2020 Program Audit Process Overview

Medicare Parts C and D Oversight and Enforcement Group

Division of Audit Operations

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Table of Contents

I. Executive Summary – 2020 Audit Process Timeline

Phase I: Audit Engagement and Universe Submission

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

Phase II: Audit Field Work

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

Phase III: Audit Reporting

- ***Condition Classification and Audit Scoring*** – CMS classifiication of non-compliance and calculation of sponsoring organization's audit score
- ***Notification of Immediate Corrective Action Required (ICAR) conditions (as applicable)*** **–** CMS notification to sponsoring organization of any conditions requiring immediate corrective action; sponsoring organization ICAR Corrective Action Plan (CAP) submission within three business days
- ***Draft Audit Report Issuance*** **–** CMS issuance of draft audit report, inclusive of condition classification and audit score, to sponsoring organization approximately 60 calendar days after exit conference
- ***Draft Audit Report Response*** **–** Sponsoring organization submission of comments to draft audit report within 10 business days of draft audit report receipt
- ***Final Audit Report Issuance*** **–** CMS issuance of final audit report with CMS responses to sponsoring organization's comments and updated audit score (*if applicable*) approximately 10 business days after receipt of sponsoring organization's comments to draft audit report

Phase IV: Audit Validation and Close Out

- ***Non-ICAR CAP Submission*** **–** Sponsoring organization's submission of non-ICAR CAPs within 30 calendar days of final audit report issuance
- ***CAP Review and Acceptance*** **–** CMS performance of CAP reasonableness review and notification to sponsoring organization of acceptance or need for revision
- ***Validation Audit*** **–** Sponsoring organization demonstration of correction of audit conditions cited in the final audit report via validation audit within 180 calendar days of CAP acceptance
- ***Audit Close Out*** **–** CMS evaluation of the validation audit report to determine whether conditions have been substantially corrected and notification of next steps or audit closure

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)[1], collectively referred to as "sponsoring organizations," that participate in these programs. These program audits measure a sponsoring organization's compliance with the terms of its contract with CMS, in particular, the requirements associated with access to medical services, drugs, and other enrollee protections required by Medicare. On an annual basis, CMS solicits feedback on the audit process from industry stakeholders through a variety of mediums. CMS uses the feedback to update and improve audit operations as well as to explore new program areas that may require oversight.

This document outlines the program audit process for 2020. CMS will send engagement letters to initiate routine audits beginning March 2020 through July 2020. Engagement letters for ad hoc audits may be sent at any time throughout the year. The program areas for the 2020 audits include:

- CDAG: Part D Coverage Determinations, Appeals, and Grievances
- CPE: Compliance Program Effectiveness
- FA: Part D Formulary and Benefit Administration
- MMP- SARAG: Medicare-Medicaid Plan Service Authorization Requests, Appeals, and Grievances
- MMP- CCQIPE: Medicare-Medicaid Plan Care Coordination Quality Improvement Program Effectiveness
- ODAG: Part C Organization Determinations, Appeals, and Grievances
- SNP-MOC: Special Needs Plans – Model of Care

III. Summary of Audit Phases

The program audit consists of four phases:

I. Audit Engagement and Universe Submission
II. Audit Field Work
III. Audit Reporting
IV. Audit Validation and Close Out

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

[1] MOEG also oversees, coordinates, and conducts audits of Programs of All-Inclusive Care for the Elderly (PACE) Organizations. Information regarding PACE audits is posted on the CMS PACE Audits Website located at https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PACE_Audits.html

Phase I: Audit Engagement and Universe Submission

The Audit Engagement and Universe Submission phase is the six-week period prior to the field work portion of the audit. During this phase, a sponsoring organization is notified that it has been selected for a program audit and is required to submit the requested data, which is outlined in the respective Program Audit Data Request document. Key milestones within Phase I include:

Engagement Letter – The Auditor-in-Charge (AIC) conducts a courtesy call to the sponsoring organization's Medicare 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 the HPMS. Attached with the engagement letter is the Audit Submission Checklist[2], which identifies all universe requests and deliverables due to CMS prior to the start of audit field work. The review period for universe files is based on a sponsoring organization's total enrollment, as outlined in CMS's program audit protocols. However, CMS reserves the right to expand the review period to ensure sufficient universe size.

Engagement Letter Follow-Up Call – Within two business days of the date of the engagement letter, auditors conduct a follow-up call with the sponsoring organization. The purpose of this call is to provide an opportunity for the sponsoring organization 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.

