sponsoring organization" in the following instruction language for the EFF_D record layout includes a PBM re-opening, a Sponsoring organization re-opening, or both: "Exclude any cases that were re-opened by the Sponsoring organization or that were dismissed or upheld by the IRE, ALJ, or MAC."

Response 72: The EFF_D record layout exclusion language means exclude cases that were re-opened by the Sponsoring organization or its first tier, downstream, or related entity.

CMS Action 72: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 73: Two commenters asked how to populate the *Date reimbursement provided* field in the EFF_D universe if it is a pre-service request (e.g. coverage determination, redetermination or at-risk determination) and is not a payment request.

Response 73: For this scenario, the Sponsoring organization may enter 'None' for the *Date reimbursement provided* field.

CMS Action 73: We added the following language to the *Date reimbursement provided* field description in the EFF_D record layout: "Enter None if it was not a post-service (payment) request." No changes were made to the burden estimate in response to these comments.

Comment 74: For the EFF_D record layout, a commenter asked how to populate the *Drug Name, Strength, and Dosage Form* field for Comprehensive Addiction and Recovery Act (CARA) requests that are not related to a specific drug (e.g. prescriber or pharmacy lock). The commenter noted that Sponsoring organizations are permitted to enter 'None' in the RD record layout if the drug name/strength/dosage form are not applicable.

Response 74: We acknowledge there may be circumstances where a drug name, strength, and dosage form are not applicable for Part D effectuations of overturned decisions by the IRE, Administrative Law Judge (ALJ) or Medicare Appeals Council (MAC). As such, we have added, "Enter None if not applicable" to the EFF_D record layout *Drug Name, Strength, and Dosage Form* field description.

CMS Action 74: We added the language, "Enter None if not applicable" to the EFF_D record layout *Drug Name, Strength, and Dosage Form* field description. No changes were made to the burden estimate in response to this comment.

Comment 75: A commenter asked whether dismissed grievances should be included in the GRV_D universe. The commenter noted the table instructions state to exclude dismissed grievances but Response 36 in the Responses to Comments Received Federal Register Notice on (CMS-10717) Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols specifically states, "Requests that have been dismissed for no AOR should be included in the applicable CDAG universe submission."

Response 75: The referenced language in Response 36 reads in full, "Requests that have been dismissed for no AOR should be included in the applicable CDAG or ODAG universe submission as indicated in the record layout instructions of the respective data requests." As indicated in the GRV_D record layout instructions, grievances dismissed during the universe request period are to be excluded from the universe.

CMS Action 75: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 76: A commenter asked if the *Resolution Description* field for the GRV_D record layout was intentionally removed and no longer expected.

Response 76: The GRV_D record layout within this collection request never included a *Resolution Description* field. We believe the commenter is referring to a different collection request (CMS-10191).

CMS Action 76: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 77: A commenter asked about compliance standard 4.3 applicable to the AR universe. The commenter noted that compliance standard 4.3 states the case file should be reviewed for the appropriate alternative second written notice to the enrollee for at-risk determinations. However, the alternative second notice is only sent to beneficiaries when the enrollee is determined to be not at-risk. The commenter asked if this compliance standard should reflect second notices for at-risk beneficiaries, or alternate second notices for not at-risk beneficiaries.

Response 77: We are clarifying the Method of Evaluation column for compliance standards 4.2 and 4.3 in the CDAG protocol. In accordance with 42 CFR § 423.153(f)(6), we updated compliance standard 4.2 to specify that the second notice is for determinations that a beneficiary is an at-risk beneficiary. In accordance with 42 CFR § 423.153(f)(7), we updated compliance standard 4.3 to specify that the alternate second notice is for determinations that a potential at-risk beneficiary is not an at-risk beneficiary.

CMS Action 77: We updated compliance standard 4.2 to read: "For each case sampled, wherein the Sponsoring organization determined the enrollee is an at-risk beneficiary, review case file documentation to determine whether the enrollee submitted preferences for prescribers or pharmacies and review for proper second written notice to the enrollee." We updated compliance standard 4.3 to read: "For each case sampled, wherein the Sponsoring organization determined the enrollee is not an at-risk beneficiary, review case file documentation for proper alternate second written notice to the enrollee." No changes were made to the burden estimate in response to this comment.

