2023 Program Audit Process Overview

Medicare Parts C and D Oversight and Enforcement Group

Division of Audit Operations

Updated November 2022

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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 2023. CMS will send engagement letters to initiate routine audits beginning February 2023 through July 2023. Engagement letters for ad hoc audits may be sent at any time throughout the year. The program areas for the 2023 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
- MMPCC: Medicare-Medicaid Plan Care Coordination
- ODAG: Part C Organization Determinations, Appeals, and Grievances
- SNPCC: Special Needs Plans Care Coordination

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 Protocol and 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 scope of each universe request is different for each program area. The CPE universe requests a list of all compliance oversight activities that occurred during the 26-week period preceding and including the date of the audit engagement letter. FA and CDAG universes are based on a Sponsoring organization's MAPD/PDP enrollment. ODAG universes are based on a Sponsoring organization's MA/MAPD enrollment. The SNPCC and MMPCC universes request all enrollees as of the date of the audit engagement letter. Finally, the MMP-SARAG universes are the 12-week period prior to and including the date of the engagement letter. CMS reserves the right to expand the review period to ensure sufficient universe size.

Engagement Letter Follow-Up Call – Within 2 business days of the date of the engagement letter, CMS conducts 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 5 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 data request and supplemental documentation files requested in the respective Program Audit Protocol and Data Request documents.

Pre-Audit Issue Summary – Within 5 business days of the date of the engagement letter, the Sponsoring organization is asked to provide a list of all disclosed issues of noncompliance that are relevant to the program areas being audited and may be detected during the audit. A disclosed issue is one that the Sponsoring organization 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 each respective program area Audit Protocol and Data Request document.

[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 Assessment – In preparation for universe integrity testing, CMS conducts a universe assessment. This assessment is a desk review of the Sponsoring organization's submitted universes and/or supplemental documentation to ensure completeness and acceptable data formatting, and to understand how a Sponsoring organization operates.

Universe Integrity Testing – Within 5 business days of receipt of universes, and prior to the live portion of the audit, CMS will schedule separate webinars, as needed, with the Sponsoring organization to verify that the data provided in the universe submissions is accurate for each program area being audited. The Sponsoring organization should have available the information and documents necessary to demonstrate that the data provided in the universes is accurate. CMS will review the Sponsoring organization's live system, or that of their delegated entities, to verify the data points in each universe during the webinar. CMS may request that the Sponsoring organization produce screenshots for additional review.

The integrity of the universe and/or supplemental documentation will be questioned if data points specific to the sample case(s) are incomplete, do not match, or cannot be verified by viewing the Sponsoring organization's systems and/or other supporting documentation. If this occurs, CMS may request the Sponsoring organization correct identified discrepancies and upload a new universe and/or supplemental documentation to the HPMS. Sponsoring organizations will have a maximum of 3 attempts to provide complete and accurate universes. These attempts may occur prior to or after the entrance conference, depending on when the issue is identified. However, 3 attempts may not always be feasible depending on when the data issues are identified and the impact that the universe resubmission request could have on the audit schedule and/or integrity of the audit findings (*e.g. Sponsoring organizations will not be allowed to resubmit universes after CMS has 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 Protocol and Data Request documents. When a Sponsoring organization is unable to provide accurate universes, CMS may still sample for other elements within the universe. While CMS reviews most samples at a case level, CPE samples are reviewed using a tracer methodology. The tracer methodology 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. The final audit field work schedule will be sent to the Sponsoring organization during the week prior to the entrance conference. The final schedule will include a 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 3 weeks. Generally, audit field work is conducted via webinar with the exception of the CPE review, which may occur 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 SNPCC, 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 CMS evaluates sample cases live in the Sponsoring organization's system(s) to determine whether the sample cases are compliant. For cases deemed pended or noncompliant, 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 CMS.

Root Cause Analysis Submissions – Sponsoring organizations must submit a root cause analysis for any noncompliance identified during the audit, as requested by CMS, using the root cause analysis template. Root cause analyses are due within 2 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. CMS may request that the Sponsoring organization revise and resubmit the root cause 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. CMS reserves the right to request a revised root cause analysis.

