Responses to Comments Received
Federal Register Notice on (CMS-10717)
Medicare Parts C and D Program Audit Protocols and Data Requests

CMS received 35 public submissions, which included 315 comments on the December 22, 2025, (CMS-10717) Medicare Parts C and D Program Audit Protocols and Data Requests proposed information collection. We then combined the unique comments into comment summaries and provided responses in the document below. Comments are categorized in the following order: those that are general in nature, those applying to the individual program areas and/or documents, and finally comments on burden.

GENERAL COMMENTS

Comment: Multiple commenters praised CMS for their continued transparency in the audit process, including through these latest proposed changes. A commenter asked whether changes made in response to comments will be shown in the audit protocol documents or only reflected in the responses to comments.

Response: We appreciate the feedback and are committed to continued transparency through the audit process. If there are changes to the audit protocol documents based on comments received, CMS will make the changes within the actual documents. A summary of all of the updates is also reflected in the Crosswalk document which will be published with the protocols.

Comment: A commenter asked if CMS could utilize attendance records from Microsoft teams meetings or webinars instead of requesting attendance logs to be uploaded after the call.

Response: We appreciate this commenters' suggestion. Based on our experience it is not unusual for multiple people to call into a webinar from the same number/location. For example, a Sponsor may have a group of people in a single conference room and call in from the same phone line. While we encourage Sponsors to use attendance logs from webinars in order to help validate the accuracy of the submitted attendance sheets, we will still need to collect attendance to ensure all unique individuals are identified.

Comment: A few commenters expressed concerns about the proposed sample selection language that was included across protocols; including in the Formulary and Benefit Administration (FA) protocol, the Part D Coverage Determinations, Appeals and Grievances (CDAG) protocol, the Part C Organization Determinations, Appeals and Grievances (ODAG) protocol, and the Special Needs Plans Care Coordination (SNPCC) protocol. Specifically, the new language indicated that CMS would select a minimum sample set in each program area rather than a maximum. These commenters requested that CMS establish a maximum number of samples and/or allow additional time between CMS providing samples to the Sponsor and the beginning of the sample review. The commenters expressed concerns that if CMS did not establish a maximum sample set, the burden of audits would be unknown.

Response: We agree with this recommendation and have made corresponding updates to all impacted protocols. Each protocol will include language that CMS will select "up to" a specific number of samples. In order to ensure continued transparency, we also added language that reflects the ability to select additional samples above the maximum if needed to investigate a specific issue; and we added language to address situations where initial samples may need to be replaced if they are not appropriate to the review. CMS may reduce the number of samples selected, but in general, we would not anticipate selecting more than the maximum number of samples in the majority of audits.

Comment: A commenter noted that CMS removed the field length fields from the record layout tables and requested confirmation that this information is no longer required.

Response: Yes, we removed the field length character limits from all protocols. There is no established character limit for each field in the record layouts.

Comment: Several commenters requested additional information on expectations for the desk review process. Specifically, commenters asked about the timeframe for sample document submission and audit process milestones. Several commenters indicated that Sponsors would need sufficient time to produce sample case files. A commenter specifically requested that Sponsors be allowed seven to 10 business days to prepare case files. Another commenter asked if the Sponsor would have an option for a desk review or a live webinar. A few commenters recommended against desk review, noting that live webinar has proven to be effective and efficient over the years; and allows for real time information sharing and resolving concerns that could lead to less questions and documentation requests from auditors.

Response: We appreciate the opportunity to clarify our intended desk review approach for program audits. While desk review may be used for certain program areas, others—such as Formulary Administration (FA)—may continue to be conducted via webinar due to the type of information presented and shared. We will notify Sponsors of the audit review method at the start of the audit and provide instructions. Regardless of the review method, we anticipate the overall audit process will remain the same, including the entrance conference, status meetings, and exit conference. Our intention is not to reduce transparency or limit Sponsor engagement. Rather, experience has shown that the desk review approach can create more productive discussions by allowing both CMS and Sponsors sufficient time to review cases before meeting to discuss questions or potential concerns. We recognize that Sponsors need adequate time to compile and submit case files. While samples for live webinar reviews have historically been provided approximately one hour before the review session, desk reviews would generally allow approximately five business days for case file preparation and submission. This additional time is intended to support complete and accurate submissions and reduce the need for real-time document gathering during audit fieldwork. We recognize the value of webinar reviews and the transparency they provide. Under a desk review approach, we would continue to engage Sponsors regarding any questions, concerns, or potential findings identified during case review.

Cases that are clearly compliant may be resolved without additional discussion, while cases requiring clarification would be discussed with Sponsors during follow-up meetings. Whenever possible, we would share questions in advance to allow Sponsors time to research and prepare responses, reducing the need for post-meeting follow-up and promoting more efficient discussions. Overall, incorporating the desk review approach into program audits preserves transparency and Sponsor engagement while providing greater flexibility and reducing the time Sponsors spend waiting during live case reviews.

Comment: A commenter requested for CMS to expand upon how the audit scope period will be chosen given that the proposed scope is not tied to the engagement notice date in any of the protocols. Another commenter expressed concerns that CMS's decision to remove the explicit reference to the calendar timeframe from which data should be pulled and instead requiring plans to "submit a 12-week period as requested by CMS" removes a guardrail that limits the audit scope to the current plan year. The commenter is concerned that removing this guardrail would allow requests for data from prior plan years. The comment recommends that CMS maintain the existing calendar-based limitation or explicitly clarify that universe submissions are restricted to the current plan year.

Response: We have modified the scope of universe request language in all corresponding protocols to clarify that the universe review periods precede and include the date of the audit engagement letter.

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

Comment: A commenter asked if CMS eliminated tracers completely or only portions of a tracer from the audit.

Response: We have removed tracers as they previously existed in the protocol. Instead of requesting that Sponsors provide a PowerPoint presentation of specific monitoring and/or auditing activity, we are now intending to have real-time discussions, during the course of the audit, about how compliance operates and how effectiveness can be determined.

Comment: A few commenters recommended that CMS integrate CPE into other audit areas rather than maintaining CPE as a standalone program area. Commenters asked CMS to clarify how CPE will be evaluated under the revised structure, how compliance effectiveness will be assessed across FA, ODAG, CDAG, and SNPCC, and how audit findings will be communicated when CPE related issues are identified.

Response: We will no longer be conducting CPE as a standalone program area during the audit. Instead, CMS will evaluate compliance oversight throughout the audit process as issues emerge across audited program areas, including FA, CDAG, ODAG, and SNPCC, as applicable. Under this integrated approach, CMS and the compliance officer will discuss compliance issues during the audit, and CMS will assess how effectively the Sponsor implements, monitors, and

remediates compliance and performance issues across operational areas. CMS will use the Compliance Oversight Activities (COA) universe, the questionnaire, and all other available information to lead discussions with the compliance officer throughout the audit on determining what compliance efforts have been effective. In order to better emphasize this effort, we have added one column into the COA universe asking Sponsors to identify which program area was related to the compliance activity. For example, if monitoring of rejected claims was done on a monthly basis, the Sponsor would select FA in that column. This will allow both the Sponsor and the CMS teams to have a clear overview of the different activities that relate to the audited areas. During fieldwork, the audit team will collaborate with the compliance officer on potential ways to improve their compliance program based on the results of the audit rather than focus on citing conditions of noncompliance related to CPE. While CMS does not intend to routinely cite conditions related to the specific compliance requirements, there may be some exceptions based on the facts and circumstances of the situation.

Comment: A few commenters requested clarification on CPE supplemental documents and supporting evidence. Commenters asked what supplemental documents were removed, whether plans may modify the optional Organizational Overview deck, and what additional evidence CMS may request throughout the audit when documentation is not collected during the initial audit process.

Response: We removed multiple supplemental data requests from the collection, including materials related to tracers, the Sponsor compliance risk assessment, and the Sponsor audit strategy. The Organizational Overview template is optional and intended to serve as a guide. Sponsors do not have to provide an overview. However, they may choose to do so without using the template at all or they may tailor or modify the template to reflect their structure and context. Under the previous process, Sponsors were required to provide supporting documentation through the tracer reviews to demonstrate their efforts to monitor and audit issues. Because we are removing the tracer approach from the CPE review, and instead will conduct interviews and real-time discussions, we do not anticipate needing additional supporting documentation in most instances. If CMS does request additional supplemental information, CMS will allow sufficient time for the compliance officer to gather and provide it.

Comment: The majority of commenters recommended that CMS retain a 6-month COA universe lookback period instead of extending it to 1 year. Commenters stated that 6 months better reflects current compliance oversight activities, avoids inclusion of outdated processes, and reduces administrative burden without limiting CMS's visibility.

Response: We agree with these commenters and modified the CPE Program Audit Protocol and Data Request to retain the 6-month lookback period instead of extending it to 1 year.

Comment: Multiple commenters requested clarification on the scope of the COA universe, and whether Fraud, Waste and Abuse (FWA) activities should be excluded from this universe. A few commenters requested CMS confirm that the previous Column ID C, asking if an activity was

related to FWA was intentionally removed, and pointed out that as a result of that column being removed the lettering for the remaining columns was incorrect. Another commenter asked if the FWA universe no longer reflects provider-based investigations involving claims and billing; how does that tie directly to activities within ODAG, CDAG, FA or SNPCC.

Response: We appreciate the comments requesting clarification on the scope of the COA universe as it relates to FWA. The Center for Program Integrity (CPI) is responsible for assessing fraud, waste and abuse; and those activities have been excluded from the CPE review. However, Sponsors may include oversight activities conducted by the Sponsor that overlap with FWA if they relate to program areas such as FA, ODAG, CDAG, or SNPCC and the Sponsor believes they are relevant to the audit. We have also updated the COA universe column identifiers to reflect sequential lettering following the removal of Column ID C.

Comment: Several commenters requested clarification on the inclusion language for the COA universe. A commenter asked if the Sponsor should include the Pharmacy Benefit Manager's (PBM's) investigational activities. Another commenter requested confirmation that activities like enrollment/disenrollment monitoring would be excluded from the COA universe. Commenters asked whether the universe should include only compliance-conducted activities, whether operational-area activities known to compliance should be included, for example activities impacting ODAG done by operational teams.

Response: We expect Sponsors to include compliance oversight activities related to the program audit areas identified in the audit engagement letter, including activities conducted by the compliance function and activities conducted by operational areas within the Sponsor's organization when compliance is aware of those activities. CMS also clarifies that activities outside the scope of the program audit, such as audits or monitoring of enrollment processes, should be excluded from the COA universe. While we did not originally have language regarding the inclusion of activities performed by someone other than the Sponsor, we have added language to capture this in the audit protocol. We understand that Sponsors may direct some entities to conduct monitoring or auditing on their behalf, such as the PBM, which the Sponsor uses as part of their overall strategy. We added language that Sponsors may include these activities, as they relate to the audited program areas, in the COA universe. We are not requiring these activities to be included as our main focus is on the activities that are conducted and led by the Sponsor itself.

Comment: A commenter requested CMS modify Column ID K (Corrective Action Required) in the COA universe. The commenter recommended keeping "N" as the response when no deficiencies were identified or when the compliance department is still assessing whether correction is needed, rather than using "NA," to maintain current practice and avoid unnecessary workflow, system, or training changes.

Response: We recognize that making modifications to columns can create downstream impacts for systems. We have therefore modified the responses in this column to reflect the options in the

currently approved protocol; which will replace “NA” with “TBD” for when corrective action is still pending.