Comment 78: For the AR record layout, a commenter asked how Sponsoring organizations should report enrollees that have at-risk determination changes that occur during the reporting period resulting in multiple enrollee notices.

Response 78: All at-risk determinations made within the universe request period would be reported in the AR universe. For program audit purposes, each at-risk determination must be listed as its own line item in the submitted universe. We have added this clarification to the AR record layout instructions.

CMS Action 78: We added, "Each at-risk determination must be listed as its own line item in the submitted universe" to the AR record layout instructions. No changes were made to the burden estimate in response to this comment.

Comment 79: A commenter requested that CMS add language to the AR record layout to include a definition of "at-risk determinations" so Sponsoring organizations can effectively populate the new universe with appropriate cases. The commenter noted that Section 30.4.4 of Chapter 2 of the Medicare Managed Care Manual provides a definition for "at-risk beneficiaries" and requested clarification as to the connection of this definition to the intention of the AR record layout.

Response 79: We have added language to the AR record layout instructions to clarify that the AR universe includes Sponsoring organization determinations that an enrollee is at-risk for prescription drug abuse and Sponsoring organization determinations that an enrollee is not at-risk for prescription drug abuse under 42 CFR § 423.153(f). We also updated the *Date the At-Risk Determination was made* field description to read: "Enter the date the at-risk or not at-risk determination was made." Questions pertaining to at-risk determination policy should be addressed to the CMS policy mailbox PartD_OM@cms.hhs.gov.

CMS Action 79: We updated the AR record layout instructions to read: "Include all at-risk determinations made by the Sponsoring organization pursuant to 42 CFR § 423.153(f) during the universe request period (i.e. Sponsoring organization determinations that an enrollee is at-risk for prescription drug abuse and Sponsoring organization determinations that an enrollee is not at-risk for prescription drug abuse under 42 CFR § 423.153(f))." We also updated the *Date the At-Risk Determination was made* field description to read: "Enter the date the at-risk or not at-risk determination was made." No changes were made to the burden estimate in response to this comment.

Comment 80: A commenter asked how to populate the *Drug Name, Strength, and Dosage Form* field for the AR universe if there are drug limitations for multiple medications.

Response 80: We have clarified the *Drug Name, Strength, and Dosage Form* field description to address how Sponsoring organizations should populate the field if there are drug limitations for multiple medications.

CMS Action 80: We updated the *Drug Name, Strength, and Dosage Form* field description in the AR record layout to read: "Enter the Drug Name, Strength, and Dosage Form applicable to the specific limitation the Sponsoring organization intends to place on the beneficiary's access to coverage for frequently abused drugs under the program. Enter Multiple if the intended limitation applies to more than one drug (e.g. beneficiary level edit blocking all opioid access, beneficiary level edit allowing a defined cumulative MME dosage). Enter None if the intended limitation is not related to a specific drug (e.g. pharmacy lock-in, prescriber lock-in)." No changes were made to the burden estimate in response to this comment.

Comment 81: A commenter asked what CMS considers as the "provided" date for the AR record layout *Date the Initial Written Notification of potential at-risk status was provided to enrollee* and *Date Second Written Notification of At-Risk Determination Provided to Enrollee* fields.

Response 81: Policy questions should be directed to the CMS policy mailbox https://appeals.lmi.org. For program audit purposes, we would accept the "provided" date based on when notification is considered delivered per the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

CMS Action 81: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 82: A commenter sought clarification on the *Date the Initial Written Notification of potential at-risk status was provided to enrollee* field in the AR record layout and noted the table instructions state the date of the Sponsoring organization's determination must fall within the universe request period. The commenter asked how to populate the *Date the Initial Written Notification of potential at-risk status was provided to enrollee* field if, during the universe request period, a second notification of at-risk determination is provided to the enrollee but the initial written notification of potential at-risk status was provided to the enrollee prior to the universe request period. The commenter asked if the Sponsoring organization should enter the date the initial notification was provided to the enrollee even if the date is before the date of the universe request period or if they should enter 'None' if no written notification was provided during the universe request period. The commenter suggested that when notices are not provided within the universe request period, the field should be populated with 'None' and that 'None' does not mean that the notification was not provided to the enrollee; rather, it means the notification was not provided during the universe request period.