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 noncompliance from the date the impact analysis is requested through the start date of the universe period, including the sample cases cited as noncompliant during the audit. CMS may validate the accuracy of the impact analysis submission(s) and/or request that the Sponsoring organization revise and resubmit the impact analysis. In the event an impact analysis cannot be produced, CMS will report that the scope of the noncompliance could not be fully measured and impacted an unknown number of parties across all applicable contracts audited[3]. CMS reviews the submitted impact analysis, in part, to quantify the effect of the cited noncompliance.

[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 noncompliance, 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.

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 analyses, impact analyses, etc.) and the schedule for the upcoming portion of the field work. The classification and scoring of audit conditions is determined after receipt and review of all audit documentation by CMS. This is discussed in more detail within the Audit Reporting section.

(Onsite) Compliance Program Effectiveness Audit – In the third week of field work, CMS may travel to the Sponsoring organization's location for a period of 4 to 5 business days to conduct the CPE portion of the audit. Otherwise, field work will continue with webinars for the CPE portion of the audit. During this time, CMS evaluates the Sponsoring organization's comprehensive approach to addressing an identified issue or noted deficiency through tracer samples.

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 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 (generally conducted onsite if CMS travels for the CPE portion of the audit). CMS will present the preliminary draft audit report to 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 to, 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, CMS provides the Sponsoring organization the preliminary draft report at the exit conference. 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)** – Audit findings that inappropriately delay, restrict or limit an enrollee's access to required medications and/or services are classified as ICARs. Generally, these are significant findings that require immediate action to mitigate impact on enrollees. The ICAR counts as two points in the audit scoring methodology.

- **Corrective Action Required (CAR)** – Audit findings that do not have an immediate impact on the enrollee's ability to request or receive medications and/or services but are still significant are classified as CARs. The CAR counts as one point in the audit scoring methodology.

- **Observation Requiring Corrective Action (ORCA)** – Audit findings that are limited in scope, or otherwise mitigated, are classified as observations requiring corrective action. Generally, these findings are less significant but require attention to ensure any enrollee impact is resolved and/or to prevent further noncompliance. Observations requiring corrective action do not count as points in the audit scoring methodology.

- **Observation** – Audit findings that are insignificant are classified as observations. Generally, these findings represent an anomaly and do not require corrective action. Observations do not count as points in the audit scoring methodology.

- **Invalid Data Submission (IDS)** – Audit finding resulting from the failure to produce an accurate or complete universe within three attempts. The IDS counts as one point in the audit scoring methodology.

Once condition classification is complete, CMS will generate an overall audit score by totaling the points from each element and program area reviewed and then dividing the total points by the total number of audit elements tested. 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 Chief Executive Officer (or primary point of contact for the audit) will be notified and immediate corrective action must be taken to stop or prevent the noncompliance from recurring. Sponsoring organizations are required to submit Corrective Action Plans (CAPs) describing the actions taken to stop the noncompliance within 3 business days of being informed of the ICAR condition(s).

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 – Noncompliance found during the audit may adversely affect CMS Part C and Part D Star Ratings. If the audit finds that a particular issue of noncompliance 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 6 months. In this phase, a Sponsoring organization has an opportunity to demonstrate to CMS that it has corrected the noncompliance 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 (CARs and ORCAs). 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 that required a CAP. The validation audit is a limited-scope audit that tests only the conditions of noncompliance requiring correction 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 noncompliance.

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 5 non-CPE conditions (*ICAR, CAR, ORCA or IDS*) that must be tested during the validation audit[4]. Once a Sponsoring organization meets or exceeds the threshold and an independent audit is required, all findings *(including CPE conditions*) 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 some 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

[4] FA conditions classified as an ORCA are not included in the number of conditions that would require an independent auditor. All FA ORCAs will be addressed by the CMS Account Manager.

independent auditor as early as possible to allow extra time for development and approval of the validation audit work plan. In addition, 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 audit 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 utilize the CMS Independent Validation Audit Work Plan template 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 3 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 noncompliance. 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 noncompliance found in sampled cases to get a better understanding of the root cause(s) and scope of the issue(s). Use CMS root cause/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 2 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 Sponsoring organization to contact the assigned CMS validation audit 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 all 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 noncompliance, as well as new issues of noncompliance (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 noncompliance.

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 enough information about the samples or transactions tested and the results of audit tests so that CMS can make an informed decision about whether audit conditions have been 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 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 noncompliance 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 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.