Questions Received Following the Final MAPD Program Audit Protocol Training Sessions

* Updates are included below in red, italicized font
February 27, 2023
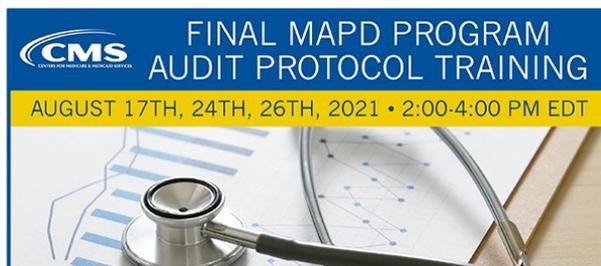
In August 2021, the Division of Audit Operations (DAO) hosted a three-part training series to provide technical assistance on the final audit protocols (CMS-10717) it will use to conduct the Medicare Part C and Part D Program Audits beginning in 2022. The recorded sessions are available on the CTEO Event Archive website: https://www.cms.gov/Outreach-and-Education/Training/CTEO/Event_Archives.

Session 1: Organization Determinations, Appeals, and Grievances (ODAG) – August 17, 2021

Organization Determinations, Appeals, and Grievances (ODAG)

Question 1: The Method of Evaluation for compliance standards 1.9 and 1.10 indicates CMS will test timeliness at the universe level to determine whether "claims from non-contracted providers and enrollees were paid or denied no later than 60 calendar days after receipt of the request." This does not align with the prompt pay provisions located at 42 CFR § 422.520(a) which state: "The contract between CMS and the MA organization must provide that the MA organization will pay 95 percent of the 'clean claims' within 30 days of receipt if they are submitted by, or on behalf of, an enrollee of an MA private fee-for-service plan or are claims for services that are not furnished under a written agreement between the organization and the provider." Is the 30-day requirement in 42 CFR § 422.520(a) only applicable to contracted provider claims going forward?

Response 1: Sponsoring organizations must adhere to the prompt pay provisions located at 42 CFR § 422.520. CMS tests claims timeliness against a 60-day timeframe for audit purposes only. Please remember, the data collection specifications and tools described in the program audit protocols, including the record layout instructions, are used for auditing and monitoring activities and by themselves should not be used to interpret policy.

Question 2: Can CMS clarify when a Sponsoring organization may enter the date or time in a field when it is not required? For example, can a Sponsoring organization's universe submission include the date and time of enrollee notification of an upheld expedited reconsideration request when the regulatory requirement does not require it but the plan chooses to send notification?

Response 2: Sponsoring organizations have the option to enter data in a field even if it is not required per the field description. For example, if a field description states, "Enter None for standard service requests and dismissed requests," Sponsoring organizations may enter a time for a standard or dismissed request if available, or they may enter 'None.'

Question 3: Should oral notification be documented in the universe if attempted, even if the Sponsoring organization was not able to reach beneficiary?

Response 3: Sponsoring organizations would only document oral notification when successful oral notification was provided to the enrollee in accordance with Section 10.5.3 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

Question 4: The instructions for the PYMT_C Record Layout state, "Include all payment organization determinations and payment reconsiderations the Sponsoring organization approved, denied or dismissed from non-contract providers, enrollees, and non-contract pharmacies during the universe request period." Additionally, the instructions state, "Include all payment requests for Part B drugs if applicable." Can CMS clarify if payment requests from contracted providers for Part B drugs should be included in the PYMT_C universe?

Response 4: All claims submitted by contracted providers would be excluded from the PYMT_C universe. This includes claims for Part B drugs submitted by contracted providers.

Question 5: Does CMS expect Sponsoring organizations to include dismissed cases that are the result of a withdrawn request in their ODAG universe submissions?

Response 5: Sponsoring organizations would exclude withdrawn cases from the ODAG universes per the record layouts instructions, even those that were dismissed as the result of a timely withdrawal request.

Question 6: The instructions for the OD Record Layout state, "If a pre-service organization determination includes more than one service, include all of the request's line items in a single row and enter the multiple line items as a single organization determination request." If an organization received a pre-service organization determination request that includes one line that is categorized by the requester as expedited and another line that is categorized as standard, how do Sponsoring organizations report this request in OD universe?