Response 82: For this scenario, Sponsoring organizations would enter the date the initial notification was provided to the enrollee (even if the date is before the date of the universe request period) in the *Date the Initial Written Notification of potential at-risk status was provided to enrollee* field. The date of the initial notice is required to calculate timeliness per compliance standard 1.6 in the CDAG protocol, "Conduct timeliness test at the universe level on at-risk determinations to determine whether the Sponsoring organization provided the second notice or the alternate second notice not less than 30 days and not more than the earlier of the date the Sponsoring organization made the relevant determination or 60 days after the date of the Sponsoring organization's initial notice."

CMS Action 82: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 83: For the AR record layout, a commenter asked for confirmation that an enrollee would be included in the universe if they meet the Overutilization Monitoring System criteria, go through case management, are not an exempt enrollee, and a decision of at-risk or not at-risk is rendered. However, an enrollee would not be included in the universe if they are still going through case management and a decision of at-risk or not at-risk has not yet been rendered. The commenter also asked if the intent for the AR universe is to include only enrollees that received notification (e.g. Initial Notice, Second Notice, Alternate Second Notice) as a part of the Drug Management Program (DMP) or whether the intent is to include all enrollees reviewed under the DMP even if they were excluded for not meeting criteria (e.g. Active Cancer-Related Pain, Hospice) or it is found that their medications are considered medically necessary after discussions with their provider(s).

Response 83: The intent for the AR record layout is to include all at-risk and not at-risk determinations made by the Sponsoring organization pursuant to 42 CFR § 423.153(f). As mentioned in Response 79 above, we have clarified the AR record layout instructions. The AR universe should not include all enrollees reviewed under a DMP. For the scenario provided, if an enrollee goes through case management, is not exempt, and a decision of at-risk or not at-risk is rendered pursuant to 42 CFR § 423.153(f), the case would be included in the universe. If an enrollee is still going through case management and a decision of at-risk or not at-risk has not yet been rendered, the case would be excluded from the AR universe.

CMS Action 83: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 84: A commenter noted that the DMP frequently asked questions guidance states that, if an enrollee appeals after 60 days from receiving the second notice, the Sponsoring organization should

attempt to resolve the issue via case management. The commenter asked whether this second review by case management should also be included in the AR universe.

Response 84: For this scenario, Sponsoring organizations would exclude the second review that was conducted after issuance of the second notice from the AR universe.

CMS Action 84: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 85: With regard to at-risk determinations, a commenter asked where the limitation should be entered by the Sponsoring organization so the correct date is populated in the universe. Specifically, the commenter asked if it is the date the Sponsoring organization entered the limitation into MARx.

Response 85: Questions pertaining to at-risk determination policy should be addressed to the CMS policy mailbox PartD_OM@cms.hhs.gov. For program audit purposes, Sponsoring organizations would populate the *Date the at-risk determination was made* field with the date the Sponsoring organization made the determination that the enrollee was either at-risk or not at-risk.

CMS Action 85: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

PART C ORGANIZATION DETERMINATIONS, APPEALS AND GRIEVANCES (ODAG)

Comment 86: One commenter requested CMS to clarify if case file documentation noting physician or other appropriate health care professional review is required for all organization determinations or whether the documentation is required only for cases which result in denials as described in compliance standard 2.2.

Response 86: We do not deviate from 42 CFR § 422.566(d) and § 422.590(g) during the review of compliance standard 2.2. Any questions pertaining to this policy should be directed to the CMS policy mailbox https://appeals.lmi.org.

CMS Action 86: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 87: One commenter requested for CMS to provide details as to what is considered an appropriate extension as referenced in compliance standard 2.4.

Response 87: We do not deviate from 42 CFR § 422.568(b), § 422.572(b), § 422.590(e), and § 422.631(d) during the review of compliance standard 2.4. Any questions pertaining to this policy should be directed to the CMS policy mailbox https://appeals.lmi.org.

CMS Action 87: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 88: One commenter asked for clarity surrounding compliance standard 1.20. Specifically, the commenter asked if Dual Eligible Special Needs Plans–Applicable Integrated (DSNP-AIPs) are required to notify the enrollee of the decision to terminate, suspend, or reduce services no later than 10 business days or calendar days prior to the action.

