



2018 Program Audit Process Overview

Medicare Parts C and D
Oversight and Enforcement Group

Division of Audit Operations

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I. Executive Summary – 2018 Audit Process Timeline

Audit Engagement and
Universe Submission
Weeks 1 - 6

- **Engagement Letter** - CMS notification to Sponsor of audit selection; identification of audit scope and logistics; and Sponsor instructions for audit document submissions
- **Universe Submission** - Sponsor submission of requested universes to CMS
- **Universe Integrity Testing** - CMS integrity testing of Sponsor's universe submissions
- **Audit Sample Selection** – CMS selects samples of cases to be tested during field work

Audit Field
work
Weeks 7 - 9

- **Entrance Conference** - Discussion of CMS audit objectives and expectations; Sponsor voluntary presentation on organization
- **Webinar Reviews** - CMS testing of sample cases live in Sponsor systems via webinar
- **Onsite Audit of Compliance Program (as applicable)** - Compliance program tracer reviews; Sponsor submission of supplemental documentation (screenshots, impact analyses, etc.); CMS documentation analysis
- **Issuance of Preliminary Draft Audit Report** - CMS issues a preliminary draft audit report to Sponsor identifying the preliminary conditions and observations noted during the audit
- **Exit Conference** - CMS review and discussion of preliminary draft audit report with Sponsor

Audit Reporting
Weeks 10 - 21

- **Notification of Immediate Corrective Action Required (ICAR) conditions (as applicable)** - CMS notification to Sponsor of any conditions requiring immediate corrective action; Sponsor ICAR Corrective Action Plan (CAP) submission within 3 business days
- **Draft Report Issuance** - Inclusive of condition classification and audit score to Sponsor approximately 60 calendar days after exit conference
- **Sponsor Response to Draft Report** - Sponsor submission of comments to draft report within 10 business days of draft report receipt
- **Final Report Issuance** - With CMS responses to Sponsor's comments and updated audit score (if applicable). Target issuance within 10 business days after receipt of Sponsor comments to draft report

Audit Validation and
Close Out
Weeks 22 - 48

- **Sponsor CAP Submission** - Sponsor submission of CAP within 30 calendar days of final report issuance
- **CMS Review and Acceptance of CAP** - CMS performance of CAP reasonableness review and notification to Sponsor of acceptance or need for revision
- **Sponsor Validation Audit** - Sponsor must undergo a validation audit to demonstrate correction of audit conditions cited in the Final Audit Report.
- **Audit Close Out** - CMS evaluation of the validation audit report to determine if conditions are corrected; if so, CMS issuance of an audit close out letter to Sponsor

II. Background

The Medicare Parts C and D Oversight and Enforcement Group (MOEG) is the Group within the Centers for Medicare & Medicaid Services (CMS) responsible for creating and administering the audit strategy to oversee the Part C and Part D programs. MOEG conducts audits of Medicare Advantage Organizations (MAOs), Prescription Drug Plans (PDPs), and Medicare-Medicaid Plans (MMPs), collectively referred to as “sponsors,” that participate in these programs. These program audits measure a sponsor’s compliance with the terms of its contract with CMS, in particular, the requirements associated with access to medical services, drugs, and other beneficiary protections required by Medicare. On an annual basis, CMS solicits feedback on the audit process from industry stakeholders through a variety of mediums. CMS utilizes the feedback to update and improve audit operations as well as to explore new program areas that may require oversight.

This document outlines the audit process for 2018. CMS will send routine engagement letters to initiate audits beginning March 2018 through September 2018. Engagement letters for unscheduled audits may be sent at any time throughout the year.

III. Summary of Audit Phases

The program audit consists of four phases:

- 1) Audit Engagement and Universe Submission
- 2) Audit Field work
- 3) Audit Reporting
- 4) Audit Validation and Close Out

The sections below describe important milestones in each phase of the audit.

Audit Engagement and Universe Submission (Weeks 1-6)

Engagement Letter – The Auditor-in-Charge (AIC) conducts a courtesy call to the sponsor’s Compliance Officer to notify the organization of the program audit. After the phone call, the AIC sends an audit engagement letter via the Health Plan Management System (HPMS). The engagement letter contains instructions for downloading important audit documents from HPMS. Attached with the engagement letter is the Audit Submission Checklist, which identifies all universe requests and deliverables due to CMS prior to the start of audit field work. A blank version of this checklist is posted on the CMS Program Audit Website located at <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html>.

Engagement Letter Follow-Up Call – **Within two business days from the date of the engagement letter**, the CMS audit team conducts a follow-up call with the sponsor. The purpose of this call is to provide an opportunity for the sponsor to ask questions about the engagement letter and audit process, as well as for CMS to emphasize important information

within the engagement letter and outline next steps in the audit process.

Universe Follow-Up Calls – Within five business days from the date of the engagement letter, CMS conducts universe follow-up calls for each program area to discuss universe requests/record layouts and to answer questions as needed.

Universes Submissions Due to CMS – Within 15 business days from the date of the engagement letter date, the sponsor must submit all requested universes to CMS following the instructions in the engagement letter.

Universe Integrity Testing – Within 7 days from the receipt of universes, CMS conducts universe integrity testing to verify the accuracy of submitted universes. To conduct this test, CMS selects sample cases from the universe and verifies the information within the sponsor's live systems, or that of their delegated entities. CMS conducts these tests virtually via webinar.

