A Compliance Officer's Guide to Successfully Navigating a 2024 CMS Program Audit

Compliance Program Effectiveness (CPE) Audit Experience and Lessons Learned during 2023 CMS Program Audits

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Agenda

Manic Monday

- Tips and Top Priorities to stay calm when selected for a program audit

Preparing for an Audit

- Highlighting CPE elements and successfully documenting FDR, Employee, and Board requirements

2023 CMS Program Audit Lessons Learned

- First-hand details to navigate the audit, tips for success and best practices

Questions

Program Audit 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) a.k.a. Sponsors
- Program audits are designed to measure a Sponsor's compliance with the terms of its contract with CMS, in particular, the requirements associated with access to medical services, drugs, and other beneficiary protections required by Medicare

Program Audit Areas

MAPD
(Medicare Advantage Prescription Drug Program)
and **PDP** (Prescription Drug Plan)

MMP
(Medicare-Medicaid Plan)

- Compliance Program Effectiveness (CPE)
- Formulary Administration (FA)
- Part D Coverage Determinations, Appeals and Grievances (CDAG)
- Part C Organization Determinations, Appeals and Grievances (ODAG)
- Special Needs Plan Care Coordination (SNPCC)
- Service Authorization Requests, Appeals and Grievances (SARAG)
- Care Coordination (MMPCC)

Cost of Non-Compliance in 2022

- Of the 26 sponsors subject to a program audit in 2022, 3 received a Civil Money Penalty (CMP). CMPs are calculated on a per-enrollee or pre-determination basis.
- CMP were based on the following 3 violations: 1) Inappropriate denials of Part D medications at the Point of Sale, 2) Inappropriate denials of Part D coverage determinations, 3) Failure to hold enrollees harmless for plan directed care
- CMS also imposed enforcement actions resulting from violations discovered through other audits and monitoring, including 3 CMPs totaling $197k for 6 violations.
- One sponsor received an enrollment suspension and mutually terminated their CMS contract in 2022
- CMS imposed aggravating factors on 6 of the 9 CMPs issued due to inappropriate denials of medical services or medications, enrollees incurring inappropriate out-of-pocket expenses, and enrollees who were delayed or denied drugs that are used to treat acute conditions that require immediate treatment
- CMS imposed 11 intermediate sanctions for financial solvency, Medical Loss Ratio (MLR) failures, and Dual-Eligible Special Needs Plans (DSNP) failures.

Types of Costs

There are four main types of costs associated with noncompliance:

1 **DIRECT**

- being required to pay a CMP;
- facing lost revenue because of a contract termination or decrease in Star ratings;
- and members leaving the plan

2 **INDIRECT**

- lost opportunity to grow membership during sanction because of the inability to market to/enroll new members;
- and members leaving the plan when they become aware of its issues of noncompliance.

3 **REPUTATIONAL**

- CMS awareness of the plan's issues of noncompliance;
- and broader public awareness of the plan's noncompliance when a plan is issued intermediate sanctions or CMS elects to terminate or not renew a plan's contract.

4 **LABOR**

- employee burnout and drop in moral; staff turnover;
- hiring and training additional employees or consultants to assist with plan remediating issues as well as all the additional reporting required by CMS.

Manic Monday

“What is it like when you receive your audit notice?”

We’ve got this!

~~Panic~~

~~Run!~~

Under Control

Audit Readiness is Key!

Top priorities when you receive your audit notice

- **Take a deep breathe - You've got this!**
- **Communicate to your CEO, Board, Employees and Key FDRs**
  - Ensure all potentially impacted areas are aware of the audit and timeline
  - Prepare communications ahead of time
- **Review documentation and universes**
  - Prepare questions for CMS Engagement Letter Call (2 business days) + Program Area Call (5 business days)
  - Pre-Audit Issue Summary (PAIS) and Supplemental Questionnaires – due in 5 business days
  - Are SNP and/or MMP Plans involved? → Special requirements
  - Data integrity review on all Universes
    - Resolve issues prior to uploading