Response 88: Sponsoring organizations must notify the enrollee within 10 calendar days prior to the action. We updated the language for clarity.

CMS Action 88: We updated the Method of Evaluation column for compliance standard 1.20 to read: "Conduct timeliness test at the universe level on adverse integrated organization determinations to determine whether the DSNP-AIP notified the enrollee of the decision to terminate, suspend, or reduce services no later than 10 calendar days prior to the action (that is, before the date on which a termination, suspension, or reduction of previously approved services becomes effective)." No changes were made to the burden estimate in response to this comment.

Comment 89: One commenter noted the 10 dismissed requests selected for review in compliance standard 3.1 will be pulled from the OD, RECON, and PYMT_C record layouts. The commenter asked CMS to confirm if dismissed requests will not be selected from the AIP record layout.

Response 89: Correct. We confirm the 10 dismissed requests will not be selected from the AIP record layout.

CMS Action 89: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 90: A few commenters requested clarity on populating the *Issue description and type of service* field. One commenter asked if Sponsoring organizations had the option to enter CPT or HCPCS codes in this field while another commenter asked if CMS expects CPT, HCPCS, NDC, or DME numbers in this field. Additionally, one commenter stated it would be difficult to include an NDC or J-code in this field as required and one commenter asked CMS for an appropriate response if neither an NDC or J-code were available. Finally, one commenter asked if CMS would consider aligning the description language for this field with CDAG.

Response 90: Sponsoring organizations do not have the option to enter CPTs, HCPCs, NDCs, or DME numbers as the sole response for this field. Sponsoring organizations may include the aforementioned codes only if they are included as part of the description (e.g. 74160 – CT Abdomen with dye; E1130 - Standard wheelchair, fixed full length arms, fixed or swing away detachable footrests). Additionally, after further consideration and to avoid any confusion, we decided to remove the following language from the *Issue description and type of service* field description: "For Part B drugs requests, include the J-Code, National Drug Code (NDC), or both" to better align with CDAG as requested.

CMS Action 90: We removed the following language from the *Issue description and type of service* field description in the OD, RECON, and PYMT_C record layouts: "For Part B drug requests, include the J-Code, National Drug Code (NDC), or both." No changes were made to the burden estimate in response to these comments.

Comment 91: One commenter asked if CMS expected PBM Part B pharmacy and/or Part B direct member reimbursement records to be included in the ODAG universes, and, if so, in what universe(s) they should be populated.

Response 91: Yes. Per the PYMT_C record layout instructions, all payment organization determinations and reconsiderations the Sponsoring organization approved, denied, or dismissed from enrollees, non-contract providers, and non-contract pharmacies during the universe period must be included in the universe. This includes pharmacy claims and direct member reimbursement requests submitted to a Sponsoring organization's Part C line of business.

CMS Action 91: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 92: One commenter requested that CMS update the description language in the *Date the Request was received* and *Time the request was received* fields in the OD record layout to read: "If a standard request was upgraded to expedited, enter the date the request was upgraded to expedited" and "If a standard request was upgraded to expedited, enter the time the request was upgraded to expedited," respectively.

Response 92: We appreciate the comment however decline to make this change. We believe the current language sufficiently describes the requested information.

CMS Action 92: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 93: One commenter noted the PYMT_C record layout instructions no longer require submission of contract provider denied claims and asked CMS to confirm if this omission was intentional.

Response 93: For this collection request, Sponsoring organizations are not required to include contract provider denied claims in the PYMT_C record layout.

CMS Action 93: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 94: One commenter requested that CMS update the *Was it a Clean Claim?* field description from "None for payment reconsiderations" to "None for DMR claims or payment reconsiderations." The commenter asked for this change based on Section 40.10 of the Part C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance which explains clean claim processing timeframes. This commenter believes the claim processing timeframes in Section 40.10 are only relevant to non-contract provider submitted claims and not enrollee submitted claims.

Response 94: We appreciate the comment however decline to make this change. Additionally, we disagree with the commenter's interpretation of the processing timeframes listed in the stated guidance of the Part C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. For policy clarification regarding payment organization determinations and reconsiderations, contact the CMS policy mailbox https://appeals.lmi.org.