Program Area Follow-Up Calls – Within five business days of the date of the engagement letter, CMS conducts universe follow-up calls for each audited program area. The purpose of these calls is to answer any questions the sponsoring organization may have regarding the universes and supplemental documentation files requested in the respective Program Audit Data Request documents.

Pre-Audit Issue Summary – Within five business days of the date of the engagement letter, the sponsoring organization is asked to provide a list of all disclosed issues of non-compliance that are relevant to the program areas being audited and may be detected during the audit. A disclosed issue is one that has been reported to CMS prior to the date of the audit engagement letter. Issues identified by CMS through on-going monitoring or other account management/oversight activities during the plan year are not considered disclosed. Sponsoring organizations should provide a description of each disclosed issue as well as the status of correction and remediation using the Pre-Audit Issue Summary (PAIS) template found in the HPMS. The sponsoring organization's Account Manager will review the PAIS to validate that disclosed issues were known to CMS prior to the date of the audit engagement letter.

Universe Submission – Within 15 business days of the date of the engagement letter, the sponsoring organization must submit all requested universes to CMS following the instructions in the engagement letter, Audit Submission Checklist and the respective program area Audit Process and Data Request.

Universe Assessment – In preparation for universe integrity testing, auditors conduct a universe assessment. This assessment is a desk review of the sponsoring organization's submitted universes and/or supplemental documentation for completeness, data formatting, and to understand how a sponsoring organization operates.

[2] A blank version of the Audit Submission 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.

Universe Integrity Testing – Within five business days of receipt of universes, and prior to the live portion of the audit, auditors will schedule a separate webinar with the sponsoring organization to verify that the dates and times provided in the CDAG, ODAG, and/or SARAG universe submissions used for calculating timeliness are accurate. The sponsoring organization should have available the information and documents necessary to demonstrate that the dates and times provided in the universes are accurate. CMS will review specific documents in the sponsoring organization's live system, or that of their delegated entities, during the webinar and may request that the sponsoring organization produce screenshots for additional review.

The integrity of the universe will be questioned if more than 1 of the 5 sample cases observed during the audit does not match the data provided in the universe. If this occurs, CMS may request a new universe to test timeliness for that universe. The resubmission request may occur before and/or after the entrance conference depending on when the issue is identified. Sponsoring organizations will have a maximum of three attempts to provide complete and accurate universes, whether these attempts all occur prior to the entrance conference or they include submissions prior to and after the entrance conference. However, three attempts may not always be feasible depending on when the data issues are identified, and the potential for impact to the audit schedule and/or integrity of the audit findings (*e.g. sponsoring organizations will not be allowed to resubmit universes after auditors have shared timeliness test results with the sponsoring organization*). When multiple attempts are made, CMS will only use the last universe submitted.

If the sponsoring organization fails to provide accurate and timely universe submissions twice, CMS will document this as an observation in the sponsoring organization's program audit report. After the third failed attempt, or when the sponsoring organization determines after fewer attempts that it is unable to provide an accurate universe within the timeframe specified during the audit, the sponsoring organization will be cited an Invalid Data Submission (IDS) condition relative to each element that cannot be tested, grouped by the type of case.

Audit Sample Selection – CMS selects targeted samples from the submitted universes to test during audit field work. Specific sample sizes vary by program area and element and are listed within the respective program area audit process and data request documents. If an IDS condition is cited for an element, auditors may still sample for other elements within the universe. While most samples are reviewed at a case level, other samples are reviewed using a tracer methodology. The tracer methodology, used in CPE, allows sponsoring organizations to tell the story of an issue or policy as it evolves over a period of time.

Coordination of Audit Field Work Schedule – The AIC coordinates with the sponsoring organization 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 sponsoring organization with the list of individual webinar sessions occurring each day to ensure the sponsoring organization 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 sponsoring organization's normal business hours, but may request alternative hours depending on the progress of audit field work.

Phase II: Audit Field Work

Program audit field work is conducted over a period of three weeks. Generally, audit field work is conducted via webinar with the exception of the CPE review, which occurs onsite during the last week of audit field work. Key milestones within Phase II include:

Notification of Sample Selection –In most program areas, CMS informs the sponsoring organization of the sample selections via the HPMS upload on the day the field work begins, approximately one hour before the start of the webinar. However, the audit team will provide sponsoring organizations with tracer sample selections two weeks prior to the entrance conference for CPE, and for SNP-MOC, samples will be provided on the Thursday before the entrance conference.

