CMS Program Audit Frequently Asked Questions (FAQs)

Medicare Parts C and D
Oversight and Enforcement Group
&
Medicare-Medicaid Coordination Office

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Purpose

CMS receives various questions about Medicare Parts C and D and Medicare-Medicaid Plan (MMP) program audits in the Parts C and D audit mailbox (part_c_part_d_audit@cms.hhs.gov) and the Medicare-Medicaid Coordination Office mailbox (mmcocapsmodel@cms.hhs.gov). Currently, we only respond to the organization that submitted the question. We believe a more useful approach is to publicly share key questions and answers, particularly when we have received the same question more than once, so that that the industry can benefit from the information and improve the audit process. We are therefore publishing this document in order to provide the questions we most frequently received in 2017 and 2018 and our responses to the questions. The questions and responses relate to Medicare Parts C and D record layouts (as found in the current protocols and data collection instruments (https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2017_Medicare_Parts_C_and_D_Program_Audit_Protocols_and_Data_Requests.zip) that expire 4/30/2020, CMS-10191, OMB 0938-1000), MMP record layouts (https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2018_MMP_AuditProtocols_and_DataRequests.zip), and program audit operations.

CMS will periodically update this document and post it on the CMS Program Audit Website (https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html). You can use the CTRL+F feature to search by key words.

A. General Audit and Validation

1. Question: During an audit, how should a sponsoring organization communicate to CMS that it does not have any cases responsive to a particular universe request (e.g., if there were no direct member reimbursement requests during the review period)?

   Answer: The sponsoring organization must upload an Excel spreadsheet to the Health Plan Management System (HPMS) at the appropriate universe level that includes a statement explaining it does not have responsive cases for this particular universe during the requested audit period.

2. Question: Will sponsoring organizations always have the opportunity to submit universes up to three times during a program audit?

   Answer: No. Three attempts may not always be feasible depending on when the data issues are identified and the potential impact to the audit schedule (*e.g. sponsoring organizations will not be allowed to resubmit universes after auditors have shared timeliness test results with the sponsoring organization*). Please see our response to this question on page 6 of our "2019 Program Audit Process Overview" document located at https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2019_Program_Audit_Process_Overview.pdf

3. Question: Should compliance issues be reported in the Pre-Audit Issue Summary (PAIS) document if they are outside of the universe period?

   Answer: Sponsoring organizations should not include in the PAIS issues of non-compliance that are outside of the universe period.

4. Question: How long is CMS' current audit cycle and can a sponsoring organization be audited more than once during that time period?

   Answer: Audit cycles have historically lasted three, four, or five years. CMS will begin a new audit cycle in 2019 and expect the length will be consistent with previous cycles. While sponsoring organizations are typically audited once per audit cycle, CMS can audit a sponsoring organization more than once during the cycle based on risk or audit referral.

5. Question: How should sponsoring organizations populate the time field within their universes when they operate across different time zones or time zones different from that of their delegated entity?

   Answer: All fields for a single case line item must be in the same time zone. For example, if the sponsoring organization has systems in Eastern Standard Time (EST) and Central Standard Time (CST), all data in a single line item for that particular case are to be converted to a single time zone.

6. Question: Can CMS offer any general tips for preparing universe submissions such as deadlines, common mistakes to avoid, etc.?

   Answer: With the exception of CPE tracer samples, **s**ponsoring organizations must provide accurate and timely universes via HPMS within 15 business days of the engagement letter date. Columns that permit the response NA should be populated as such (i.e., not N/A). Ensure that all fields are populated (i.e. do not leave any fields blank and do not skip columns). If a sponsoring organization has questions about how to populate a field during the audit, the organization should ask the program-area Team Lead for clarification before submitting the universe.

7. Question: Which program audit protocols would apply to program audits of organizations that offer Medicare-Medicaid Plans (MMP)?

   Answer: Program audits of sponsoring organizations with MAPD and MMP contracts will include the following program areas: CDAG, FA, ODAG, CPE, MMP-SARAG, and MMP-CCQIPE. The SNP-MOC program area would also apply if the sponsoring organization has at least one contract that offers a SNP.

   Program audits of MMP-only sponsoring organizations will include the following program areas: CDAG, FA, CPE, MMP-SARAG, and MMP-CCQIPE. MMP members will be excluded from ODAG universes, which is why ODAG would not be included in a

program audit of MMP-only sponsoring organizations. Additionally, the elements reviewed for ODAG and MMP-SARAG are similar; thus, MMP-SARAG takes the place of ODAG for MMP-only sponsoring organizations.

8. Question: Does CMS require independent validation audit (IVA) vendors to use a doctor, or another clinician (nurse), when validating correction of conditions that are clinical in nature (i.e. those cited under Clinical Decision Making in CDAG and ODAG program areas)?

Answer: For IVA purposes, CMS requires IVA vendors to use the same level of clinician that the sponsoring organization used (or was required to use) to evaluate the request or appeal.

9. Question: If a sponsoring organization has to undergo a revalidation audit in 2019, but the original program audit was conducted in 2018, which validation policies apply to the revalidation? For instance, starting in 2019, IVA vendors have to have 2 auditors per area to complete the IVAs; will this sponsoring organization need one auditor per area (2018 requirements) or 2 (2019 requirements)?

Answer: Using your example, since the revalidation applies to a sponsoring organization's 2018 program audit, the IVA vendor can move forward with the same level of effort it provided to the sponsoring organization on the initial validation. If this is a new engagement for the IVA vendor, meaning that another IVA performed the first validation of this sponsoring organization and a new IVA vendor was hired to conduct only the revalidation, CMS would request the IVA vendor hired for the revalidation follow the 2019 guidance and use 2 auditors per program area.

B. Compliance Program Effectiveness (CPE)

1. Question: What documentation does CMS want to receive from a sponsoring organization whose review period crosses calendar years?

Answer: If the audit review crosses calendar years, sponsoring organizations must provide the requested documentation (e.g. standards of conduct/code of conduct documents, audit and monitoring work plans, Corporate Compliance/Medicare Compliance/Fraud Waste Abuse (FWA) plan, formal risk assessments, etc.) that covers the entire audit period.

2. Question: Does CMS want sponsoring organizations to submit multiple versions of any of the requested documents if they were created and/or revised during the review period?

