



Medicare Advantage & Prescription Drug
Program Audit Process Overview

Center for Medicare

Medicare Part C and Part D Oversight and Enforcement Group
Division of Audit Operations

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INTRODUCTION

The Centers for Medicare & Medicaid Services (CMS) Medicare Part C and Part D Oversight and Enforcement Group (MOEG) conducts program audits of Prescription Drug Plan (PDP) and Medicare Advantage Organization (MAO) Sponsoring Organizations (SO)¹ who enter into contracts with the Center for Medicare (CM). CMS updates the program audit process annually based on comments received from the industry via email, conference events, industry listening sessions, and the post audit questionnaire distributed at the conclusion of each audit.

PLANNING AND PREPARATION

Pre-Audit Activities

- **Start Notice/Engagement Letter** – The Auditor-in-Charge (AIC) contacts the SO’s compliance officer via phone and then sends an audit engagement letter including instructions for downloading audit process and data request documents to the SO 6 weeks prior to the first day of the audit. This communication notifies the SO that they have been selected for audit. It specifies the areas for audit under consideration. The letter also states when and where the audit will take place as well as CMS requirements with regard to facility/records access, information needed prior to the audit, on-site space requirements, key personnel and system requirements.
- **Follow-Up Call** – The AIC conducts a follow-up call with the SO and the audit team 1-2 days after the date of the engagement letter. The purpose of this call is to review the audit process, timelines, and CMS expectations and address any questions the SO may have regarding the audit process. Other details are covered regarding CMS requirements mentioned in the engagement letter.
- **Pre-Audit Issue Summary Submitted to CMS from the SO** – Within 5 business days of receiving the engagement letter the SO will submit the pre-audit issue summary (Attachment VIII) summarizing any previously disclosed or self-identified issues.
- **Universe Request Conference Calls** – Prior to upload of the universe documents, CMS will conduct conference calls with the SO to discuss the universe requests and answer questions.

¹ Please note that the term “sponsoring organization” is used to refer to PDPs, MAOs, and Section 1876 Cost Plans.

- **Universe Submission to CMS from the SO** – Within 15 business days of receiving the engagement letter the SO uploads all requested data to a Secure File Transfer Protocol (SFTP) per instructions provided in the universe request and by the SFTP administrator.
- **Universe Validation Webinar** – After the universes have been uploaded by the SO, CMS will hold a Universe validation webinar with the SO to verify accuracy of dates in the universe.
- **Send SO Audit Schedule** – CMS will send the SO a schedule of audit activities for the week of the webinar and onsite audit. The schedule will list individual review sessions occurring on each day during the two-week audit period.

WEBINAR & ON-SITE AUDIT ACTIVITIES

The first week of audit will begin with an entrance conference, and continue with the audit of all applicable operational areas (Part D Formulary and Benefit Administration (FA); Part D Coverage Determinations, Appeals, and Grievances (CDAG); Part C Organization Determinations, Appeals, Grievances (ODAG); and Special Needs Plan-Model of Care (SNP-MOC) conducted virtually via webinar². CMS prohibits the recording or taping of all audit activities. During the second week, the Part D Medication Therapy Management (MTM) will be conducted virtually and the Part C and Part D Compliance Program Effectiveness team will arrive on-site to conduct the audit of the SO's compliance program effectiveness. This will allow the compliance officer to be actively engaged during the audit of all operational areas and it will allow the audit team to deliver more focused results in a timely manner.

FA, MTM, CDAG, and ODAG samples are provided at least 1 hour before the entrance conference. CPE samples are provided 4 business days before the entrance conference. SNP MOC samples are provided 2 business days before the entrance conference.

- **Entrance Conference** – The audit starts with an entrance conference facilitated by the AIC. The purpose of this conference is to make introductions, review the CMS audit approach and expectations, answer questions, and allow the SO to make a presentation on their behalf regarding their company.
- **Conducting the audit week #1 – operational areas via webinar** – TeamLeads (TL) conduct the audit using audit protocols and record audit results as declared by the TL. TLs will review sample cases live in the SO's system and determine findings in real time (although some determinations may be pended due to additional data requests). This allows CMS to be transparent with potential audit failures. In addition, the SO is expected to provide any supporting documentation as requested by CMS personnel.

² Not all audits are conducted virtually. CMS reserves the right to conduct the audit onsite if needed. Instructions for Provider Network Adequacy (PNA) are forthcoming.

CMS conducts the audits virtually with secure webinar technology. The TL is responsible for ensuring that all necessary technology, including webinar rooms, conference lines, and physical rooms for team members are setup appropriately. Webinar technology is tested prior to the start of the audit.

Expectations of staffing are the same for both physical and virtual audits. Findings are usually determined in real time as CMS and the SO discuss each sample case.