Entrance Conference – Audit field work begins with an entrance conference held on the morning of the first day of field work. The AIC leads the meeting, reviews the schedule, and discusses expectations for the week. The sponsoring organization 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 the first week, but may continue into the second week. During the webinar audits, the sponsoring organization is expected to present its supporting documentation while auditors evaluate sample cases live in the sponsoring organization's system(s) to determine whether the sample cases are compliant. For cases deemed pended or non-compliant, the sponsoring organization must take screen shots or otherwise upload the supporting documentation, as requested, to the HPMS using the designated naming convention and within the timeframe specified by auditors.

Root Cause Analysis Submissions – A root cause analysis must be submitted for any non-compliance identified during the audit, as requested by auditors. The sponsoring organization's root cause analysis must describe the issue identified and the methodology used to determine the root cause and full scope of the impact. Root cause analysis templates are due within two business days of the request and must be uploaded to the HPMS as instructed by CMS. CMS will review the submission and instruct the sponsoring organization on next steps for completing an impact analysis. NOTE: A root cause analysis may evolve as sponsoring organizations look further into issues and prepare their impact analyses (discussed below). Sponsoring organizations should provide updated root cause analyses, as necessary, to ensure the stated cause reflects the total impact identified.

Impact Analysis Submissions – Within 10 business days of the request, sponsoring organizations must upload the impact analysis to the HPMS as instructed by CMS. The impact analysis must identify all parties subjected to or impacted by the issue of non-compliance, including the sample cases cited as non-compliant during the audit. CMS may validate the accuracy of the impact analysis submission(s). In the event an impact analysis cannot be produced, CMS will report that the scope of the non-compliance could not be fully measured and impacted an unknown number of parties across all applicable contracts audited[3]. Auditors review the submitted impact analysis, in part, to quantify the effect of the cited non-compliance. The process for quantifying drug and/or enrollee impact for submitted impact analyses is detailed below:

[3] Alternatively, sponsoring organizations that are unable to quantify the exact or total impact by the requested due date may choose to estimate the impact (e.g., *at least 200 enrollees impacted*) by the requested due date, so long as the sponsoring organization (1) continues to quantify the non-compliance, and (2) provides CMS with an updated impact analysis with total impact at the time of its submission of comments to the draft audit report.

Single Impact Analysis:

Enrollees:

- Use Enrollee ID in the Member Impact tab of the submitted impact analysis. "Remove Duplicates" feature in Excel for the Enrollee ID column.
- Report the count of unique values that remain.

Medications:

- Use RxCUI in the Drug Impact tab of the submitted impact analysis. "Remove Duplicates" in Excel for the RxCUI column.
- Report the count of unique values that remain.

Multiple Impact Analyses:

Enrollees:

- Use approach above for "Enrollees" for each impact analysis. Add together the values from each impact analysis. **Note**: The same enrollee would be counted more than once if it appeared in multiple impact analyses.

Medications:

- Use approach above for "Medications" for each impact analysis. Add together the values from each impact analysis. **Note**: The same medication would be counted more than once if it appeared in multiple impact analyses.

Status Conference(s) – CMS conducts a status conference with the sponsoring organization at the end of each webinar week to discuss the status of supporting audit documentation requests (*e.g.* screenshots, root cause analysis, impact analysis, etc.) and the schedule for the onsite portion of the field work. The classification and scoring of audit conditions is determined after receipt and review of all audit documentation by auditors. This is discussed in more detail within the Audit Reporting section.

Onsite Compliance Program Effectiveness Audit – During the third week of field work, CPE auditors travel to the sponsoring organization's location to conduct the CPE portion of the audit. CPE auditors remain onsite for a period of four to five business days to evaluate sample cases and conduct interviews. To review tracer samples, auditors evaluate the sponsoring organization's comprehensive approach to addressing an identified issue or noted deficiency.

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 sponsoring organization, identifying all potential conditions and observations noted during the audit. The AIC issues this report via the 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). Auditors will walk through the preliminary draft audit report with the sponsoring organization and discuss any other outstanding requests for information. During the exit conference, the sponsoring organization may ask questions about the findings and provide any follow-up information as appropriate. Sponsoring organizations will have an opportunity to formally respond or provide comments for CMS consideration during the draft audit report process.

