Audit Validation and Close Out for CMS Program Audits
(Updated April 2, 2018)

I. Background

CMS conducts program audits of Medicare Advantage Organizations (MAOs), Prescription Drug Plans (PDPs), and Medicare-Medicaid Plans (MMPs), collectively referred to as "sponsoring organizations." 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 beneficiary protections required by Medicare. When non-compliance is found, an audit condition[i] is reported and sponsoring organizations are required to take corrective action to remediate the issue. The Audit Validation and Close Out phase of the audit ensures that all originally reported audit conditions have been substantially corrected. Therefore, CMS requires that sponsoring organizations undergo a "validation audit" to demonstrate correction of all reported audit conditions. CMS determines whether the audit can be closed based on the results of the validation audit and any supplemental information provided by the sponsoring organization.

This document outlines CMS's expectation during the Audit Validation and Close Out phase of the program audit.

II. Scope and Timing of the Validation Audit

The validation audit is a limited-scope audit that tests only the conditions of non-compliance found during the initial program audit. 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 Corrective Action Plan (CAP) was fully implemented; it measures whether the CAP achieved its intended result by remediating the non-compliance.

Sponsoring organizations subject to program audits in 2018 and beyond have 180[ii] 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.

Other than 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.

III.   Auditor Selection

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) and 423.504(d)(2). CMS will make this determination and clearly state whether CMS or an independent auditor will be conducting the validation audit in the CMS Final Audit Report. Generally, CMS requires the hiring of an independent auditor when there are more than 5 conditions that must be tested during the validation audit.

When an independent auditor is required, the sponsoring organization is responsible for soliciting and hiring an independent audit organization that is qualified to conduct the audit and is free of any conflicts of interest.

The sponsoring organization is responsible for ensuring the independent audit firm 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, 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 operational areas of Medicare Part C and Part D 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 if 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 individual guidance.

IV.   **Development and Submission of the 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 fieldwork.

When an independent auditor is conducting the validation audit, CMS expects the independent audit organization to develop the audit work plan with input from the sponsoring organization. The format and design of the work plan is at the discretion of the auditor, but it must deliver the following information and content in a succinct and easy to understand format:

- The name of the auditing organization, the names and qualifications of the auditors that will be conducting the validation audit, and what part (or program area) of the audit individuals will be auditing.
- A detailed timeline or schedule of all audit activities, including universe submissions, universe integrity testing, fieldwork, report submission, and any other key milestones in the audit process.
- A list of all audit conditions that are within scope of the validation audit.
- Descriptions of how each condition will tested. Include documents or universes that will be collected, universe integrity testing procedures, universe periods subject to review, contract numbers subject to review, sample selection methodology, number of samples to be selected, and compliance standards applicable to the samples selected.
- A general description of the audit report format and content that will be delivered.

In addition to this content, CMS recommends that auditors follow these basic principles when developing the audit work plan and conducting the audit:

- Utilize standard integrity 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.
- Universe review periods can vary, but should generally follow the lengths used in this initial CMS program audit. Since Compliance Program Effectiveness and Special Needs Plans – Model of Care universe periods are greater than 1 year, these universes must be shorter and should be determined based on the audit approach to testing the condition.
- When selecting samples, target samples that could be related to the original root cause of non-compliance. Look for similar reject message codes, drugs, service types, etc. A

minimum of ten samples must be selected for a single condition. If a minimum of ten samples cannot be achieved, propose alternative approaches to evaluating the condition (i.e. 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 and scope of the issue. Utilize CMS impact analysis templates as needed to collect information.

Once the validation audit work plan is complete, 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 two to three weeks to complete this process and for approval of a final work plan.

V.   Conducting the Audit and Delivery of the 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, CMS must be contacted and the change must be discussed and approved. 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 organizations responsibility to submit the final validation audit report to CMS by the deadline.

Similar to the audit work plan, CMS does not require the validation audit report in a particular template. However, the report must deliver the following information in a narrative form:

- The name of the auditing organization that conducted the audit.
- A list of all audit conditions that were tested during the audit.
- The outcome of the transactions or sample cases tested for each condition.
- A description of the criteria, cause and effect of any non-compliance found during the validation audit. This includes references to failed case samples, impact analyses, universe results, and other information that supports 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 may also provide any additional information they would like CMS to consider with the submission of the final validation audit report. Upon review of the validation audit report and any additional information, CMS may request a follow-up call to discuss outstanding questions or request additional information from the independent auditor or the sponsoring organization.

Upon receipt of all information and responses, CMS will make a determination about 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 audit 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 it is determined that the audit conditions have not be substantially corrected, the audit will remain open and the sponsoring organization must resubmit CAPs and undergo another validation audit for the remaining uncorrected conditions.

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[i] Conditions subject to validation audit include Immediate Correction Action Required (ICAR), Corrective Action Required (CAR), and Invalid Data Submission (IDS) CAR condition types.

[ii] Sponsoring organizations subject to program audits prior to 2018 have 150 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. Sponsoring organizations may submit extension requests to their CMS validation lead.