- **Preliminary Exit Conference – conducted after the end of week #1** – CMS will discuss the operational findings identified during the operational audit.
- **Conducting the audit week #2 - On-Site Compliance** – The compliance team will conduct management interviews, operations and system walk-throughs, as well as review samples. The logistics for these activities are discussed prior to the on-site visit. Findings for compliance elements are communicated as soon as CMS comes to a determination. CMS will consider the results of the operational audit in week #1 during the evaluation of the compliance audit. This portion of the audit will generally last 3-4 days.
- **Final Exit Conference – conducted after the end of week #2** – Following week 2 of the audit, the AIC conducts an exit conference with the SO to provide audit results and next steps. The SO is afforded the opportunity to ask questions about the results and audit findings and provide any follow-up information as appropriate. The goal during the audit is to be transparent so there are no surprises at the exit conference.

POST AUDIT ACTIVITIES

- **Draft Audit Report Preparation and Issuance to SO** – At the conclusion of the audit, CMS prepares and issues a draft audit report (goal is within 60 days of the conclusion of the audit). The SO has 10 business days to respond to the draft audit report with comments to CMS. CMS will review the SO's comments and determine if the comments warrant a change to the report. CMS may disagree or agree with the SO's comments. CMS has the final decision in making changes to the final audit report.

- **Issuing the Final Audit report and Corrective Action Requirement(s)** – CMS issues the final audit report (the goal is within 10 days from receiving the SO comments). CMS provides the SO with 7 days to submit a corrective action plan for correcting any deficiencies (a corrective action plan is required within 3 business days for immediate corrective actions). Depending on the results of the audits, SOs may be subject to an enforcement action (e.g., civil money penalty (CMP) or sanction).
 - **Immediate Corrective Action Required (ICAR)** - If CMS identifies systemic deficiencies during an audit that are so severe that they require immediate correction, the SO will be cited an ICAR. These types of issues would be limited to situations where the identified deficiency resulted in a lack of access to medications and/or services or posed an immediate threat to enrollee health and safety. The SO has 3 business days from formal email notification to provide their plan to address or remediate the deficiency. For example, if CMS identified that a SO's formulary was programmed incorrectly resulting in inappropriate denials of needed medications, while the sponsor may not be able to re-program their formulary in 3 business days, the SO would have to demonstrate to CMS the work around they implemented to immediately ensure that enrollees were receiving needed medications. The ICAR counts as two points in the audit scoring methodology.
 - **Corrective Action Required** – If CMS identifies systemic deficiencies during an audit that must be corrected, but the correction can wait until the audit report is issued, the SO will be cited a CAR. These issues may affect beneficiaries, but are not of a nature that immediately affects their health and safety. Generally, they involve deficiencies with respect to non-existent or inadequate policies and procedures, systems, internal controls, training, operations or staffing. The SO will be afforded a total of seven (7) calendar days from the issuance of the final audit report to submit a corrective action plan for all conditions with a “corrective action required (CAR)” in appendix A. The SO should include a brief summary describing the process and give a timeframe for correction. Once submitted, CMS will review the corrective action plans. Once accepted by CMS, the SO will have 150 calendar days from the date of acceptance of the corrective action plan to undergo a validation (unless extension is requested and granted). The CAR counts as one point in the audit scoring methodology.
 - **Observations**—If CMS identifies conditions of non-compliance that are not systemic, or represent a “one-off issue” the SO will be cited an observation. A “one-off issue” may be an issue dealing with one employee or a singular case that was lost or misidentified. Observations do not count in the audit scoring methodology.

- **Invalid Data Submission (IDS)** – An IDS condition is cited when a SO fails to produce an accurate universe within 3 attempts. IDS conditions are new for 2016 and are cited for each element that cannot be tested, grouped by type of case (e.g., *CMS was unable to evaluate timeliness for your coverage determinations (standard or expedited, pre-service or payment), due to invalid data submission(s)*). When the SO goes through their audit validation, they must produce the universes that auditors were unable to test during the original audit, to demonstrate their compliance with CMS requirements. The IDS condition will count as one point in the audit scoring methodology.
- **Validation of CARs & ICARs**—In order to validate correction of the ICAR and/or CAR conditions, the SO may be required to hire an independent auditor (IA) to conduct a validation of correction of audit deficiencies. The purpose of the validation review is for the SO to demonstrate corrections of the conditions of noncompliance identified in this CMS audit final audit report and to serve as the basis for the CEO to attest that these conditions are corrected and are not likely to recur. If any of the corrective actions are not effective, the SO will need to implement new CAPs and repeat the validation process until the CEO can attest to correction. This is the validation process for 2015 program audits and is subject to change for future audit years.
- **Closing the Audit** – Once CMS determines that all deficiencies have been corrected, the SO will receive an audit close out letter. If issues remain, the Account Manager decides next steps (e.g., escalating compliance actions from original audit).