Phase III: Audit Reporting

Audit reporting occurs in multiple stages beginning at the conclusion of audit field work. As previously mentioned, auditors first share audit results with the sponsoring organization at the exit conference via the preliminary draft report. However, the findings in this preliminary draft report are subject to additional review and evaluation after all supporting documentation has been received and evaluated, at which point classification occurs. Key milestones within Phase III include:

Condition Classification and Audit Scoring – Upon receipt of all audit documentation, auditors 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, and ensure consistency in classification of audit conditions across all audits in accordance with the following definitions:

Immediate Corrective Action Required (ICAR) – If CMS identifies systemic deficiencies during an audit that are so severe that they require immediate correction, the sponsoring organization is cited an ICAR. Identified issues of this nature would be limited to situations where the condition resulted in an enrollee's lack of access to medications and/or services, or posed an immediate threat to an enrollee's health and safety[4]. The ICAR counts as two 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 sponsoring organization is cited a CAR. While these issues may affect enrollees, they are not of such a severe nature that enrollees' immediate health and safety is affected. Generally, CARs involve non-compliance with respect to non-existent or inadequate policies and procedures, systems, internal controls, training, operations, or staffing. The CAR counts as one 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 sponsoring organization is cited an observation. Observations do not count as points in the audit scoring methodology.

Invalid Data Submission (IDS) – CMS cites an IDS condition when the sponsoring organization 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 a sponsoring organization's coverage determinations (standard or expedited, pre-service, or payment) due to invalid data submission(s). The IDS condition counts as one point in the audit scoring methodology.

Once condition classification is complete, CMS will add the score for that audit element to the scores for the remainder of the audit elements in a given program area and then divide that number (i.e., total score) by the number of audit elements tested to determine the sponsoring organization's overall audit score. Some elements and program areas may not apply to certain sponsoring organizations and therefore will not be considered when calculating program area and overall audit scores.

Notification of Immediate Corrective Action Required (ICAR) Conditions – If ICAR conditions are identified, the sponsoring organization's Medicare Compliance Officer (or primary point of contact for

[4] If CMS determines that a disclosed issue was promptly identified, corrected (or is actively undergoing correction), and the risk to enrollees has been mitigated, CMS will not apply the ICAR condition classification to that condition.

the audit) will be notified and immediate corrective action must be taken to stop or prevent the non-compliance from recurring. Sponsoring organizations 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 Sponsoring Organization – 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 exit conference. The sponsoring organization 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 sponsoring organization submits in the HPMS and determines if the comments warrant a change in the final audit report.

Issuance of the Final Audit Report – CMS normally issues the final audit report within 10 business days from receipt of the sponsoring organization's comments to the draft audit report. The final audit report contains the final audit score and classification of conditions noted during the audit.

Audit Feedback – Following issuance of the final audit report, CMS will send sponsoring organizations a link to participate in an optional and anonymous feedback questionnaire. CMS uses feedback collected from the questionnaire to improve the program audit process.

Referral for Enforcement Action – Conditions noted in the audit may be referred to the Division of Compliance Enforcement (DCE) to determine if an enforcement action (Civil Money Penalty, sanction, or contract termination) is warranted. If an audit is referred to DCE, sponsoring organizations will be notified by a DCE Enforcement Lead.

Impact on Performance Measures – Non-compliance found during the audit may adversely affect CMS Part C and Part D 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 if the data set is deemed inaccurate or biased (per CMS Star Ratings regulation).

Phase IV: Audit Validation and Close Out

The final phase of the program audit process is the longest phase as it occurs over a period of approximately six months. In this phase, a sponsoring organization has an opportunity to demonstrate to CMS that it has corrected the non-compliance that was identified during the program audit. Key milestones within Phase IV include:

Submission of Non-ICAR Corrective Action Plans (CAPs) – Sponsoring organizations have 30 calendar days from the issuance of the final audit report to submit CAPs associated with non-ICAR conditions. Typically, observations do not require a CAP submission; however, CMS reserves the right to request CAPs for observations and will explicitly request them in the audit report when required. Upon receipt of the CAPs, CMS performs a reasonableness review and notifies the sponsoring organization 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 sponsoring organizations to demonstrate correction of all conditions cited in the final audit report by undergoing a validation audit. Conditions subject to validation audit include those which required a CAP. The validation audit is a limited-scope audit that tests only the conditions of non-compliance found during the initial program audit. For the validation audit, sponsoring organizations that received an IDS condition must produce the universes that auditors were unable to test

during the original audit to demonstrate their compliance with CMS requirements. Similar to the initial program audit, the validation audit is outcome focused and tests the compliance of actual transactions whenever possible. The validation audit does not measure or evaluate whether a CAP was fully implemented; it measures whether the CAP achieved its intended result by remediating the non-compliance.

