2017 Program Audit Process Overview

Medicare Parts C and D
Oversight and Enforcement Group

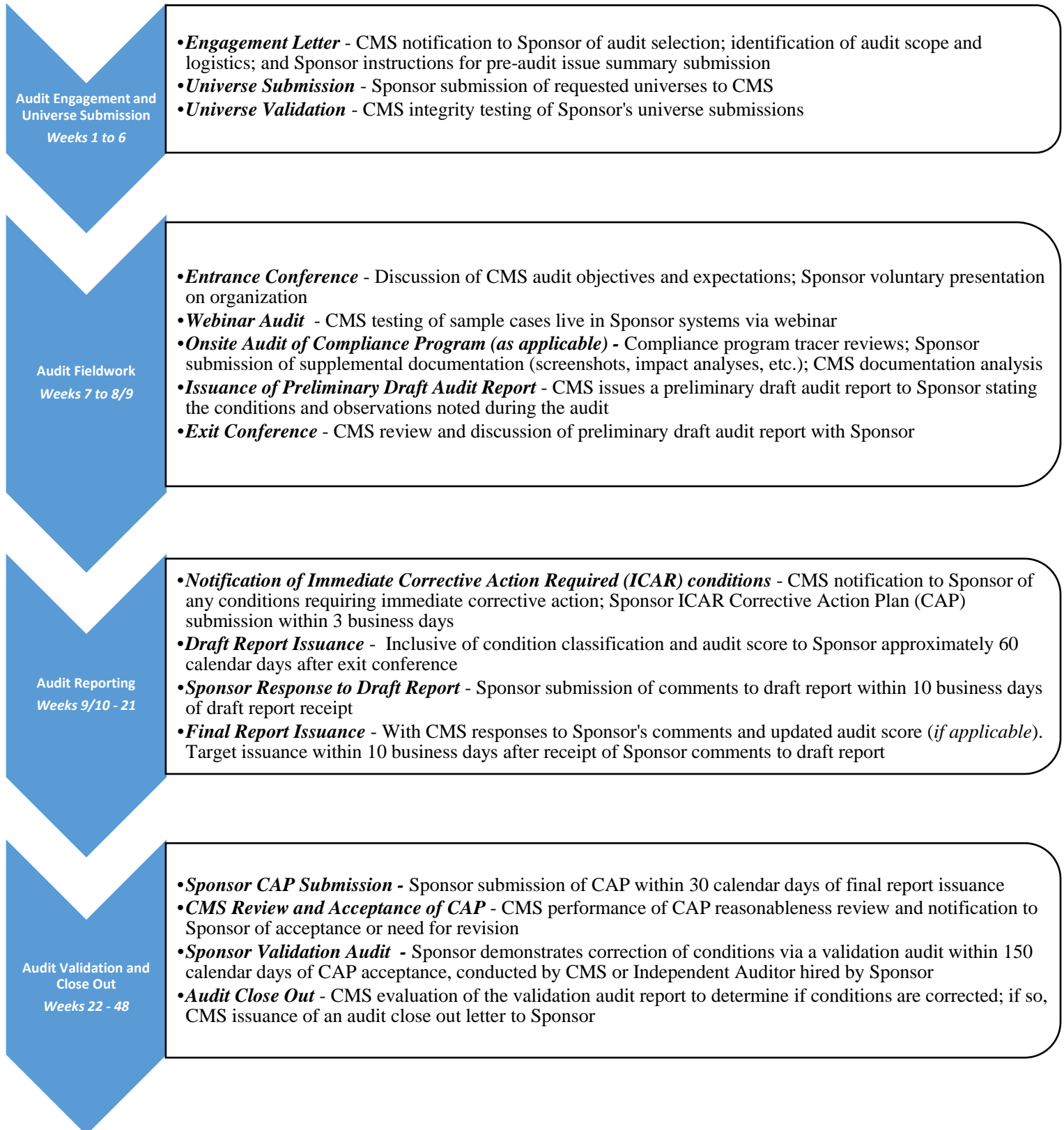Division of Audit Operations

Updated December 2016

Table of Contents

I.   Executive Summary – 2017 Audit Process Timeline

Audit Engagement and Universe Submission
Weeks 1 to 6

- *Engagement Letter* - CMS notification to Sponsor of audit selection; identification of audit scope and logistics; and Sponsor instructions for pre-audit issue summary submission
- *Universe Submission* - Sponsor submission of requested universes to CMS
- *Universe Validation* - CMS integrity testing of Sponsor's universe submissions

Audit Fieldwork
Weeks 7 to 8/9

- *Entrance Conference* - Discussion of CMS audit objectives and expectations; Sponsor voluntary presentation on organization
- *Webinar Audit* - 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 stating the conditions and observations noted during the audit
- *Exit Conference* - CMS review and discussion of preliminary draft audit report with Sponsor

Audit Reporting
Weeks 9/10 - 21

- *Notification of Immediate Corrective Action Required (ICAR) conditions* - 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 demonstrates correction of conditions via a validation audit within 150 calendar days of CAP acceptance, conducted by CMS or Independent Auditor hired by Sponsor
- *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 need oversight.