CMS Action 94: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 95: One commenter asked which response is applicable in the *Was the initial organization determination request denied for lack of medical necessity?* field description in the PYMT_C record layout if a Sponsoring organization denies a claim for lack of pre-authorization on services requiring pre-authorization. The commenter said none of the current choices are appropriate.

Response 95: We do not define lack of medical necessity for program audit purposes. Sponsoring organizations should use their definition of medical necessity to populate this field.

CMS Action 95: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 96: One commenter noted a payment impact analysis was not included in CMS-10191 and requested that CMS publish an updated payment impact analysis in the final version of this collection request (CMS-10717).

Response 96: For this collection request, auditors will use the ODAG universe record layouts to request impact analyses if noncompliance is identified during the course of an audit. Auditors will identify which record layout Sponsoring organizations should use for the impact analysis at the time of the request. Sponsoring organizations must submit each requested impact analysis, comprehensive of all contracts and Plan Benefit Packages identified in the audit engagement letter, in either Microsoft Excel (.xlsx) file format with a header row or Text (.txt) file format without a header. Any questions pertaining to CMS-10191 should be directed to the Part C and Part D audit mailbox part_c_part_d_audit@cms.hhs.gov.

CMS Action 96: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 97: A few commenters asked for clarification on the *Part B Drug?* description language in the OD and RECON record layouts. Two commenters asked CMS to clarify the following description language in the *Part B Drug Request?* field: "…or Part D drug that is part of a Sponsor's step therapy requirement for a Part B drug." A separate commenter requested only primary Part B drug requests be assessed for compliance with new Part B drug timeframes, and Part B drug requests that are ancillary to pre-service requests for medical procedures be adjusted to reflect the organization determination timeframes.

Response 97: We appreciate the comments. After further consideration, we have decided to remove the following language from the *Part B Drug Request?* field description: "Sponsor organizations must indicate 'Y' for any pre-service request that includes a Part B drug (primary or ancillary) or Part D drug that is part of a Sponsor's step therapy requirement for a Part B drug." The field description now reads: "Enter Y for Yes N for No." Sponsoring organizations should enter 'Y' if the request for a Part B drug is primary and processed by their Part C line of business.

CMS Action 97: We removed the following language from the *Part B Drug Request?* field description: "Sponsor organizations must indicate 'Y' for any pre-service request that includes a Part B drug (primary or ancillary) or Part D drug that is part of a Sponsor's step therapy requirement for a Part B drug" in the OD and RECON record layouts. No changes were made to the burden estimate in response to these comments.

Comment 98: Multiple commenters noted there is not an option for standard requests in the field description for *Time oral notification provided to enrollee* and *Time written notification provided to enrollee* in the OD record layout and *Time oral notification provided to enrollee* and *Time forwarded to IRE* in the RECON record layout. These commenters asked if 'None' would be the appropriate response.

Response 98: Per the field descriptions, the *Time oral notification provided to enrollee* and *Time written notification provided to enrollee* in the OD record layout and the *Time oral notification provided to enrollee* and *Time forwarded to IRE* in the RECON record layout are specific to expedited requests and Part B drug requests. Sponsoring organizations should enter 'None' for standard pre-service requests that do not fall under the Part B drug timeframes. In light of comments received, we have updated the OD and RECON record layout descriptions to clearly address standard service requests.

CMS Action 98: Within the OD and RECON record layouts, we added options for standard service requests in the applicable date and time fields. No changes were made to the burden estimate in response to these comments.

Comment 99: One commenter asked if the *Date forwarded to IRE* and *Time forwarded to IRE* fields in the RECON record layout should only be populated with cases that were forwarded for being untimely. Another commenter requested for CMS to update the description language in the *Date forwarded to IRE* field to account for dismissed requests.

Response 99: The intent of these fields is to capture each instance of IRE auto-forwards for both standard and expedited reconsiderations. Sponsoring organizations are required to forward all pre-service upheld reconsideration decisions to the IRE, including untimely cases. We do not think an update to the description language for these fields is required for dismissed requests. If the request was not forwarded to the IRE 'None' should be entered per the field descriptions.

CMS Action 99: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 100: A number of commenters noted the *Request Determination* field in the RECON record layout did not include an option for dismissed requests in the field description and asked for CMS to include this option.