Answer: If a document is created or revised during the review period, sponsoring organizations should provide both the original and/or revised version in use during the review period.

3. Question: How should sponsoring organizations provide auditors with documents that have multiple versions that are responsive to the audit request?

   Answer: If multiple versions of a requested document are being submitted, upload one zip file to HPMS that includes all versions of the requested document, and follow the instructions found in the Audit Submission Checklist that is attached to the audit engagement letter.

4. Question: How should a sponsoring organization populate the First Tier Entity (FTE) contract effective date in Table 1: FTEAM if a FTE went through a merger? What about non-contracted providers?

   Answer: **Please note, population of the FTE Contract Effective Date field is suspended for the 2019 Program Audits. To the extent that an organization would like to populate and submit this data element, it is not prohibited from doing so.**

   If a sponsoring organization contracts with a FTE, and that FTE goes through a merger/acquisition, populate the date of original contract inception. Any merger or acquisition occurring later does not affect the original contract inception date with the FTE. For non-contracted providers, indicate "non-contracted" in Column C FTE Contract Effective Date.

5. Question: How should sponsoring organizations populate Table 2: ECT, Column H if an employee has more than one job?

   Answer: If an employee fills multiple roles (e.g., full-time employee and governing body member), identify all roles in this field separated by a forward slash (e.g., full-time/BOD).

6. Question: How does CMS distinguish between internal and external auditors in Table 3: IA, Column C "Auditor Type" and Table 4: IM, Column C "Monitor Type?"

   Answer: Sponsoring organizations must provide the name/position of the individual who conducted the audit or monitoring activity. If it was an external auditor, sponsoring organizations should state the name of the firm/company and indicate "external auditor." If the auditor is internal staff, the sponsoring organization must name the individual and his/her position.

7. Question: How should sponsoring organizations populate the CPE universes with FWA activities now that CMS has eliminated the FWAM record layout?

   Answer: With the elimination of the FWAM record layout, the expectation is to

transition the FWA investigations into Tables 3: IA, 4; IM, or 1: FTEAM when fulfilling the data universe requests. The IA and IM record layouts must be used for internal auditing and monitoring activities, including FWA investigations, performed by the sponsoring organization. FWA investigations specific to downstream and related entities would be excluded from the IA and IM universes. The FTEAM record layout must be used for external auditing and monitoring activities, including FWA investigations performed by the sponsoring organization or the FTE. Focused FWA investigative activities of individual providers or groups must be included in the IA, IM or FTEAM universe, depending on the sponsoring organization's contractual relationships with such providers or groups.

8. Question: Does CMS have any style or length preferences for the customized organizational structure and governance PowerPoint presentation (Attachment I-C)?

Answer: CMS does not have any style or length requirements for the presentation. Sponsoring organizations can use an appendix or outline type format to show the reporting structure, as long as the content is responsive to the information requested in the template.

9. Question: What documentation does CMS want to see in response to its request for formal risk assessments and compliance performance mechanisms?

Answer: Compliance performance mechanisms are any mechanism that the sponsoring organization uses to measure the performance of the compliance program. They can include dashboards, self-assessments, surveys, or any other tools or mechanisms (outside of the risk assessment) that the organization uses to identify potential compliance risks. An example is monthly compliance dashboards that track the goals and statuses of the identified risk or issue.

10. Question: Does CMS have a template for submission of audit and monitoring work plans and should activities that are planned but not yet started be included in the submission?

Answer: CMS does not provide templates for audit and monitoring work plans. The sponsoring organization has the discretion to present this information however is most effective. Planned auditing/monitoring activities that have not commenced or have not been completed during the audit period must still be included.

11. Question: How should sponsoring organizations list an issue that involves both compliance and FWA in Column F of Table 1: FTEAM, or Column D in Table 3: IA and Table 4: IM?

Answer: In situations where the activity can be both compliance and FWA related,

sponsoring organizations should list "FWA" in the record layout and, during the universe validation process, the sponsoring organization can explain to the audit team which issues are related to both compliance and FWA.

12. Question: In Table 1: FTEAM, Column G, or in Table 3: IA and Table 4: IM, Column E, how should sponsoring organizations list the auditing or monitoring frequency for oversight activities that occur on a daily basis?

Answer: Sponsoring organizations should not include an individual entry each time a daily activity occurs. Rather, daily oversight activities must be rolled up into an aggregate time period of one month and must be included in the requested universe(s) each time the aggregate time period into which they were rolled occurred.

13. Question: How should sponsoring organizations populate the "Description of Deficiencies" field in Table 1: FTEAM, Table 3: IA, and Table 4: IM, if there is more than one deficiency identified during the audit or monitoring activity?

Answer: When completing the Description of Deficiencies column, list the deficiencies out in a 1:1 correlation. For example, if the sponsoring organization indicated there were five deficiencies in the preceding column, Number of Deficiencies, each deficiency should be listed separately as follows: "Deficiency 1 was _____; deficiency 2 was _____;" and so on.

14. Question: Does CMS require sponsoring organizations to populate the corrective action plans (CAPs) in the "Corrective Action Description" field in Table 1: FTEAM, Table 3: IA, and Table 4: IM, in any particular order? For instance, must the CAPs appear in the same order as the deficiencies noted in previous columns of the universe?

Answer: No. A sponsoring organization must list all CAPs, including those corrective actions that have been taken and those that are still pending, but is not required to list them in a specific order.

15. Question: In the HPMS memo titled "2019 Program Audits" (https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2019ProgramAuditHPMSMemo.pdf) that was published on December 4, 2018, CMS discussed monitoring call center routing in the CPE review. Can CMS provide additional information regarding how call center routing will be evaluated, and what CMS will expect of sponsoring organizations in order to perform such review? Will CMS issue additional guidance in advance of the 2019 audits that further details CMS's approach?

Answer: During the onsite portion of the CPE review, a sponsoring organization should

be prepared to discuss how it oversees its incoming calls (e.g. those calls previously collected via the Part C and Part D Call Log record layouts) to ensure calls are properly routed, classified, and processed. CMS does not intend to issue additional guidance regarding its audit approach in advance of the 2019 audits.