Comment: A few commenters asked for clarification on Column ID L, (Description of Corrective Action Required), in the CPE COA universe. A commenter asked whether each deficiency reported in Column ID I must have a separate corrective action description in Column ID L, and another commenter **r**ecommended increasing the character limit, so Sponsors have enough space to describe corrective actions. Another commenter stated that requiring narrative descriptions would increase administrative burden due to limited system capabilities and manual entry needs and recommended retaining the prior yes/no corrective action field instead.

Response: We appreciate the opportunity to provide additional guidance on this field. There is no requirement or guidance on how detailed the description of correction needs to be for purposes of this field. If one corrective action addresses multiple deficiencies, the Sponsor may describe that corrective action once. Additionally, the description may be high level to summarize the type of correction taken. There is no character limit for this field, and similar to how we formatted other protocols, we have removed the two columns related to character limits from the universe to reduce confusion.

Comment: Several commenters requested clarification on COA universe date fields, including how to report activities that began before or continued during the audit period, whether committee presentation may be used as the completion date, and whether example dates reflect the effective date of the proposed protocol changes.

Response: We generally expect Sponsors to include activities that were either started or completed within the 6-month universe period. For a large-scale investigation that was started before the universe period, and was ongoing, that activity would not need to be included. However, for ongoing routine activity, such as daily monitoring or monthly monitoring, those items would be included, as they have defined start and stop dates within the universe period even though they recur. For recurring activities, such as daily or monthly activities, Sponsors should report them as aggregated monthly entries for each month in which the activity occurred during the audit period. For Column ID G (Completion Date), Sponsors should report the date the activity was considered complete based on their internal process, which may include presentation to a committee if that is when the activity is deemed complete. CMS also clarifies that dates included in the protocol examples are illustrative only and do not represent the effective date of the proposed audit protocol changes.

Comment: A commenter requested clarification on how CMS will evaluate corrective actions reported in the COA universe. Specifically, the commenter asked whether CMS would consider an issue mitigated if it was identified and corrected before or during the audit, or whether CMS may still cite it as an audit condition.

Response: Ultimately, a demonstration of an effective compliance program would include evidence that monitoring identified an issue, and correction was quickly made and proved effective through no repeat issues. Part of the reason CMS is modifying our approach to compliance is to more closely associate it with what the other program area teams are seeing during fieldwork. If a program area team lead finds potential noncompliance during audit, but through discussions with the team and compliance officer they can validate that the issue was effectively corrected, the team will consider that information when bringing the condition to CMS leadership. If the team can determine, based on available evidence, that correction is no longer necessary to either avoid a reoccurrence or to remediate enrollees, the Program Audit Consistency Team (PACT) may decide a Corrective Action Required (CAR) is not necessary.

Comment: A commenter asked CMS to clarify whether Column ID I (Number of Deficiencies) should reflect the number of deficiencies identified rather than the number of impacted cases.

Response: We clarify that Sponsors should report the number of deficiencies, findings, or issues identified, consistent with how they define and track deficiencies within their audit processes. Generally, this should reflect the count of deficiencies rather than the number of impacted cases.

Comment: A few commenters requested clarification on the phrase "internal audit practices and oversight mechanisms" for the CPE preliminary compliance officer interview. Commenters asked CMS to provide examples and clarify whether this refers to the Sponsor's internal audit department, compliance monitoring and auditing activities, or broader oversight processes.

Response: We clarify that these discussions will focus on the Sponsor's Medicare Parts C and D activities and oversight, including relevant internal department activities when they relate to Medicare Parts C and D. Additional discussion topics will be informed by CMS's review of the Questionnaire and the COA universe. The bullets in the protocol of additional topics for the pre-audit interview are examples and may not apply in all scenarios. If a Sponsor does not have internal audit processes, then a discussion in that area would not occur. Generally speaking, discussions will be based on the circumstances and unique structure of each individual compliance program.

Comment: A commenter asked for clarification on whether there is still a requirement to have an annual CPE audit by an independent auditor. The commenter noted that, while there was not a specific change in the Compliance Program manual chapters, the commenter would appreciate guidance as to the expectations for plans completing these audits given the CPE protocol changes.

Response: While policy questions are outside the scope of this data collection; we can confirm that we will not be reviewing or assessing this during the program audit.

PART D FORMULARY AND BENEFIT ADMINISTRATION (FA)

Comment: Several commenters asked to clarify instructions for submission of universe data related to eligibility rejections, specifically beneficiary level data when an enrollee cannot be identified due to pharmacy submitted information. A commenter stated this would be a significant shift in how universes were pulled and would increase the burden associated with providing the information, which may impact reliability. This commenter noted that the new instructions would require the FA universe generation to be a Pharmacy Benefit Management (PBM) level data pull, which may lead to inadvertent exposure of beneficiary data. Another commenter indicated that there was a risk of including beneficiaries that are not associated with the plan even when the denials are cross walked with the BIN/PCN/Group due to inaccurate pharmacy data; and this commenter requested CMS clarify that only beneficiary data that has been validated by the Sponsor as "enrolled/eligible" be included.

Response: We appreciate these commenters' suggestions. We would like to clarify that we have not made any changes to how we expect the data in these universes to be pulled and submitted from how it is done currently. Instead, in order to increase transparency, we added instructions that are verbally given to audited Sponsors now during FA Universe Calls directly into our protocol. These instructions are also included in the 2023 User Group Resource Document which is available on the CMS webpage along with the audit protocols[1]. Sponsor must include all claim denials submitted and cross walked to the contract/PBP utilizing: BIN, PCN, and Group in order for CMS to fully validate the reason for denial using CMS enrollment systems. We re-arranged the instructions in the protocol to better emphasize this point, and we reworded the language to emphasize that these should be claims that can be cross walked to the contract. When an enrollee cannot be identified in the Sponsor's system based on pharmacy submitted claim information, "NA" may be entered in the following fields populated by the Sponsor: Universe Tables 1 and 2, Column ID A (Enrollee ID), Column ID E (Enrollment Effective Date), Column ID F (Effective Disenrollment Date), and Column ID I (PBP).

Comment: A few commenters requested clarification on Column ID J (Drug Name, Strength, and Dosage Form) field because these are not populated by the pharmacy. One of these commenters added that the drug name may be reported differently across PBM systems and requested CMS remove the following language in the field "as submitted by the pharmacy". The other commenter requested that CMS remove the field drug name and continue collecting only Column ID K (NDC).

Response: We agree that this information is not reported by the pharmacy, and we have updated the field description for Column ID J (Drug Name, Strength, and Dosage Form) to remove the language: "as submitted by the pharmacy". This will allow the Sponsor to populate this information based on the pharmacy submitted National Drug Code (NDC). We also updated the field description to clarify that the full drug name should be provided in this field. We are adding

[1] https://www.cms.gov/medicare/audits-compliance/part-c-d/program-audits

this field to more accurately analyze the universes and to ensure appropriate samples are selected.

Comment: A few commenters requested clarification on fields that should be populated "as submitted by the pharmacy" and how data errors will be handled due to errors in pharmacy submitted data. One commenter requested clarification on how CMS would evaluate the data discrepancies on audit and requested that CMS confirm that Column ID A (Enrollee ID) would also be based on a pharmacy data submission, even if it is inaccurate.

Response: We appreciate the commenters' recommendations on these fields. These instructions are consistent with how CMS has instructed Sponsors to populate the universe for the last few years. However, for increased transparency, we have added those instructions into the corresponding record layout fields for this version of the protocol. The pharmacy submitted fields should continue to be populated by the pharmacy, to avoid manipulation of the data. Discrepancies occurring due to missing or invalid pharmacy submitted data would result in corresponding rejected claims that are reflective of the error. The fields populated by the Sponsor include: Column ID A (Enrollee ID), Column ID E (Enrollment Effective Date), Column ID F (Effective Disenrollment Date), Column ID H (Contract ID), Column ID I (PBP), Column ID J (Drug Name Strength, and Dosage Form), Column ID M (Date of Rejection), Column ID S (Reject Reason Code), and Column ID T (Pharmacy Message). All other fields should be populated as submitted by the pharmacy.

Comment: Several commenters expressed concerns regarding the "other requested data" fields in the Universe Tables 1 and 2. These commenters stated that these fields would require ad-hoc reporting and/or manual data submissions which could increase burden and result in errors. Additionally, these commenters expressed concerns that their ability to meaningfully comment on the potential data requests is removed since CMS has not indicated what potential data fields might be included.

Response: We appreciate these concerns, and after further consideration CMS has decided to remove the "other requested data" fields in Universe Tables 1 and 2, Column IDs U, V, and W (Other requested data).

Comment: A commenter requested clarification on Column ID E (Enrollment Effective Date) and whether the date should reflect the plan's enrollment system or the adjudication system.

Response: We clarify that the enrollment dates should be populated based on the Sponsor's enrollment system.

Comment: A commenter asked about the use of previously submitted and accepted Prescription Drug Event (PDE) records since the Sponsor is no longer being requested to provide a universe of PDE information during audit.

Response: We previously used PDE records to identify prior history and select eligible samples. We agree with commenters that PDE information will no longer be requested as a separate audit universe. We will continue using all available information both from internal data repositories, and while conducting audit fieldwork, to assess compliance with CMS formulary requirements.

Comment: A commenter requested CMS define the "scope of non-compliance" field in the impact analysis template. This commenter requested that this term be defined as beneficiary impact.

Response: We agree that some definition of "scope" is helpful; however, we do not think that only considering enrollee impact is the appropriate use of this field. While enrollees impacted is certainly an important part of determining the full scope, an organization may find the scope is larger than just a specific number of enrollees. Therefore, we are going to define this field in all applicable impact analyses as "Please describe how this noncompliance impacted your organization including its impact to any entities, systems and/or processes, as well as any potential enrollee impact. This expanded definition is vital for both the organization and CMS to understand the impact to enrollees, but also to ensure the Sponsor conducted a full investigation into the cause, and ultimately to ensure an effective corrective action plan.

PART D COVERAGE DETERMINATIONS, APPEALS, AND GRIEVANCES (CDAG)

Comment: A commenter requested clarification on proposed language in Processing of Coverage Requests compliance standard 2.3 on reviewing cases for coordination of benefits. This commenter requested clarification on whether CMS would be assessing for other Medicare coverage (i.e., Part B versus Part D) or would CMS be considering other health insurance coverage.

Response: We clarify that our program audits are focused on Medicare covered services and would be reviewing for appropriate coordination of Medicare services; for example, coordination between Part B and Part D coverage. We do not intend this review to assess coordination with other health insurance coverage outside of Medicare.

Comment: In reviewing compliance standard 1.16, a commenter asked whether Sponsors are to include at-risk determinations in Tables 1-4, which were formerly contained in Table 7: Comprehensive Addiction and Recovery Act (CARA) At-Risk Determinations universe.

Response: We clarify that Sponsors should continue to submit appeals of at-risk determinations in Table 4: Standard and Expedited Redeterminations (RD), and at-risk determinations that were fully or partially overturned by the Independent Review Entity (IRE), Administrative Law Judge (ALJ), or Medicare Appeals Council (MAC) in Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC (EFF_D). We would not expect to see at-risk determinations in Tables 1, 2 or 3.

Comment: A few commenters requested clarification on sampling cases that are not typical approvals or denials. A commenter asked CMS to clarify how reopening cases are incorporated into sample selection and another commenter asked how dismissal cases are sampled.

Response: We clarify that reopening samples are included within the selected approval and denial case samples. For example, when selecting 30 denied samples, CMS may select a few reopened denied cases as part of that set of 30. As for dismissals, compliance standard 3.1 in the CDAG Program Audit Protocol and Data Request details how dismissal cases will be sampled and reviewed.