Response 6: Sponsoring organizations must populate the OD universe according to how each request was processed. If the Sponsoring organization processed each request separately (one under the standard timeframe and one under the expedited timeframe), each request must be included on its own line in the universe. If a Sponsoring organization processes multi-line pre-service requests separately (i.e. makes a decision and provides notification individually for each request, even under the same timeframe), each request must be included on its own line in the universe submission.

Question 7: In the PYMT_C Record Layout, *Date claim/reconsideration was paid* field, can you please clarify if the date payment was made is considered when the check was generated or the date the check was mailed.

Response 7: For program audit purposes, CMS aligned this field with Section 10.5.3 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. Sponsoring organizations must enter the date a check was mailed or, for electronic payments (i.e., EFTs), enter the date the plan distributes the funds for payment.

Question 8: Can CMS provide further clarification on what it is considered to "provide notification of the determination," "send a notice," "provide notice," and "deliver a written letter" to the enrollee to be determined compliant? Can you please specify if Sponsoring organizations are able to utilize online notification for enrollees and providers in ODAG?

Response 8: In general, auditors rely on 42 CFR Subpart M and guidance found in Sections 10.5.3 and 10.4.4 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, to test the manner and timeliness of required notification.

Question 9: Please advise how Sponsoring organizations are to report a case for DSNP enrollees in which a service covered by both Medicare & Medicaid, is denied under Medicare and approved under Medicaid coverage criteria?

Response 9: Sponsoring organizations must include these requests within the appropriate universe, based on the type of request, as 'Denied' in the *Request Determination* field. If a DSNP case is sampled for review, CMS will ensure appropriate notification was issued to the enrollee, inclusive of all applicable appeal rights.

Question 10: Does the same criteria applied to OD/Recon extensions (i.e., records needed from non-participating provider) also apply to grievances?

Response 10: When a Sponsoring organization takes an extension on a grievance, CMS will review the case file for documentation stating how the delay is in the interest of the enrollee per 42 CFR § 422.564(e).

Question 11: Can CMS provide examples of what is considered denied for lack of medical necessity?

Response 11: CMS does not strictly define lack of medical necessity for program audit purposes. Sponsoring organizations must apply their definition and populate this field in the universe submission according to that definition.

Question 12: *How should Sponsoring organizations populate the PYMT_C Record Layout, Was the initial organization determination request denied for lack of medical necessity? field, if the request was processed as a payment organization determination?*

Response 12: *Sponsoring organizations would populate the Was the initial organization determination request denied for lack of medical necessity? field with 'None' when the Was the request processed as an OD or Recon? field is populated as 'OD'.*

Question 13: Should Sponsoring organizations exclude cases from the RECON and PYMT_C universes that were overturned by the IRE/ALJ/MAC and included in EFF_C universe?

Response 13: Each ODAG record layout is separate and distinct. All upheld decisions made within the requested universe period must be included within the appropriate universe. All IRE overturns received within the universe period must be included in the EFF_C universe, whether or not they are also included in a different universe.

Question 14: Per the training transcript/presentation, CMS stated, "For the *Part B drug request?* field, Sponsoring organizations should enter 'Y' for yes if the request for a Part B drug is primary and processed by their Part C line of business." How does CMS define "primary?"

Response 14: Sponsoring organizations would respond 'Y' if the request was processed under the Part B drug timeframes by their Part C line of business. For more information regarding Part C service and Part B drug processing timeframes, please contact the policy mailbox: https://appeals.lmi.org/.

Question 15: Should Sponsoring organizations include drugs processed at the point of sale in the PYMT_C universe?

Response 15: Sponsoring organizations would not include drugs processed at the point of sale in the PYMT_C universe. Per the PYMT_C Record Layout instructions, Sponsoring organizations must include all payment organization determinations and payment reconsiderations the Sponsoring organization approved, denied or dismissed from non-contract providers, enrollees, and non-contract pharmacies during the universe request period.

Question 16: What can a Sponsoring organization provide during an audit as evidence notification was provided to an enrollee?

Response 16: CMS will accept as evidence, for example, mailroom logs that show when notifications were sent, mail receipts (USPS, Fedex, etc.), or evidence of electronic notification if requested by the enrollee.

Question 17: If DSNP-AIP approval notifications include the date the DSNP-AIP will terminate the coverage, should the *Date DSNP-AIP notified enrollee of its decision to reduce, suspend or terminate services* field in the AIP Record Layout be populated with the same date as the *Date written notification provided to enrollee* field?