Sponsoring organizations have 180 calendar days from the date that all CAPs are accepted by CMS to complete a validation audit and submit the validation audit report to CMS for review. To mark the beginning of this period, a CMS validation audit lead will contact the Medicare Compliance Officer to schedule a call to discuss this process in more detail. With the exception of the validation audit report due date, sponsoring organizations may determine the timing and scheduling of validation audit activities within that 180 day period. For example, if a sponsoring organization was able to quickly correct certain audit conditions, a sponsoring organization may choose to audit specific program areas and/or conditions earlier in the 180 day period than others. However, prior to conducting any validation audit work, the audit work plan must be reviewed and approved by CMS. Finally, sponsoring organizations may submit a request for extension of the 180 day deadline as needed and as early in the process as possible. Requests for an extension must be made in writing to the CMS validation audit lead. The written request for extension must include a new target due date and a justification for why the extension should be granted. CMS will consider these requests on a case-by-case basis.

Auditor Selection for Validation Audit – The validation audit must be conducted by CMS or by an independent auditor hired by the sponsoring organization, pursuant to 42 CFR §422.503(d)(2)(iv) and §423.504(d)(2)(iv). CMS will make this determination and clearly state whether CMS or an independent auditor will be conducting the validation audit in the final audit report. Generally, CMS requires the hiring of an independent auditor when there are more than five non-CPE conditions that must be tested during the validation audit. Once a sponsoring organization meets or exceeds the threshold and an independent audit is required, all findings *(including CPE conditions and any observations requiring a CAP*) identified during the program audit must be validated by the independent auditor. Likewise, if the sponsoring organization's audit results were below the threshold, CMS would conduct the validation of all findings.

When an independent auditor is required, the sponsoring organization is responsible for soliciting and hiring an independent audit organization that meets the following standards prior to entering into a contract with the firm to conduct the independent validation audit:

- Is not employed, represented or considered to be a first-tier, downstream or related entity by the sponsoring organization (the definitions of these terms are in the federal regulations at 42 CFR §422.500 and §423.501).
- Is free of conflict of interest. A conflict of interest occurs when a person or person's objectivity in performing the validation audit is compromised by their proximity or relationship to the immediate task, and can possibly give cause for influencing a decision. Here are two common examples of when a conflict of interest is and is not present:
    - Conflict of Interest: Consultants who provide management consulting to the sponsoring organization, assist the sponsoring organization with its audit-related operations, and/or assist with the correction of audit conditions.
    - No conflict of Interest: Consultants used to conduct mock audits, pre-assessments, or prior independent audits and have never provided consult or assistance with the correction of audit findings. For example, sponsoring organizations are not precluded from selecting the same independent auditing firm that conducts their annual external CPE audit, as long as the firm has not provided consulting services or assistance with the correction of audit findings.

- Has sufficient subject matter and clinical expertise in the Medicare Part C and Part D program areas that are included in the audit. Licensed pharmacists, physicians, or registered nurses may be required depending on the scope of the validation audit.

CMS does not provide independent auditor recommendations and does not have a list of pre-approved auditors for hire. CMS recommends that sponsoring organizations solicit proposals and select an independent auditor as early as possible to allow extra time for development and approval of the validation audit work plan. Also, sponsoring organizations will need to complete an attestation in the HPMS Audit Module that the selected audit organization is free of any conflicts of interest. Sponsoring organizations with specific questions as to whether a potential conflict of interest exists should contact their CMS validation lead for guidance.

Development and Submission of Validation Audit Work Plan – The development of a thorough and complete validation audit work plan is a critical step in the validation and close out process. Before any audit work is executed, the validation audit work plan must be reviewed and approved by CMS. If CMS is conducting the validation audit, CMS will design the audit work plan and inform the sponsoring organization about how the audit will be conducted and what information/universes will need to be submitted. Sponsoring organizations will be asked to provide input on the universe periods subject to review and the timing and execution of the field work.