16. Question: Can CMS clarify the inclusion and exclusion criteria for Table 2: ECT that is found in the Attachment I CPE Audit Process and Data Request document (https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2017_Medicare_Parts_C_and_D_Program_Audit_Protocols_and_Data_Requests.zip)? Specifically, the instructions say to "Include: all current employees…responsible for oversight of the Medicare program who worked/served at any time during the audit review period. However, the instructions go on to say, "Exclude: individuals that…do not work on the Medicare Parts C and/or D line of business as of the date of the audit engagement letter." Should a sponsoring organization include or exclude from the universe an employee who does not work on Medicare C/D operations at the time of the engagement letter but is still a current employee who worked on Medicare C/D operations earlier in the audit review period?

Answer: CMS' clarification is that only individuals that have left the sponsoring organization, have been terminated, or resigned must be excluded. Sponsoring organizations should include individuals that do not currently work on the Medicare Parts C and/or D line of business as of the date of the audit engagement letter, but worked in that line of business during the audit period, as mentioned in the inclusion language.

Please note that population of the following Table 2: ECT columns is suspended for the 2019 Program Audits:

- **Column I: Medicare Compliance Department Employee;**
- **Column J: Compliance Department Job Description;**
- **Column K: Compliance Committee Member; and**
- **Column L: Compliance Committee Member's Role**

To the extent that a sponsoring organization would like to populate and submit these data elements, it is not prohibited from doing so.

C. Part D Formulary and Benefit Administration (FA)

1. Question: Given the recent move to the Medicare Beneficiary Identifier (MBI) from the Health Insurance Claim Number (HICN) for CMS reporting purposes, can CMS clarify what sponsoring organizations should enter in the FA universes that request the HICN as the beneficiary identifier?

Answer: As stated in the HPMS memo issued November 18, 2016, titled "Social

Security Number Removal Initiative (SSNRI) Selected Updates for Medicare Advantage and Part D Plans," (https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Annual/SysHPMS-Memo-2016-Qtr4.zip), the MBI replaced the SSN-based HICN on Medicare cards starting in 2018. The transition period where CMS will accept either the HICN or MBI when submitting data to the agency will continue through December 31, 2019. Therefore, in audit record layouts currently requiring submission of a HICN, sponsoring organizations can enter either the MBI or HICN for 2018 and 2019 program audits. As the format of the MBI is distinctly different than the HICN, it is not necessary to add a MBI qualifier.

2. Question: In what format does CMS require the National Drug Code (NDC) field be populated in the requested FA universes?

Answer: The 11-Digit National Drug Code (NDC) must be populated in the format provided in the National Council for Prescription Drug Program's (NCPDP) data dictionary.

3. Question: What should a sponsoring organization enter in the NDC field of the rejected claims universe(s) if the NDC on the claim was found to be invalid while processing the case?

Answer: The rejected claims universes, Tables 1: RCFA, 2: RCT-N, and 3: RCT-P, should include the NDCs that were submitted on that claim regardless of whether the NDC was determined to be invalid after processing.

4. Question: How should sponsoring organizations populate the NDC field of the rejected claims universe(s) for compound claims?

Answer: For multi-ingredient compound claims that contain a value with spaces, hyphens, or other special characters in the "11-Digit National Drug Code," it is appropriate for the sponsoring organization to populate this field as it was received from the pharmacy. However, when the pharmacy submits a value greater than 11 characters in the NDC field, a sponsoring organization may enter "valueXeeded" in the field.

5. Question: When members change plans from one plan benefit package (PBP) to another, what date should be entered as the enrollment effective date?

Answer: The effective date of enrollment for the beneficiary (PBP level) submitted in the rejected claims universes (i.e. Tables 1 through 3) should be relevant to the contract and plan ID of the enrollee at the time of each claim. In Table 5: NM, a separate record should be entered each time an enrollee is enrolled and considered a new member.

6. Question: Does CMS require an NCPDP value in the "Patient Residence" and "Pharmacy Service Type" fields found in Table 1: RCFA, Table 2: RCT-N, and Table 3: RCT-P?

Answer: The patient residence and pharmacy service type values must reflect what was submitted by the pharmacy on the claim. While this may typically be an NCPDP value, other values submitted on the claim would be accepted. Answer "UNK" if these fields are left blank by the pharmacy.

7. Question: How should sponsoring organizations populate the "Reject Reason Code" in the rejected claims universes (i.e. Table 1: RCFA, Table 2: RCT-N, and Table 3: RCT-P) if both reject codes and pharmacy messaging exist for a rejected claim, but the exact association between the reject code and pharmacy message cannot be identified?

Answer: When the exact association between a reject code and pharmacy message cannot be identified, the sponsoring organization is permitted to enter the individual reject codes in the "Reject Reason Code" field followed by all of the messaging for that claim in the "Pharmacy Message" field. This should be repeated for all reject reason codes appearing for that rejected claim.

8. Question: What data must be submitted in rejected claims universes, Tables 1: RCFA, 2: RCT-N, and 3: RCT-P?

Answer: Submit ALL rejected point of sale claims routed to the sponsoring organization. Data must not be filtered under any circumstances.

9. Question: What data must be submitted in Table 4: PDE?

Answer: Include only standing paid claims for the period requested for enrollees from the rejected claims transition universes, Table 2: RCT-N and Table 3: RCT-P.

10. Question: How should sponsoring organizations determine if an enrollee is to be treated as a "new" member in order to populate Table 5: NM?

Answer: Populate the New Member universe to include only enrollees for which the sponsoring organization does not utilize prior claims history. In some cases, the sponsoring organization may have the full claims history for the enrollee from the most recent PBP and, thus, the sponsoring organization may be able to determine new versus ongoing therapy. In this example, the enrollee should not be included in the New Member universe since they are determined to be a continuing enrollee.

11. Question: When populating the impact analysis, how should sponsoring organizations calculate the number of days an enrollee went without medication (target or related)?

Answer: When completing Column AB for rejected claims in the member impact tab, if there was a subsequent paid claim for the same drug, utilize the following formula: [(Date of Subsequent Paid Claim for the Same Drug) - (Date of Rejected Claim)]. If there was a subsequent paid claim for a related drug, utilize the following formula: [(Date of Paid Claim for a Related Drug) - (Date of Rejected Claim)].

