

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 115 comments on the July 6, 2026, (CMS-10717) Medicare Parts C and D Program Audit Protocols and Data Requests proposed Paperwork Reduction Act (PRA) 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 applying to multiple program areas, individual program comments and/or documents, and finally comments on burden.

MULTIPLE PROGRAM AREAS

Comment: Several commenters requested clarification on CMS's intent to implement desk reviews. One commenter recommended CMS not use desk reviews because that approach has proven to be administratively burdensome and resource-intensive. One commenter requested CMS provides more clarity regarding desk review expectations including how often desk reviews will be used and whether certain audit elements will remain subject to live reviews. These commenters requested CMS allow Sponsors flexibility to choose the option of either a desk review, a live webinar review, or a hybrid approach based on which method will produce complete and accurate information most efficiently.

Response: We appreciate the concerns from commenters on how desk review may be implemented in program audits. We believe that desk review offers a more transparent, less burdensome way to audit, while still preserving the transparency of our audit process. However, we understand that some Sponsors remain concerned about the potential burden of collecting and submitting case file documentation. We continue to explore all options for our program audits, both in how we incorporate desk review into the audit process as well as when we would use webinars as the primary approach. We will consider how to best communicate our intended approach, including what information may warrant inclusion in the annual updates memorandum versus what information is Sponsor specific and included in an audit engagement letter.

Comment: A few commenters requested CMS provide Sponsors with a longer timeframe to produce requested case files for desk review audits. The commenters noted the shift from live-review audits to desk reviews is a significant change that will require time to adequately implement processes for compiling and submitting audit ready case files. The commenters stated a longer submission timeframe will allow sufficient time to gather documentation that may reside across multiple systems, operational areas, or delegated entities, reduce the risk of administrative errors, and support submission accuracy and completeness. Commenters recommended extending the timeframe for providing case files from 5 business days to anywhere from 7 days to 15 business days.

Response: We continue to consider how a desk review may impact an audited Sponsor and will factor this into future planning. While we believe that 5 business days is generally sufficient to prepare most case files, we will extend the time as needed based on the types of case files and the number of case files requested. For example, if we determine that we need full case files in advance of fieldwork for all Part C denial decisions, we may extend the timeframe to ensure sufficient time for the Sponsor to prepare.

Comment: A commenter suggested CMS apply proportionality to root cause analyses, impact analyses, timeliness mitigation reviews, and validation activities. The commenter requested CMS permit integrated responses when the same facts support multiple analyses, allow processor universe-level methods when they reliably identify the full affected population, and require case-level review whenever individualized enrollee impact, remediation, or reimbursement must be determined. Further, this commenter suggested additional time is allowed when provider outreach, clinical review, source-system investigation, or validation is necessary.

Response: We appreciate this comment. We currently consider the full circumstances of each issue when reviewing root causes, impact analyses (IAs), and case-level findings. Sponsors should discuss their questions and recommended approaches to root cause analyses and/or impact analyses with the auditor-in-charge in order to ensure that their intended approach is sufficient. We encourage and support Sponsors in identifying when cases or causes may overlap; or when impact may be easily identified through a universe generation. Additionally, if a Sponsor needs additional time to complete provider outreach, clinical review, or other steps to fully assess an issue or determine enrollee impact, CMS will take this into account.

Comment: A commenter provided recommendations on the Rural Health Transformation Program (CMS-10949).

Response: This comment is outside the scope of this PRA package.

Comment: A commenter supported the direction of the proposed changes but requested Sponsors have a minimum of 90 days between publication of the final protocols and the start of audit activities to implement the proposed revisions. The commenter identified several revisions that would require substantial operational and system modifications. Specifically, the commenter noted the expanded inclusion criteria for Part C Organization Determinations, Appeals and Grievances (ODAG) Tables 1-3 and the inclusion of open grievances in Part D Coverage Determinations, Appeals and Grievances (CDAG) and ODAG will require substantial system and reporting modifications.

Response: We agree with the importance of allowing sufficient time for Sponsors to implement the changes associated with the collection request prior to the start of the 2027 audit year. CMS continues to work toward the goal of finalizing this collection request such that stakeholders are afforded the maximum amount of time possible to update their systems. We have also eliminated

a few of the proposals that we think would have increased what system changes are necessary, including eliminating the inclusion of open grievances in CDAG and ODAG.

Comment: Commenters expressed concern regarding the requirement to include grievances in CDAG and ODAG that remain open beyond the applicable resolution timeframe. A commenter noted the language was ambiguous and requested additional clarification. The other commenter stated this change would require substantial system and reporting modifications.

Response: We appreciate the commenter's request for clarification. After further consideration, CMS is removing the request to include grievances older than 30 days as of the time of the engagement letter that have not received a response from the Table 4: GRV_C and Table 6: GRV_D record layout instructions. The record layout instructions will request inclusion of all grievances the Sponsor responded to, dismissed, or were withdrawn during the universe period.

Comment: A commenter noted that CMS removed character limits from the program audit protocol record layouts but requested clarification on whether Sponsors may continue to use internal character limits for grievance description fields when submitting grievance universe data, provided sufficient information is available to support CMS review and audit activities.

Response: We appreciate the commenter's question. While we have removed the field length character limits from the applicable record layouts, organizations may continue using internal character limits if that assists in preparing and submitting requested information in the manner specified by CMS.

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

Comment: A commenter sought confirmation on whether their understanding that the "investigational universe" should be limited to compliance investigations directly related to the applicable program audit areas (e.g., Formulary Administration (FA), ODAG, CDAG, and Special Needs Plans Care Coordination (SNPCC)), including investigations involving potential noncompliance with formulary exceptions, organization determinations, appeals and grievances, SNP care coordination, or other requirements within those audited areas.