Response 17: No, the *Date DSNP-AIP notified enrollee of its decision to reduce, suspend or terminate services* field would be populated with the date the AIP notified the enrollee that previously approved services were being reduced, suspended, or terminated. The *Date written notification provided to enrollee/provider* field would be populated with the date the DSNP-AIP

notified the enrollee/provider of its reconsidered decision. If the enrollee did not appeal, enter 'N' per the field description.

Question 18: If one service line denies on a claim for one of the exclusion reasons listed in the instructions for the PYMT_C Record Layout, but the other service lines deny for other reasons, or pay, should Sponsoring organizations exclude the entire payment request from their Table 3 universe submission?

Response 18: No, multi-line claims would only be excluded if all lines in the claim deny for one of the reasons included in the PYMT_C Record Layout instructions.

Question 19: In the PYMT_C Record Layout, what is the difference between the *Date the reconsideration was paid* field and the *Date the written notification provided to the provider* field?

Response 19: The *Date claim/reconsideration was paid* field collects the date Sponsoring organizations issued payment to either an enrollee or provider, depending on who submitted the request, for both payment ODs and payment reconsiderations. Sponsoring organizations must enter the date a check was mailed or, for electronic payments (i.e., EFTs), enter the date the plan distributes the funds for payment per Section 10.5.3 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

The *Date Written Notification Provided to Provider* field collects the date Sponsoring organizations notified the provider of their decision. This date may be the same as the date the claim or payment reconsideration was paid, or, the date of a remittance advice or explanation of payment. For denied payment OD requests, Sponsoring organizations would enter the date it notified the provider of the denied claim. For denied payment reconsiderations, enter 'None' if notice was not issued to the provider. Enter 'None' if the enrollee submitted the claim.

Question 20: We understand that dismissed organization determinations and reconsiderations would be included the applicable ODAG universes. However, do we include in universe submissions the administrative appeal of a dismissed organization determination?

Response 20: If the Sponsoring organization dismissed an organization determination or reconsideration request and that determination falls within the universe request period, the dismissed case(s) would be included in the applicable ODAG universe(s). The appeal of the plan's dismissal would be excluded from the ODAG universes. If a dismissal decision is subsequently overturned on appeal or vacated and the coverage request is reviewed within the universe request period, the Sponsoring organization would include the case in the appropriate universe (depending on how the case was processed by the Sponsoring organization).

Question 21: How should Sponsoring organizations report requests that do not require prior authorization?

Response 21: Sponsoring organizations may exclude requests that do not require a prior authorization. However, if an enrollee submits a request to the Sponsoring organization asking

for a determination on services that do not require a prior authorization, then they must be included within the applicable ODAG universe.

Question 22: Does the instruction for the PYMT_C Record Layout to "include all payment organization determinations and payment reconsiderations from non-contract providers, enrollees, and non-contract pharmacies" apply to payment requests for Part B drugs and payment requests for supplemental services that meet the criteria defined at 42 CFR § 422.100(c)(2)?

Response 22: Yes, the instruction for the PYMT_C Record Layout to include all payment organization determinations and payment reconsiderations from non-contract providers, enrollees, and non-contract pharmacies applies to payment requests for Part B drugs and payment requests for supplemental services that meet the criteria defined at 42 CFR § 422.100(c)(2). Sponsoring organizations are to exclude payment organization determination and payment reconsideration requests from contract providers.

Question 23: Are Part B drugs processed at the point of sale excluded from the PYMT_C universe?

Response 23: Yes, Part B drugs processed at the point of sale are excluded from the PYMT_C universe. Sponsoring organizations are to exclude all point-of-sale transactions (drugs and items) from the PYMT_C universe.

Question 24: How should a partially approved claim be entered in the PYMT_C Record Layout?

Response 24: Partially approved claims would be entered as 'Denied' in the PYMT_C Request Determination field. In these cases, please populate Column O Date claim/reconsideration was paid with 'None'.

Question 25: Although the ODAG protocol indicates submissions that do not strictly adhere to the record layout specifications will be rejected, CMS can allow for field lengths greater than the field lengths listed in the protocol if needed (for example, CMS can allow greater than 50 characters and 1,800 characters in these fields if needed).

Response 25: CMS can allow greater than 50 characters and 1,800 characters in these fields if needed.