Comment: A few commenters requested that CMS update the appeal filing timeframe from 60 calendar days to 65 calendar days in Table 3 Column ID J (Date the Request was Received) and Table 4 Column IDs J (Date the Request was Received) and K (Time the Request was Received) to align with the updated appeal timeframe.

Response: We agree with commenters and have updated these field descriptions to reflect the current appeal filing timeframe of 65 days.

Comment: For Table 3, when a request is partially approved and two letters are sent, one for the approval and one for the denial, a commenter asked whether this would be reported as two separate line items in the universe since two notifications were sent. Another commenter requested clarification on how to report a scenario with a non-exception denial and an exception approval (i.e., safety edit exception approved) and whether that would be reported as a single line item in the universe as denied.

Response: We appreciate the commenters' questions regarding how to submit cases that may involve multiple parts of a request. For purposes of audit, we ask Sponsors to populate cases in the universe based on the notification they sent. In the scenario where a service is partially approved, and the Sponsor sends both an approval notice and a separate denial notice, that would be reported as two line items in the universe. If a Sponsor processed two different parts of a single request (for example an exception and a non-exception request) but issued a single notification that discussed both parts of that request; the Sponsor would populate a single line item in the universe. If that single notification addressed both a partial approval and a partial denial, the case would be marked as a denial in the universe.

Comment: A commenter requested clarification on how CMS intends to treat open and in-progress cases during the universe integrity review for the grievance universe. Since these cases are still under active review, the commenter noted that certain data elements included in the universe, such as grievance category or status, may differ from information ultimately reflected in the case documentation.

Response: We clarify that Sponsors would populate the grievance universe with the information as it is known at the time of the data pull. If at a later point in time the information differs based

on the processing of the case CMS would take that information into consideration and would not cite the organization for inaccurate data.

Comment: Several commenters requested for CMS to revise the NDC field description in the CDAG universes to better align with how NDC's are applicable in coverage requests since a pharmacy cannot submit coverage requests. The commenters noted that NDC's are rarely included in coverage determination or redetermination requests as those requests are typically for the drug regardless of the NDC, and at times Sponsors receive requests where they are unable to identify an NDC. The commenters requested clarification on how to populate the NDC field when the Sponsor has exhausted attempts to find a representative NDC, or when requests are received for something that is not a drug and has no NDC.

Response: We appreciate these commenters' concerns, and we agree that there may be instances where either there is no corresponding NDC, or the NDC may be unknown despite efforts from the Sponsor to identify an NDC. We have revised the NDC field description to "If there are no Part D ingredients for a multi-ingredient compound claim or the NDC is unknown enter None". We have also removed instructions in the field description that reference pharmacy submissions since pharmacies do not submit coverage determination requests.

Comment: A commenter requested clarification on fields in Tables 1, 2 and 4 related to effectuation dates and times, and noted that there are situations where an effectuation is not necessary for requests that are approved. For example, coverage requests for drugs which are already on the formulary without any utilization management (UM) edits or when UM requirements have already been met. The commenter requested clarification on how to populate these fields when effectuation in the system is not needed.

Response: We appreciate the question. When no effectuation is required, Sponsors may enter "None" in these fields.

Comment: For Tables 1-4 a commenter requested confirmation that dismissals should be included and withdrawals should be excluded.

Response: We confirm that for Tables 1-4 dismissal cases should be included and withdrawn cases are excluded. Additionally, in Table 4, appeals of dismissals or requests to vacate dismissals are also excluded. The inclusion instructions for these Tables already specify these requirements; therefore, we did not make changes in response to this comment.

Comment: One commenter asked whether Column ID V (Coverage Request Initiated) and Column ID W (Date coverage request was initiated) fields in the grievance universe should be populated in every instance where a coverage request is initiated in connection with a grievance; including both cases where the Sponsor initiates a coverage request during the enrollee's initial call, as well as cases where a coverage request is initiated after reviewing the grievance. Another commenter asked whether these fields only apply to a coverage request related to the specific issues addressed in the grievance or whether they also include any coverage request submitted

with the grievance. A few additional commenters noted that reporting this information within a single audit universe may be challenging, would likely require system modifications, and may be burdensome to implement in the 2027 audit season.

Response: We expect Sponsors to populate these fields for any instance where the issue or issues within the specific complaint/grievance prompted a coverage request. This includes cases where the Sponsor initiates a coverage request during the enrollee's initial call, as well as cases where the Sponsor initiates a coverage request after reviewing the grievance later. To clarify, we have updated the Column ID V (Coverage Request Initiated?) field description to clarify that we are interested in related coverage determinations that are initiated as a result of the grievance/complaint. We acknowledge that Sponsors need sufficient lead time to operationalize changes to program audit data collection and submissions. As such, we have minimized updates in the interest of limiting programming updates and will provide Sponsors with as much time as possible to prepare for 2027 audits.

Comment: A commenter asked for confirmation that CDAG universes would not be flagged for data integrity if a case is designated as "Denied" in the universe but also has an effectuation date entered due to a partial approval.

Response: We confirm that this would not create a data integrity issue. The record layout instructions state to enter any request denied in whole or in part as "Denied" in the CDAG universes, and for requests denied in part, to include data regarding the approval and effectuation of the favorable portion of the decision in the applicable fields in the record layout. **Comment:** A few commenters requested clarification on how to populate the Plan Benefit Package (PBP) field in the CDAG universes if the pre-benefit request does not have a date of service and recommended that CMS change the field description to clarify that CMS wants the PBP effective on the date of the request. Another commenter requested clarification on how to populate this field in the grievance universe and asked that CMS maintain the current flexibility allowed in producing PBP data as it can sometimes be difficult to obtain from other systems. Alternatively, this commenter requested that CMS consider allowing blanks for when a grievance may come in from someone that does not have a PBP assigned or lacks current coverage.

Response: We agree with this recommendation; and we are clarifying the PBP field descriptions across the corresponding Tables to specify that we want the PBP applicable for purposes of the request/grievance. We also added an option to enter None if there is no PBP available.

Comment: A few commenters asked whether grievances under an approved 14-day extension are included in Table 6. Another commenter recommended grievances that were open due to a timely extension not be included in the universe, and this commenter recommended an update to the instructions to ensure those cases are not included.

Response: We appreciate the comments received on grievances that require an extension. We have added an instruction to the Table 6: Part D Standard and Expedited Grievances (GRV_D)

Record Layout to include grievances that have been extended. We understand that some grievances may not have a notification as the result of an appropriate extension, and Sponsors will not be penalized during the audit for those cases.

Comment: A commenter requested clarification on the placement of the instruction "Enter any request denied in whole or in part as Denied" in the Table 2 inclusion instructions. The commenter noted the language is currently a sub-bullet of the "If a request has multiple exception types" instruction suggesting that the change indicates this instruction now only applies to a request that has multiple exceptions.

Response: We agree with this commenter that the instruction as a sub-bullet is confusing. We expect the instruction "Enter any request denied in whole or in part as Denied…" to apply to all requests and have updated the instructions in all applicable tables.

Comment: A commenter requested clarification on how to submit reopenings in Tables 1-4; and whether the Sponsor should enter “None” for all reopenings or only those reopenings initiated by the Sponsor.

Response: We appreciate the opportunity to clarify this field. We would expect the Sponsor to enter “None” only for those cases where the Sponsor initiated the reopening. If an enrollee requested the reopening, a Sponsor would enter “E” for Enrollee in that field.

Comment: A commenter requested clarification on what constitutes "denied in part" for Table 3 payment requests, specifically how plans should classify reimbursement outcomes in scenarios where a claim is partially paid due to benefit design. The commenter provided an example where the beneficiary submits a paper claim with a receipt for $100 dollars and the plan adjudicates the claim, applies a portion to the deductible, and reimburses the amount remaining after deducting the copay.

Response: We note that policy questions regarding how these requests should be processed are outside the scope of this data collection. For audit purposes, Sponsors should report case dispositions in the universe consistent with how the cases were processed. For example, if a Sponsor considers a case to be an approval, the Sponsor should report it as an approval in the universe.

Comment: A commenter requested confirmation that dismissed grievances are limited to cases dismissed due to failure to return requested Authority of Representation (AoR) documentation, and do not include other dismissal scenarios.

Response: We are requesting that Sponsors populate this universe based on how they process and categorize grievances, including when (and if) they dismiss grievances.

Comment: A commenter requested CMS add instructions to address cases in Table 5: Part D Effectuations of Overturned Decisions by IRE, ALJ or MAC that were reopened by the IRE/ALJ/MAC and ultimately dismissed or upheld.

Response: We appreciate this comment. The protocol instructions for Table 5 excludes cases that were dismissed or upheld by the IRE, ALJ or MAC; however, that exclusion was combined with another instruction. To improve clarity, we revised Table 5 instructions and separated the language into two separate bullets. This exclusion would apply to all instances in which the IRE, ALJ, MAC dismissed or upheld a denial or appeal; including cases that were reopened and subsequently upheld by the IRE, ALJ, or MAC.

Comment: A commenter asked for clarification on how to report grievances in Table 6 when the grievance involves multiple issues. The commenter noted that Table 6 audit protocols currently require these grievances to be consolidated and reported as a single line item in the audit universe. However, the commenter noted that Medicare Part D Reporting Requirements state that if an enrollee files a grievance about multiple issues during a call or in writing, the unique issues should be reported as separate grievances.

Response: We appreciate the comment, However, for program audit purposes, grievances involving multiple issues should continue to be consolidated and reported as a single line item in Table 6, consistent with the audit protocol instructions. Although this approach differs from Medicare Part D Reporting Requirements, it is consistent with how we have historically collected program audit data and is intended to reduce burden on Sponsors.

Comment: A commenter noted that documentation regarding timeliness is now included in the Supporting Documentation Submission section of the protocol and asked what types of documentation may be requested.

Response: We added information into this section for transparency to ensure that Sponsors were aware of the types of documentation that may be reviewed during different parts of the audit. CMS will continue reviewing timeliness at a universe level and not through specific case review. However, during the universe integrity testing, CMS will need to see some sample information in the webinar, including evidence of when a request was received (showing the date and time) and evidence when notification was rendered.

PART C ORGANIZATION DETERMINATIONS, APPEALS, AND GRIEVANCES (ODAG)

Comment: A commenter thanks CMS for their oversight in Medicare Advantage (MA) but warned CMS that data collection will only be effective if CMS, not MA Organizations (MAOs), determine what data is submitted and audited. This commenter referenced a pattern of MAO practices that undermined data integrity and that denied providers and members their rights, including: improper use of proprietary clinical criteria, inappropriate claim denials and downgrades, and the creation of parallel "internal dispute" processes that bypass the official CMS ODAG appeals pathway. This commenter noted that because these practices keep adverse determinations invisible to CMS and the Independent Review Entity (IRE), current audit

universes fail to capture them. The commenter recommended that CMS investigate discrepancies between provider shadow claims and MAO encounter data (a "missing encounter" universe), potentially using AI for analysis, and leverage the new CMS provider complaint portal as an additional audit data source. Additionally, this commenter recommended that CMS create an avenue for CMS and IRE review of cases that MAOs do not consider organization determinations (ODs), and to focus on data mining for denials of inpatient admissions and readmissions.

Response: We appreciate the commenters' suggestions on the data collection efforts we use to assess compliance in MA. We will continue using the resources currently available to us while exploring other methods for assessing compliance with all available tools and information, including data collected in other parts of the agency, to strengthen our oversight efforts. We also welcome comments from industry on how we could collect information that is not currently captured in the audit universes.