Response: We assume this commenter is referring to the compliance oversight activities universe in the CPE protocol, and we confirm that we expect any investigations included within that universe to relate to an audited program area.

PART D FORMULARY AND BENEFIT ADMINISTRATION

Comment: For Tables 1 and 2, a commenter recommended revising Column ID J (Drug Name, Strength, and Dosage Form) to clarify that Sponsors should populate the field using information

from the plan's drug database based on the pharmacy-submitted National Drug Code (NDC) and enter "NA" when the NDC is invalid or cannot be found in the plan's drug database.

Response: We are in agreement with this recommendation. Column ID J (Drug Name, Strength, and Dosage Form) has been updated to read: Enter the full drug name, strength, and dosage form as provided by the Sponsor, utilizing the information populated from the pharmacy submitted NDC. Enter NA if the NDC is invalid or not found in Part D plan's drug database.

Comment: A commenter requested clarification on populating Table 3, Column ID E (Enrollment Effective Date) and Column ID F (Effective Disenrollment Date), and asked whether a change in plan benefit package should be treated as a new enrollment and corresponding disenrollment.

Response: No changes have been made to populating the Enrollment Effective Date and Effective Disenrollment Date fields based on plan benefit package (PBP) changes, and Sponsors should continue reporting the enrollment effective date for the enrollee's current PBP (and disenrollment date if applicable). We modified the field description for those fields to remove "plan ID" and instead reference the enrollee's PBP. For purposes of determining a "new" enrollee for potential inclusion in the Table 3 universe, Sponsors should consider the relevant inclusion language for the table. Specifically, for enrollees with PBP changes, Sponsors that do not utilize prior claims history should include these enrollees in the New Enrollee Universe, Table 3. Conversely, if an enrollee is newly enrolled in a PBP, and the Sponsor does utilize prior claims history that will be used to determine ongoing therapy, the Sponsor should not report that enrollee in Table 3.

Comment: For FA Tables 1 and 2, a commenter expressed concerns that including claim denials based on BIN, PCN, and Group could result in enrollee information being associated with a Sponsor when the individual was not enrolled in the plan due to inaccurate pharmacy-submitted data. The commenter stated that this represents a significant change from its current process, which requires rejected claims to match to loaded eligibility before information is provided to a Sponsor to protect privacy and data integrity. The commenter recommended that CMS retain the universe criteria in the currently approved FA protocol, which does not reference BIN, PCN, or Group.

Response: After careful consideration, we will remove the following instructions in the FA Protocols: Include claim denials using the BIN, PCN, and Group that can be cross walked to the contract/PBP. This instruction, while new in the protocol, has been provided by CMS to audited organizations verbally, and we continue to encourage Sponsors to submit universes considering this instruction. However, for Sponsors that are not already submitting information based on these instructions, we will not require any changes to be made to how universes are currently prepared and submitted. While we are removing this wording from the universe inclusion instructions, we encourage Sponsors to work with their Pharmacy Benefit Managers (PBMs) on how claims are being identified and submitted to Sponsors.

Comment: For Tables 1 and 2, a commenter expressed concerns with requiring pharmacy-submitted information for Column ID B (Enrollee First Name), Column ID C (Enrollee Last Name), Column ID D (Date of Birth), and Column ID G (Cardholder ID), noting that inaccurate pharmacy-submitted information may create discrepancies and make it more difficult to identify enrollees. The commenter recommended that CMS retain the field descriptions in the currently approved FA protocol, which do not specify that the information be populated “as submitted by the pharmacy.”

Response: Following a review of comments, we are removing the instructions for Column IDs B, C, D, and G that instruct Sponsor to submit these fields as submitted by the pharmacy. We understand that some Sponsors are currently populating those fields with data as submitted by the pharmacy, and for those Sponsors, that method is still an acceptable process. However, for Sponsors that are currently reconciling pharmacy submitted data to ensure accuracy prior to submitting universes, we will not require changes in that approach in this protocol.

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

Comment: A commenter requested clarification regarding reporting partially approved requests in CDAG universes. The commenter noted the instructions state that requests denied in whole or in part should be reported as ‘Denied’ in Table 1 Column ID X, Table 2 Column ID N, Table 3 Column ID M, and Table 4 Column ID O (Request Determination) field, however the instructions also state to report approval and effectuation information for the favorable portion of the decision.

Response: Partially favorable decisions should be populated as a ‘Denied’ request determination in CDAG universes. For these types of cases, Sponsors would include data regarding the approval and effectuation of the favorable portion of the decision in other applicable fields (e.g., (Expiration date of the approval), (Date effectuated in the system), (Time effectuated in the system)). Sponsors are expected to populate universe data according to how they processed the case.

Comment: A commenter asked which coverage determination letter should be used for FIDE members.

Response: We appreciate the comment; however, policy questions are outside the scope of this data collection package. Please send policy questions to the applicable CMS portals and/or email addresses.

Comment: For CDAG universe Tables 1-4, a commenter asked whether they could enter ‘None’ for the following fields for auto-forwarded cases: (Date effectuated in the system), (Time effectuated in the system), (Date oral notification provided to enrollee), (Time oral notification provided to enrollee), (Expiration date of the approval), (Date written notification provided to enrollee) and (Time written notification provided to enrollee). If CMS expects the Sponsor to

include this information for all request determinations when any of the above actions are taken, the commenter recommended that we include that instruction.