Prepare for CMS Calls

- **CMS Engagement Letter Call**
  - 2 Business days after receiving engagement letter
  - Opportunity for Sponsor to ask questions and obtain clarification

- **Program Area Follow-Up Calls**
  - 5 Business days after receiving engagement letter
  - Universe follow-up calls with each audited program area
  - Opportunity for Sponsor to ask questions regarding data requests and supplemental documentation files

- **Pre-audit Issue Summary (PAIS)**
  - Due within 5 business days of the date of the engagement letter
  - Sponsor to provide a list of all issues of non-compliance relevant to the program areas being audited that Sponsor disclosed to CMS prior to the date of the audit engagement letter.

- **Supplemental Questionnaires (FA, SNPCC, MMPCC)**
  - Due within 5 business days of the date of the engagement letter

Prepare for CMS Meetings

Meet with all relevant Program Areas and FDRs to solicit questions and feedback

Compliance Oversight Activity (COA) Universe Development

- **Due 15 business from date of the engagement letter**
- **Follow the CMS CPE Audit Protocols + Review Thoroughly**
  - **Layout:** Deviations from the record layout will cause a universe rejection
    - Validate dates are in correct format
    - Ensure data entries are acceptable and follow the Description
  - **Timeframe**: 26 Week period preceding and including the date of the audit engagement letter
    - Ensure the Activity Start and Completion Dates reflect when the activity occurred, not the timeframe that was subject to the review
  - **Validate**:
    - Confirm COA universe contains all Oversight & FWA Activities outlined in monitoring & Auditing workplan
    - Validate entries are alignment with frequency
      - *Example: Ensure monthly items are listed monthly (6 times)*
    - Use consistent naming conventions
    - Confirm there are no blank fields

Tracer Development

CMS will select 6 Tracers from the COA Universe

- **Follow CMS Protocols for Tracer Development – (CPE Protocol, Page 17)**
- **Sponsors have flexibility in how they prepare Tracers, but must ensure Tracers contain all necessary information**

A. Oversight of the issue or activity

B. Compliance & business operations units involved

C. Detailed explanation of the issue / activity

D. Root Cause Analysis

E. Specific Actions Taken in response to the detected issue

F. Processes and Procedures that were revised due to the issue

Tracer Development (con't)

G. Steps taken to correct the issue at Sponsor and/or FDRs
   - Including a timeline of when issue was corrected or expected completion dates

H. How the Issue was Escalated
   - Senior Management, Compliance Committee, Governing Body, etc.

I. Relevant communications within Sponsor and with FDR(s) regarding issue

J. Each Prevention control and Safeguard Implemented

Be sure the Tracer contains all relevant information.
The CMS Auditor will use the Tracer to evaluate how well the Plan Detected, Corrected and Prevented non-compliance and/or FWA.

Tracer Best Practices

Effective Tracer presentations:

(1) Contain evidence and supporting materials, either through embedded documents or snips of documents,

(2) Tell the Story of how the sponsor detected, corrected and prevented non-compliance & FWA

Ensure all Relevant Parties participate in the Tracer Presentation to answer questions and provide clarity, when needed

Practice – Practice – Practice

Conduct mock Tracer presentations with all relevant parties. The most knowledgeable person may not always be the best presenter.

Be prepared to answer questions from CMS, especially related to the non-compliance, corrective actions and controls to prevent future reoccurrence.

Preparing for a CMS Audit

Audit Readiness

Sponsors can achieve a high level of audit readiness by

Implementing An Effective Compliance Program

Performing Mock Audits – Universes, Samples, Interviews & Tracers

Reviewing Prior CMS Audit Reports

CMS Compliance Program Requirements

- The Centers for Medicare & Medicaid Services (CMS) requires Sponsors to implement and maintain an effective compliance program for its Medicare plans
  - Medicare Managed Care Manual (MMCM) Chapter 21 - Compliance Program Guidelines
  - Prescription Drug Benefit Manual Chapter 9 - Compliance Program Guidelines

An effective compliance program must:

- ✓ Articulate and demonstrate an organization's commitment to legal and ethical conduct
- ✓ Provide guidance on how to handle compliance questions and concerns
- ✓ Provide guidance on how to identify and report compliance violations

What is an Effective Compliance Program?

