The Independent Auditor Process for Audits and Sanctions

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The Independent Auditor Process for Program Audits and Intermediate Sanctions

Roadmap

- Introduction
- Regulatory Authority
- Current Implementation
- Factors for Requiring an Independent Auditor
- Hiring an Independent Auditor
- Validation Audit: Work Plan Development & Approval Process
- CMS' Review of the Independent Auditor's Findings Report

Introduction

- One or more of the Sponsor's contracts has been audited by CMS
- The audit resulted in deficiencies that must be corrected, some of which may have become the basis for intermediate sanctions
- CMS may require the Sponsor to hire an Independent Auditor (IA) as part of the remediation process

Regulatory Authority

- CMS may require a Sponsor to hire an IA to determine if the deficiencies that were found during a program audit and/or were the basis for a sanction have been corrected and are not likely to recur
- Program Audits: *42 C.F.R. §§ 422.503(d) & 423.504(d)*
- Intermediate Sanctions: *§§ 422.756(c) & 423.756(c)*

What Does This Mean?

An Independent Auditor may be required as a result of:

- Conditions of non-compliance identified in a Sponsor's Program Audit Final Report
- The imposition of intermediate sanctions

Current Implementation

Program Audits

- In early 2016, the Medicare Parts C and D Oversight and Enforcement Group (MOEG) began implementing this authority with respect to program audits
- The Division of Audit Operations (DAO) in MOEG required 19 of 23 (83%) Sponsors to hire an IA to validate correction of deficiencies identified in 2015 program audits

Current Implementation (cont.)

Intermediate Sanctions

- In 2015 and early 2016, the Division of Compliance Enforcement (DCE) in MOEG imposed intermediate sanctions against 3 Sponsors, all of whom were required to hire an IA to conduct the validation audit
  - 2 stemmed from program audits conducted in 2015
  - 1 was based on a history of noncompliance for failing to correct deficiencies identified in a 2012 program audit, 2013 validation audit, and a 2015 program audit
- 2 are in the sanction monitoring phase and have not attested that all deficiencies have been corrected
- 1 has been released from sanction following submission and review of the IA Findings Report

Factors for Requiring an Independent Auditor

Program Audits

- Sponsors *may* be required to hire an IA
- A variety of factors are considered when deciding whether to invoke this authority, including, but not limited to:
  - The Sponsor's audit score
  - The number of universes and other data needed to validate correction of deficiencies
  - Whether an intermediate sanction was imposed as a result of the audit
  - Previous enforcement actions taken against the Sponsor for related issues

Factors for Requiring an Independent Auditor (cont.)

Intermediate Sanctions

- We will *most likely* require Sponsors under sanction to hire an IA if the sanction was the result of deficiencies uncovered during a program audit
- In this situation, the Sponsor will be required to hire an IA to validate both sanction-related and non-sanction related deficiencies

Hiring an Independent Auditor

- **CMS Requirements**
  - The IA must have subject matter expertise in the areas being audited
    - Things to Consider
      - Documented history of working in the areas of Parts C and D compliance
      - Understanding of industry best practices
      - Familiarity with how CMS conducts audits
      - Obtained certificates, degrees, specialized trainings, or other credentials demonstrating in-depth knowledge of Parts C and D requirements
  - The relationship between the Sponsor and the IA must be truly independent and free of conflicts of interest (actual or perceived)

Hiring an Independent Auditor (cont.)

Examples of Independent Relationships

- A consulting firm that has no prior experience with the Sponsor's Medicare/Medicaid lines of business, and the relationship is otherwise free of any financial, personal, or professional considerations which would compromise (or give the appearance of compromising) the objectivity of the validation process
- An external Quality Review Organization (EQROs) or quality improvement organization (QIO) that is contracted with a State Medicaid agency or the sponsoring organization to perform quality and other non-audit related activities
- A contractor *not affiliated* with the sponsoring organization who was hired in the past to perform a "pre-review," "mock audit," or "pre-assessment" of Sponsor's operations
  - Provided that the organization did not recommend corrective actions to take and/or assist in correcting operational problems through consult

Hiring an Independent Auditor (cont.)

Examples of Conflicts of Interest

- A consulting firm that previously assisted the Sponsor in creating systems, processes, policies, or procedures to operationalize Part C and Part D requirements
- A contractor who assists the Sponsor in preparing its Part C and Part D data for CMS reporting requirements
- Internal corporate audit team
- A contractor or consulting firm that assisted the Sponsor in developing corrective action plans to remediate deficiencies related to Part C and Part D requirements

Hiring an Independent Auditor (cont.)