Response: As previously mentioned, Sponsors are to populate universe data according to how they processed the case. If the Sponsor took any of these actions, the Sponsor would enter the data in the universe and would not enter 'None'. However, for any fields where the Sponsor did not take a corresponding action as a result of auto-forwarding the case, 'None' would be an appropriate response in those fields. We have also made an additional clarification related to auto-forwards. For the (Date of Determination) and (Time of Determination) fields in Tables 1-4 we have added, "For auto-forward cases enter the date/time the case file was closed as untimely."

Comment: A commenter noted that in the General Layout Instructions CMS lists three exclusions: exclude enrollees whose coverage is not yet effective as of the date of the engagement letter; exclude requests that are pending a decision; and exclude requests where a decision has not been issued while the Sponsoring organization awaits the appropriate representative documentation. The commenter asked whether these three exclusions apply to all CDAG universe tables.

Response: We have updated the General Record Layout instructions to include the following language, "these general instructions below apply to all record layouts unless the individual record layout instructions provide more specific guidance." As noted within these responses, we have removed open and pending grievances from CDAG Table 6. With this change, all three of these exclusions now apply to all CDAG universe tables.

Comment: For the Column ID U (Date effectuated in the system) in Table 3 PYMT_D, a commenter requested clarification on whether the Sponsor should capture the effectuation of the drug for payment, coverage determination, or claim processing, along with manual claim processing for the retrospective date of service if they are not the same date and time. For example, oftentimes for a payment request, there could be an override/authorization effectuation either for a retrospective date of service or both retroactive and prospective coverage.

Response: If for some requests effectuation of the approval has to be done/entered into the system in multiple ways or through different processes, enter the earliest date that the approval was effectuated in the system.

Comment: A commenter requested additional information on the PBP field description updates for CDAG, and noted CMS updated the language from the 60-day draft protocol updates from "Enter the PBP effective on the date of service" to "Enter the PBP applicable for purposes of the request." The commenter requested CMS to provide additional information on what "applicable to the request" means.

Response: We recognize that PBP information is not always available or current at the time of the request and have revised the field description to allow for population of the most accurate

information specific to the request. While reviewing the universes in response to comments, we considered the wording in all fields and made an additional edit to ensure clarification for Sponsors populating the requested information. Specifically, for Table 4, Column ID W (Was the initial coverage determination request denied for lack of medical necessity?) we added the word “initial” into the field name so it now reads (“Was the initial coverage determination request denied for lack of medical necessity?”)

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

Comment: A commenter expressed concerns regarding Medicare Advantage Organizations’ use of internal coverage criteria when determining medical necessity for inpatient hospital services and recommended that CMS use multiple artificial intelligence tools to review and summarize clinical literature, verify supporting sources, and compare the results with internal coverage criteria used by Sponsors to assess compliance with applicable regulatory requirements.

Response: We thank the commenter for their comments and recommendations regarding Medicare Advantage coverage requirements, the use of internal coverage criteria, and approaches to evaluating compliance. We added a compliance standard related to coverage criteria into the protocol when initially proposing modifications and we intend to finalize that compliance standard and review criteria during the review of denials. We continue to assess the best methods for ensuring that review is appropriately done without overly burdening organizations or audit teams.

Comment: A commenter agreed the transition to Service Level Data (SLD) will reduce the burden associated with program audits. However, this commenter expressed concerns that CMS has not released adequate guidance for Dual Eligible Special Needs Plans (D-SNP) including Highly Integrated (HIDE) and Fully Integrated (FIDE) Dual Eligible SNPs regarding how plans should report Medicaid benefits passed through to D-SNPs via the State Medicaid Agency Contract (SMAC) in the 2025 memo “Service Level Data Collection for Initial Determinations and Appeals – Pilot Participation.” This commenter noted D-SNPs are generally smaller than other MA plans that would be disproportionately burdened by new reporting requirements and stressed the importance for robust guidance with enough preparation time to ensure compliance.

Response: Thank you for your comment. This comment is outside the scope of this PRA package.

Comment: A commenter requested CMS publish a list of National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) that are fully established.

Response: Thank you for your comment. This comment is outside the scope of this PRA package.

Comment: A few commenters requested CMS update the number of samples selected for Universe Integrity Testing (UIT) to five per universe for consistency across program areas. A commenter requested CMS identify the total number of samples that will be selected for UIT and asked CMS to confirm that UIT samples will be provided to Sponsors approximately one hour prior to the scheduled universe integrity webinar.

Response: We appreciate the comments; however, we are not updating the number of samples selected for universe integrity testing to mirror other program areas. Due to the variety of cases CMS collects in the ODAG universes, and the number of delegated entities that may process these requests, it is necessary to select up to ten samples per universe to ensure the accuracy of data submitted in each universe. While we are maintaining the flexibility to select up to ten samples from universes, there may be instances where we can select less samples from a **particular** universe, such as grievances, or when a single entity is responsible for processing all cases within a universe. We confirm UIT samples will be provided at least one hour prior to the scheduled universe integrity call, and we have updated the protocol accordingly.

Comment: A commenter appreciated CMS's decision to move toward an "up to" sample size methodology but encouraged CMS to clearly communicate anticipated maximum sample thresholds to facilitate planning and resource allocation.

Response: We appreciate this comment. We will not routinely select more samples than what is identified in compliance standards 2.1, 3.1, and 3.2, and we may request less in some circumstances. The protocol indicates a maximum number that may be selected in the course of a routine program audit, but direct guidance on specific sample selection will be communicated with the issuance of the audit engagement letter.

Comment: Commenters requested clarification on the timeframe CMS will apply to concurrent reviews.