Audit Sample Selection – CMS selects samples from the submitted universes to test during audit field work. In most program areas, CMS informs the sponsor of the sample selections via HPMS upload on the day the field work begins, approximately 1 hour before the start of the webinar. However, the audit team will provide sponsors with tracer sample selections two weeks prior to the entrance conference for Compliance Program Effectiveness (CPE), and for Special Needs Plan – Model of Care, samples will be provided two business days before the entrance conference.

Coordination of Audit Field work Schedule – The AIC coordinates with the sponsor to schedule the field work phase of the audit. Within a week prior to the entrance conference, the AIC sends the finalized audit field work schedule to the sponsor with the list of individual webinar sessions occurring each day to ensure the sponsor has appropriate staff available for each session. Please note, webinars for various program areas run concurrently, so adequate staff will need to be available to support each webinar. In addition, CMS aims to adhere to the sponsor's normal business hours, but may request alternative hours depending on the progress of audit field work.

Audit Field work (Weeks 7-9)

Entrance Conference – Audit field work begins with an entrance conference held on the morning of the first day of field work. The AIC will lead the meeting, review the schedule, and discuss expectations for the week. The sponsor will also have an opportunity to make a presentation about its organization.

Webinar Reviews – Webinar audits will begin as listed in the field work schedule and will normally conclude by the end of week 7. When more than 5 program areas are being audited, webinars may continue into week 8. This scheduled additional week of field work is new in 2018 and is meant to provide sponsors with additional time to respond to audit requests and prepare for the onsite CPE audit the following week. During webinar based audits, the audit team will evaluate sample cases live in the sponsor's system to determine

whether the case is compliant or non-compliant. For cases deemed non-compliant, the sponsor must upload requested screenshots and other supporting documentation to HPMS. The classification and scoring of audit conditions is determined after receipt and review of all audit documentation by the audit team. This is discussed in more detail in the Audit Reporting section.

Onsite Compliance Program Effectiveness Audit (as applicable) – The CMS audit team conducts an in-person audit of the sponsor’s compliance program over a period of 4 to 5 days. This occurs during week 9, which is the last and final week of scheduled field work.

Issuance of Preliminary Draft Audit Report - At the conclusion of the audit field work phase, the AIC issues a preliminary draft audit report to the sponsor, identifying the conditions and observations noted during the audit. The AIC issues this report in HPMS at least one hour prior to the exit conference.

Exit Conference – The final day of field work concludes with an exit conference (conducted onsite if CPE is part of the audit). The audit team will walk through the preliminary draft audit report with the sponsor and discuss any other outstanding requests for information. During the exit conference, the Sponsor can ask questions about the findings and provide any follow-up information as appropriate.

Audit Reporting (Weeks 10-21)

Notification of Immediate Corrective Action Required (ICAR) conditions – Upon receipt of all audit documentation, the audit team will meet with Program Audit Consistency Teams (PACTs) for each program area included in the audit. PACTs serve as the subject matter experts on programs and audit policy for their respective program areas and ensure consistency in classification of audit conditions across all audits. The PACTs will assist the audit team with the classification of conditions according to the following definitions:

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.

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.

Invalid Data Submission (IDS) – CMS cites an IDS condition when the Sponsor fails to produce an accurate or complete universe within three attempts. An IDS condition 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.

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 as points in the audit scoring methodology.

Once ICAR conditions are identified, the sponsor’s Compliance Officer (or primary point of contact for the audit) will be notified and immediate corrective action must be taken to stop or prevent the non-compliance from recurring. Sponsors are required to submit Corrective Action Plans (CAPs) describing the actions taken to stop the non-compliance within three business days of being informed of the ICAR condition.

Draft Audit Report Preparation and Issuance to Sponsor – CMS prepares a draft audit report (inclusive of condition classification and an audit score) with a target for issuance of 60 calendar days from the 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.

Issuance of the Final Audit Report and Scoring – CMS aims to issue the final audit report within 10 business days from receipt of the sponsor’s comments to the draft audit report. The final report contains the final audit score and classification of conditions noted during the audit.

Referral for Enforcement Action – At the conclusion of the audit, the conditions noted in the audit may be referred to the Division of Compliance Enforcement (DCE) for an independent evaluation of whether an enforcement action of Civil Money Penalties, sanctions, or contract termination is warranted.

Impact on Performance Measures – Non-compliance found during the audit may adversely affect CMS Part C and Part D Star Ratings and/or Application Cycle Past Performance Reviews. For CMS Star Ratings, if the audit finds that a particular issue of non-compliance impacts the data source for a Star measure, the Star measure may be reduced to 1 Star if the data set is deemed inaccurate or biased (per CMS Star Ratings policy). As an example, a Star Ratings measure, which uses data reported to the Independent Review Entity (IRE) as the data source, may be reduced if the audit finds that a sponsor’s non-compliance resulted in the IRE failing to receive all cases as required for a given contract. For Past Performance Reviews, a sponsor may receive a negative past performance point if its core audit score represents an outlier when compared to all audit reports issued during the 14-month past performance period,

consistent with the past performance review methodology CMS issues each year.

Audit Validation and Close Out

Submission of Non-ICAR Corrective Action Plans (CAPs) – Sponsors have 30 calendar days from the issuance of the final audit report to submit CAPs associated with CAR and IDS conditions. Normally, observations do not require a CAP; however, CMS does reserve the right to request CAPs for observations and will explicitly request this in the report when required.

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

Validation Audit—CMS requires that sponsors demonstrate correction of conditions noted in the final audit report by undergoing a validation audit. **For more detailed information on the validation audit process, please see the “Program Audit Validation Close Out” document posted on the program audit website.**

Audit Close Out– If the validation audit demonstrates substantial correction of conditions has occurred, CMS will close the audit and send an audit close out letter to the sponsor.