Question 26: How should Sponsoring organizations populate the Date DSNP-AIP notified enrollee of its decision to reduce, suspend or terminate services field in the AIP Record Layout?

Response 26: Sponsoring organizations would populate the notification date based on written notification.

Session 2: Formulary Administration (FA) & Coverage Determinations, Appeals, and Grievances (CDAG) – August 24, 2021

Formulary Administration (FA)

Question _27_: For the _NDC_ field, if a multi-ingredient compound claim rejected prior to applying pricing to the ingredients, Sponsoring organizations would be unable to determine which NDC is the most expensive and therefore would be unable to determine which NDC would have been submitted on the PDE. May Sponsoring organizations just select any Part D NDC within the compound in these cases?

Response _27_: In situations when the PDE is unavailable, submit this field as blank in the universe.

Question _28_: What is the purpose of submitting all PDEs for all enrollees with a November or December effective enrollment date? What information would CMS use when selecting rejected claims samples for an enrollee with a November or December effective enrollment date who has had no rejected claims at all?

Response _28_: Per the FA Protocol, data is collected to ensure "Enrollees with a November or December effective enrollment date are afforded a full continuing enrollee transition benefit." Samples will be targeted utilizing the PDE and RCT universes. CMS will reference data in the PDE universe to target rejected claims samples from the RCT universe.

Question _29_: If a member switches to a new Plan Benefit Package (PBP) within a contract, but the two PBPs use different formularies, should the enrollment in the second PBP still be excluded from the New Enrollee (NE) universe? The Pharmacy Benefit Manager (PBM) would still have claims history to use in adjudication. Similarly, if a member switches to a new contract under the same plan sponsor, but the formulary is the same and the PBM is using the previous claim history in adjudication, should they be excluded from the NE universe?

Response _29_: Using this example, if the Sponsoring organization or its PBM utilized claims history for this member, the record layout instructions would still apply and CMS would not expect to see this member in the NE universe submission. If a Sponsoring organization does not utilize claims history for this member, the member would be included in the NE universe. This instruction also applies to enrollees in employer group waiver plans (800 series PBPs).

Question _30_: For members switching to a new PBP within a contract, is there a minimum amount of claims history that should be considered when determining whether to include the new PBP enrollment in the New Enrollee (NE) universe?

Response _30_: In general, if the claims system has a minimum of 108-day history that is available, these members would not be included in the NE universe regardless of when the enrollee switched PBPs.

Question _31_: If a member has a gap in coverage within the same PBP, should they be included in the NE universe?

Response _31_: In this instance, the enrollee would be included in the NE universe since the enrollee experienced a gap in claims history. Only those enrollees with continuous claims history would be excluded from the NE universe.

Question _32_: When *an enrollee cannot be identified in the Sponsoring organization's system based on pharmacy submitted claim information,* certain fields in the record layout cannot be identified such as the Enrollment Effective Date and Effective Disenrollment date. What should be populated in this scenario?

Response _32_: Sponsoring organizations must include all claims submitted utilizing the Sponsoring organization's BIN/PCN/Group that can be cross walked to the contract. In the RCFA and RCT universes, populate all fields as submitted by the pharmacy including: *Enrollee First Name, Enrollee Last Name, Date of Birth, Cardholder ID, NDC, Date of Service, Claim Quantity, Claim Days Supply, Patient Residence, Pharmacy Service Type, Compound Code.* Sponsoring organizations may enter 'NA' in fields where the field description allows for it and those that are populated by the Sponsoring organization in a situation where there may not be an enrollee match in the system. These fields include: *MBI, Enrollment Effective Date, Effective Disenrollment Date, and Plan ID.*

Question _33_: What is the difference between "Methodology to Determine Full Scope of Impact" in the Root Cause Analysis Template and *Methodology for Identifying Impact of Noncompliance* field in Table 1IA: Impact Analysis Summary (IAS) Record Layout?

Response _33_: There is no difference between these requests. Sponsoring organizations must describe the process undertaken to determine the full scope of impact in each scenario.

Coverage Determinations, Appeals, and Grievances (CDAG)

Question _34_: Can Sponsoring organizations enter 'None' for the *NDC* field if a blank field is submitted by the pharmacy or delegate?