Response: Thank you for the comment. Now that the Table 1 Organization Determinations (OD) universe contains multiple types of organizations determinations with different timeframes, we will be analyzing how to best apply the timeliness standards for each type. For plan-initiated concurrent reviews, since there is no clear "receipt" date, we will remove those from our timeliness assessments for purposes of audit. While we won't generally run timeliness on those determinations, we will still sample them as part of our clinical review during fieldwork.

Comment: Several commenters requested clarification on populating concurrent reviews into Table 1: OD. Commenters requested clarification on concurrent reviews consisting of multiple separate reviews for the same Skilled Nursing Facility (SNF) stay. The commenters asked if each review should be recorded separately on the universe even when all reviews are associated with the same admission and authorization number. A commenter requested clarification on how to populate single concurrent reviews that result in multiple dispositions, dates of service, units,

service spans, or notices. A commenter requested clarification on what constitutes a reportable organization determination within the context of concurrent utilization management activities.

Response: Thank you for your comment. The instructions for Table 1: OD require Sponsors to include all organization determinations the Sponsor approved, denied or dismissed during the universe request period. This includes all determinations related to items, services, and Part B drugs where a substantive (fully favorable, partially favorable, and adverse) decision has been made and all decisions to dismiss a request for coverage. When an organization approves a pre-service request for SNF admission and subsequently reviews and approves additional time in the SNF through one or more concurrent stay reviews, or if the enrollee indicates they want to continue receiving services in the SNF in accordance with the original organization determination, each substantive decision related to that stay must be included on its own line. Sponsors must include the associated authorization or claim number for each substantive decision even when all reviews are associated with the same admission and authorization number. This direction is consistent with how decisions will be reported for SLD to ensure Sponsors do not have to change how they report these decisions during the transition from audit universes to SLD submissions. Questions pertaining to what qualifies as a substantive decision should be directed to the applicable policy experts at CMS.

Comment: A commenter requested clarification regarding the reporting requirements for concurrent and plan-initiated organization determinations to support consistent implementation of ODAG Universe Table 1. Specifically, the commenter requested guidance on the appropriate date and time to report in Table 1: OD, Column H "Date the request was received" and Column I "Time the request was received" for plan-initiated reviews. The commenter indicated organizations may reasonably apply different methodologies when identifying universe records. Such variability could result in inconsistent population development, duplicate reporting, omission of substantive coverage determinations, inaccurate timeliness calculations, and potential universe integrity concerns.

Response: Thank you for the comment. Per the description for Column H (Date the request was received) and Column I (Time the request was received) in Table 1: OD, Sponsors should enter the date and time the Sponsor initiated the review. CMS will not include plan-initiated concurrent review decisions in our assessment of a Sponsor's compliance with the regulatory timeframes identified in 42 CFR subpart M.

Comment: A commenter requested CMS provides additional clarification regarding the addition of "P for Plan" in the description field for Column ID V (Who made the request?) in Table 1: OD. The commenter stated use of this option is not identified in the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. The commenter asked if this response option should be used to include requests initiated due to a Grievance and/or a need potentially identified by care coordination.

Response: We appreciate the opportunity to provide clarification. CMS does not instruct Sponsors on when this option should be used. However, we recognize that Sponsors may initiate coverage determinations when they become aware of enrollees who are receiving care and will make substantive decisions that must comply with all applicable requirements. In these instances, Sponsors would use the option of "P for Plan" in the description field for Column ID V (Who made the request?) in Table 1: OD.

Comment: A few commenters raised concerns regarding the proposed prior authorization indicator field. A commenter requested clarification on how to populate the field when a single organization determination includes multiple line items with different prior authorization requirements. Another commenter raised operational and data integrity concerns related to identifying and reporting prior authorization requirements across multiple systems and recommended that CMS consider implementation flexibility, additional guidance on acceptable data sources, or a phased approach before incorporating the field into audit scoring.

Response: We appreciate the opportunity to provide clarification related to populating this field. We updated the description in Column ID Z to clarify that when a request includes more than one service or item, Sponsors should enter 'Y' if any service or item included in the request requires prior authorization. While Sponsors must choose the best method for gathering and providing this information, we will continue to assess potential operational challenges and provide training or technical guidance as needed.

Comment: Several commenters requested clarification and revisions to the Table 1 Column ID AA (Notification Type) field. Commenters noted that the proposed notification types do not account for the range of written notifications that may be provided for organization determinations, including Coverage Decision Letters (CDLs), approval notices, dismissal notices, discharge notices, and other written notifications. Commenters also requested clarification on how to report cases involving more than one written notification and how the Notification Type should correspond to the date/time the written notification was provided.

Response: We appreciate the commenters' recommendations. CMS agrees and has revised the instructions for the (Notification Type) field in the Standard and Expedited Coverage Organization Determinations (OD) record layout to clarify the applicable written notification types that should be reported. Because all substantive organization determinations must be reported as a separate line item in the universe, we do not anticipate that there will be many instances where multiple types of notifications are provided for a single line. However, in the case there are multiple notification types, Sponsors only need to populate the field with a single notification type. Additionally, we would generally expect the type of notification provided to reflect the notification that timeliness is based off for purposes of written notification date.

Comment: A few commenters noted the CY 2025 CMS final rule (CMS-4205-F) codified the transition of untimely appeals from health plans to the QIO. The commenters recommended the instructions for Table 2: RECON are updated to remove the inclusion of reconsideration determinations related to "termination of SNF, CORF, and HH services made to the Sponsoring organization because the timeframe for filing with the QIO expired" and update the exclusion criteria to exclude all appeals submitted to the QIO regarding a Sponsors decision to terminate coverage of SNF, CORF, and HH services.

Response: We agree with the commenters and have updated the instructions to remove this statement from the inclusion language for Table 2: RECON.