Comment: A few commenters requested clarification on compliance standard 1.1; noting that two timeframes apply based on whether a service requires prior authorization. However, the commenters noted Table 1: Standard and Expedited Organization Determinations (OD) Record Layout does not have a field to capture if a service requires prior authorization. These commenters requested clarification on how the test would be applied without a specific field in the universe to indicate which services were applicable.

Response: We tried to limit changes to the ODAG universes since we understand Sponsors will be working on system modifications to pull the new Service Level Data Collection for Initial Determinations and Appeals (hereinafter referred to as Service Level Data). However, we agree that this is an important field in order to understand whether Sponsors are adhering to the new timeframes for services requiring prior authorization. We have added a field into Table 1 to capture whether a Sponsor requires prior authorization for the requested item, service, or drug.

Comment: A commenter requested clarification on compliance standard 2.7 which includes two universe tables (Table 3 payment and Table 5 reopenings) but the method of evaluation references reopenings and not payment requests.

Response: We appreciate the opportunity to clarify the addition of compliance standard 2.7. This compliance standard will assess whether requests approved through prior authorization of coverage or payment or through concurrent determination made during an enrollee's receipt of inpatient or outpatient services were not later denied by a Sponsor on the basis of medical necessity. We updated the method of evaluation field for compliance standard 2.7 to reflect this approach. This compliance standard may be assessed through the review of a reopening or through a review of a denied claim; therefore, both of these universes (Tables 3 and 5) are referenced

Comment: Several commenters had technical recommendations/comments on compliance standards. A commenter made some technical suggestions for compliance standards 1.3, 1.4, 1.6, and 3.1; including noting a missing bullet in one, and an incorrect word in the others. Another commenter noted an error in one of the citations for compliance standard 3.1. A different commenter suggested that for compliance standards 2.4 and 2.7, CMS move the Table 5 Reopened Part C Determinations universe to below the service level data to be consistent with how those Tables are ordered in other compliance standards.

Response: We agree with these technical suggestions and have made the corresponding changes.

Comment: Several commenters requested clarification on whether CMS had inadvertently removed compliance standard 1.7 which assessed timeliness of expedited grievances. One commenter noted that CMS had moved the assessment of expedited grievances timeliness to a different element and requested CMS add it back to compliance standard 1.7.

Response: We appreciate the opportunity to clarify the change in assessing compliance with expedited grievances timeframes. First, we confirm the timeliness assessment to determine if a Sponsor responded to expedited grievances within 24 hours has been removed. Instead, CMS will select expedited grievances (if available) for review during the Classification of Requests audit element. If any findings are noted, including findings related to the expedited grievance being untimely, we will request a root cause analysis to understand what occurred and, when appropriate, an impact analysis to determine the full scope of the noncompliance.

Comment: A few commenters requested that CMS add the 24-hour timeframe for forwarding an upheld denial to the IRE into relevant compliance standards. One of these commenters requested clarification that the 24-hour timeframe still applies.

Response: We updated compliance standard 1.4 to include the 24-hour timeframe to forward upheld reconsiderations to the IRE.

Comment: A commenter requested clarification on what timeframe applies to retrospective/post-service (non-claim) requests, and whether the payment timeframe applies.

Response: We appreciate the comment; however, policy questions are outside the scope of this data collection package. For purposes of audit, Sponsors should include cases based on how they were processed. All cases processed as payment organization determinations should be put into Table 3.

Comment: A commenter agreed with CMS that organization determinations should be reported by the authorization number, even in situations where a single OD has multiple individual items requested. Another commenter asked CMS to release examples of how to populate ODs that might cover multiple services, some approved and some denied.

Response: We appreciate the commenters' support on having ODs reported by authorization number**.** In instances where multiple services are requested, some approved and some denied, we would expect Sponsors to report this information based on how many unique determinations they processed. For example, if they assigned a single authorization or case number to the request, despite multiple services being requested, this would be a single line item in the universe. The OD would be reported as denied since, in this example, some of the services were denied. However, if the Sponsor's process is to split the request into multiple organization determinations, each with a unique authorization, and notification, then each unique authorization should be reported in a single line.

Comment: A commenter noted that CMS reduced the review period for Table 3: Payment Organization Determinations and Reconsiderations and supported this change due to the volume of claims data.

Response: We appreciate the support for this change. While we originally limited the payment universes significantly; following a review of comments we have decided that in order to fully assess compliance with some requirements, a slightly larger universe period for payment determinations is necessary. We increased the universe period to two weeks, and four weeks based on the size of the organization. This is still a reduction from the previous universe periods and should allow us to strike a balance between reduced burden and conducting an appropriate oversight of payment decisions.

Comment: A commenter requested clarification on the Universe Integrity Testing compliance standard, and whether 10 samples would be pulled for each universe or if more samples may be pulled. The commenter also asked how those samples would interact with the 40 denied samples noted in compliance standard 2.1.

Response: We appreciate the opportunity to provide clarification. We have modified the language in the protocol to say that we may pull up to 10 samples per universe for purposes of universe integrity testing. We may pull less samples for some universes, such as grievances, or when a single entity is responsible for processing all cases within a universe. Samples selected for universe integrity testing do not directly interact with samples selected for review in the Processing of Coverage Request audit element. However, samples selected for universe integrity testing do not prohibit the same sample(s) from being selected for review as described in compliance standard 2.1.

Comment: One commenter noted that CDAG and ODAG have always been consistent with the number of samples selected, but the proposed protocol has those two areas differing in sample size. This commenter asked if this change was intentional.

Response: Yes, this was an intentional change. We have increased the number of samples in ODAG due to the types of organization determinations CMS will review which includes decisions made prior to an enrollee receiving an item, service, or Part B drug and decisions made

concurrently while an enrollee receives care, as well as decisions to terminate coverage of post-acute care. Additionally, there is a wide variety of entities that process Part C requests. To ensure a thorough review of the variety of requests processed by Sponsors and their delegated entities, it is necessary to expand the number of samples reviewed to assess compliance across more of the Sponsor's operations. However, this is a maximum number for the sample set, and CMS may not always select 40 denials in every audit.

Comment: A few commenters requested clarification on the new Timeliness Mitigation tool and when it might be used in audit. One of these commenters asked for confirmation that the timeliness mitigation tool would be used when CMS began using the quarterly service level data submissions and asked if CMS would only request review of potentially untimely cases from those quarterly submissions. Another commenter asked how the use of the Timeliness Mitigation Tool would impact findings. A commenter asked if a threshold would be applied, or whether a single untimely case could trigger a review of the entire universe.

Response: We will continue to collect audit universes from Sponsors, as needed, until the applicable service level data becomes available. Once those data are available, we will suspend collection of Universe Tables 1 - 3. We anticipate using the Timeliness Mitigation Tool after transitioning to the service level data collection process. The tool will be used to evaluate whether factors associated with untimely cases mitigate or resolve potential non-compliance. We will establish internal thresholds to determine when use of the Timeliness Mitigation Tool is warranted do not anticipate requesting this analysis based on a single untimely case.

Comment: A commenter requested clarification on the intent of CMS reviewing coverage and utilization management requirements finalized in CMS-4201-F.

Response: We confirm our intent to review some of the requirements that were finalized in CMS-4201-F; including but not limited to whether the Sponsor created and utilized internal coverage criteria in accordance with the CMS requirements. In order to reduce burden and avoid duplication, CMS did not finalize a separate audit protocol to assess internal coverage criteria in MA as part of the Utilization Management PRA package (CMS-10913). Instead, we added compliance standard 2.4 to the ODAG protocol, which incorporates an assessment of coverage criteria, including internal coverage criteria, into the ODAG program audits.

Comment: A few commenters requested clarification on the transition to using service level data for purposes of audit. A commenter asked for guidance on when CMS intends to transition to the use of quarterly data versus audit universes, and another asked if the quarterly data would be used for audits conducted in 2027. Another commenter asked for information on the lookback period of the quarterly data submission when it is being used for audit and noticed the information may not accurately reflect current activity. A commenter asked for clarification on what audit universes the service level data would replace. A commenter recommended that CMS not use the quarterly data for purposes of case selection or timeliness, especially pilot data, and if

CMS does use it, recommended inclusion of additional fields into the quarterly data collection to allow for an accurate assessment of timeliness.

Response: Based on comments from industry we have heard throughout the years, including in response to a recent Request for Information (RFI) related to burden reduction, we understand that Sponsors would like us to reduce duplicative reporting and leverage existing data sources whenever possible. In response, we are committed to using the service level data, when available, to supplement and/or replace certain audit universes in order to reduce unnecessary burden. We will stop collecting certain audit universes at that time; specifically, Tables 1, 2 and 3. We will issue a memo to the industry when we believe the transition to service level data will occur. We understand that the service level data may not be as recent as the audit data we currently collect, but we are trying to weigh the benefit of recent data against the burden of producing data twice; once for the service level collection and then again for audit. Lastly, comments specifically about the service level data collection, including recommendations of fields, are outside the scope of this data collection package.

Comment: A commenter commended CMS on trying to shift to using quarterly service level data to replace audit universes and reduce duplication. This commenter requested that CMS not revise the inclusion language in Table 1 to include concurrent reviews since it was increasing burden on Sponsors when ultimately the table would be eliminated once service level data is utilized. Additionally, this commenter noted that there was no clear benefit to adding this change, or regulatory change that warranted this update.

Response: We appreciate the commenter's support to transition to service level data, but we disagree with the commenter on the inclusion of concurrent reviews in Table 1. This inclusion is in response to the CMS final rule CMS-4208-F which clarified that concurrent reviews are organization determinations that must be processed in accordance with Subpart M requirements. Additionally, concurrent reviews will be requested and included as a part of the service level data collection so this inclusion is consistent with how Sponsors will be expected to report that data as well. While we do not intend to collect Table 1 once the service level data is available, we do not anticipate that data being available before 2028 so the inclusion of concurrent reviews into Table 1 is necessary to assess Sponsor compliance.

Comment: A commenter requested clarification on what documentation CMS would expect to see when a request is received through a Sponsor Application Programming Interface (API).

Response: We would expect to see similar documentation for requests submitted through an API as we would for requests submitted through fax or other electronic portals. The Sponsor would be asked to provide the relevant documentation that would show CMS that the regulatory requirements related to processing of organization determinations and appeals were satisfied.

Comment: Multiple commenters requested clarification on CMS' instruction to add concurrent reviews into the audit universes. A commenter asked if these reviews would be captured in Table

1 or Table 2. Another commenter asked if there was any limitation on the types of concurrent reviews that should be included. A commenter asked if a drop in a level of care would be included, for example if a request to continue staying in an acute rehab facility was denied, but skilled nursing facility care was approved. A commenter asked if there was a label for concurrent review to separate expedited from standard. A commenter requested clarification as a result of Table 1 being called "Initial" determinations as it relates to some reviews, including but not limited to; terminations when an enrollee no longer meets the level of care, appeals related to terminations of services, and which communications may fall within this category. A commenter requested that CMS clarify whether plans should include all concurrent decisions (approvals and denials) or just denials on the audit universes. The commenter also stated there is currently no option for the requestor to indicate that the plan initiated the concurrent review. The commenter requested guidance on how to populate that field when there is no external requestor. Another commenter suggested that other field changes may be needed in order to ensure consistency in how Sponsors report concurrent reviews in the universe.