D. Part D Coverage Determinations, Appeals, and Grievances (CDAG)

1. Question: If a sponsoring organization offers a 'live chat' feature to current enrollees when they are logged in to a secure enrollee portal, does CMS expect records of those discussions would need to be included in the call log universe?

Answer: **Please note, collection of Table 16, Call Logs Part D, is suspended for the 2019 Program Audits**. If CMS were collecting this data, sponsoring organizations would exclude live chats in the call log universe because they are not calls. However, if a "chat" involves either a complaint or coverage request, CMS would expect to see the resultant case in the applicable universe(s) for the 2019 Program Audits (e.g. if it was a grievance it would appear in the grievance universe, and if it was a coverage determination (CD) it would appear in the respective CD universe).

2. Question: For the redetermination universes (Tables 6 through 8 - SRD, DMRRD, and ERD, respectively), the following fields are requested: *"Was the request denied for lack of medical necessity?"* and *"If denied for lack of medical necessity, was the review completed by a physician?"* Should these fields be populated based on the results of the initial coverage determination decision or the redetermination decision?

Answer: The field asking *"Was the request denied for lack of medical necessity?"* refers to the initial coverage determination decision. The field asking *"If denied for lack of medical necessity, was the review completed by a physician?"* refers to the redetermination decision.

3. Question: When a sponsoring organization issues a denial under Part D on the basis that the drug is a non-Part D drug but determines the drug is covered under Part A or Part B, should record layouts 1-10 include these decisions?

Answer: Sponsoring organizations should include cases based on how the requests were processed. If the sponsoring organization initially processed the request as a coverage determination (i.e. and issued a Part D denial notice), then the request must be included in the applicable Part D coverage determination universe. If the sponsoring organization

only ever processed the request as an organization determination (OD), then the request must be included in the applicable Part C organization determination universe.

4. Question: Should sponsoring organizations report the first or the last good faith effort in the "Date Oral Notification Provided to enrollee" and "Time Oral Notification Provided to enrollee" fields of the universe if several attempts are made to provide an enrollee with the outcome of his/her request? In some instances, the last attempt may exceed the allowed turn-around time for a case.

Answer: If a sponsoring organization makes several good faith attempts to provide an enrollee (or authorized representative) with the outcome of his or her case but is not able to successfully reach the enrollee or leave a voice mail, the sponsoring organization would enter the date of the last good faith attempt that was made within the applicable processing timeframe. If the only attempt to notify the enrollee was made after the applicable processing timeframe, the date and time should be entered as it occurred.

5. Question: For coverage requests that require an Appointment of Representative (AOR) form, is the timeliness calculation based on the AOR receipt date?

Answer: The timeliness calculation is based on the AOR receipt date only if the AOR was received after the coverage request was received by the sponsoring organization. If the sponsoring organization already had a valid AOR on file when the coverage request was received, the timeliness calculation would be based on the date of the request.

6. Question: What does "provided" mean in the field that asks, "Date Written Notification Provided to Enrollee?"

Answer: "Provided" means when the notification left the sponsoring organization or its delegated entity. If a mail vendor is used, "provided" is the date the notification left the mail vendor. If the sponsoring organization sends the notification via US mail, "provided" is the date the notification left the sponsoring organization. In some instances, systems are programmed to capture the date letters are generated (as opposed to the "mailing date" as required in the "Notification Date" field of the record layout). Requiring a sponsoring organization to manually look up actual mail dates for purposes of submitting a universe may be too cumbersome. As a result, CMS will allow a sponsoring organization to apply the worst-case scenario from the applicable mailing policy. For example, if a sponsoring organization's policy is to mail letters within two to four days of generating the letters, the organization would add four days to the date the letters are generated for purposes of populating the "Date Written Notification Provided to enrollee" field in the universe. CMS would accept this date during the integrity test so long as the samples selected during the integrity test demonstrate that the actual mailing date was on or before the "Notification Date" entered in the applicable field of the

submitted universe.

7. Question: How should a sponsoring organization populate the "Date Reimbursement Provided" field in the applicable CDAG universes if the enrollee has yet to be reimbursed?

Answer: Enter NA if the request was not approved, was approved but the payment has not yet been provided, or was approved but did not result in reimbursement to the enrollee.

8. Question: How should a sponsoring organization populate the "Resolution Description" field in Table 14: SGD and Table 15: EGD when a Part D grievance was dismissed for lack of AOR form?

Answer: Grievances that have been dismissed and thus, not processed, should not be included in Table 14: SGD or Table 15: EGD.

9. Question: How should sponsoring organizations identify reopened cases in CDAG universes?

Answer: In the following tables and columns, enter the date and/or time the decision was made to re-open the case for any case that has a "Request Disposition" entered as "re-opened approved" or "re-opened denied:"

- Table 1: SCD, Column R;
- Table 2: SCDER, Column W;
- Table 3: DMRCD, Column O;
- Table 4: ECD, Column T;
- Table 5: ECDER, Column Y;
- Table 6: SRD, Column R;
- Table 7: DMRRD, Column Q; and
- Table 8: ERD, Column V.

NOTE: The original coverage determination or redetermination is considered a separate case for purposes of audit and must be included in the universe if the request falls within the audit review period.

10. Question: Should sponsoring organizations include cases that are still awaiting a supporting statement in the Table 2: SCDER and Table 5: ECDER universes?

Answer: Yes. Include "tolled" cases still awaiting the physician supporting statement.

11. Question: Instructions for Table 11: SIAM, Table 12: DMRRE, and Table 13: EIAM instruct sponsoring organizations to include reimbursement requests that were overturned by the independent review entity (IRE), administrative law judge (ALJ), or Medicare Administrative Contractor (MAC). Are these instructions meant to include any requests that were partially overturned, as well?

Answer: Yes; include all requests that were overturned, even partially overturned, by the IRE, ALJ or MAC.

12. Question: How should a sponsoring organization populate the "Plan ID" field in the CDAG universes when an enrollee has not officially enrolled yet, or has disenrolled from the sponsoring organization when the request for coverage or grievance has been received?

Answer: If the request was received prior to the enrollee being effective in a plan, enter the Plan ID that will be in place at the time of the enrollment effective date. If the request or grievance was received after the enrollee disenrolled from a plan but has not joined another plan within the organization, enter the Plan ID that was in place at the time of the request.