- An effective compliance program encourages a culture of compliance within an organization and, at a minimum:
  - Prevents, detects, and corrects non-compliance
  - Is fully implemented and is tailored to an organization's unique operations and circumstances
  - Has adequate resources
  - Promotes the organization's Standards of Conduct
  - Establishes clear lines of communication for reporting non-compliance
- An ***effective compliance program is essential*** to prevent, detect, and correct Medicare non-compliance as well as fraud, waste, and abuse (FWA).
  - **It must, at a minimum, include the seven core compliance program requirements**
    - Sections 50.1 – 50.7 of Chapters 9 and 21 of the MMCM

Seven Core Compliance Program Requirements

1 **Written Standards of Conduct, Policies and Procedures**

These articulate the Sponsor's commitment to comply with all applicable Federal and State standards and describe compliance expectations according to the Standards of Conduct.

2 **Compliance Officer, Compliance Committee, and High-Level Oversight**

Sponsor must designate a compliance officer and compliance committee accountable and responsible for the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program. Senior management and governing body must be engaged and exercise reasonable oversight of the compliance program.

3 **Effective Training and Education**

Training that covers the elements of the compliance plan as well as preventing, detecting, and reporting Fraud, Waste, and Abuse (FWA). This requirement also includes training and education tailored to the different employees and their responsibilities and job functions.

Seven Core Compliance Program Requirements

4 Effective Lines of Communication

Make effective lines of communication accessible to all, ensure confidentiality, and provide methods for anonymous and good-faith compliance issue reporting at Sponsor and first-tier, downstream, and related entity (FDR) levels.

5 Well-Publicized Disciplinary Standards

Sponsor mush enforce standards through well-publicized disciplinary guidelines.

6 Effective System for Routine Monitoring, Auditing, and Identifying Compliance Risks

Conduct routine monitoring and auditing of Sponsor's and FDR's operations to evaluate compliance with CMS requirements as well as the overall effectiveness of the compliance program.

7 Procedures and System for Prompt Response to Compliance Issues

The Sponsor must use effective measures to respond promptly to non-compliance and undertake appropriate corrective action.

Policies and Procedures

- Sponsors must have policies and procedures that are detailed and specific, and describe operation of compliance program:
  - Compliance reporting structure
  - Training requirements
  - Reporting mechanisms
  - How investigations are conducted and issues resolved
  - Processes for Monitoring and Auditing
- Update annually and when changes to laws and requirements are enacted
- Should be easy to read and understand

General Compliance Training Topics

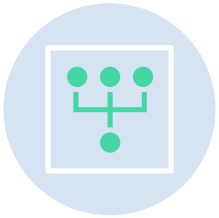
The following are examples of topics the general compliance training program should communicate:

- A description of the compliance program
- An overview of how to ask compliance questions, request compliance clarification or report suspected or detected noncompliance
- The requirement to report to the sponsor actual or suspected Medicare program noncompliance or potential FWA
- A review of the disciplinary guidelines for non-compliant or fraudulent behavior
- Attendance and participation in compliance and FWA training programs as a condition of continued employment and a criterion to be included in employee evaluations
- A review of policies related to contracting with the government
- A review of potential conflicts of interest and the sponsor's system for disclosure of conflicts of interest
- An overview of Health Insurance Portability and Accountability Act (HIPAA), Health Information Technology for Economic and Clinical Health (HITECH), and the CMS Data Use Agreement, if applicable
- An overview of the monitoring and auditing process
- A review of the laws that govern employee conduct in the Medicare program

Development of a System to Identify Compliance Risks

Sponsors must establish and implement policies and procedures to conduct a formal baseline assessment of compliance and FWA risk areas, such as through a risk assessment.