Comment: A commenter requested clarification regarding the Table 2: RECON and Table 3: PYMT_C universe exclusion criteria. The commenter recommended the exclusion language state: "Exclude withdrawals, appeals of initial organization determination dismissals, appeal of dismissals to the IRE and requests to vacate dismissals" to promote clarity and maintain consistency between the ODAG and CDAG program areas.

Response: We appreciate the commenter's recommendations. We confirm appeals of initial organization determination dismissals and requests to vacate dismissals are excluded from Table 2: RECON. This exclusion is listed in the instructions for Table 2: RECON. We have also updated the exclusion language for Table 3: PYMT_C to clarify the types of determinations that should be excluded from these universes.

Comment: A commenter asked for CMS to provide a comprehensive list of Medicaid-only service codes that should be excluded from Universe Table 3: PYMT_C to ensure consistent reporting and universe population across organizations.

Response: Thank you for your comment. Since Medicaid coverage varies in each state, we are unable to provide a comprehensive list of Medicaid-only service codes.

Comment: Several commenters requested clarification on retrospective reviews. Commenters requested clarification on which table retrospective reviews should be included in. A commenter asked if retrospective reviews are subject to a 7-day turnaround timeframe.

Response: Thank you for your comment. Post-service authorization requests, or retrospective reviews, are subject to all applicable rules related to payment organization determinations and should be included in Table 3: PYMT_C.

Comment: A few commenters requested clarification regarding which reopenings are considered initiated by the Sponsor or its first tier, downstream or related entity (FDR) and should therefore be reported in the Reopened Part C Determinations (RCD) universe. One commenter requested clarification and examples regarding whether the term "initiated by the Sponsoring Organization" is limited to reopenings independently identified and initiated by the Sponsor or

its FDR, without a request or submission from an external party. Another commenter specifically requested clarification on whether Sponsoring Organization-initiated requests for reopening at the Independent Review Entity (IRE) level should be included in the RCD universe.

Response: We appreciate the commenter's request for clarification. We have revised the Table 5 instructions to clarify reopening requests submitted by enrollees, providers, an IRE, Administrative Law Judge (ALJ), or the Medicare Appeals Council (MAC) should be excluded from Table 5: RCD. The only reopenings that should be included in this universe are reopenings that the Sponsor or FDR prompted or initiated a reopening for, without first receiving a request from an enrollee or other individual.

Comment: A commenter identified the instructions for Table 5: RCD instruct plans to populate the universe based on Column ID L rather than Column ID Q and asked if this was a mistake.

Response: Thank you for the comment. We agree this was an error and we have updated the instructions for Table 5: RCD to instruct Sponsors to populate the universe using Column ID Q.

Comment: A commenter raised concerns regarding the operational complexity and administrative burden associated with implementing the new Reopened Part C Determinations (RCD) universe and recommended that CMS further evaluate whether the compliance benefits of the new universe outweigh the additional reporting and data validation burden on Sponsors.

Response: We appreciate the commenter's concerns regarding the potential operational and administrative burden associated with implementing the new Reopened Part C Determinations (RCD) universe. We believe the dedicated reopening universe is necessary to separately capture applicable reopening activity and is retaining the requirement as proposed. In order to alleviate unnecessary burden on Sponsors, we have aligned the requested data with CMS reporting requirements so that any system changes are limited.

Comment: A few commenters requested clarification regarding the Table 2 RECON universe requirements for reopened determinations, including which reopenings should be included or excluded. A commenter also recommended removing reconsideration determinations related to favorable organization determinations that were reopened and revised from Table 2 to avoid potential duplication with the reopening universe.

Response: Thank you for your comment. We agree clarification is needed of the inclusion instructions in Table 2. We updated the inclusion instructions related to reopenings in Table 2: RECON. Specifically, we included language that excludes all reopenings of reconsidered decisions. We also updated language to clarify that we do expect appeals (reconsiderations) of reopened and revised favorable organization determinations to be submitted.

Comment: Several commenters requested clarification regarding the reporting requirements for payment organization determinations in Table 3: PYMT_C. Commenters requested clarification on when a payment organization determination may be reported when a claim was not submitted, when ‘None’ should be entered for applicable fields, and which non-claim payment organization determination scenarios should be included in the universe. A commenter also recommended incorporating prior CMS guidance regarding the reporting of organization determinations into the applicable field instructions.

Response: We appreciate the commenters’ requests for clarification. Sponsors should report organization determinations in the applicable universe based on how the request is processed. Section 40.12.1 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance provides additional clarification regarding payment organization determinations, and Sponsor should submit any further policy questions to CMS outside of this PRA package. For purposes of this audit universe, Sponsors should populate the universe with all determinations that they classified and processed as payment determinations; both approvals and denials. When the payment organization determination was not made upon submission of a claim, Sponsors should use the date of notification (approved or denied) to determine if the payment determination should be included in the universe. Additionally, based on comments we received requesting clarification on where cases may be included in universes, and to more closely align with the new SLD collection, we are renaming Table 1 and Table 2 to insert “Coverage” into the titles. All coverage organization determinations (initial determinations) will be reported in Table 1; all coverage reconsiderations (standard and expedited) will be reported in Table 2; and any payment organization determinations and appeals will be reported in Table 3.

Comment: A commenter recommended revising the instructions for Column ID U (Was the payment organization determination request denied for lack of medical necessity?) of the PYMT_C record layout to incorporate prior CMS guidance regarding how the field should be populated when the request was processed as an organization determination.