- **CMS remains neutral in the hiring process**
  - Does not recommend IAs
  - Does not disclose which IAs have worked with Sponsors in the past
- Barring any conflicts of interest, Sponsors under sanction may use the same IA to validate correction of both sanction-related and non-sanction related deficiencies

Validation Audit: Work Plan Development & Approval Process

Program Audits

- **Scope**
  - Limited to those conditions identified in the Final Audit Report that do not result in an intermediate sanction
  - New issues that arise after issuance of the Final Audit Report through self-disclosure or monitoring efforts do not need to be included in the work plan

Validation Audit: Work Plan Development & Approval Process (cont.)

Intermediate Sanctions

- **Scope**
  - Limited to the conditions in the Final Audit Report which formed the basis for the intermediate sanction
  - New issues that arise after imposition of the sanction, but before the start of the validation audit, may or may not be required to be included in the work plan
    - New issue sufficiently relates to deficiencies that formed the basis for the sanction → include in work plan
    - New issue not related to deficiencies used to support the sanction → do not include in work plan; will be referred to the Regional Office Account Manager for monitoring

Validation Audit: Work Plan Development & Approval Process (cont.)

Tips for Developing a Work Plan Timeline

- Clearly identify each step in the work plan timeline
  - For example: hold entrance conference, submit universes, select samples, the IA will provide samples to Sponsor, conduct universe validation (ODAG/CDAG), conduct webinar reviews, draft the report, send final report to CMS
  - For each of the above tasks, identify the responsible party (Sponsor or IA), key due dates/timeframes, document date task has been completed, etc.

Validation Audit: Work Plan Development & Approval Process (cont.)

General Tips for Developing a Work Plan

- Describe how the integrity of the universes will be tested
- Determine which conditions require the use of samples to validate correction, and describe how those samples will be selected (e.g., random or targeted)
- Timeliness issues must be validated at the universe level
- CMS' Invalid Data Submission policy is not applicable in this process
  - Describe how universe submission issues will be handled
- Describe how each audit element will be tested
- Describe how it will be determined that policies and procedures are working as intended when sampling cannot be performed
- Identify how you plan to report the information in the final audit report (CMS' final audit report format may be used)

Validation Audit: Work Plan Development & Approval Process (cont.)

General Tips for Developing a Work Plan (continued)

- If an audit resulted in both non-sanction and sanction related deficiencies, the Sponsor may either:
  - Submit two separate work plans: (1) one that addresses the non-sanction related deficiencies and (2) another that deals with the sanction related deficiencies; or
  - Submit one work plan addressing both the non-sanction and sanction related deficiencies
    - If the Sponsor submits one work plan addressing both, it must clearly distinguish which conditions apply to non-sanction related deficiencies and which apply to sanction related deficiencies
- Sponsors may prioritize validation of sanction-related deficiencies over non-sanction related deficiencies or choose to perform both parts of the validation audit concurrently

Work Plan Development & Approval Process

- **Review and Approval**
  - DAO will review the work plan for the non-sanction related deficiencies, and DCE will review the work plan for the sanction related deficiencies
  - DAO/DCE may hold a call with the Sponsor & IA to discuss issues related to the work plan prior to the start of the validation
  - DAO/DCE will inform the Sponsor via email when the work plan has been approved
- Once the validation has begun, CMS may reach out to the Sponsor to ensure that the validation is on track and that the validation findings report will be submitted according to the agreed upon timeline

CMS' Review of the Independent Auditor's Findings Report

- **Program Audits & Intermediate Sanctions**
  - CMS reserves the right to determine whether deficiencies have been sufficiently corrected for purposes of closing a program audit or lifting a sanction when applicable
  - In making its determination, CMS evaluates the IA's Findings Report and any other supplemental information the Sponsor submits

CMS' Review of the Independent Auditor's Findings Report (cont.)

- **Program Audits**
  - **Validation Passes**
    - CMS will hold a call with Sponsor & IA (*if needed*) to address issues in the validation findings report
    - CMS will inform Sponsor via phone call once it deems deficiencies have been corrected and the audit will be closed
    - CMS will issue notice to the Sponsor indicating that the audit has been closed

CMS' Review of the Independent Auditor's Findings Report (cont.)

- **Program Audits**
  - **Validation Fails**
    - MOEG/DAO will:
      - Refer the Sponsor to MOEG/DCE for a possible enforcement action; and
      - Require the Sponsor to undergo another validation audit (re-validation)
    - The Sponsor may use the same IA for the re-validation, so long as their relationship remains free of conflicting interests. Alternatively, Sponsors may hire a different IA for the re-validation.

CMS' Review of the Independent Auditor's Findings Report (cont.)