- Must account for all Medicare business operational areas and FDRs



Factors that sponsors may consider in determining the risks associated with each area include but are not limited to: Size of department; Complexity of work; Amount of training that has taken place; Past compliance issues; and Budget.

Risks identified by the risk assessment must be ranked to determine which risk areas will have the greatest impact on the sponsor, and the sponsor must prioritize the monitoring and auditing strategy accordingly.

Risk assessment results inform the development of the monitoring and auditing work plan

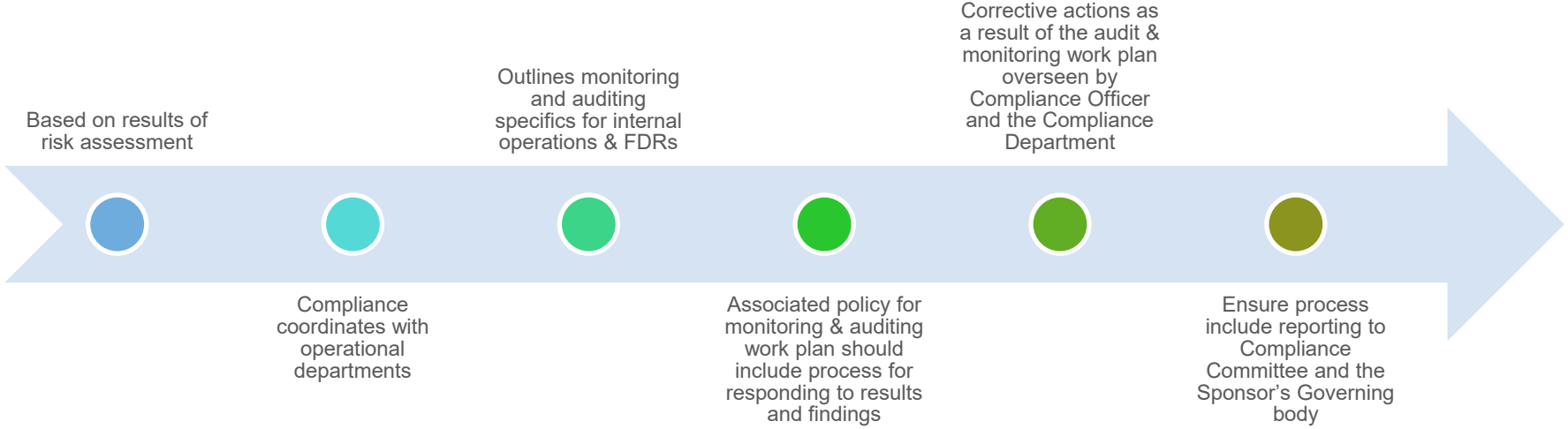
Routine Monitoring, Auditing, and Identification of Compliance Risks

- Sponsors must establish and implement an effective system for routine monitoring and identification of compliance risks:
  - Internal monitoring and audits
  - External audits, as appropriate
  - Monitor/audit sponsor and first tier, downstream, and related entities (FDRs)
  - Compliance with CMS requirements
  - Effectiveness of Compliance Program

Routine Monitoring and Auditing: Definitions

- Sponsors must undertake monitoring and auditing to test and confirm compliance with Medicare regulations, sub-regulatory guidance, contractual agreements, and all applicable Federal and State laws, as well as internal policies and procedures to protect against Medicare program noncompliance and potential FWA.
- Internal monitoring activities include regular reviews confirming ongoing compliance and taking effective corrective actions.
  - Routine Monitoring performed internally (each operational area) and by Compliance Dept.
- Internal auditing is a formal review of compliance with a particular set of standards (for example, policies, procedures, laws, and regulations) used as base measures.
  - Audit function may be a separate department or performed by the Compliance department
  - No self-policing by operational areas; must be independent
  - Must audit the effectiveness of the compliance program and share results with governing body