Response _34_: No, 'None' is not an option for the *NDC* field description within the CDAG Program Audit Protocol and Data Request. The protocol states that characters are required in all requested fields unless otherwise specified. An example of when a blank entry is acceptable for CDAG is the *NDC* field. As indicated in the *NDC* field description, Sponsoring organizations may populate the *NDC* field as blank if a blank field is submitted by the pharmacy or delegate. *Sponsoring organizations may also populate this field as blank if there are no Part D ingredients for a multi-ingredient compound claim.*

Question _35_: In the CD Record Layout, *Formulary UM Type* field, the description states, "Enter the formulary UM criteria the enrollee satisfied or was attempting to satisfy." This indicates the request was approved or denied. Does this mean Sponsoring organizations would only enter 'PA,' 'ST,' or 'SE' for approved and denied cases? The field description also states, "Enter None if the enrollee did not satisfy or was not attempting to satisfy Prior Authorization and/or Step Therapy criteria." This indicates the request was denied or dismissed. Does this mean Sponsoring organizations would enter 'None' for denied and dismissed cases? Or is 'None' only meant to be used for requests of drugs already on the formulary without restriction?

Response *35*: For the *Formulary UM Type* field, Sponsoring organizations would enter the formulary UM criteria that the enrollee satisfied or was attempting to satisfy for all case disposition/determination types. Sponsoring organizations would enter 'None' if the enrollee did not satisfy, or was not attempting to satisfy, prior authorization and/or step therapy criteria. An example of this would be a request for a drug already on the formulary without restriction that the Sponsoring organization processed as a coverage determination.

Question *36*: Does the safety edit utilization management type pertain to both the exceptions and coverage determination universes?

Response *36*: Yes, the safety edit utilization management type could apply to exceptions as well as coverage determinations. 'SE' is an option for both the *Formulary UM Type* field in the CD record layout and the *UM Exception Type* field in the CDER Record Layout. Sponsoring organizations are to include safety edit requests within the CDER universe. For the CD universe, Sponsoring organizations may enter 'SE' for the *Formulary UM Type* field for cases where the safety edit is for an enrollee who appears opioid naïve but wants to show evidence that s/he meets the criteria as not opioid naïve.

Question *37*: If a request has both a quantity limit (QL) and step therapy (ST) how would Sponsoring organizations populate the *UM Exception Type* field?

Response *37*: Per the *UM Exception Type* field description, if multiple UM exception criteria apply, enter the criteria that served as the basis for the Sponsoring organization's decision to either approve or deny the request.

Question *38*: For the *Request Determination* field in Universe Table 1: CD, Universe Table 2: CDER, and Universe Table 4: RD, should Sponsoring organizations report the determination as 'Dismissed' when a request is for a drug already on the formulary with no restriction?

Response *38*: For program audit purposes, Sponsoring organizations would enter 'Dismissed' only when the coverage request was processed as a dismissal. Otherwise, Sponsoring organizations would enter 'Approved', 'Denied', 'IRE auto-forward', 'Re-opened Approved' or 'Re-opened Denied.'

Question *39*: In the PYMT_D Record Layout, *Who made the request?* field, if the prescriber made the request should this field be populated as 'ER' or 'P'?

Response *39*: Sponsoring organizations are to follow the *Who made the request?* field description and enter 'P' for prescribing physician or other prescriber if they made the request.

Question *40*: In the RD Record Layout, *Is this a protected class drug?* field, when would the 'None' option apply?

Response *40*: Sponsoring organizations may enter 'None' if this field does not apply, for example for an at-risk redetermination.

Question *41*: Should the *Authorization or Claim Number* field in the RD Record Layout be populated with the denied coverage determination claim or authorization number or the claim or authorization number when an appeal is favorable?

Response *41*: In the RD Record Layout, populate the *Authorization or Claim Number* field with the associated authorization or claim number specific to the redetermination request.

Question *42*: For Universe Table 5: EFF_D Column ID K *Time the overturn decision was received*, should the time be included for all case types or only expedited cases?

Response *42*: Sponsoring organizations would include the time the overturn decision was received for all case types, including coverage determinations, redeterminations, or at-risk determinations fully or partially overturned by the IRE, ALJ or MAC requiring an effectuation as pre-benefit, post-service (payment), or an at-risk determination received from the IRE, ALJ, or MAC during the universe request period.

Question *43*: Should Sponsoring organizations be excluding all dismissed grievances or only cases that were dismissed as a result of being withdrawn by a party to the grievance from the GRV_D universe?

Response *43*: Sponsoring organizations must exclude all dismissed grievances from the GRV_D universe submission.