13. Question: What should sponsoring organizations list as the Issue Description for claims that were rejected/denied based on the provider being on the Preclusion List?

Answer: Please exclude from the CDAG universe submissions any cases that were rejected/denied as a result of the provider being on the Preclusion List (as this is not a coverage request). However, if the enrollee contacts the sponsoring organization to find another provider in the area to furnish these services (because an enrollee always has the right to seek a coverage decision from the sponsoring organization if there's a question regarding coverage for an item, service or drug), CMS would expect to see that coverage request in the applicable CDAG universe(s).

14. Question: Will CMS evaluate sponsoring organizations' implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) through the program audit process? Specifically, are sponsoring organizations expected to document beneficiary at-risk determinations and redeterminations via the program audit universe submission process?

Answer: CARA required CMS to establish a framework allowing Part D sponsors to limit at-risk beneficiaries' access to coverage for frequently abused drugs via drug management programs starting in 2019. The term "at-risk beneficiary" is defined in 42 CFR § 423.100. For 2019, we clarify that beneficiary at-risk determinations are not defined as coverage determinations. As a result, at-risk determination data will not be

collected via the program audit universe record layouts for coverage determinations in 2019. However, if a beneficiary appeals the at-risk determination (and subsequent limitation on coverage), the appeal is a redetermination and would be entered into Table 6: SRD and Table 8: ERD, as applicable.

E. Part C Organization Determinations, Appeals, and Grievances (ODAG)

1. Question: What date should a sponsoring organization enter as the date paid (e.g. in Table 3: Claims, Table 4: DMR, or Table 7: PREC) when the sponsoring organization contracts with an outside vendor to mail checks?

Answer: "Paid" or "issued payment" means when the payment left the sponsoring organization. If a payment vendor is used for electronic payment, enter the date the electronic payment left the sponsoring organization (as the sponsoring organization set the payment in motion). If the sponsoring organization sends a check via a mail vendor, enter the date the check left the mail vendor. If the sponsoring organization sends a check via US mail, enter the date the check left the sponsoring organization.

2. Question: Should sponsoring organizations include all payment requests from non-contracted providers (NCPs) in the Table 3: Claims universe regardless of who the payments were sent to, or does CMS only want sponsoring organizations to enter payment requests from NCPs when the payments are sent to the providers?

Answer: Please include all payment requests from NCPs.

3. Question: When a pre-service request was for multiple services, and some of those services were denied and some were approved, would CMS expect to see two dispositions populated in Column Q "Request Disposition" and multiple dates populated in the notification columns to represent both the approval and denial letters? Or should sponsoring organizations populate two separate lines on the universe with the same authorization number?

Answer: As noted on page 5 of the ODAG Audit Process and Data Request document (https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2017_Medicare_Parts_C_and_D_Program_Audit_Protocols_and_Data_Requests.zip), partially favorable decisions are treated as denials for audit purposes. If a pre-service organization determination includes more than one service, all of the request's line items should be included in a single row as a single organization determination request.

4. Question: In the ODAG record layout instructions, the "Request Disposition" field states that all untimely and pending cases should be treated as denials for the purposes of populating the rest of the record layouts' fields. Can CMS clarify what a sponsoring organization should enter in the "Request Disposition" field if the sponsoring organization approves a request after the adjudication timeframe has passed; should the request be entered as an approval or denial in the "Request Disposition" field?

   Answer: Approved cases must be submitted as "approved." Only cases that are both untimely and outstanding should be submitted as "denied" for the purposes of the universe. For example, if a case was paid but payment was untimely, enter the date paid (as opposed to listing the case as denied) because it does not meet the criteria of being outstanding.

5. Question: For purposes of the Table 6: EREC universe submission, what is the difference between a denied case and a case that was denied with IRE Auto-Forwarding?

   Answer: Only cases that are both untimely and outstanding must be submitted as "denied" for the purposes of universe submission. Cases that have been sent to the IRE must be entered as "Denied with IRE Auto-Forward."

6. Question: Should sponsoring organizations include the following retrospective reviews in ODAG universes: reviews that occur when the sponsoring organization finds out about admission to a long-term care (LTC) facility sometime after admission but before the LTC facility has actually submitted a claim; and reviews that occur when the enrollee submits a pre-authorization request for a service they have already received?

   Answer: For audit purposes, retrospective reviews do not qualify as ODs and therefore should be excluded from the universe data. Only a sponsoring organization's decision on coverage that is effectuated as approved/paid or denied should be in the universe submission. Therefore, the approval or denial of the post-service claim is the only decision that should be submitted for the audit. A pre-service OD must be made before services are rendered. Any circumstance where a coverage decision is made AFTER the services have been rendered (retrospective reviews) does not qualify as a coverage decision until the claim is approved or denied.

7. Question: Should sponsoring organizations include point of sale retail pharmacy claims (paid or denied) in ODAG Table 3: Claims?

   Answer: Part B drugs processed under Part C as paid or rejected at the point of sale should not be included in ODAG Table 3. However, if the enrollee pays for the drug at the point of sale and is seeking reimbursement, sponsoring organizations should include the reimbursement request in Table 4: DMR.

8. Question: Are there any additional inclusion/exclusion clarifications that a sponsoring organization should be aware of before preparing to submit the ODAG universes?

Answer: Please refer to the following inclusion/exclusion clarifications:

- Exclude requests that require an AOR but the AOR has not been received as of the date of the universe submission from Tables 1: SOD, 2: EOD, 4: DMR, 5: SREC, 6: EREC, 11: GRV_S, and 12: GRV_E.
- Exclude requests for services that do not require a prior-authorization from Tables 1: SOD and 2: EOD.
- Include all supplemental services, such as dental and vision (as is specified for Tables 1: SOD and 2: EOD) and exclude payment requests that were denied due to eligibility (i.e., enrollees who were not enrolled on the date of service, providers not accepting assignment), or unassigned claims in/from Tables 3: Claims and 4: DMR.
- Include payment requests related to services that do not require a prior-authorization in Tables 3: Claims, 4: DMR, and 7: PREC.
- Include requests for Part B Drugs that were processed as organization determinations in Tables 1: SOD and 2: EOD.