Development of the Monitoring & Auditing Workplan



Audit Schedule and Methodology

- The audit workplan must include a schedule that lists all auditing activities for calendar year
  - Operational areas and First Tier Entities
  - Combination of desk and on-site audits
  - Target samples and audit techniques that focus on risk

Prepare audit report with findings that includes the following:

Audit Report	
Audit Objectives	Scope & Methodology
Findings	Condition
Criteria	Cause
Effect	Recommendations

CMS Performance Audit Protocols and Best Practices and Common Findings can be used as a guide

Monitoring & Auditing of First Tier, Downstream, and Related Entities

- Sponsors are responsible for the lawful and compliant administration of the Medicare Parts C and D benefits under their contracts with CMS, regardless of whether the sponsor has delegated some of that responsibility to First Tier, Downstream, and Related Entities (FDRs)
- Sponsors must develop a system to monitor and audit first-tier entities
  - Must ensure first-tier entities fulfill compliance program requirements and that they apply compliance program requirements to and monitor compliance of downstream entities
  - Sponsors must have a Third-Party Marketing Organization (TPMO) Oversight Plan (Per 2024 Final Rule)
- When a Sponsor has a large number of first tier entities, making it impractical and/or cost prohibitive to monitor all its first tier entities, Sponsor may perform an FDR risk assessment to:
  - Identify highest risk first tier entities
  - Select a reasonable number of first tier entities annually from the highest risk groups
- When corrective action is needed, Sponsors must ensure corrective actions are taken by the entity

Mock Audits

- Sponsors can test audit readiness of internal operations and impacted FDRs through mock audits.
- A mock program audit helps plans prepare for an actual CMS audit by
  - Developing a process and cadence for formally responding to audits
  - Uncovering gaps in processes
  - Enhancing communication with FDRs
    - Including evaluating their ability to assist in audit activities, such as compiling universes with your Pharmacy Benefit Manager (PBM) and other key vendors
  - Populating member universes, which would be due 15 days after receiving an audit engagement letter
  - Validating member universes

Review Audit reports published by CMS

Sponsors can prepare for audits by reviewing prior year audit reports published by CMS, which include lessons learned and best practices.

From the 2022 audit cycle, CMS published the following CPE insights in July 2023:

Compliance issues were not quickly addressed and corrected

- Compliance procedures weren't explicit in instructing users when to initiate corrective actions in response to identified issues.
- Corrective action plans fell short of addressing the root cause of the noncompliance and, therefore, did not remediate the noncompliance as intended.

SPONSOR TIP: Sponsors can evaluate current work instructions for clarity, make necessary updates, and support their expectations around prevention, detection, and correction of noncompliance with supplemental training.

Systems for monitoring, auditing, and identifying compliance risks weren't comprehensive or current

- Sponsors may have established and implemented effective oversight within their own organizations but did not include monitoring and auditing of activities performed by their delegated entities.
- Sponsors did not align their oversight of Part B timeliness with updated CMS requirements; therefore, noncompliance was not detected.

SPONSOR TIP: Sponsors should ensure timely updates to their auditing and monitoring plans in accordance with updates to CMS regulations.

Employee and Board Requirements

Preparing for CMS' Review

CMS' approach has changed from Desk Level to a **Hybrid Audit**

- Provide evidence to CMS
- Demonstrate systems to CMS and answer questions

Employee & Board Training Records

- Be prepared to demonstrate your systems and training

First Tier Entity (FTE)

- Demonstrate your processes for providing FTEs with your organization's Code of Conduct and compliance policies

2023 CMS Program Audit Lessons Learned

Common CPE Audit Findings

- CMS CPE Findings and Focus Points
  - Heavy focus on Compliance knowledge of FDR and business / required metric monitoring
  - COA desk level reviews can result in CMS meetings and resubmission
  - Continued focus on oversight of delegated entities
  - ECT session variations, from fully offline review to online review with a complete walkthrough of training process and documentation – be prepared to show all systems!
  - CPE auditors continue to join other program area sessions

CPE Tracer Sample Detail

- Typically, CMS will select Tracer Samples covering the following topics:
  - ✓ PBM Oversight (and other FDRs depending on COA content)
  - ✓ Proper Call Classification Oversight and Contact Center Monitoring
  - ✓ Enrollment
  - ✓ COA items showing significant or numerous issues with various reporting
- Saw Provider Directory and CPE Annual Program Review as tracers this year
- Auditor will evaluate how the Plan detects, corrects, and prevents non-compliance and FWA

What can you do now to prepare for 2024's Audits?