Response: We appreciate the commenter’s recommendation. For ODAG Table 3, Column ID U, the field would be populated as ‘Y’ if the initial organization determination was denied for lack of medical necessity. If the organization determination request was not denied for lack of medical necessity, this field would be populated with ‘N’. This applies for both initial payment organization determinations and, if the request is payment reconsideration, to the initial payment organization determination that proceeded the payment reconsideration. The ‘None’ option would apply if the initial payment or payment reconsideration request was approved or dismissed. CMS has revised the description for Table 3, Column ID U to include “For payment reconsiderations, populate this field based on whether the initial payment determination was denied for lack of medical necessity.”

Comment: A few commenters requested clarification regarding the reporting of the Column ID I (AOR/Equivalent Notice Receipt Date) in the grievance universe when the requestor is an enrollee representative and no AOR or equivalent written notice was received or required, including for dismissed and First Call Resolution grievances.

Response: We appreciate the commenters' questions. Sponsors should populate the universe as they processed the case, and based on the information they collect. When a grievance is dismissed because an AOR/Equivalent Notice was not received, or when an AOR is not required, Sponsors would enter 'None' in Column ID I (AOR/Equivalent Notice Receipt Date) and Column ID J (AOR/Equivalent Notice Receipt Time). Sponsors should populate Column ID U (Who made the request?) with either 'E' for enrollee or 'ER' for enrollee representative based on how they recognize the requestor.

Comment: Several commenters requested clarity on how and when the transition to service level data (SLD) will occur and how it will impact existing audit processes. Some commenters asked CMS to provide a defined transition plan that specifies which universes will be retired and which will remain, whether parallel reporting (SLD and audit universes together) will be required during a transition period, whether there are potential scenarios beyond the initial SLD submission where plans would still need to populate audit universe tables, and if audit review periods will change once the transition to SLD occurs. A commenter recommends that CMS continue permitting plans to use universe data even after SLD has been submitted, noting that SLD does not yet capture all data elements needed to accurately assess timeliness, case processing, and compliance.

Response: We appreciate the opportunity to provide clarification on the transition to SLD. While we understand that transitioning to a different data set for purposes of audit may require some adjustments, we are committed to reducing duplicative reporting, and when available, to supplement and/or replace certain audit universes. As stated in the ODAG Audit Protocol and Data Request, we will stop collecting Tables 1, 2, and 3 once SLD is fully operational. We will issue a memo to the industry when we believe the transition to SLD will occur to allow Sponsors sufficient time to prepare for the transition. We expect to rely on SLD alone and do not intend on requiring Sponsors to submit duplicative audit universe tables in addition to SLD, although we are committed to working with Sponsors to ensure a smooth and successful transition. Once SLD data is available, we intend to consider all available information, but we do not anticipate selecting more samples than what is included in the audit protocols. Finally, we recognize SLD does not capture all fields that are currently included in the ODAG universes. We have created the ODAG Timeliness Mitigation Analysis (ODAG-TMA) to account for the specific fields that are not captured in SLD. When cases have been identified as untimely based on an analysis of SLD, Sponsors will have an opportunity to populate any applicable mitigating factors for each case. CMS will account for this information in our timeliness assessment.

Comment: Several commenters requested clarification on the Timeliness Mitigation Analysis (ODAG-TMA). A commenter asked if Sponsors are expected to review and provide mitigating information for all non-contract payment organization determinations included in the Timeliness Mitigation Analysis under 42 CFR §422.520, or only for those determinations that fall outside the 95 percent timeliness threshold described in the guidance. A few commenters requested CMS includes a Waiver of Liability (WoL) receipt date field, and time verbal notification provided field, and time a denied reconsideration was forwarded to the independent review entity field to the ODAG-TMA to ensure timeliness standards are accurately evaluated. A commenter requested clarification regarding how CMS intended to use information generated through this tool, particularly whether CMS will monitor or evaluate the frequency with which organizations perform data scrubbing, corrections, or resubmissions.

Response: We intend to use the ODAG-TMA only for Sponsors selected for audit. We will populate the ODAG-TMA with cases that have been identified as untimely based on an analysis of the quarterly SLD submission. Sponsors will provide additional information on these cases that is not collected in the SLD in order to mitigate cases that may otherwise appear untimely. In order to prevent undue burden, we will consider whether we need to request mitigation on all untimely cases or only a portion of the cases. We agree with commenters and have added a Waiver of Liability (WoL) receipt date field, time verbal notification provided field, and time a denied reconsideration was forwarded to the independent review entity field into the ODAG-TMA.

SPECIAL NEEDS PLANS CARE COORDINATION (SNPCC)

Comment: A commenter requested that CMS make a few modifications to the audit protocol to more clearly define the audit process and ensure consistency. First, the commenter recommended that CMS not request additional information or increase the scope of an audit on an ad hoc basis. The commenter asked how many alternate samples will /could be selected beyond the initial 30 sample cases, and under what circumstances would those alternate cases be reviewed. Second, the commenter requested that CMS cite the specific regulatory citations and/ or Model of Care (MOC) requirements when making requests during audit or noting potential noncompliance.

Response: We appreciate the comment. While we do not intend to routinely expand the scope of our review or data collection outside of the specified parameters in the protocol, we do want to ensure transparency by affirmatively stating that we reserve the right to ask for additional information when needed in response to concerns of noncompliance and/or access to care issues. We will ensure that we provide clear communication to any Sponsors when additional information is needed that specifies both the amount of information needed and the rationale for the request. We agree that auditors should always include specific citations to regulatory requirements and the MOC when needed. This is already a routine part of our audit process and we will continue to oversee auditors to ensure they follow this direction.

Comment: A commenter stated that Compliance Standard 3.2 should not apply to “All D-SNP types” and specifically requested that Applicable Integrated Plans (AIPs) be excluded because the Medicaid coordination activities evaluated under this standard are not applicable to AIPs given their integrated nature.