9. Question**:** "IRE auto-forward due to untimely decision" is considered a valid value in ODAG Table 4: DMR, Column M; Table 5: SREC, Column Q; Table 6: EREC, Column Q; and Table 7: PREC, Column K. Should this value be used when both the decision and notification are late, or only when the member notification was late (but the decision was made on time)?

Answer: The phrase "IRE auto-forward due to untimely decision" is meant to capture the date a case was auto-forwarded to the IRE upon recognition that the case was untimely and, therefore, no decision was made by the sponsoring organization (i.e., the request was neither approved or denied as a result of a clinical review).

10. Question: What should sponsoring organizations enter in the universes that request the date the enrollee was notified that his/her request has been forwarded to IRE given the updates that were made to 42 CFR § 422.590 in the final Part C and D rule that became effective on January 1, 2019?

Answer: Because sponsoring organizations are no longer required to notify enrollees when their requests are forwarded to the IRE, sponsoring organizations can enter NA in the applicable field (i.e., Column ID R in Table 4; Column ID Z in Table 5; and Column ID AD in Table 6).

F. Special Needs Plans – Model of Care (SNP-MOC)

1. Question: What date should be populated in Table 1: SNPE for "Enrollment Effective Date" for enrollees who are retroactively enrolled? For example, if a member enrolled in a SNP on 3/13/18 but the enrollment was retroactive to 1/1/18, which date would be populated in column J?

Answer: The sponsoring organization would enter 1/1/18 as the enrollment effective date, following the required record layout format of CCYY/MM/DD.

2. Question: Should sponsoring organizations limit its universe of enrollees in Table 1: SNPE to one entry per enrollee, or would sponsoring organizations repeat the enrollee's name in the universe to account for plan changes as a result of a merger?

Answer: If a sponsoring organization experienced PBP mergers, acquisitions, or like changes, it must include separate entries with enrollee information for each contract/plan in which s/he was enrolled during the 13 continuous months.

3. Question: How should a sponsoring organization account for the cumulative dollar amount of Part C and Part D claims (i.e. Columns Q and R of Table 1: SNPE) when part of the claim is denied and part is approved/paid?

Answer: For claims with multiple line items, if any line within a claim is paid, the claim must be reported as part of the cumulative dollar amount of claims paid (i.e. Column Q). In addition, the cumulative dollar amount in Columns Q and R must include Medicare and Medicaid claims data for D-SNP enrollees.

4. Question: What should sponsoring organizations consider when populating Table 1: SNPE, Columns M, N, and O?

Answer: Sponsoring organizations should populate Table 1: SNPE, Columns M, N, and O as they relate to conducting and completing annual HRAs. Specifically, Column M is asking whether or not the sponsoring organization conducted an annual HRA during the 13-month audit period. Column N is asking the sponsoring organization to enter the date the annual HRA was conducted during the 13-month audit period if the sponsoring organization entered "Yes" in Column M. Finally, Column O is asking the sponsoring organization to enter the date of the previous annual HRA/reassessment if the previous assessment date is different from the date that the initial HRA was conducted (as noted in Column L). If the previous assessment date was that of the initial HRA date, sponsoring organizations should enter "NA" in Column O.

5. Question: What should a sponsoring organization enter in Table 1: SNPE, Column K if

the health risk assessment (HRA) was completed beyond the 90-day timeframe or not completed and returned by the enrollee?

Answer: Column K of Table 1: SNPE must be populated based on initial HRAs that were completed by the enrollee and returned to the sponsoring organization within 90 days of enrollment. If the initial HRA was not completed and returned within 90 days, enter "No". Similarly, if the enrollee did not complete and return an annual HRA during the current audit period, the sponsoring organization should enter "No" in Column M of Table 1: SNPE.

6. Question: How should a sponsoring organization populate Table 1: SNPE when it tried to conduct an initial and/or annual HRA but the enrollee did not return the form?

Answer: The sponsoring organization must enter "NA" in Column L if the enrollee did not complete and return the initial HRA and/or enter "NA" in Column N if the enrollee did not complete and return the annual HRA conducted during the current audit period. The sponsoring organization will have an opportunity during the audit to provide due diligence outreach detail during sample case review.

7. Question: When enrollees occasionally refuse to cooperate or participate in annual assessments, will the sponsoring organization be penalized during an audit as a result of their refusal?

Answer: If the SNP performs outreach in accordance with its CMS approved model of care and sufficiently documents the enrollee's refusal and lack of cooperation, auditors would apply a mitigating factor to a condition of noncompliance that resulted from the sponsoring organization's failure to conduct an annual health risk assessment.

G. Medicare Medicaid Plan - Service Authorization Requests, Appeals, and Grievances (MMP-SARAG)

The following MMP-SARAG FAQs supplement ODAG FAQs 1, 2, 3, 4, 5, and 7.

1. Question: Should Medicaid services/items be included in Tables 1: MSSAR, 2: MESAR, 3: M-Claims, 4: MSPLA, 5: MEPLA and 6: M_SFHEFF?

Answer: MMP-SARAG universes must include requests by MMP members, their providers, and their authorized representatives for covered services, and/or payment for such services, and prescription drugs processed under Medicare Part B, but will exclude all other prescription drug requests. Therefore, service authorization requests, claims, appeals, and grievances concerning Medicaid services, should be included in MMP-SARAG universes. However, universes related solely to the Medicare external appeals

process would only have cases that involve Medicare services. This would be the case for Tables 7: M_IREEFF, 8: M_IREClaimsEFF and 9: ALJMACEFF, which concern IRE, ALJ, and MAC overturns. See the table under the timeliness tests subsection in the Universe Preparation & Submission Section of the MMP-SARAG protocol for the listing of universes that would have Medicare services only (i.e., Tables 7 through 9).

2. Question: Should Medicare and Medicaid provider payment requests be reported separately in the Table 3: M_Claims universe?

Answer: For the M_Claims universe, if a claim has more than one line item, include all of the claim's line items in a single row and enter the multiple line items as a single claim. Claims with different claims numbers should be included on separate rows.

3. Question: Would MMP-SARAG universes include subsequent requests for previously approved services?

Answer: Subsequent requests to continue previously approved services should be treated as separate requests from the initial requests and included in the MMP-SARAG universes.