Question *44*: In the GRV_D Record Layout, are fields *AOR/Equivalent notice Receipt Date* and *AOR/Equivalent notice Receipt Time* restricted to only the Appointment of Representative (AOR) and its equivalent notice? What if the authorization documentation received is a Power of Attorney or other legal forms of authorization/appointment? Would these two fields still apply?

Response *44*: The *AOR/Equivalent notice Receipt Date* and *AOR/Equivalent notice Receipt Time* fields in the GRV_D Record Layout apply to both the OMB-approved Form CMS-1696 AOR and an equivalent written notice. For CMS program audits, this information is collected in accordance with Section 20.2 – Appointment of Representative (AOR) Form or Equivalent Written Notice of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

Question *45*: Should Sponsoring organizations populate the AR universe exclusively with all potential at-risk beneficiaries (PARBs) who received the initial notification letter? If not, can CMS please define the universe using the OMS process flows (ORF/SRF)?

Response *45*: Sponsoring organizations would not include all enrollees reviewed under a Drug Management Program (DMP) or all enrollees who received the initial notification letter in an AR universe. Sponsoring organizations should consider information such as whether the beneficiary went through case management, whether the beneficiary is exempt, and whether the Sponsoring organizations made a decision of at-risk or not at-risk pursuant to 42 CFR § 423.153(f) in order to determine whether the case would be included in the AR universe. Sponsoring organizations may use OMS response forms and case flows to assist in identifying beneficiaries for inclusion

in the AR universe, however, for CMS program audits, the AR universe includes all at-risk and not at-risk determinations that were made by the Sponsoring organization pursuant to § 423.153(f). *Sponsors are to exclude cases from the AR universe involving an enrollee who meets the definition of an exempted beneficiary at 42 CFR § 423.100. If an enrollee goes through case management, is not exempt, and an at-risk/not at-risk decision is rendered (pursuant to 42 CFR § 423.153(f)) the case would be included in the AR universe. If an enrollee is still going through case management or the Sponsor determines the potentially at-risk beneficiary is exempt through the case management process and did not make an at-risk determination the case would be excluded from the AR universe. Sponsors should also exclude information regarding extensions of at-risk determinations from the AR Universe.*

Question *46*: The AR Record Layout instructions state to include all at-risk determinations, but in the fourth bullet it states to exclude appeals of at-risk-determinations. Does this mean that only initial determinations should be included?

Response *46*: Per the AR Record Layout instructions, Sponsoring organizations would include all at-risk determinations made by the Sponsoring organization pursuant to 42 CFR §423.153(f) during the universe request period. At-risk redeterminations (*i.e.*, appeals of at-risk determinations) are to be included in the RD universe.

Question *47*: In the AR Record Layout, *Date the At-Risk Determination was made* field, is this the date the clinical determination was made to restrict or not restrict the member (*e.g.*, decided to send the initial notification letter) or is it the date the Sponsoring organization decided to send the second notification letter?

Response *47*: The *Date the at-risk determination was made* field is to be populated with the date the at-risk determination was made by the Sponsoring organization (*e.g.*, the date the limitation was entered by the Sponsoring organization or the date the clinical determination was made to restrict or not restrict the member). This is not the date the Sponsoring organization sent the initial notice or subsequent notices to the beneficiary. There are separate fields in the AR record Layout for these respective dates.

Question 48: We understand that dismissed coverage determinations and redeterminations would be included the applicable CDAG universes. However, do we include the administrative appeal of a dismissed coverage determination in universe submissions?

Response 48: If the Sponsoring organization dismissed a coverage determination or redetermination request and that determination falls within the universe request period, the dismissed case(s) would be included in the applicable CDAG universe(s). The appeal of the plan's dismissal would be excluded from the CDAG universes. If a dismissal decision is subsequently overturned on appeal or vacated and the coverage request is reviewed within the universe request period, the Sponsoring organization would include the case in the appropriate universe (depending on how the case was processed by the Sponsoring organization).

Question 49: How should a Sponsoring organization populate the Date of Determination field for untimely coverage determinations or redeterminations auto-forwarded to IRE?

Response 49: The Sponsoring organization may enter date/time case file was closed as untimely/began preparing file for IRE.

Question 50: What should we do if the Sponsoring organization's Category of the Issue and Grievance Description field contents exceed the Field Lengths?

