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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## 1. Executive Summary - Audit Process Timeline

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Program Audit Process Overview

II. Background

The Medicare Parts C and D Oversight and Enforcement Group (MEOG) is the entity within the Centers for Medicare & Medicaid Services (CMS) responsible for formulating and administering the program audit strategy for Medicare Advantage Organizations (MAOs) and Medicare Prescription Drug Plan (PDP) Sponsoring Organizations (hereafter referred to as Sponsors). CMS’ Program audits aim to provide CMS with reasonable assurance that Sponsors are delivering benefits in accordance with the terms of their contracts and benefit packages.

On an annual basis, CMS solicits feedback on audit processes from MAO and PDP industry participants through a variety of mediums. CMS uses the relevant feedback to update and improve audit planning, fieldwork, and reporting to ensure the integrity of the MAO and PDP programs and the protection of the health and safety of Medicare beneficiaries.

III. Summary of Audit Phases

Every successful audit is based on sound planning and an atmosphere of constructive involvement and communication between CMS and the Sponsor. CMS’ objective is to involve Sponsor management and staff throughout each phase of the audit, with the goal of achieving a better understanding of the Sponsor’s operations and the ensuing audit results.

MOEG’s program audit process consists of four phases:

1) Audit Engagement and Universe Submission
2) Audit Fieldwork
3) Audit Reporting
4) Audit Validation and Close Out

The audit phases and critical milestones associated with each are discussed in the following paragraphs.

1. Audit Engagement and Universe Submission

1.1 - Engagement Letter – Approximately 6 weeks prior to the entrance conference, the Auditor-in-Charge (AIC) contacts the Sponsor’s compliance officer via phone to notify the Sponsor it has been selected for a program audit. The AIC follows up the courtesy call by sending an audit engagement letter via the Health Plan Management System (HPMS) that includes, at a minimum, the following information:

- Timeframe and location of the program audit
- Instructions for downloading audit process and data request documents from HPMS
• Plan documentation that must be submitted to CMS prior to the audit
• CMS facility/records access requirements
• Onsite space requirements
• System requirements
• Key Personnel requirements

1.2 - Follow-Up Call – Within 2 business days from the date of the engagement letter, the AIC and the CMS audit team conduct a follow-up call with the Sponsor. The purpose of the call is to confirm key information in the engagement letter regarding CMS audit process expectations, the audit schedule, and universe requirements, and to address questions the Sponsor may have regarding the audit.

1.3 - Universe Request Conference Calls – Within 5 business days of the date of the engagement letter, CMS conducts conference calls with the Sponsor to discuss the universe requests/record layouts for each review area and answer questions.

1.4 - Universe Submission to CMS – Within 15 business days of the engagement letter date, the Sponsor must submit all requested universes to CMS following the instructions in the engagement letter.

1.5 - Universe Validation Webinar – Within 1 week of Sponsor upload of the Coverage Determinations, Appeals, and Grievances (CDAG) and/or Organization Determinations, Appeals, and Grievances (ODAG) universes, CMS holds a validation webinar with the Sponsor to verify accuracy of dates in the aforementioned universes.

1.6 - Coordination and Transmission of Audit Schedule – The CMS AIC works with the Team Leads and Sponsor to schedule the individual program area review sessions for the fieldwork phase of the audit. The CMS AIC sends the finalized audit schedule to the Sponsor with the list of individual review sessions occurring each day during fieldwork to ensure the Sponsor has appropriate staff available for each session.

2. Audit Fieldwork

General Overview of Webinar and Onsite Audit Activities - The audit begins with an entrance conference, and then proceeds with the audit of all applicable operational areas.

CMS customarily conducts the audits of each operational area virtually via webinar, with the exception of the Compliance Program Effectiveness (CPE) audit, which is performed onsite at the Sponsor’s location. However, CMS reserves the right to conduct the entire audit onsite if needed. CMS prohibits the recording or taping of any audit activities.

With the exception of SNP-MOC and CPE, CMS provides its selected samples for each day’s review of the operational areas to the Sponsor via upload to HPMS approximately 1 hour prior to the start of each webinar. CMS provides the Sponsor with the CPE samples 4
business days before the entrance conference and the SNP-MOC samples 2 business days before the entrance conference.

2.1 - Entrance Conference – The audit starts with an entrance conference facilitated by the AIC that is held the morning of the first day of the audit. The purpose of this conference is to make introductions, review the CMS audit approach and expectations, answer questions, and allow the Sponsor an opportunity to make a presentation on behalf of its company.

2.2 - Webinar Reviews - CMS conducts simultaneous audits of the operational areas virtually using CMS’ secure webinar technology. Team Lead (TLs) are responsible for monitoring the webinar room during the audit and expelling anyone who is unknown to the audit team in order to protect information.

Using the audit protocols as a guide, the TLs review sample cases live in the Sponsor’s system. The Sponsor is required to upload screenshots or other supporting documentation requested by CMS personnel for any cases that CMS identifies as non-compliant with CMS regulations. While CMS aims to be transparent and to determine findings in real time, classification and scoring of conditions will not be determined until all audit documentation is received. Then, CMS Program Audit Consistency Teams assist in the classification of audit findings to ensure consistency across all audits.