4. Question: What should sponsoring organizations enter in the universes that request the date the enrollee was notified that his/her request has been forwarded to IRE given the updates that were made to 42 CFR § 422.590 in the final Part C and D rule that became effective on January 1, 2019?

Answer: Because sponsoring organizations, including MMPs, are no longer required to notify enrollees when their requests are forwarded to the IRE, sponsoring organizations can enter NA in the applicable field (i.e., MMP-SARAG Table 4, Column AA and Table 5, Column AG).

5. Question: For Tables 4: MSPLA; 5: MEPLA; and 6: M_SFHEFF, how should "Does the Request Appeal a Notice of Action (NOA) Decision" be populated?

Answer: Respond to this field based on whether the appeal resulted from a NOA decision that relayed a termination, suspension, or reduction of a previously authorized service. Appeals of NOAs may qualify for aid pending appeal. Each MMP three-way contract states what steps a member must take to qualify for aid pending appeal and under what circumstances. If the sponsoring organization provided, or should have provided, notification to the member that services would be terminated or reduced, and the member appealed the termination or reduction in services, the response to the field would be "Y". The response would be "N" if the appeal was not filed in response to a reduction or termination of a service that the sponsoring organization had been providing.

6. Question: "IRE/IAHO auto-forward due to untimely decision" is considered a valid value in Table 4: MSPLA, Column R and Table 5: MEPLA, Column T. Should this value be used when both the decision and notification are late or only when the member notification was late (but the decision was made on time)?

Answer: The phrase "IRE/IAHO auto-forward due to untimely decision" is meant to capture the date a case was auto-forwarded to the IRE (i.e., when the sponsoring organization recognized that it did not make a timely decision).

7. Question: For purposes of Tables 4: MSPLA and 5: MEPLA universe submissions, what is the difference between a denied case and a case that was denied with IRE/IAHO auto-forward?

Answer: For Tables 4 and 5, cases that are both untimely and outstanding are "denied" and denied cases that have been sent to the IRE/IAHO must be entered as "Denied with IRE/IAHO auto-forward."

8. Question: Table 10: GRV_S and Table 11: GRV_E, Column F (Person Who Made the Request), indicate a response field length of 2, although one of the acceptable values is "NCP" (3 characters). Please confirm that it is permissible to enter 3 characters in these columns.

Answer: Sponsoring organizations may use 3 characters to provide the response "NCP" to Column F in Tables 10 and 11.

9. Question: How should sponsoring organizations populate Table 9: MMP ALJ and MAC Cases Requiring Effectuation (M_ALJMACEFF), column P (Date Written Notification Provided to the IRE)?

Answer: Populate the field with the date written notification of the sponsoring organization's effectuation was sent to the IRE, not the ALJ/MAC as stated in the field description.

10. Question: Does a sponsoring organization need to collect enrollee calls fielded by first tier, down-stream and related entities (FDRs) in the call log universe? If so, how do we determine which FDR calls should be included versus excluded?

Answer: **Please note, collection of Table 12, MMP Call Logs, is suspended for 2019 Program Audits.**

If CMS were collecting this data, a sponsoring organization must include all calls

(except exclude any calls related to Part D) received by the sponsoring organization (or delegated entity) from MMP enrollees or their representatives received by or transferred to the enrollee customer service line. Please also include calls transferred by a vendor to the sponsoring organization's customer service line in the creation of SARAG Table 12 (MCL).

11. Question: Are there any additional inclusion/exclusion clarifications that a sponsoring organization should be aware of before preparing to submit the MMP-SARAG universes?

Answer: Please refer to the following inclusion/exclusion clarifications:

- Exclude requests that require an AOR but the AOR has not been received as of the date of the universe submission from Tables 1: MSSAR, 2: MESAR, 4: MSPLA, 5: MEPLA, 10: MGRV_S, and 11: MGRV_E.
- Exclude requests for services that do not require a prior-authorization from Tables 1: MSSAR, 2: MESAR, 4: MSPLA, and 5: MEPLA.
- Tables 3: M_Claims: Exclude payment requests that were denied due to eligibility (i.e., enrollees who were not enrolled on the date of service, providers not accepting assignment), or unassigned claims in/from Tables 3: M_Claims. Include payment requests related to services that do not require a prior-authorization.

H. Medicare Medicaid Plan – Care Coordination and Quality Improvement Program (MMP-CCQIPE)

1. Question: Would sponsoring organizations include the member's primary care physician in Table 1, Column C (First Tier, Downstream, and Related Entities)?

Answer: Please include all FDRs that implement or manage the care (e.g., conduct HRAs or Individual Care Plans (ICPs)). If there are no FDRs, enter NA.

2. Question: For Table 1: MMPM, fields H and I (Member's Initial Risk Stratification Level and Date of Member Initial Risk Stratification Level) assignment, should sponsoring organizations populate the fields according to the initial "Rating Category" assigned to the member by the state as of the member's effective date of enrollment, or should the sponsoring organization populate fields H and I with the "Rating Category" as determined by the sponsoring organization following the first/initial HRA?

Answer: Please note that some three-way contracts use different terms for what is the "risk stratification" level in Table 1. Terms such as rating categories in a three-way contract would be equivalent to the risk stratification levels used to populate Table 1: MMPM. Populate fields H and I with the initial rating category assigned to the member by the state as of the member's effective date of enrollment.

3. Question: Where the demonstration-specific three-way contract requires initial HRA completion within a timeframe that differs from the completion standard under MMP Core Measure 2.1 (e.g., 75 days in the contract vs. 90 days under Core Measure 2.1), which standard should we use to note whether the initial HRA was completed timely in column J of Table 1?

   Answer: Sponsoring organizations are audited based on the requirements of the three-way contract in each specific demonstration. As a result, for Table 1, sponsoring organizations are required to respond based on the initial HRA timeframe in that demonstration-specific three-way contract.

4. Question: How should sponsoring organizations populate Table 1: MMPM, column K (Date initial HRA was completed) when the sponsoring organization was not required to conduct a new initial assessment due to a previous assessment conducted with another MMP prior to, but no earlier than one year before enrollment into the member's current MMP?