Response 50: Although the CDAG protocol indicates submissions that do not strictly adhere to the record layout specifications will be rejected, CMS can allow for field lengths greater than the field lengths listed in the protocol if needed (for example, CMS can allow greater than 50 characters and 1,800 characters in these fields if needed).

Question 51: How should Sponsoring organizations populate the *Date the Initial Written Notification of potential at-risk status was provided to enrollee* and *Date Second Written Notification of At-Risk Determination Provided to Enrollee* Fields in the AR universe?*

Response 51: For the Date the Initial Written Notification of potential at-risk status was provided to enrollee and Date Second Written Notification of At-Risk Determination Provided to Enrollee Fields in the AR universe, for program audit purposes, CMS would accept the notification date based on Section 10.5.3 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

Question 52: How should a Sponsoring organization populate the If an enrollee edit was used, date the edit was effectuated in the system field?

Response 52: The Contract Year 2023 Part D Drug Management Program Guidance clarified that the date of the relevant at-risk determination (as mentioned in 42 CFR§ 423.153(f)(8)(i)) is the date the limitation is implemented by the plan (i.e. the effective date of the edit/limitation). As such, for the CDAG Table 7 If an enrollee edit was used, date the edit was effectuated in the system field, Sponsors are to enter the date the limitation is implemented by the Sponsor (i.e. the effective date of the edit/limitation).

Session 3: Compliance Program Effectiveness (CPE) & Special Needs Plans Care Coordination (SNPCC) – August 26, 2021

Compliance Program Effectiveness (CPE)

Question 53: Will CMS be conducting employee interviews as it did years ago of a Sponsoring organization's employees to gain their knowledge of the compliance program, who the compliance officer is, where to report a compliance issue, etc.?

Response 53: No, CMS no longer conducts employee interviews. However, CMS will conduct at least two interviews, sometimes three, depending on how an organization is structured, during its CPE review. These interviews will be with a Sponsoring organization's compliance officer, individuals responsible for Special Investigations and Fraud, Waste, and Abuse oversight, and finally, individuals responsible for First Tier, Downstream, and related entity oversight. In some

circumstances, an organization is structured in a manner where the SIU/FWA team is part of the Compliance Team. In these instances, CMS will host one interview with both teams simultaneously.

Question *54*: CMS indicated that it would select targeted samples of 20 audit participants and two First Tier Entities (FTEs) from attendance logs and impacted individuals and entities from tracer presentations, supporting documentation and/or supplemental documentation. Does this replace the samples that were previously selected from the ECT universe that is no longer required? Does "supporting documentation and/or supplemental documentation" include those employees that will be documented in the Organizational Structure and Governance Presentation template? Also, if there are not 20 unique samples available, how does CMS address that?

Response *54*: The ECT universe is not part of the CPE Program Audit Protocol and Data Request in CMS-10717. As such, the targeted samples of 20 audit participants and two First Tier Entities (FTEs) from attendance logs and impacted individuals and entities from tracers, supporting documentation and/or supplemental documentation replaces the samples that were previously selected from the ECT universe that is no longer collected. The Organizational Structure and Governance Presentation template is part of the supporting documentation/supplemental documentation and CMS may select samples from this document. CMS will select 20 audit participants and two FTEs when available.

Question *55*: Are all types of investigations conducted by Compliance or SIU team to be included in the Compliance Oversight Activity (COA) universe?

Response *55*: Sponsoring organizations must include all types of investigations conducted by the Compliance or SIU team and by operational business areas related to the Sponsoring organization's Medicare Advantage (Part C) and/or Prescription Drug (Part D) business. This would include oversight activities of First Tier Entities (FTEs). Please enter the name of the Sponsoring organization's department, operational area, or First Tier Entity that is the focus of the oversight activity in the *Component* Field. *If the Sponsor conducts an audit/monitoring activity under which multiple components are included, the Sponsor may populate the Component field in Universe Table 1: Compliance Oversight Activities (COA) with each of the component names separated by a comma.*

Question *56*: If a contracted vendor (e.g. Secret Shop vendor) conducts an audit on a Sponsoring organization's behalf, is that audit activity to be included on the COA table?

Response *56*: Yes, if the audit activity is related to the Sponsoring organization's Medicare Advantage (Part C) and/or Prescription Drug (Part D) business.