Response 100: We agree with the commenters' suggestion and have updated the *Request Determination* field description in the RECON record layout to include dismissed requests.

CMS Action 100: We added "Dismissed" in the *Request Determination* field description in the RECON record layout. No changes were made to the burden estimate in response to these comments.

Comment 101: One commenter stated the description language in the *Was an expedited request made but processed as standard?* field in the RECON record layout was unclear. Particularly, the commenter asked CMS to clarify what is meant by, "For dismissed requests, populate based on how the request was received." This commenter noted dismissed requests are not processed.

Response 101: Sponsoring organizations may enter 'None' in this field when a request is dismissed. We updated the description for the *Was an expedited request made but processed as standard?* field in the RECON record layout.

CMS Action 101: We removed the following language from the field description for *Was an expedited request made but processed as standard?* in the RECON record layout: "For dismissed requests, populate based on how the request was received." We added the following language to the field description: "or the request was dismissed." No changes were made to the burden estimate in response to this comment.

Comment 102: One commenter noted that CMS did not account for overturned reconsiderations in the *If request denied, date services were terminated, reduced, suspended* field description in the AIP record layout. The commenter asked if 'None' would be the appropriate response.

Response 102: We agree with the commenter's suggestion and updated the *If request denied, date services were terminated, reduced, suspended* field description in the AIP record layout to account for approved reconsideration requests.

CMS Action 102: We updated the field description for *If request denied, date services were terminated, reduced, suspended* in the AIP record layout to read: "Enter None if the reconsideration was approved or if the decision was not appealed as indicated by N in column ID J." No changes were made to the burden estimate in response to this comment.

Comment 103: Two commenters noted CMS did not include requests that do not require a prior authorization from the list of exclusions in the OD record layout instructions. The commenter asked CMS to confirm if this was intentional.

Response 103: We intentionally did not include requests that do not require a prior authorization as an exclusion from the OD and RECON record layout instructions. If a service does not require a prior authorization but an enrollee, their physician, or a representative acting on their behalf makes a request for that service, then the request must be included in the appropriate universe submission. The appropriate record layout is determined by the request itself (i.e. standard OD, standard reconsideration, expedited OD, etc.).

CMS Action 103: No changes were made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 104: One commenter noted the values of 'NF,' 'NE,' and 'None' were added to the proposed RECON, PYMT_C, and EFF_C record layouts. The commenter asked for CMS to eliminate these options and use N/A since it is operationally burdensome to populate multiple values when no action was taken in all cases.

Response 104: We agree with the commenter's recommendation and, for this reason, did not include 'NA,' 'NF,' and 'NE' as an option in the RECON, PYMT_C, and EFF_C record layouts. In response to comments received during the sixty-day comment period, we simplified the field descriptions within the ODAG record layouts by allowing Sponsoring organizations to enter 'None' in place of these options.

CMS Action 104: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 105: One commenter asked CMS to clarify if Sponsoring organizations should include cases reviewed by Quality Improvement Organizations (QIO) and subsequently overturned by the ALJ or MAC in the EFF_C universe.

Response 105: ALJ or MAC cases arising from QIO determinations of denied discharges should not be included in a Sponsoring organization's EFF_C universe submission.

CMS Action 105: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 106: One commenter requested for CMS to clarify whether all pre-service organization determinations during the review period should be included in the Part B Drug record layout or just those that require a prior authorization for Part B benefits.

Response 106: Per CMS Action 227 in the Responses to Comments Received Federal Register Notice on (CMS-10717) Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols, we removed the Part B Drug record layout from the ODAG Data Request, and updated the OD and RECON record layouts to accommodate inclusion of pre-service Part B drug organization determination and reconsideration requests into the respective universes. All pre-service requests must now be included in either the OD or RECON record layout.

CMS Action 106: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 107: One commenter noted the EFF_C record layout does not have a field that accounts for Part B drug requests, similar to the OD and RECON record layout. The commenter asked how CMS would assess timeliness on Part B drug requests for IRE effectuations without this field.

Response 107: We agree with the commenter and have added a *Part B Drug Request?* field to the EFF_C record layout.

CMS Action 107: We added *Part B Drug Request?* field to the EFF_C record layout. No changes were made to the burden estimate in response to this comment.