Response: We appreciate the opportunity for clarification. In order to maintain consistency with how the service level data collection will include organization determinations, we have modified our audit universe inclusion language. In Table 1, Sponsors should include all organization determinations (both standard and expedited) related to items, services, and Part B drugs made before the provision of the item, service, or Part B drug requested (both subject to and not subject to prior authorization requirements), and all organization determinations made contemporaneously while an enrollee is receiving the item, service, or Part B drug (including substantive decisions made by the Sponsor without first receiving a request). Additionally, Sponsors must include all reductions, or premature discontinuations, of previously approved authorized ongoing courses of treatment, and all organization determinations that result in a termination to end coverage in post-acute care facilities (HHA, CORF, SNF). Specifically, we want all organization determinations that involve a substantive decision (for example a decision to deny or discharge) to be included. We also removed the term "initial" from the inclusion language to reduce confusion. We do not believe that it is necessary to add a field specific to expedited or standard concurrent reviews because there is already a field (Column ID N) that asks for expedited or standard processing for all organization determinations. We also made a few minor changes to other field descriptions to clarify how cases may be entered for concurrent reviews or other types of determinations; including in Column ID V (Who made the request) to account for instances when the Sponsor initiated a review rather than an enrollee or provider. We added the option to enter "P" for Plan in this field which aligns with how the service level data collection is asking for information to be submitted. Additionally, while appeals of concurrent reviews may be entered into Table 2, we would not expect to see the initial plan decision of a concurrent review in that universe.

Comment: A few commenters requested clarification on post-service requests and how to include them in audit universes.

Response: We request that Sponsors include cases as they are processed for purposes of audit. Cases processed as payment organization determinations should be included in Table 3, and cases processed as coverage organization determinations (non-payment) should be included in Table 1.

Comment: A commenter requested clarification about whether a universe should be submitted in a single time zone.

Response: We are requesting that all fields for a single line item within the universe be submitted in the same time zone. For example, if the Sponsor has systems in EST and CST, all data in a single line item must be in a single time zone. We further clarify that we do not require the entire universe to be submitted in a single time zone. For instance, if a Sponsor has operations in two time zones and processes two distinct requests in each time zone, each line item may be in the time zone that processed the request so long as the entire line is submitted in the same time zone.

Comment: A commenter requested confirmation that CMS would release the excel versions of the Impact Analyses and not just the PDF versions.

Response: Yes, once finalized the excel versions of the Impact Analyses will be posted on the CMS website.

Comment: A commenter asked for clarification on whether auditors should have a clinical background when conducting a review of appeals and grievances.

Response: We use a combination of clinical and nonclinical staff to review Part C organization determinations, appeals and grievances.

Comment: A commenter asked if CMS intended to select samples from the quarterly data submissions of contract provider claims or whether CMS would only select noncontract provider claims similar to how the audits review claims now.

Response: We are discussing internally whether audit samples will include any contracted provider claims. If we do include any contract provider claims, we will include those as part of our normal set of samples and we will not expand the number of samples selected.

Comment: Several commenters asked for clarification or made recommendations to the inclusion and exclusion language for the audit universes. A commenter asked for clarification on what CMS meant in the inclusion language in Table 1 by "Failure of the MA organization to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee." A commenter requested clarification on the scope of reviews to be included as organization determinations within Table 1. The commenter specifically requested confirmation on whether the following scenarios fall within the purview of

the information requested in Table 1, concurrent review decisions that result in a change in the level of care (e.g. from inpatient to observation status); partial denials of an admission, such as inpatient days that are denied due to benefit exhaustion; and post-service or retrospective denials. Another commenter also requested that CMS add back in withdraws and reopenings with the exclusions list for the record layout as these cases would be duplicative of Table 5. A commenter requested CMS add "withdraws" back to the exclusion language in Table 2 and asked that CMS add reopenings and retrospective reviews to the exclusion list for Table 3. A commenter asked for clarification on whether post-acute care/QIO appeals should be included in Table 2. A commenter requested CMS add a bullet into the instructions for Table 2 reconsiderations that says requests to appeal or vacate dismissals should be excluded from the universe. This commenter noted that the addition of that bullet would align ODAG with how CDAG handles those exclusions.

Response: We appreciate the opportunity for clarification. We modified the inclusion language in Table 1 to better account for the different types of organization determinations as defined by the regulation. We expect all organization determinations processed by the Sponsor or FDR, other than the ones specifically excluded, to be included in this table. However, we revised our inclusion language to be clearer on the types of ODs that may be included, and to provide examples. Additionally, we updated our exclusion language in response to comment, and we have specifically excluded withdrawals and reopenings from Table 1. For Table 2, we updated the exclusion language to specifically exclude withdrawals, appeals of dismissals and requests to vacate dismissals, as well as reopenings of requests that were initiated by the Sponsor. We also modified the exclusion language to exclude appeals that were timely submitted to the QIO related to decisions to terminate services. Finally, we excluded re-openings from Table 3.

Comment: A commenter asked if there was a character limit on the grievance field description in Table 4.

Response: There is not a character limit for any of the universe fields.

Comment: A few commenters requested clarification on Table 5. A commenter requested clarification on whether Table 5 would continue to be collected once service level data was being used and noted that the collection seemed duplicative. The same commenter requested clarification on how to report reopenings. For example, if a provider submits new and material evidence that allows for a decision to be overturned, this commenter requested that the reopening be excluded from this Table since the Sponsor did not initiate the reopening. Another commenter recommended CMS use the existing reporting data for reopenings rather than collect this Table.

Response: We appreciate the comments on Table 5. We do intend to collect this universe after we shift to using the service level data in place of Tables 1, 2 and 3 in the audits. We do not believe this will be duplicative because Table 5 is limited to Sponsor initiated reopenings which are currently excluded from the service level data collection. If that changes, and this universe becomes duplicative, we will consider suspending its collection. We also confirm that we are

only interested in reopenings initiated by the Sponsor, and not reopenings requested by an enrollee or provider.

Comment: A commenter requested clarification on Column ID W in Table 1 and Column ID AA in Table 2, and the use of "pre-service" within that field. The commenter noted that, as written, only pre-service denials would require an explanation.

Response: We agree with this commenter, and we have modified the field description in these two tables. We originally made limited changes to fields since our intention is to shift to service level data at some point, but we believe this update to the field description language is necessary given the change in inclusion language for the tables.

Comment: A commenter asked for clarification on Table 2, Column ID G which asks for the authorization or claim number. The commenter noted that a single appeal could include multiple claim numbers and asked if providing the primary authorization or claim number would suffice in this column.

Response: We understand that multiple claim or authorization numbers may be applicable to a single appeal. The authorization or claim number field in all ODAG record layouts is primarily used so Sponsor**s** can quickly identify sample cases within its system(s) during program audit sample review. We have learned that Sponsors track coverage requests differently and allow flexibility within this field in an effort to minimize burden.

Comment: A commenter requested that CMS confirm that it meant to remove the table that related to overturned IRE/ALJ/MAC decisions. The commenter asked how CMS intended to assess compliance with these items moving forward. This commenter also asked CMS to confirm that it did not intend to use the old Table 7 related to terminations of care moving forward.

Response: We deliberately removed this universe from the ODAG protocol. We will continue to review compliance with this requirement through case review. For example, when reviewing a denied appeal, we will ask to see that the appeal was automatically forwarded to the IRE. We also confirm that we do not intend to have a separate universe for terminations of care because those decisions will now be included in Table 1.

Comment: A commenter requested that CMS refine the proposed language in Column ID R (Date oral notification provided to enrollee) to be more precise by adding language similar to the CDAG protocol: "Enter None for standard cases, dismissed cases, if no oral notification was provided, or if oral notice was not successful." A couple of commenters noted a discrepancy between the data requested in Column ID H (Date the request was received) and the Part C and D Guidance in Section 50.2.1 (Guidelines for Accepting Level 1 Appeal Requests) which states appeal requests must be filed within 65 calendar days of the final determination. Several commenters requested consistency with reporting data across different universe tables. Specifically, these commenters noted discrepancy in similar fields in CDAG and ODAG. A commenter noted that in the ODAG Table 4, Column ID V (Was the grievance withdrawn or

dismissed?) the instructions state to report "NA" when the grievance was processed and not withdrawn or dismissed; however, in the CDAG Table 6, Column ID U (Was the grievance withdrawn or dismissed), the instructions state to report "P". Likewise, for ODAG Table 4, Column ID X (Date coverage request was initiated), the instructions state to enter "NA"; however, in the corresponding CDAG Table 6: Column ID W (Date coverage request was initiated), the instructions state to report "None." Finally, Column ID U (Was the grievance withdrawn or dismissed) of CDAG Table 6 instructs Sponsors to report "P"; however, the ODAG Table 4, Column ID V (Was the grievance withdrawn or dismissed) instructs Sponsors to report "NA". The commenter requests CMS to clarify whether it intends for these fields to operate differently for Part C and Part D grievances, and if not, the commenter suggests aligning the response instructions for consistency in reporting and reduced confusion.

Response: We appreciate the request to be as consistent as possible between the CDAG and ODAG protocols, and we agree we should be consistent where we can within the field descriptions. We have reviewed both protocols to try and align the wording of the fields as much as possible. We have also updated the fields that discuss the 60-day appeal filing timeframe to say 65 days.

Comment: A commenter requested CMS clarification on the ODAG Table 2 instructions regarding whether all reconsideration determinations of adverse organization determinations are to be included or if it is only pre-service appeals that should be included.

Response: We appreciate the question, and we want to clarify that we want all coverage appeals to be included in Table 2 including prior authorization (pre-service appeals), appeals on concurrent reviews, etc. Only payment appeals should be excluded and placed in Table 3.

Comment: A commenter requested clarification on the instructions for ODAG Table 3. The instructions for Table 4 require Sponsors determined to be an applicable integrated plan, as defined by 42 C.F.R. 422.561, to populate the universe with grievances related to Medicare coverage only. However, Table 3 does not include similar exclusion language for applicable integrated plans. The commenter requests that CMS confirm whether Sponsors that meet the definition of an applicable integrated plan should populate Table 3 with Medicare services only or with a different approach.

Response: We appreciate the suggestion and we are going to add exclusion language into Tables 1, 2 and 3 instructing Sponsors to exclude Medicaid only service requests and/or payments.

Comment: Several commenters expressed concerns with the proposed requirement to include grievances that are open and past the 30-day due date as it would require substantial programming updates for audit tables. A commenter requested CMS consider aligning the requirement with existing grievance reporting structures to avoid duplicative administrative burden. The other commenter requested clarification on whether the Sponsor should exclude grievances while waiting for authorized representative documentation. A commenter requested

clarification on the proposed requirement to include grievances older than 30 days as of the engagement letter that have not received a response. The commenter asks CMS to clarify whether this requirement applies to cases under an approved extension and whether plans are expected to include extended cases that still fall within allowable timeframes. A commenter recommended revising the inclusion language in ODAG Table 4 to state "include all grievances the Sponsoring organization responded/issued notification or should have responded/issued the notification during the universe request period" to exclude valid extensions taken that were not yet untimely.

Response: We appreciate the commenters' concerns. While we made minor modifications to the inclusion language for this table, we are still requesting grievances older than 30 days where oral or written notification has not been provided. The inclusion of the grievance is based on the date the Sponsor provided notification (Column ID Q or S) or the date that the Sponsor should have provided notification. For grievances where an extension was taken, Sponsors would enter 'Y' in Column ID P (Was a timeframe extension taken) and 'None' in Columns IDs Q, R, S, and T (Date oral notification provided to enrollee, Time oral notification provided to enrollee, Date written notification provided to enrollee, and Time written notification provided to enrollee). Our timeliness test will account for grievances where notification has not been issued and within the applicable timeframes when a Sponsor has invoked an extension.