2.3 - Onsite Compliance Program Effectiveness Audit (as applicable) – Over a period of 4 to 5 days, the CMS compliance team conducts management interviews, system walk-throughs, and tracer sample reviews to determine the effectiveness of the Sponsor’s compliance program. CMS discusses the logistics for these activities with the Sponsor prior to the onsite visit. CMS also considers the results of the operational webinar audits during the evaluation of the compliance audit. For audits including MMP contracts, this audit will be conducted during week 9 (third week of audit fieldwork), instead of week 8. Compliance Program Effectiveness may not be included in the scope of all program audits.

2.4 - Issuance of Preliminary Draft Audit Report - At the conclusion of the audit fieldwork phase, the AIC issues a preliminary draft audit report to the Sponsor stating the conditions and observations noted during the audit. This report is issued at least an hour prior to the exit conference.

2.5 - Exit Conference – The final day of fieldwork concludes with an onsite exit conference when the audit team walks through the preliminary draft audit report with the Sponsor. During the exit conference, the Sponsor can ask questions about the findings and provide any follow-up information as appropriate.

3. Audit Reporting

3.1 - Draft Audit Report Preparation and Issuance to Sponsor – After fieldwork is completed, CMS prepares a draft audit report (*inclusive of condition classification and an audit score*) with a target for issuance of 60 calendar days from date of the final exit
conference. The Sponsor has 10 business days to respond to the draft audit report with comments to CMS. CMS takes into consideration and responds to any comments the Sponsor has in regard to the draft audit report, and determines if the comments warrant a change to the final report.

3.2. - Issuance of the Final Audit Report and Scoring – CMS aims to issue the final audit report within 10 business days from receipt of Sponsor’s comments on the draft audit report. The final report contains Sponsor’s final audit score and classification of conditions noted during the audit. CMS classifies conditions by the immediacy of the corrective action required and point value assessed. The condition classifications are outlined below:

3.2.1 - Immediate Corrective Action Required (ICAR) - If CMS identifies systemic deficiencies during an audit so severe that they require immediate correction, the Sponsor is cited an ICAR. Identified issues of this nature would be limited to situations where the condition resulted in a beneficiary’s lack of access to medications and/or services, or posed an immediate threat to beneficiary health and safety. The ICAR counts as 2 points in the audit scoring methodology.

3.2.2 - Corrective Action Required (CAR) – If CMS identifies systemic conditions during an audit that must be corrected, but the correction can wait until the audit report is issued, the Sponsor is cited a CAR. While these issues may affect beneficiaries, they are not of such a severe nature that beneficiaries’ immediate health and safety is affected. Generally, CARs involve deficiencies with respect to non-existent or inadequate policies and procedures, systems, internal controls, training, operations, or staffing. The CAR counts as 1 point in the audit scoring methodology.

3.2.3 - Invalid Data Submission (IDS) – CMS cites an IDS condition when the Sponsor fails to produce an accurate universe within 3 attempts. An IDS is a new condition for 2016, and it is cited for each element that cannot be tested, grouped by type of case. As an example, CMS would cite an IDS condition if auditors were unable to evaluate timeliness for Sponsor’s coverage determinations (standard or expedited, pre-service, or payment) due to invalid data submission(s). The IDS condition counts as 1 point in the audit scoring methodology.

3.2.4 - Observations — If CMS identifies cases of non-compliance that are not systemic, or represent an anomaly or “one-off” issue, the Sponsor is cited an observation. Observations do not count in the audit scoring methodology.

3.3 - Referral for Enforcement Action – At the conclusion of the audit, the conditions noted in the audit will be referred to the Division of Compliance Enforcement for an independent evaluation of whether an enforcement action of Civil Monetary Penalties, sanctions, or contract termination is warranted.
4. **Audit Correction and Close Out**

4.1 - **Submission of Corrective Action Plans (CAPs)** – Due to the immediate nature of ICARs, CMS requires Sponsors to provide its plan to address or remediate any ICAR conditions within 3 business days from formal email notification. An example of this type of condition would be if CMS determined a Sponsor’s formulary was incorrectly programmed resulting in inappropriate denials of a beneficiary’s needed medications. While the Sponsor may not be able to re-program their formulary in 3 business days, the Sponsor would have to demonstrate to CMS the work around it implemented to immediately ensure beneficiaries were receiving needed medications.

The Sponsor has 30 calendar days from the issuance of the final audit report to submit CAPs explaining how it will correct all CARs identified in the final audit report. Normally, IDS conditions and observations do not require a CAP; however, CMS does reserve the right to request CAPs for observations. In addition, although the Sponsor is not required to submit a CAP for IDS conditions, the Sponsor must produce the universes during audit validation and demonstrate compliance with CMS requirements.

Upon receipt of the CAPs, CMS performs a reasonableness review and notifies Sponsor of either CAP acceptance or the need for additional information. CMS continues the reasonableness review process until it deems all CAPs acceptable.

4.2 – **Validation Audit**—CMS requires Sponsors to demonstrate correction of all conditions noted in the final audit report within 150 calendar days of CAP acceptance. CMS may conduct the validation review or CMS may require the Sponsor to hire an Independent Auditor (IA) to conduct the validation. CMS advises sponsors at the time of issuance of the final audit report if an IA is required to validate correction of conditions noted.

If the validation audit finds that significant audit findings are still present (not corrected), another validation audit may be required.

4.3 - **Audit Close Out**– If the validation audit demonstrates that substantial correction of conditions has occurred, CMS will close the audit and send a close out letter to the Sponsor.