Comment 108: One commenter asked if payment requests that also have a PA edit should be reported in both the payment and pre-service universes. The commenter received feedback regarding the CDAG data collection requests that stated these requests should only be populated in the payment table and asked CMS to align the 2 program areas and require population of such a request in the PYMT_C record layout only.

Response 108: We believe the commenter is referring to requests for Part B drugs and not Part C services. We do not expect payment requests that also have a PA edit to be included in both the pre-service and post-service record layouts. Sponsoring organizations should contact the policy mailbox for clarification related to reviewing Part B drugs for continued use when a payment request is received https://dpapportal.lmi.org/dpapmailbox/.

CMS Action 108: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 109: One commenter expressed concern over CMS requiring Sponsoring organizations to bundle multiple services in one line item of a universe as described in the OD record layout instructions. The commenter believes bundling multiple services and decisions as one line item in the ODAG universe will pose administrative challenges and jeopardize accuracy. The commenter asked CMS to allow reporting at the line level to avoid undue burden and data integrity challenges in program audits.

Response 109: We clarify that the instruction pertaining to requests with more than one service is not a new requirement. We believe it's necessary for Sponsoring organizations to include all of the request's line items in a single row and enter the multiple line items as a single organization determination request so that our testing accurately reflects the outcome of the enrollee's experience with Sponsoring organizations as it relates to their coverage requests.

CMS Action 109: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 110: Two commenters requested additional clarification on the ODAG instructions for the PYMT_C record layout. A commenter requested guidance on whether member-submitted claims should always be reported using the *Date written notification provided to enrollee* field, regardless of being paid or denied, or whether the member-submitted paid claims will be pulled by the *Date claim/reconsideration was paid* field. The current instructions for this record layout instruct Sponsoring organizations to "submit payment organization determinations (claims) based on the date the claim was paid (Column O) or notification of the denial to the provider (if provider submitted the claim -Column Q) or enrollee (if the enrollee submitted the claim – Column P)." Another commenter asked if the following exclusion language applied to both payment organization determinations and reconsiderations as the instructions do not specify: "Exclude any payment requests that were denied due to invalid billing codes, eligibility (i.e.

enrollees who were not enrolled on the dates of service, providers not accepting assignment) or, recoupment of payment, including pending determination of other primary insurance such as automobile, worker's compensation, etc."

Response 110: For approved payment organization determination requests and reconsideration requests submitted by non-contract providers and enrollees, Sponsoring organizations should use the *Date claim/reconsideration was paid* field to submit the PYMT_C universe. For denied payment organization determination requests, Sponsoring organizations should use the *Date written notification provided to provider* field if a non-contract provider submitted the claim, and should use the *Date written notification provided to enrollee* field if an enrollee submitted the claim. For denied payment reconsideration requests, Sponsoring organizations should use the *Date Forwarded to the IRE* field for requests from both non-contract providers and enrollees. Additionally, the exclusions listed in the PYMT_C record layout instructions apply to both payment organization determinations and reconsiderations.

CMS Action 110: No changes were made to the protocol in response to these comments. No changes were made to the burden estimate in response to these comments.

Comment 111: One commenter requested for CMS to update the description language in the *Date written notification provided to enrollee* field in the RECON record layout to read: "Enter None if no written notification was provided or required."

Response 111: We appreciate the suggestion however decline to make this change. Sponsoring organizations may enter 'None' if no written notification was provided.

CMS Action 111: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 112: Two commenters noted an error in the PYMT_C record layout instructions. The current instructions state, "Submit dismissed requests based on the date of the decision to dismiss (Column M)." Both commenters noted the *Date of Determination* field is Column N.

Response 112: We agree and updated the instructions to reflect the appropriate column ID.

CMS Action 112: We updated the PYMT_C record layout instructions to read: "Submit payment organization determinations (claims) based on the date the claim was paid (Column O) or notification of the denial to the provider (if provider submitted the claim - Column Q) or enrollee (if the enrollee submitted the claim – Column P). Submit payment reconsiderations based on the date the overturned reconsideration was paid or, for upheld reconsiderations, submit based on the date the case was forwarded to the IRE. Submit dismissed requests based on the date of the decision to dismiss (Column N)." No changes were made to the burden estimate in response to these comments.