Question *57*: Please confirm CMS is requesting 26 weeks of data from the date of the engagement letter instead of 12 months.

Response *57*: Correct. Sponsoring organizations will submit a list of all compliance oversight activities that occurred during the 26-week period preceding and including the date of the audit engagement letter.

Question 58: What if the Description of Deficiencies exceeds the 1000 Field Length?

Response 58: Although the CPE protocol indicates submissions that do not strictly adhere to the record layout specifications will be rejected, CMS can allow for field lengths greater than the field lengths listed in the protocol if needed (for example, CMS can allow greater than 1000 characters in the Description of Deficiencies field if needed).

Special Needs Plans Care Coordination

Question 59: In the SNPE Record Layout, *Date Initial HRA (IHRA) was completed* field, should the EXC-10 rule be based on the initial due date being over 10 years versus the initial completion date? In other words, whether there was or was not an initial HRA completed in cases of unable to contact (UTC)/refusals, should Sponsoring organizations use EXC-10 if the IHRA was due more than 10 years ago per record retention policy? The way the field description is written, Sponsoring organizations can only use EXC-10 if there is an initial HRA completed. Can Sponsoring organizations also use EXC-10 based on when the HRA would have been due?

Response 59: Yes, Sponsoring organizations can also use EXC-10 if the IHRA due date was greater than 10 years ago.

Question 60: For the field *Date of previous HRA* (Column ID J) in the SNPE Record Layout, if the most recent HRA was the initial HRA, do Sponsoring organizations enter the date of the IHRA or 'None' for Column ID J? Presumably the answer is None but confirmation would be welcome. This comes up because it would seem strange if Column IDs I, J, and K could all be the same date given the instructions in Column ID J state "This is the date of the most recently completed HRA prior to the date entered in Column ID I."

Response 60: Correct. In this example, if the most recent HRA was the initial HRA, and there was no previous HRA conducted, please enter 'None' in Column ID J.

Question 61: For the field *Did all members of enrollee's ICT receive annual MOC training?* (Column ID W) in the Care Coordination Impact Analysis (CC-IA) Record Layout, if no ICT was created as per Column ID S, *Was an ICT created?* Should Sponsoring organizations enter 'N' or 'NA'? NA is not given as an option but N isn't quite logically coherent.

Response 61: The instruction for this table is to include all enrollees impacted by the care coordination issue as specified in the request for an impact analysis. Sponsoring organizations will be instructed to complete this field only if it relates to the cited noncompliance. In the example provided, if no ICT was created, this field would not be requested.

Question 62: In the CC-IA Record Layout, *If an ICP was created, were the identified needs addressed* field, there appears to be a typo in the field length. The field length allows for one character but 'NA' is a response option.

Response 62: This was an oversight and Sponsoring organizations may still enter 'NA' in this field.

Question 63: In the CC-IA Record Layout, *Did all members of enrollee's ICT receive annual MOC training? ICT is specific to each enrollee's individualized needs* field, the field name seems to contain some additional instruction. Is that an official part of the field name? How should this be populated this when the Sponsoring organization provides this table at the time of the audit?

Response 63: The instruction for this field is "Did all members of enrollee's ICT receive annual MOC training?" Please populate using 'Y' or 'N.' The additional information is not meant for instruction.

Question 64: The If an ICP was created, were the identified needs addressed? field allows for an entry of 'NA'; however, the Field Length is listed as 1.

Response 64: This is an error in the Table 1IA: Care Coordination Impact Analysis (CC-IA) Record Layout of the SNPCC protocol. For the If an ICP was created, were the identified needs addressed? CMS will accept a Field Length of two (2) characters.

Question 65: In Table 2IA: HRA Timeliness Impact Analysis (HRAT-IA) Record Layout, *Date of first IHRA outreach attempt* and *Date of last IHRA outreach attempt* fields, if only one outreach was attempted, are these two fields populated with the same date? If no outreach attempts were made at all, are these populated with 'NA', which is not given as an option?

Response 65: If only one outreach attempt was made, please populate both fields with the same date. Please leave blank if no outreach attempts were made.

Question 66: In the HRAT-IA Record Layout, *Date the HRA - Unable to Contact (UTC) Letter was sent to non-responding enrollee* field, is this field meant to capture the UTC letter for the IHRA or AHRA, or just the latest available?

Response 66: This field must capture the date of the latest available HRA (Initial or Annual) unable to contact letter.