Response: We disagree that compliance standard 3.2 should not apply to All D-SNP types. For AIP D-SNPs that provide Medicaid services, we will consider them to have met this compliance standard if the AIP D-SNP can provide documentation that it provided the service. For policy questions related to this topic, please contact CMS.

Comment: A commenter requested CMS clarify whether participation by the member/authorized representative and the care manager, both members of the interdisciplinary care team (ICT), is sufficient for initial development of the individualized care plan (ICP).

Response: Policy questions are outside the scope of this PRA package. For purposes of audit, we will assess ICT composition against both the regulation and the Sponsors approved MOC.

Comment: Multiple commenters expressed concerns regarding the lookback period for health risk assessment (HRA) and individualized care plan (ICP) data fields in SNPCC Universe Table 1, noting the burden associated with retrieving historical information, including data that may extend back 10 years or longer. Commenters recommended that CMS limit the timeframe for HRA and ICP data to 24 or 36 months preceding the audit engagement letter. A commenter also requested clarification on reporting the initial ICP date for long-enrolled members and suggested allowing an EXC-10 value when the initial ICP date exceeds 10 years.

Response: To address concerns regarding the Table 1 lookback periods and to reduce burden associated with the submission of data requests, CMS has split the requested universe information into two distinct universes; one for new enrollees and one for continuing enrollees. While we did not add any fields that were not in the original record layout, we did remove fields from each universe that are not necessary for that population. For example, in the continuing enrollee universe we no longer ask for initial HRA or initial ICP dates since we know they will be older than a year. The new Table 1 will only include enrollees that are newly enrolled in the SNP plan within the 12 months prior to the issuance of the engagement letter. For those enrollees, the Sponsor will be asked to populate information on the initial HRA and the initial ICP. For the second table, Table 2, that table will collect all enrollees that are continuing (enrolled for more than 12 months in the SNP). We will not collect any information on initial HRAs for those enrollees and instead will collect information on annual HRAs. In addition to splitting the two universes, we have added instructions for the continuing enrollee universe that we will not collect data more than 3 years old for fields such as “most recent HRA” and “previous HRA”. However, since the date of the most recent HRA helps determine the timeframe for the annual assessments, we have added this column into the timeliness mitigation tool which may be requested when enrollees have more than 3 years without an HRA.

Comment: A commenter recommended that CMS apply the same reporting logic used for Column J (Date Initial HRA (IHRA) Was Completed) to Column L (Date of the Initial Individualized Care Plan (ICP) Creation). Several commenters asked whether plans are expected to report the original Initial ICP Date regardless of age or whether an exception, such as EXC-5 or EXC-10, should be permitted for older Initial ICP Dates.

Response: Thank you for your comment. As noted previously, we are splitting the original universe into two universes, one for new enrollees and one for continuing enrollees. Initial HRAs and ICPs will only be collected in the new enrollee universe which we believe will significantly reduce burden on organizations.

Comment: A few commenters requested clarification on how to populate Column ID G (SNP Enrollment Effective Date) in SNPCC Universe Table 1, when an enrollee changes contracts, PBPs, or SNP plan types within the same Sponsoring organization.

Response: For purposes of the enrollment effective date, Sponsors should use the member's original enrollment date in a SNP contract, even if there was a PBP change, as long as there was no break in coverage greater than 90 days. We have added these instructions into the inclusion language for Table 1 and 2 to help Sponsors identify which employees are considered “new” and which should be considered “continuing”.

Comment: A commenter asked for clarification on how Sponsors should distinguish between contracts when loading data into HPMS since the Contract/PBP data elements have been removed throughout the proposed protocols.

Response: We are not sure what the commenter means as we have retained the contract ID and PBP columns for SNPCC.

Comment: A few commenters requested clarification regarding how hospital or SNF admissions should be identified and reported in Column ID O (Was there a Hospital or SNF admission?). These commenters requested clarification on how CMS defines a hospital admission (and asked if observation stays should be included), clarification on the applicable 26-week lookback period and whether the admission or the discharge date needs to fall within that period, and for clarification on the what data sources the Sponsor should use to identify admissions.

Response: We appreciate the opportunity to provide clarification. Sponsors should enter ‘Yes’ if the enrollee had any hospitalization or SNF activity during the 26-week look back period (starting from the date of the audit engagement letter). For purposes of calculating this, Sponsors should consider if either an admission or a discharge occurred during this period of time. We do not need for Sponsors to include observation stays within these counts. As for the data Sponsors should use, we do not require any specific data sets to be considered and Sponsors should determine the best way for their organization to populate this information. Generally, we would consider Encounter data as a primary source for identifying hospitalizations (inpatient stays) and

potentially claims data. If a Sponsors MOC defines “admission”, Sponsors should use that to help them populate the requested information.

Comment: Several commenters had questions surrounding the parameters for providing samples for integrity testing. A commenter stated it is not clear from CMS’s previous response if the 1-hour timeframe applies to the SNPCC Universe Integrity Testing samples as well as the samples for the case review/fieldwork portion of the SNPCC audit. A commenter recommended reducing the sample size to up to 5 samples for the Table 1 Universe Integrity SNPCC to be consistent with other program areas. Another commenter indicated that there is not sufficient time given to plans to gather all the necessary data together prior to the scheduled integrity testing webinar and recommends that CMS implement the same timeframe suggested in their response to previous comments—which is to provide the plan with the samples for integrity testing at the same time that they specify the sample for case review/fieldwork—that is, the Thursday prior to the entrance conference when the audit is conducted via webinar.