Comment 113: Two commenters noted the description language for the *AOR/Equivalent Notice Receipt Time* field in the GRV_C record layout references dismissed requests. One of the commenters noted that dismissed requests, per the instructions for the GRV_C record layout, are excluded and asked CMS to make the appropriate updates to the field description.

Response 113: We agree and have updated the field description language to exclude dismissed requests.

CMS Action 113: We updated the *AOR/Equivalent notice Receipt Time* field description in the GRV_C record layout to read: "For expedited grievances, enter the time the Appointment of Representative (AOR) form or equivalent written notice was received by the Sponsoring organization. Submit in

HH:MM:SS format (e.g. 23:59:59). Enter None for standard grievances or if an AOR or equivalent written notice was not received or required." No changes were made to the burden estimate in response to these comments.

Comment 114: One commenter asked for clarification on the difference between "Date oral notification of resolution provided to enrollees" referenced in CMS-10191 and "Enter the date oral notification was provided to the enrollee" as referenced in this collection request.

Response 114: We aligned ODAG data field names and descriptions within this collection request for consistency with the CDAG record layouts, when possible.

CMS Action 114: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 115: One commenter inquired about the GRV_C record layout instructions. The commenter asked CMS which date a Sponsoring organization should use to determine inclusion in the universe if a grievance notification was completed both orally and in writing.

Response 115: Per the GRV_C record layout instructions, Sponsoring organizations should populate the GRV_C record layout if either the *Date oral notification provided to enrollee* or the *Date written notification provided to enrollee* (Column ID Q or S) falls within the universe request period.

CMS Action 115: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 116: One commenter asked CMS to confirm the AIP record layout should be populated by Dual Eligible – Special Needs Plans (D-SNPs) that have been identified by CMS as applicable integrated plans. This commenter suggested CMS update the inclusion/exclusion criteria to specify which organizations must populate this table.

Response 116: We agree with the commenter and have updated the AIP instructions to clearly indicate which Sponsoring organizations must populate the AIP record layout.

CMS Action 116: CMS added the following language to the AIP record layout instructions: "The AIP record layout must be submitted by all Sponsoring organizations determined to be an applicable integrated plan as defined by 42 CFR § 422.561 and have been notified by CMS of their status."

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Comment 117: One commenter expressed appreciation for CMS's reinstatement of the original timeframe for providing samples.

Response 117: We thank the commenter for their support and believe that providing the 30 care coordination samples the Thursday prior to the start of audit field work will allow sufficient time for Sponsoring organizations to prepare for the live audit.

CMS Action 117: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 118: One commenter appreciated the example in the Method of Evaluation section that clarifies what auditors may review to assess compliance standard 1.8 "…(e.g. documented phone calls, letters to/from providers regarding member care, etc.)." The commenter requested that CMS provide a similar example of what auditors may review to assess whether each enrollee's "Primary care provider (PCP) was involved in coordination of care and communications" as indicated in compliance standard 1.9.

Response 118: Auditors will be looking for evidence of primary care provider (PCP) involvement with other members of the ICT.

CMS Action 118: We have added examples to compliance standard 1.9 to read: "Primary care provider (PCP) was involved in coordination of care and communications (e.g. ICT meeting attendee lists or other documentation reflecting PCP interaction with ICT members)." No changes were made to the burden estimate in response to this comment.

Comment 119: One commenter referred to the revised instructions for the SNPE record layout that reads: "List all current SNP enrollees as of the date of the audit engagement letter." The commenter requested that CMS consider aligning the universe review period for the MMP protocol with the D-SNP protocol in the interest of reducing burden for plans that have both an MMP program and a D-SNP program.

Response 119: This comment is beyond the scope of this collection request.

CMS Action 119: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 120: One commenter asked if CMS will request a root cause analysis connected to the HRAT-IA if mitigating factors documented in the impact analysis are sufficient to preclude the Sponsoring organization from an audit finding.

Response 120: We will request a root cause analysis in conjunction with the HRAT-IA whenever the results of the applicable universe-level timeliness assessment fall below our internal threshold.

CMS Action 120: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 121: One commenter asked CMS to specify the threshold that will be used in requiring an HRAT-IA.

Response 121: Thresholds for requiring impact analysis submissions remain internal to CMS.

CMS Action 121: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.