   Answer: Populate column K with the response "NA" when the initial assessment has been completed by another MMP within a year of the current MMP enrollment date. Prior to submitting the MMPM universe, sponsoring organizations with members who transferred to the MMP from a Medicaid-only plan, or another MMP should discuss with auditors how member transfers affected initial HRA completion.

5. Question: For the quality improvement program effectiveness portion of the protocol, sponsoring organizations must produce documentation showing "evidence of data collection/results of internal analysis/evaluation, including reports generated based on findings from internal analysis." What documentation will satisfy this request?

   Answer: To satisfy this request, sponsoring organizations may provide a copy of reports that the oversight team uses to track and/or report the quality improvement program evaluation metrics. This may include the quality oversight committee's annual report to the Governing Board and/or plan leadership as well as other periodic monitoring reports. CMS' intent is to assess how the sponsoring organization is monitoring the quality improvement program, including how the sponsoring organization determines when corrective action plans and/or modifications to the quality improvement program are necessary.

6. Question: Per the HPMS memo titled, "Changes to the Medicare Advantage Quality Improvement Program Regulations and Quality Improvement Project and Chronic Care Improvement Program Requirements" released on October 10, 2018 (https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2018-WK2-Oct-

8-12.zip), effective January 1, 2019, MMPs are no longer required to conduct quality improvement projects (QIPs). However, the instructions for Table 2 state to include each quality improvement project metric. Are sponsoring organizations still required to provide quality improvement projects in this table?

Answer: Sponsoring organizations are still required to have quality improvement plans and conduct quality activities as described in the three-way contract. Sponsoring organizations should include those activities identified in their Quality Improvement (QI) Work Plan in Table 2.

7. Question: For Table 2: QIPE, should sponsoring organizations include projects identified within each/both QI Work Plans in effect during the audit period? If some projects conclude at the end of the 2018 and are not carried over into the 2019 QI Work Plan, should those projects still be included in the universe?

Answer: If the quality measure was tracked as per the QI Work Plans effective during the audit review period, include the measure in the universe. If a measure was actively tracked per the QI Work Plan at any point during the audit review period, include it in the universe.

8. Question: For an annually assessed metric on Table 2: QIPE, which timeframes should be used? For example, if a metric baseline was established in 2019, there will be no measurement period result for measurement periods 1 or 2.

Answer: Sponsoring organizations should indicate "NA" if no measurement was collected for certain columns as indicated.

9. Question: How should sponsoring organizations populate Table 2: QIPE universe fields such as F (Target Goal) and K (Measurement Period 1 Result) for qualitative measures?

Answer: QI Programs include quantitative and qualitative data collection. Therefore, qualitative measures should also be submitted in Table 2. Sponsoring organizations must submit data in the required format per the MMP-CCQIPE Audit Process and Data Request. For Target Goal and Measurement Result, the sponsoring organization should provide an explanation of the qualitative results, instead of numeric results. The sponsoring organization may exceed the 10 character limit for the response, as long as the row contains fewer than 4,000 characters combined.

10. Question: For sponsoring organizations with multiple lines of business, if some quality improvement activities have performance measures that are measured collectively, (e.g., measured at the Medicaid product level for all Medicaid products, including the MMP), rather than at the MMP line of business level, should the sponsoring organization report

performance for the measure at the combined Medicaid product level in the QIPE universe, or exclude it?

Answer: Sponsoring organizations must comply with any three-way contract requirements regarding performance measures. CMS would generally expect sponsoring organizations to provide quality improvement measure results that are specific to their MMP line of business, but understand that in rare cases, measures may not be tracked separately for the MMP line of business. For the QIPE universe, sponsoring organizations should report quality improvement measures even if they combine data from the MMP line of business and other lines of business. For such measures, sponsoring organizations should explain that the performance measure is inclusive of MMP data and other lines of business in the Data Source column.

11. Question: Please clarify CMSs expectations regarding the use of "Corrective Action Plans" for quality improvement activities, as referenced in Columns M and N of MMP-CCQIPE Table 2.

Answer: Sponsoring organizations should provide information on the initiatives that the sponsoring organization implemented to improve the measure's performance when the measure goal was not met.

Appendix

Please refer to the following list of CMS resource mailboxes for questions that extend beyond the purview of Medicare Parts C and D program audits.

CMS Group Mailboxes:

- Medicare Parts C and D Oversight and Enforcement Group (MOEG)
  - PACE audits: PACEAuditQs@cms.hhs.gov
  - Timeliness monitoring project: Timelinessmonitoring@cms.hhs.gov

- Medicare Enrollment and Appeals Group (MEAG)
  - Part C appeals: Part_C_appeals@cms.hhs.gov
  - Part D appeals: PartD_appeals@cms.hhs.gov
    - (Includes at-risk redetermination/appeal policy questions)

- Medicare Drug Benefit and C and D Data Group (MDBG)
  - Star ratings: PartCandDstarratings@cms.hhs.gov
  - Part D policy: PartDpolicy@cms.hhs.gov
  - At-risk determination policy: PartD_OM@cms.hhs.gov
  - Part D formulary: PartDformularies@cms.hhs.gov
  - Part D benefits: PartDbenefits@cms.hhs.gov
  - Part D transition: PartDtransition@cms.hhs.gov
  - MTM: PartD_mtm@cms.hhs.gov
  - Part C reporting requirements: PartCplanreporting@cms.hhs.gov
  - Part D reporting requirements: PartD-planreporting@cms.hhs.gov
  - Part D hospice payments: PartD_cob@cms.hhs.gov

- Medicare Drug and Health Plan Contract Administration Group (MCAG)
  - Part C policy: https://dpap.lmi.org
  - Part C bids: https://MABenefitsMailbox.lmi.org
  - PACE policy questions: https://dmao.lmi.org
  - Provider network adequacy (PNA): PartCcompliance@cms.hhs.gov

- Medicare-Medicaid Coordination Office (MMCO)
  - Medicare-Medicaid Plan (MMP) reporting process: MMCOCapsReporting@cms.hhs.gov
  - MMP policy and operations: MMCOCapsModel@cms.hhs.gov
  - State Technical Assistance: MMCO_DSNPOperations@cms.hhs.gov

- Office of Financial Management (OFM)
  - Financial audits: MAPDaudits@cms.hhs.gov