Comment: A few commenters requested clarification on the new field in the grievance universe which asks if a coverage request was initiated. The commenters recommended clarification on what the field meant, and whether it was asking if it applied if a coverage request was requested after the grievance. Another commenter noted that the new fields in ODAG Table 4, Column ID V (Coverage Request Initiated?) and Column ID W (Date Coverage Request was Initiated) will require system enhancements for Sponsors to ensure accurate, consistent, and compliant implementation.

Response: We appreciate this recommendation. Similar to the comments in CDAG, we have modified the field description to better clarify what we are asking. Specifically, we are interested in whether the specific complaint/grievance that was made triggered the initiation of an organization determination or appeal; whether that is simultaneous to the grievance being received/initiated or after the fact (for example if an appeals manager discovered that the processing should have included a coverage decision). We modified the language to say that we are interested in whether a coverage determination was initiated as a result of the grievance. We acknowledge that Sponsors need sufficient lead time to operationalize changes to program audit data collection and submissions. As such, CMS has minimized updates in the interest of limiting programming updates and will provide Sponsors with as much time as possible to prepare for 2027 audits.

Comment: Several commenters requested clarification on the removal of reopening exclusion language from multiple existing tables while CMS simultaneously introduced a new standalone

table for reopening activity. Commenters noted that having both the reopening table and removing the exclusion language is duplicative and creates additional reporting burden for Sponsors. A commenter requested CMS to clarify whether reopenings should be excluded from Tables 1, 2 and 3, to ensure data integrity. Another commenter recommended either including reopening data in existing tables or moving forward with the new standalone table.

Response: As noted above, we have added reopenings back into the exclusion list in Tables 1, 2 and 3. Therefore, reopenings should be excluded from these tables. We appreciate the recommendation of including reopening data into existing tables. However, plan reopenings are excluded from the Service Level Data collection. Accordingly, we are incorporating Universe Table 5 into this protocol to collect data that is not included in the Service Level Data collection.

Comment: A commenter requested clarification on the implementation timeline of the proposal to replace Tables 1-3. This same commenter also recommended that CMS finalize the technical specifications before finalizing the required data source for audits. Finally, a commenter noted that the utilization of service level data in lieu of ODAG Tables 1-3 causes significant challenges for Sponsors, as Sponsors will have to be prepared to produce multiple, different data sets depending on timing of the audit engagement letter.

Response: We will notify Sponsors when collection of Tables 1-3 is discontinued in-lieu of using service level data. Our intent is to avoid duplication of efforts and rely on the service level data collection as soon as it is available.

Comment: CMS received a few comments for ODAG Table 1. A commenter requested clarification on whether it is CMS's expectation that claims/payment data is included in Table 1. Another commenter requested clarification on whether reopenings should be included in ODAG Table 1 since the 2027 draft protocols removed reopenings as an exclusion. The commenter recommended adding exclusion for reopenings back into the ODAG Table 1 instructions as the new ODAG Table 5 includes reopenings.

Response: We appreciate the comment and would like to clarify that, per the instructions for Table 1, requests for payment, including both initial payment determinations and reconsideration requests for payment, are excluded and therefore should not be included in Table 1. Additionally, as noted above, reopenings have been added back to the exclusion list for Table 1 and should be reported in Universe Table 5, as applicable.

Comment: A commenter requested clarification on CMS's rationale for proposing different reporting periods for the Part C and Part D universe tables and how this change aligns with the proposal to use the service level data collection for Part C in place of ODAG Tables 1, 2 and 3.

Response: We appreciate the comment. While we strive to align protocols and data fields where we can, there are some nuances between universes and/or program areas where we believe differences are valuable. As a result, we made some modifications to the ODAG and CDAG protocols that are not always aligned with each other. For example, we removed the

IRE/ALJ/MAC overturn table from ODAG, while keeping that table in the CDAG audit protocol. These changes were intentional and based on previous audit experience. With respect to service level data, we are currently proposing to collect service level data in Part C. Accordingly, only the ODAG audit protocols would be impacted by this proposed data collection.

Comment: CMS received multiple comments and questions on Table 5. A commenter requested that CMS align the reopening data request with the Part C reporting Sponsors are already doing to improve efficiency and reduce burden on Sponsors. Another commenter requested confirmation that the reopening universe should only include reopened payment organization determinations from non-contracted providers to align with ODAG Table 3 and the current Part C reporting requirement, both of which exclude payment ODs from contracted providers. A commenter specifically requested that CMS explicitly state whether the universe only includes reopenings at the plan level or those remanded to the plan by the IRE for reopening. A commenter asked for confirmation if a payment organization determination has multiple lines that are reopened that the reopening would only appear on the reopening universe on one line. Another commenter requested clarification on whether reopenings initiated within the universe request period but not yet finalized should be excluded from the universe because Column ID N (Reopened Disposition) contains a value of "Denied" which appears to indicate that any reopening during the universe request period should be included. The same commenter requested clarification on whether reopenings initiated within the universe request period but not yet finalized should be excluded given that the inclusion criteria references reopenings that were "reopened and revised". Two commenters requested clarification on CMS's intended application of the ANR category, with one commenter requesting specific examples of scenarios that would appropriately be classified as ANR and the other commenter recommended CMS update the Column ID N description to remove "ANR for Approved without revision from the original approval" to align with the general layout instructions. A commenter requested clarification on whether a reopening that results in a payment rate change, but does not alter the underlying approval of coverage should be reported as "ANR" or "AR" for purposes of Column N. Next, the commenter requested that CMS confirm if a Payment Organization Determination (claim) is denied in part and approved in part, which response should be utilized: "ANR" or "AR". A commenter asked for definitions for the reasons to reopen a requesting Column ID M (Reason for Reopening).

Response: We appreciate the opportunity for clarification of reopenings that are in the proposed Table 5: Reopened Part C Determinations of the ODAG protocol. We appreciate commenters' concerns about duplication and potential overlap between reporting requirements, service level data, and the ODAG universes. First, we would confirm that we are only intending to capture Sponsor initiated re-openings that were reopened and revised within the universe period for purposes of audit. As of now, plan reopenings are excluded from the service level data collection so this would not result in duplication. We understand that Part C reporting requirements collects

reopenings in some capacity, so to eliminate any potential difficulties, we have revised our audit universe to align with the data fields collected in the reporting requirements. The exception to this will be the first five fields which will include enrollee name, contract ID, PBP, and whether or not an FDR was involved in the reopening. Otherwise, the remaining columns will directly align with reporting requirements to ease burden on Sponsors, including the reason for the reopening. We will continue assessing the information collected by CMS, and if we determine we can use existing reporting requirements or the new service level data, we will eliminate this universe from our collection. Our Table 5 reopenings universe is not limited to noncontract providers and should include all Sponsor initiated reopenings that were both reopened and revised. We are confirming, however, that we are only interested in collecting reopenings initiated by the Sponsor (not the IRE, ALJ or other entity). Additionally, we would not expect to see reopenings that were still open. We clarified the inclusion language to make these points clear; including that reopenings should be included based on the date notification of the reopened decision was provided.

Comment: A couple of commenters had questions about ODAG Table 3. One commenter requested confirmation on previously released guidance from February 27, 2023, titled "Questions Received Following the Final MAPD Program Audit Protocol Training Sessions" that Sponsors would not include drugs processed at the point of sale in Table 3 and whether that guidance remains CMS's current position and whether Part B point-of-sale pharmacy claims continue to be excluded from the scope of ODAG Table 3. The other commenter requested that CMS re-add "reopens" to the list of excluded payment requests to minimize duplication in reporting reopenings in both Table 3 and Table 5.

Response: We clarify that if a Sponsor considers a paid point-of-sale Part B drug transaction to be an organization determination, it may be reported in Table 1 to be consistent with service level data requirements. However, point-of-sale rejections that are not considered or processed as organization determinations do not need to be reported. Accordingly, Part B point-of-sale pharmacy claims are included only when they are treated as organization determinations by the Sponsor. We did not make any changes regarding the exclusion of reopenings from Table 3.

Comment: A commenter requested that CMS add a field to Table 1 related to whether a service requires prior authorization and is, therefore, subject to a different timeframe. The commenter noted that adding this field would be required if CMS were going to assess compliance with the new prior authorization timeframes.

Response: We agree with this suggestion, and we have added a field to Table 1 to ask whether or not prior authorization was required for that service.

Comment: A commenter asked if CMS could explain the difference between supplemental services and value-added items and services.

Response: We refer the commenter to Chapter 4 of the Medicare Managed Care Manual for information on the difference between supplemental services and value-added items and services for purposes of populating this field.

Comment: A commenter requested CMS to consider allowing Sponsors more time to implement the new audit protocols given the volume of work that would be required for universe configuration. The commenter recommended CMS provide a minimum full year before implementing protocols in the following fiscal year.

Response: While we appreciate this suggestion, the majority of universes are largely unchanged from the previously approved protocol. We will finalize the protocol as quickly as possible prior to January 2027 to allow sufficient time for programming systems.

Comment: A commenter recommended CMS align the annual reporting requirements with audit universes to reduce administrative burden.

Response: We appreciate the recommendation; however, our audit universes are more detailed and specific than the reporting data. Once the CMS Part C service level data becomes operational, we will stop collecting some ODAG audit universes in an effort to reduce duplication and burden on Sponsors. We have also aligned our Table 5 with the yearly reporting requirements to reduce burden on Sponsors.

Comment: A commenter requested clarification on expanded review periods. The commenter requested that CMS define the circumstances under which expanded review would be exercised; clarify the potential length of such an expanded review period; indicate how and when notification will be provided; and specify expected turnaround times if additional materials are requested.

Response: We do not intend to use an expanded review period for the majority of audits that are conducted. However, to the extent we find a specific issue that could impact enrollee access, or a potential concern that warrants further review, we reserve the right to expand the review in order to properly investigate it. If this becomes necessary, we will immediately communicate the concern to the Sponsor and identify the impact and additional documentation requests.

SPECIAL NEEDS PLANS CARE COORDINATION (SNPCC)

Comment: Multiple commenters requested clarification on the timeline associated with conveying selected samples to Sponsors for both webinars and desk reviews. A few commenters stated that one hour to prepare SNPCC samples prior to a webinar is insufficient given the complexity of the cases, the documentation generated across multiple platforms, and the time needed to retrieve enrollee specific documentation. Another commenter asked CMS to set a fixed deadline for desk review submission case files to support audit readiness and consistency.

Response: We recognize that Sponsors need sufficient time to prepare samples, even when the audit is done during a live webinar. Therefore, SNPCC samples will be provided the Thursday

prior to the entrance conference when the audit is conducted via webinar. If SNPCC is conducted through a desk review, Sponsors will be provided additional time to allow for sufficient case file preparation. In order to ensure transparency, we added these sample timelines into the protocol.

Comment: A few commenters requested clarification on the SNPCC update to the integrity testing sampling language to address the number of samples that will be selected. These commenters noted that the language indicated a minimum sample set, but asked CMS if there were a maximum number of samples that would be selected for purposes of integrity testing.

Response: We have modified this language to say that CMS will select up to 10 samples for integrity testing in the protocol.

Comment: Multiple commenters requested clarification on what integration level of D-SNP is applicable to each of the three new D-SNP elements: compliance standards 3.1, 3.2, and 3.3. A commenter asked CMS to consider making compliance standards 3.2 and 3.3 not applicable to Highly Integrated Dual Eligible (HIDE) and Fully Integrated Dual Eligible (FIDE) plans. Another commenter requested CMS to make compliance standard 3.2 only applicable to Applicable Integrated Plans (AIPs) as coordination only D-SNPs enrollees can present significant operational challenges to Sponsors due to a lack of enrollee level Medicaid plan data.