Response: Thank you for your comment. During a SNPCC integrity webinar, we will verify that the HRA and ICP dates included in the submitted universe agree with the Sponsor’s source documents in the system before the universe is used for further testing. Sponsor will be provided up to 10 samples for this test 1 hour in advance of the webinar. We will continue to use up to 10 samples as a standard size for SNPCC integrity testing, to verify an appropriate mix of SNP types, contracts, FDRs and other factors; however, now that the universe has been split into two universes, we will sample 5 cases from each universe for purpose of integrity testing. For fieldwork (webinar), we will provide the Sponsor samples for the 30-case file review the Thursday prior to the engagement letter issuance, to allow Sponsors sufficient time to prepare for that review, and we will provide them 5 business days before fieldwork if the review is being done by desk review.

Comment: Several commenters expressed concerns about the burden associated with SNPCC Impact Analysis. A commenter expressed concerns about field, Column J, which asks, “If an individualized care plan (ICP) was created, were the identified needs addressed.” The commenter noted that responding to this field may require labor intensive, manual review of enrollee health risk assessments (HRAs) and ICPs to identify needs and determine whether those needs were addressed in the ICP, particularly when applied at the population level within the Impact Analysis timeframe. A commenter requested clarification on the instruction to populate ‘NA’ for the column (If enrollee experienced a change in health status or experienced a transition of care (TOC) event during the IA request period). Another commenter requested that CMS remove the (Was an ICP Created) data field from the impact analysis data table.

Response: Thank you for your comment. To reduce sponsor burden CMS has removed the impact analysis from the SNPCC program area. CMS will continue, however, to request a root cause analysis for any potential issue of noncompliance. The root cause analysis will continue to explore the underlying issues that led to the noncompliance and will help inform CMS and the

Sponsor on appropriate next steps for corrective action. Since SNPCC will no longer routinely request enrollee impact, we have added a word version of the root cause analysis template into this PRA package which we think will allow for better communication of noncompliance. While we are removing the impact analysis from the audit package, we will continue to make them available on our webpage for Sponsors to use as a part of their own monitoring and auditing. We encourage Sponsors to use these tools on their own as they build corrective action plans and develop comprehensive strategies to address noncompliance.

Comment: A commenter requested that CMS include the Desk Review Case File Cover Sheet referenced in the SNPCC protocol as part of the audit instructions or instruments available to Sponsoring organizations to provide additional clarity regarding case file submission requirements.

Response: We appreciate the recommendation. When necessary, case file cover sheets will be provided to Sponsors on audit, but we do not feel it is necessary to include them in the PRA package. Depending on the audit and the case files, we may limit the documentation being requested in a case file and the cover sheet will be modified based on the facts and circumstances of the audit and the type of review being conducted. However, the cover sheets will not collect more documentation than what is specified in the protocol. In order to ensure continued understanding and transparency, we will conduct training on the SNPCC protocol and, as part of the training, will discuss the potential desk review approach and requested case file documentation.

Comment: A commenter mentioned that in previous years, the SNP section contained bulleted guidance regarding different scenarios and asked if that information will be available in a separate document.

Response: We are not sure what the commenter is referencing with this comment. The SNPCC protocol contains a bulleted section titled "Supporting Documentation Submissions" which lists examples of what auditors may request during a program audit.

Comment: A few commenters asked CMS to reconsider collecting the timeliness mitigation data requested in the SNPCC HRA Timeliness Mitigation Analysis, noting that it duplicates HRA data SNPs already collect and provide annually for the Part C SNP Care Management measure and associated Data Validation Audit, and recommend that CMS leverage the existing data or allow Sponsors to submit it in the same format.

Response: Thank you for your comment. We do not believe this request duplicates current CMS data collections. While we recognize that Sponsors submit aggregate reporting information to CMS on SNP HRA timeliness, the enrollee specific data mentioned by the commenter is not collected or maintained by CMS. Any enrollee specific data goes directly to the data validation contractor which is not contracted with CMS. Therefore, any data collected through that method cannot be used for purposes of audit.

Comment: A commenter requested clarification on the types of supporting documentation Sponsors should provide when documentation regarding timeliness is requested during SNPCC audit fieldwork.

Response: Sponsors should expect to provide evidence of outreach attempts, including phone attempts and letters sent to enrollees for potentially untimely HRA cases using the HRA Mitigation request. Specific details around the data fields requested for timeliness mitigation can be found in the HRA Timeliness Mitigation Analysis tool.

Supporting Statement A

Comment: A few commenters identified the burden estimate did not accurately reflect the time required to implement the revised protocols. A commenter noted the burden estimate measures the final response at the Sponsor level and underestimates the combined effect of multiple changes such as data mapping, testing, system changes, reconciliation, clinical review, quality assurance, and validation. The other commenter stated the burden level estimates in the crosswalk reflect changes made in isolation and understate the cumulative impact of multiple changes made at the same time across multiple entities.

Response: We appreciate these commenters' concerns, but we think that our estimates appropriately capture the burden on Sponsors, including for system modifications. We haven't made a substantial number of changes this year, so the system modifications were already built into our estimates with the increased burden in year 1. In response to the 30-day comments, we made additional changes that we believe significantly reduce the burden on organizations; including removing a proposed change from the FA universe instructions, streamlining the data collected in SNPCC to reduce old data from being requested, and removing the SNPCC Impact Analysis. Despite these additional reductions, in response to concerns that we underestimated our original burden estimates, we are not reducing the hours in the burden estimate in order to more accurately reflect the burden for audit. For purposes of the crosswalk, we are required to capture individual line-item burden changes and we have done our best to assess the burden of the individual changes made to the program audit protocols. For a totality of the burden estimate, we have combined our estimates into the Supporting Statement A.