- **Intermediate Sanctions**
  - **Validation Passes**
    - CMS will schedule a call with the Sponsor informing them that a determination has been made to lift the intermediate sanction
    - CMS will send an official notice of this determination to the Sponsor and post it to our public website
    - At this point, the Sponsor may begin to enroll and market to eligible Medicare beneficiaries if the sanction involved a suspension of marketing and enrollment activities
    - Monitoring activities will be transitioned back to the Regional Office Account Manager
    - CMS may continue to monitor the Sponsor post-sanction for certain unresolved issues (e.g., a ban on low-income subsidy auto-enrollments may continue post-sanction for a limited time)

CMS' Review of the Independent Auditor's Findings Report (cont.)

- **Intermediate Sanctions**
  - **Validation Fails**
    - Depending on the severity of the failures found during validation, CMS may either:
      - Impose an escalated enforcement action (e.g., contract termination) against the Sponsor; or
      - Require the Sponsor to undergo another validation audit (re-validation)
    - Sponsors required to undergo another validation:
      - Will remain under sanction until it can successfully pass a validation audit
      - May use the same IA for the re-validation or hire a different IA

Questions?

CMS Audit Mailbox

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The Independent Auditor Process for Audits and Sanctions

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Preparing for Successful CMS Medicare Part D Validation Audit

Overview of SilverScript

- SilverScript Insurance Company (SSIC) is a wholly owned subsidiary of CVS Health Corporation, which includes pharmacies, retail clinics, and PBMs
- SSIC has participated as a Med D Plan in the Medicare Part D Plan since 2006
- SSIC currently operates in all 50 states, including District of Columbia and Puerto Rico
- SSIC offers individual plans and EGWPs
- Today SSIC provides Medicare Part D coverage to more than 5.3 million beneficiaries
- SSIC is currently a 4 STAR Plan

Working With CMS During Program Audit and Independent Validation

- CMS conducted a standard Program Audit of SSIC in the Spring of 2015
  - Formulary
  - Transition Fill
  - CDAG-Timeliness
  - Compliance Program Effectiveness
- CMS issued the Final Audit Report in November 2015
- SSIC began the Independent Audit Validation Exercise in December 2015 and completed the validation process in February 2016
- CMS closed the 2015 Program Audit of SSIC March 23, 2016

Agenda and Objectives

- Objective: Selecting and working with Independent Auditors to assure a positive CMS validation audit outcome.
- Agenda
  - Overview
  - Selection of an Independent Audit Firm
  - Preparing for the Validation Exercise
  - Establish Overall Leadership and Teams
  - Communication Strategies
  - Lessons Learned

Selection of Independent Auditor

- CMS does not recommend IA firms – rather sets requirements
  - Independent, no conflict of interest, and subject matter expertise
- Plan sponsor and IA develop validation work plan – CMS approves
  - Communication is key to meeting CMS expectations
- Conducting the validation
  - Data integrity, unfettered access; if case failure, conduct BIA
- Reporting validation results
  - Plan sponsors review with IA, then submit to CMS
- CMS reviews and follow-up

Use Time Wisely during Audit to be Ready for Validation

- Establish an organizational structure (Validation Audit Task Force) with goals to:
  - Promote readiness for validation
  - Establish dedicated resources
  - Establish a process for mock validation exercises
  - Select IA firm
- Validation Audit Readiness Task Force *supports* business owners
  - Runs mock validation activities
  - Disciplined approach to test, triage, and prioritize activities and process
  - Helps ensure the right focus of subject matter experts and responsible leaders

Engage Subject Matter Experts – Establish Overall Leadership

- The SSIC Validation Audit Readiness Structure:
  - Executive Sponsor
  - Plan Chief Compliance Officer chairs Validation Readiness Task Force
  - Business Unit Leaders accountable for their activities
  - Validation Audit Command Center
- Med D Plan Chief Compliance Officer manages deliverables and publishes “Source of Truth” used to manage validation readiness and validation exercise
- Meet on regular basis to pulse check readiness and validation
  - Communicate with IA firm and CMS – keep all channels open

Communication Strategy

- Plan Sponsor Executive Leadership must be fully engaged and invested in the process
- Validation Audit Readiness Task Force: Drives situational awareness and communicates to Leadership
- Communication Best Practices:
  - Be inquisitive, seek clarity, leave no question unanswered
  - Corporate Governance – keep leaders informed and engaged
  - Engage all stakeholders: CMS, IA, Compliance, and Operational Teams

Best Practices during the Validation Audit Process

- Engage CMS Audit Team Leader and collaborate
- Work closely with your IA Firm
- Strategic use of external consulting can be very helpful
- Test rigorously ahead of IA validation exercise
- Operate with a sense of urgency – do not delay actions to remediate
- Communicate and collaborate

Thank You!

Questions?