Response: We appreciate the question and have added additional clarification to the protocol to clarify what D-SNP integration level is applicable to each of the three new D-SNP compliance standards. The additional clarification of integration level is specific to and in agreement with the regulatory requirement associated with each of the three new D-SNP compliance standards. Please note, when determining the D-SNP plan type, Sponsors should refer to the final State Medicaid Agency Contract (SMAC) review integration status results report provided to organizations by CMS in August prior to the beginning of each contract year.

Comment: A commenter appreciated the addition of "as warranted" in the compliance standard 2.3, as it relates to the responsibility to review/modify care plans following changes in enrollees' health statuses. The commenter requested confirmation that a Sponsor will be evaluated for this compliance standard based on its approved Model of Care (MOC). The commenter asked CMS to clearly define the MOC as the clear source for determining "as warranted", to avoid inconsistency in the evaluation of this audit element.

Response: We agree that if the MOC provides clarity or additional interpretation to changes in health status, CMS would assess compliance with both the regulatory standard and the MOC. We do not believe a change is necessary within compliance standard 2.3. The MOC reference is included in the "Criteria" column for each compliance standard where we believe the MOC will be applicable when assessing compliance.

Comment: A commenter requested clarification on compliance standard 2.7 and whether "annually" may be satisfied by either one face-to-face encounter per calendar year, or by implementing a rolling 365-day process, and if both approaches are sufficient to meet the

standard. Additionally, this commenter requested CMS confirm that this compliance standard will be assessed based on the approved MOC, especially as it relates to attempts to conduct a face-to-face when an enrollee may refuse.

Response: For purposes of audit, we will be assessing if a Sponsor attempts a face-to-face encounter annually, in accordance with specifications outlined in their MOC.

Comment: A commenter submitted multiple concerns related to the new compliance standard D-SNP 3.1 – Integrated Health Risk Assessments (HRAs). These concerns highlighted the operational challenges to satisfying the regulatory requirement of a single integrated HRA; including inconsistent integration timeframes between the federal government and states, state required assessments that cannot be integrated, differing tools and systems for different assessment types, member burden and state specific requirements.

Response: We note that policy questions and operational concerns are outside of the scope of this data collection package. For audit purposes, we will assess how the Sponsor is complying with the regulatory requirement related to having an integrated HRA for AIPs. We routinely consider all available information, including potential mitigating information related to state-specific rules or other challenges that Sponsors may face.

Comment: A few commenters submitted questions related to D-SNP compliance standard 3.2 - Coordination of Medicaid related services assistance. A few commenters were asking what CMS considers acceptable for "offered to coordinate and provide Medicaid assistance": with another commenter asking specifically for "offer" to be defined in context of coordinating services. This commenter requested CMS to weigh in on whether written notification to the enrollee informing them about the availability of Medicaid assistance would be sufficient to satisfy this compliance standard on audit. A different commenter asked for clarification on when the requirement applies, what are the plan's responsibilities versus the states, what the timeliness expectations were, and what would be considered acceptable documentation.

Response: We clarify D-SNPs may offer assistance in many ways, including advising enrollees to call providers and recommending the questions to ask. Offers of assistance may be made in writing or verbally, provided the interaction is appropriately documented. When an enrollee requests assistance, that assistance may include helping the enrollee obtain medical documentation, identifying necessary forms to file, or referring the enrollee to an organization with greater expertise, such as a state ombudsman or other relevant assistance programs. We do not intend to be overly prescriptive regarding the types of assistance a D-SNP must offer, or how a D-SNP operationalizes its processes, and the examples provided are not intended to be exhaustive. Further, we note that the regulation at 42 CFR § 422.562(a)(5), does not require the D-SNP to represent its enrollees in Medicaid matters. To address the concerns raised by commenters, we revised the compliance standard to better distinguish between offering assistance and providing assistance to enrollees.

Comment: A commentor asked CMS to consider including the phrase “in accordance with the Model of Care (MOC) or as defined in supporting documentation,” within compliance standard 2.5 - "Review the selected samples to determine if the enrollee/caregiver/ representative was involved in the ICP development".

Response: Thank you for your comment. We agree that if the MOC provides clarity or additional interpretation to compliance standard 2.5, CMS would assess compliance with both the regulatory standard and the MOC. We do not believe a change is necessary within compliance standard 2.5. The MOC reference is included in the Criteria column for each compliance standard where we believe the MOC will be applicable when assessing compliance.

Comment: A commenter acknowledged CMS’ efforts to align compliance standard 2.2 with the new regulatory requirements in 42 CFR § 422.101(f) that shift care plans from a medical model to a more person-centered model. The commenter expressed concerns, however, that person-centered care plans are appropriate for certain populations, such as D-SNP enrollees and those with well-controlled chronic conditions, but noted that for other populations, such as Institutional Special Needs Plan (I-SNP) and Chronic Condition Special Needs Plan (C-SNP) enrollees, a medically focused care plan may be more appropriate due to the complexity and nature of their conditions and needs. This commenter asked if the intent of the audit element was to ensure at least one goal within the care plan is person-centered. Additionally, this commenter requested guidance on whether there are any future expectations for in-person encounters as part of the person-centered care planning process.

Response: We modified this compliance standard to reflect the regulatory requirements that a care plan be person-centered. We agree that for some enrollees, care plans may be more medically focused based on the needs of the enrollee. This compliance test will assess a Sponsor’s compliance with the regulatory requirements, while considering the MOC and the needs of the enrollee. Policy questions and concerns are outside the scope of this PRA package and should be directed to the appropriate policy group within CMS.

Comment: A commenter requested CMS to include clarifying language to specify that the D-SNP integration element 3.1 and the associated impact analysis field "H" which relate to integrated HRAs would only be applicable on or after Calendar Year 2027 to align with when the regulatory requirement becomes applicable.

Response: We do not intend to use this protocol prior to January 1, 2027; and therefore, would not assess this standard before that date. Additionally, we would discuss implementation of the integrated HRA process during the course of audit fieldwork, taking into account how Sponsors have come into compliance with this new requirement.

Comment: A commenter expressed concerns that the proposed D-SNP coordination audit element 3.3 may duplicate existing reporting requirements. Additionally, the commenter stated that the compliance standard is related to notifications of admission, but that these notifications

can be submitted by the Sponsor, the state or other third parties. This commenter noted that when submitted by the state or third parties, the Sponsor may not have ready access to that documentation to share in a sample review audit. To reduce any potential for duplicate reporting and help reduce the financial and administrative burden on Sponsors, the commenter recommended that CMS consider removing this data element for compliance standard 3.3. The commenter also suggested CMS either remove the associated column in the SNPCC Impact Analysis Column ID AB or add the option of NA to account for reporting in cases where an enrollee has not experienced a facility admission or where state guidance does not require notification, such as when an enrollee does not meet the high-risk population definition. Lastly, the commenter is seeking clarification from CMS regarding the scope of facility admissions included in this impact analysis. Specifically, it would be helpful to confirm whether only skilled nursing facility admissions are in scope, as the current language references "admission to a facility".

Response: We appreciate the commenters' concerns and recognize that notification requirements may change based on the state, and that other entities may provide the notification. However, the Sponsor maintains the ultimate responsibility for ensuring notification is completed. Sponsors should discuss with the CMS audit team how the Sponsor implements this requirement and the state rules that apply during fieldwork. We will not request data for the associated impact analysis Column AB when an enrollee has not experienced a facility admission or where state guidance does not require notification. We will only request data when noncompliance is evidenced to determine full impact. Lastly, the definition of "facility" is intended to include hospitalizations, SNFs, or any other inpatient facility.

Comment: A few commenters mentioned that the description in Table 1, Column ID L (Date of previous HRA) incorrectly mentions Column ID I, when it should be Column ID K (Date of most recent HRA) due to the new fields included in the table.

Response: We agree that the column description incorrectly mentions Column ID I, when it should be Column ID K. However, in response to other comments, we removed and modified other columns and have re-lettered all columns accordingly.

Comment: Multiple commenters submitted questions related to Table 1, Column IDs H (SNP Enrollment Effective Date), I (Most Recent Plan Change Effective Date) and J (Most Recent Plan Change Effective Date for non-continuous enrollment). A few commenters asked for clarification on how these fields should be populated and requested examples. Another commenter asked if initial HRA timeliness would ever be calculated on Column I instead of Column H; and if timeliness would ever be calculated based on J. This commenter recommended Column ID J be removed as it is unnecessary. Several commenters requested clarification on how to populate Column ID J, noting operational challenges due to multiple systems and retroactive corrections. A commenter asked if PBP changes count as re-enrollment, and how a Sponsor should report this information if different dates exist. Another commenter asked how

retroactive Medicaid updates should be handled. Lastly, a commenter recommended that if Column ID J remains, the field should be a Yes or No response instead of a date.

Response: We appreciate the opportunity to clarify Table 1 Column IDs H, I, and J. After further consideration of the comments, we have removed Column ID I and Column ID J from the protocol. We intend to calculate timeliness of initial HRAs based on a comparison between Column ID H (now Column ID G) and Column ID M (now Column ID J). During audit fieldwork, we will discuss with Sponsors their process related to re-enrollment as well as retrospective Medicaid updates. Information regarding HRA updates based on plan changes will be considered during the HRA timeliness mitigation process.

Comment: A few commenters submitted questions related to Table 1, Column ID F (First Tier, Downstream, and Related Entity). A commenter asked for clarification on what FDRs Sponsors should include for example, all entities that support care coordination activities, utilization management delegations, or something else. Another commenter asked if multiple entities could be included in this field. Several commenters suggested limiting the FDRs to those that support the Model of Care and suggested excluding state directed Medicaid/ Long-term services and supports (LTSS) providers from FDR categorization. Another commenter pointed out that CMS had removed this field from the 2021 protocol and indicated that adding it back would increase burden. Additionally, if the field is added back, the commenter requested clarification on the time period that the field would cover (e.g., FDRs assigned at the time of the universe request or FDRs that were assigned at any point during the review period).

Response: We appreciate the comments and have removed Column ID F from the protocol. We will continue to collect relevant FDR information in the SNPCC questionnaire.

Comment: Several commenters asked for clarification around how CMS would assess timeliness on audit. A commentor asked for clarification surrounding the standalone timeliness documentation that is referenced in the supporting documentation section of the protocol, specifically, what documentation would CMS expect to be submitted. Another commentor recommended that CMS provide additional clarity regarding the threshold at which the HRA Mitigation Analysis will be required. Another commentor recommended that CMS set a statistically valid percentage standard benchmark when reviewing potentially untimely cases, before requesting the Sponsor to complete the HRA timeliness mitigation tool.

Response: When we review timeliness at the universe level, we use an internal standard benchmark to determine when additional information is needed, and we do not request the Sponsor provide the HRA timeliness mitigation analysis tool (HRA-TMA) when that benchmark is met. If timeliness falls below the CMS internal benchmark, auditors will determine if outreach mitigation data is necessary, and for which cases, and will then request the Sponsor complete the HRA-TMA. The HRA mitigation tool is used to provide Sponsors an opportunity to mitigate IHRA and AHRA timeliness results by providing CMS with outreach attempts conducted. We

included language within the "Scope of Timeliness Mitigation Analysis" Table to clarify this process. Additionally, the "Verification of Information Collected" section of the protocol related to timeliness has also been updated because we reserve the right to validate outreach attempts and may need documentation to support the information that is provided by the Sponsor related to timely HRAs. For example, documentation showing the dates of the outreach attempts.

Comment: A commentor noted that they maintain a continuous, longitudinal care plan and requested clarification on if plans should report the most recent longitudinal Individualized Care Plan (ICP) update and exclude short-term or transition specific plans for Table 1, Column ID O (Date of most recent Individualized Care Plan (ICP)).