This document outlines the audit process for 2017. CMS will send routine engagement letters to initiate audits beginning February 21, 2017 through September 25, 2017. 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 Fieldwork
3) Audit Reporting
4) Audit Validation and Close Out

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

1. <u>Audit Engagement and Universe Submission</u>

1.1 - 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) that includes 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 audit fieldwork
- CMS facility/records access requirements
- Onsite Visit Information and Requests
- Key Personnel requirements

1.2 - Follow-Up Call – Within two business days from the issuance of the engagement letter, the CMS audit team conducts a follow-up call with the sponsor. The purpose of the

call is to provide an opportunity for the sponsor to ask questions about the engagement letter or audit process, as well as for CMS to emphasize important information within the engagement letter and outline next steps in the audit process.

1.3 - Universe Request Calls – Within 5 business days of the issuance of the engagement letter, CMS conducts universe request calls for each program area to discuss universe requests/record layouts and to answer questions as needed.

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 Integrity Testing – Within 1 week of the receipt of universes, CMS conducts universe integrity testing to verify the accuracy of submitted universes. To conduct this test, CMS selects samples of cases in the universe and matches the information to the sponsor's live systems. CMS conducts these tests virtually via webinar.

1.6 - Coordination of Audit Fieldwork Schedule – The AIC coordinates with its team and the sponsor to schedule individual program area review sessions during the fieldwork phase of the audit. Within a week prior to the entrance conference, the AIC sends the finalized audit fieldwork schedule to the sponsor with the list of individual webinar sessions occurring each day during fieldwork to ensure the sponsor has appropriate staff available for each session. Please note, webinars for various program areas run concurrently, so different 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 fieldwork.

2. <u>Audit Fieldwork</u>

2.1 - Entrance Conference – Audit fieldwork begins with an entrance conference held on the morning of the first day of fieldwork. 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.

2.2 – Audit Sample Selection – CMS selects samples from the submitted universes to test during audit fieldwork. CMS informs the sponsor of the sample selection via HPMS upload for each program area as follows:
- For CPE – CMS provides its selected tracer samples approximately two weeks prior to the entrance conference. Then, the sponsor must prepare tracer summaries for submission to the audit team by the entrance conference.
- For MTM – CMS provides its selected samples five business days before the scheduled webinars begin. Since MTM occurs during week 2 of fieldwork, CMS usually provides these samples on the date of the entrance conference.
- For SNP-MOC – CMS provides its selected samples two business days before the entrance conference.

- For all other program areas – CMS provides its selected samples for each day's review approximately one hour prior to the start of the scheduled webinar.

2.3 - Webinar Reviews – After the entrance conference, webinar audits will begin as listed in the fieldwork schedule. CMS uses secure webinar technology and audit staff will monitor the webinar room and expel anyone who is unknown to the audit team or sponsor. 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.

2.4 - 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. This audit usually occurs during the second week of fieldwork, or week 8 of the 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.

2.5 - 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 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.

2.6 - Exit Conference – The final day of fieldwork 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.

3. <u>Audit Reporting</u>

3.1 – 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 programmatic and audit policy for their respective program area 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 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.

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.

Once ICAR conditions are identified, the AIC will email the sponsor's Compliance Officer (or primary point of contact for the audit), informing the sponsor of the ICAR conditions and that immediate corrective action must be taken within 3 business days to stop or prevent the non-compliance from recurring.

3.2 - 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.

3.3 - 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 on the draft audit report. The final report contains the final audit score and classification of conditions noted during the audit.

3.4 - 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 Money Penalties, sanctions, or contract termination is warranted.

3.5 – 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.

4. <u>Audit Validation and Close Out</u>

4.1 - Submission of Corrective Action Plans (CAPs) – Due to the immediate nature of ICARs, CMS requires that sponsors submit CAPs and remediate any ICAR conditions within three business days from formal email notification. It is critical that sponsors take immediate action to stop or prevent the non-compliance from occurring within three business days even if the CAP may take many weeks (or months) to fully implement.

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 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 that sponsors demonstrate correction of conditions noted in the final audit report within 150 calendar days of CMS' acceptance of all CAPs. CMS may conduct the validation audit or CMS may require the sponsor to hire an independent auditor to conduct the validation audit. CMS informs sponsors whether an independent auditor is required in the Final Audit report. If the validation audit finds that significant audit conditions are still present (not corrected), another validation audit may be required.

4.3 - 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.