When an independent auditor is conducting the validation audit, the independent audit organization must prepare an audit validation work plan with input from the sponsoring organization and/or the sponsoring organization's delegated entities, as applicable. Once the Independent Audit Validation Work Plan is complete, the sponsoring organization must submit it to CMS for review and approval. Usually a follow up call is required with the sponsoring organization, independent auditor, and CMS to answer questions about the work plan and to request modifications. It may take approximately three weeks to complete this process and approve a final work plan.

CMS recommends that auditors follow these basic principles when developing the audit work plan and conducting the audit:

- Use standard testing procedures that ensure the integrity and completeness of universes submitted by sponsoring organizations.
- Test actual transactions and compliance outcomes; do not test whether the CAP was fully implemented. If limited transactions are available, a CAP review may be done to supplement the audit.
- Evaluate timeliness processing conditions at the universe level; do not sample cases. Compliance with timeliness processing requirements must be assessed for all applicable cases within the universe.
- Align the duration of universe review periods with those requested in the initial CMS program audit, when feasible.
- Target samples related to the original root cause(s) of non-compliance. Look for similar reject message codes, drugs, service types, etc. A minimum of 10 samples must be selected for a single condition. If a minimum of 10 samples cannot be achieved, propose alternative approaches to evaluate the condition (e.g., extend period of review, run test claims).
- Request impact analyses for non-compliance found in sampled cases to get a better understanding of the root cause(s) and scope of the issue(s). Use CMS impact analysis templates, as needed, to collect information.
- Include a summary of any Medicare-related work previously performed for the sponsoring organization by the independent auditing firm to assist CMS in assessing potential conflicts of interest.

- Identify a minimum of two auditors per program area, including their credentials.
- Provide a copy of the proposed validation audit report template.

Conducting the Validation Audit & Delivery of Validation Audit Report – Auditors must conduct the validation audit in accordance with the approved work plan. If the audit team must deviate from the approved work plan, auditors must work with the Sponsor to contact the assigned CMS validation lead to discuss the recommended change and to obtain approval. If CMS is conducting the audit, the results of the audit will be reported in a letter from CMS. If an independent auditor is conducting the audit, the audit report must be submitted to the sponsoring organization. It is the sponsoring organization's responsibility to submit the final validation audit report to CMS, without modification, by the deadline. The sponsoring organization must copy the independent auditor on this submission in order to demonstrate completion of a complete and full independent review under 42 CFR §422.503(d)(2)(iv) and §423.504(d)(2)(iv).

CMS does not require the validation audit report in a particular format. However, at a minimum, the report must include:

- Independent auditing firm's identifying information;
- Objective, scope, and methodology of the validation audit;
- Summary of results (i.e., detailed outcome of transactions or sample cases tested for each condition), less any opinion about any individual audit condition's classification or correction;
- Description of criteria, cause, and effect of any non-compliance, as well as new issues of non-compliance (i.e., new conditions not previously cited in the initial audit report) found during the validation audit, including references to failed case samples, impact analyses, universe record layouts, and other information that support the non-compliance.

Validation audit reports submitted by independent auditors do not require an opinion by the auditor about whether any individual audit condition has been corrected. The report must focus on delivering the results of audit tests so that CMS can make an informed decision about whether audit conditions have been substantially corrected and the audit can be closed. Sponsoring organizations should also provide any additional information addressing any concerns with, or rebuttals to, the validation audit report when submitting the final validation audit report. After reviewing the validation audit report and any additional information provided by the sponsoring organization, CMS may request a follow-up call to discuss outstanding questions or request additional information from the independent auditor or the sponsoring organization.

Audit Close Out – CMS determines whether the audit can be closed based on the results in the validation audit report and any supplemental information provided by the sponsoring organization. Upon receipt of all information, CMS will determine if the validation audit demonstrates substantial correction of the conditions and whether the audit can be closed. CMS will communicate its decision in a letter sent to the sponsoring organization. The letter will also contain information about any uncorrected recurring conditions and/or new conditions that were found during the audit. If CMS determines that the audit can be closed, any isolated issues of non-compliance that remain will be referred to the CMS Account Manager for follow up with the sponsoring organization. If CMS determines that the audit conditions have not been substantially corrected, the audit will remain open and the sponsoring organization must submit new CAPs and undergo another validation audit for the remaining uncorrected conditions. In addition, any uncorrected conditions that require another validation audit may be referred to DCE to determine if an enforcement action is warranted.