Response: Thank you for your comment. We would expect Sponsors to enter the date of the most recent update to the continuous ICP, which may include transitions or any other change in health status updates.

Comment: A commentor asked CMS to clarify how timeliness testing of ICPs will be conducted to ensure that Sponsors who adhere to routine outreach and ICP update requirements are not subject to unnecessary impact analysis submissions given that the SNP record layout does not support the fields necessary for such timeliness testing.

Response: Thank you for your comment. CMS has added a column to Table 1 to collect the "Date of the Initial ICP". CMS will calculate ICP timeliness on a universe level, using the SNP enrollment date along with the date of the initial ICP in accordance with the regulatory guidance.

Comment: A few commenters expressed concerns with the addition of Column ID R (For D-SNP enrollees, were there any Medicaid specific services or needs identified) to Table 1. The commenters expressed concerns that generating this field would be difficult due to system alignments, and data limitations. Additionally, a commenter expressed similar concerns with the associated impact analysis Column Z (For D-SNP enrollees, if a Medicaid specific service or need was identified, was the provision of the service or need arranged and/or coordinated?) in the SNPCC Impact table, and suggested CMS reconsider or add an "N/A" option to account for situations where enrollees did not have a need to file an appeal or grievance.

Response: Thank you for your comment. We have removed Column ID R from the universe and removed the associated SNPCC Impact Column ID Z.

Comment: Several commenters asked for clarification related to Table 1, Column ID Q (Was there a hospital or SNF admission?). A commenter asked what data sources should be used to populate this field and asked if it should be based on claims data or some other data source outlined by CMS. Another commenter asked for clarification on what defines a hospitalization; and asked if CMS was referring to short term acute care stays, long term acute care stays, inpatient behavioral health stays and/or inpatient rehabilitation stays. Lastly, a commenter asked how to populate this field if the enrollee was already in a SNF (I-SNP) at time of enrollment.

Response: We appreciate the opportunity to clarify this field. First, there are no parameters on what data source to use when identifying enrollees with admissions activity; Sponsors may use any and all sources that are relevant, including claims data. Second, we would consider hospitalizations to include acute inpatient stays, long-term acute care stays, inpatient rehabilitation stays, and behavioral health hospitalizations. Lastly, this field is only intended to capture current admissions during the 26-week look back; we would not expect to see "Y" in the field for someone that was already residing in a SNF at the time of enrollment. We have modified the field description to better define these items in response to comments.

Comment: A commenter requested confirmation on the requirements for outreach attempts. Specifically, the commenter asked if outreach efforts conducted before the IHRA due date, including those made prior to the enrollee's effective date, are allowed to be counted toward satisfying the outreach requirements.

Response: We agree with the commenter that outreach attempts conducted prior to the IHRA due date, which is the period prior to the date of enrollment through the 90 days after, is relevant and may be entered into the applicable columns in the SNPCC HRATMA. We also removed Column ID I of the IHRA tab and Column ID K of the AHRA tabs since they are no longer necessary.

Comment: A commenter suggested CMS consider adding the phrase "or if the ICP was not yet due" to the "NA" notation within the SNPCC Impact Column ID L. Additionally, the commenter requested clarification about whether reporting should be limited to newly created ICPs, or, if enrollees with existing ICPs should also be included when their ICP is updated in accordance with the MOC.

Response: We have removed the "NA" option from Column ID L of the SNPCC Impact, as well as from Columns K and M. We do not believe NA is a necessary option because we will only request an impact analysis in response to noted noncompliance. Additionally, we will remove columns that do not apply to limit confusion. In order to ensure transparency, we have added a new column in the impact tab asking if an ICP created.

Comment: A commenter requested that CMS provide additional clarification on Column U of the SNPCC Impact tab. Specifically, the commenter asked about the distinction between entering "N" for No and "NA" in instances where an ICT was not established.

Response: We appreciate the opportunity to provide clarification. For this field, Sponsors should enter "Yes" if the ICT was involved in the plan of care and enter "No" if the Sponsor had an ICT, but the ICT was not involved in the plan of care. We would only expect "NA" to be answered when an ICT was not created (i.e., there was not ICT).

Comment: A commenter suggested the addition of an "N/A" option for SNPCC Impact at Column ID Z "was assistance provided to the enrollee when filing for Medicaid-related appeals

and/ or grievance" to account for situations where enrollees did not have a need to file an appeal or grievance.

Response: Thank you for your comment, CMS has decided to remove this column from the Impact Tab.

Comment: A commenter requested additional clarification from CMS on the SNPCC questionnaire, question #4 regarding the enrollee portal access. Specifically, this commenter asked how descriptive the response should be; and whether CMS is looking for a description of the eligibility process, or whether CMS is only asking about how the Sponsor communicates with enrollees about the portal. Additionally, the commenter noted that some delegate entities may have their own portals for enrollees to use, and the commenter asked CMS if these should be considered too.

Response: We appreciate the opportunity for clarification. This question is intended to help us understand how Sponsors may communicate information with enrollees, and how those communications are tracked when information is shared electronically, such as through an online portal. If a Sponsor's MOC references the use of an online portal, we are interested in understanding the process for sharing ICPs, health literacy materials, and any other information with enrollees, as well as how the Sponsor ensures the enrollee has access to that information. If the delegated entity is responsible for managing the online portal for ICPs and other health literacy sharing, Sponsors should describe that process in their response to Question #4.

Comment: One commenter requested clarification regarding the language added to the supplemental questionnaire for question 8, specifically the phrase "or who decline to participate." Specifically, this commenter asked CMS if they should describe "Do Not Contact" procedures alongside instances where enrollees explicitly decline participation, since some enrollees specifically ask the Sponsor not to contact them.

Response: We appreciate the opportunity for clarification. This question is to gather information on how the Sponsor conducts outreach for purposes of HRAs and ICPs. If a part of that process includes consideration of whether an enrollee has specifically asked not to be contacted, then the Sponsor should explain that in the response.

VALIDATION

Comment: A commenter asked CMS to explain how the process will change from using a Work Plan to using a Validation Report. The commenter wants to know if the Work Plan will be removed completely and how CMS will review the audit methods before the actual review work begins.

Response: We clarify that the Validation Audit Work Plan (VAWP) is not being eliminated. The VAWP remains a required document for independent validator-led audits and must be submitted for CMS approval prior to the validation audit taking place. To promote transparency, we

included both a template VAWP and a template validation report into the PRA package. In the past, we have frequently requested clarification or revisions to submitted validation audit work plans and validation reports. By providing templates for both documents, we aim to improve consistency and reduce the need for resubmissions.

Comment: A **c**ommenter asked CMS to explain whether independent validation auditors must use the exact case tables provided by CMS or if they can add extra documentation to them.

Response: We believe this question is related to the validation audit report template which includes a table for case summaries. This report template was created as a result of receiving numerous validation audit reports over the years that were either incomplete or did not clearly explain what happened at the case level. We would request that validation audit reports be submitted with the information included in the template. However, if additional supporting documentation is necessary, it may be attached as needed.

Comment: A commenter asks if there are minimum requirements for what must be included in summaries of sampled cases.

Response: We appreciate your comment. Case summaries should be detailed enough for us to understand what the auditor observed and why the case was determined to be compliant or noncompliant. The level of detail may vary based on the type of case and the condition that is being assessed. At a minimum, we would want to understand the specific facts of the case that were noted and pertinent to the condition being tested.

Comment: A commenter asked what standards a data universe must meet to pass integrity checks and when it would need to be corrected and submitted again.

Response: We expect that independent auditors establish appropriate thresholds to assess the accuracy of a universe. Those thresholds must be submitted as part of the validation audit workplan and will be approved by CMS prior to use. We added a sentence into the VAWP to clarify this request.

Comment: The commenters ask how CMS will address 'new' issues identified by an independent validation auditor that were not identified during the original audit. They want to know whether Sponsors will need to submit a new corrective action plan (CAP) and whether the new findings could lead to additional CMS oversight or expanded validation activities.

Response: We clarify that audit issues or conditions that are identified during the validation audit that were not originally noted in the initial program audit are referred to the CMS Account Manager (AM) for follow-up. However, CMS reserves the right to determine whether additional or alternative follow-up is warranted based on the nature, severity and circumstances of the issue identified.

Comment: A commenter asked whether the validation report should follow the same sampling requirements used in the program audit protocols. The commenter also suggested that CMS provide a crosswalk or comparison guide to make the requirements easier to understand.

Response: We appreciate the commenter's question**.** The same audit protocols used during the original program audit should also be used when conducting the validation review for the applicable program area(s). However, the number of samples selected during the validation audit can vary depending on the type of condition being validated. The proposed sample sizes should be documented in the validation audit workplan and approved by CMS.

Comment: A commenter asked CMS to explain what "other activities" it may use during validation activities, besides audits, to check that corrective action plans are completed correctly and on time. The commenter also asked for examples of these activities.

Response: We may use alternative activities such as targeted documentation reviews and webinars to validate that corrective action plans have been implemented accurately and timely. For example, we may review updated materials (e.g., revised notification templates) to confirm required changes or use webinars to verify implementation and understanding. We will also attempt to use information already gathered by the Sponsor in their own monitoring activities to assess correction when possible and to reduce unnecessary burden by requesting universes when it may not be necessary.

Supporting Statement A

Comment: A commenter requested clarification on supporting statement A and the section on special circumstances. This commenter asked what to anticipate within these special requests, and whether it includes items like data integrity testing or limited scope audits.

Response: We clarify that this section is intended to account for situations not otherwise specified within this protocol package. For example, if we conduct an unscheduled audit based on beneficiary access concerns, timeframes that would otherwise be granted may need to be reduced to ensure beneficiary safety.

Comment: One commenter noted that the burden was reduced from 150 hours to 100 hours over a span of 2-3 years based on the shift to service level data reporting. The commenter noted that while service level data reporting will replace the use of some audit universe tables, the service level data is still classified as pre-fieldwork data and therefore there should not be a reduction in burden. Another commenter noted that the audit data and the quarterly service level data collection will increase administrative burden and duplicate efforts; and that the service level data collection will require plans to maintain audit-level data year-round. This commenter also noted that many of the fields between the audit universes and the service level data collection overlap; but due to differences in some places Sponsors would need to build and maintain

multiple technical programs for the two different data sets. This commenter also noted the value in requesting the quarterly data is unclear and may overly burden small plans. Another commenter noted that CMS reduced the hours of pre-fieldwork universe submission as a result of not making changes to the ODAG universe fields, but that CMS did not account for the updated inclusion language in the universes which would increase burden.

Response: We appreciate the commenters' concerns regarding potential burden. Based on requests from industry to CMS to avoid duplication and use available data; we are transitioning from collecting audit universes in Part C, to using service level data collected by CMS for audit purposes. This transition will occur once the service level data collection is fully operational. Until then, we must continue collecting audit universes to ensure appropriate oversight in Part C. Comments regarding the burden of the service level data collection are outside the scope of this package. Similarly, the burden associated with service level data was calculated in that specific data collection package and, therefore, is not considered for this data collection effort. We do agree with commenters that including additional types of organization determination requests may increase burden in the pre-fieldwork stage, and we have updated Supporting Statement A accordingly. Specifically, we have increased the hours in year 1 from 150 to 175 to account for the inclusion of different types of ODs into Tables 1 and 2 in the ODAG universe, we only increased the numbers for the first-year burden because we anticipate not needing to collect Tables 1, 2 and 3 by the second and third year of this audit protocol package.