- CMS focused and routine audits will be conducted January through July 2024
- Ensure new requirements related to coverage criteria and utilization management (UM) from the 2024 Final Rule are appropriately implemented
  - Will be included in both Routine and Focused CMS Audits
- Know your FDR list, assess risk and implement a monitoring plan.
  - Develop and implement a TPMO Oversight Plan (if applicable)
- Know what required metrics are monitored and ensure Compliance oversight
- Ensure your COA includes all oversight activities in your auditing and monitoring plans and can be produced for regular review

Prepare for 2024's Audits

- Update (and keep updated) – Governance Presentation and Questionnaires.
  - Be sure all content and responses align across documents, with the COA and with the Auditing & Monitoring plan.
- Ensure training records and Code of Conduct distribution documentation is maintained and easily accessible.
- Make sure minutes of key meetings (Compliance Committee, Board/Audit Committee, key Operational meetings that support compliance) are being maintained and easily accessible for audit purposes.
- Review any "email" record-keeping and transition to processes that are more easily accessed for audit purposes. Documentation is key!

CPE

On-Going Monthly Activities

- COA regularly updated, reviewed and ready
- Business metric monitoring documented and shared with Compliance
- Compliance and FWA training program at 100%

By December 31, 2023 (YE)

- FDR end of year attestations complete and recorded (if applicable)
- Risk Assessment Complete and FDR & Internal monitoring and audit schedule prepared

By March 31, 2024 (Q1)

- Governance presentation created, reviewed and ready
- Compliance Officer, FDR and SIU Questionnaires prepared
- Risk Assessment and Work Plans created prior to January 2024, approved and underway!

The Number 1 Tip for a Successful Audit: Have a Plan

Leadership

- One lead for each area
- One lead for the overall audit

Plan Ahead

- Outline Dates
- Define Roles
- Before and during audit
- Logistics/ Facilities

Communicate the Plan

- CEO to all employees
- Affected areas
- FDRs

Universes

- Validate – layout/technical, as well as data
- Ask questions

Pull Samples

- Review samples with live team and offline

Prepare Narratives

- Specific to known issues and in general
- Pull mock samples and have staff practice speaking to known issues

Helpful Audit Hints

- On-line systems will be needed for demonstration
  - Prepare well in advance of the audit
  - Test capabilities – make sure that all know what is being demonstrated and have a plan
    - Check for screen views – can all be seen?
    - Is WebEx (other systems) available for all involved?
  - Have Information Technology (IT) staff available to ensure systems are working
  - Driver: Make sure all applications NOT being used for audit are CLOSED (e.g., IM, email)
  - Do NOT use CMS IM chat on Webex
- During Audit:
  - DOCUMENT – Fill out worksheets, including completion of notes, criteria, cause and effect
  - Quickly tune-in to the auditor's desired response pattern
- Confirm Daily Request Log: Repeat to auditor, sign-off on uploads

Key Players

Primary Webinar Driver	
Primary Speaker (SME)	Can be the same as the driver, but not required
Screen Shots / Capture	Must be the same screens as showing within the audit
Action Item Owner	Someone not attending the audit that can immediately begin to follow up on any action items due at the end of the day or following day
Scribe / Note Taker	Track each of the samples, along with final disposition Track each action item, Root Cause Statements or Impact analyses requested

Audit Presentation Hints

- Turn off all pop-ups, IM, emails, and anything else that will be a distraction (Including a busy desktop)
- Signed into all applicable systems that will be used
- Identify yourself when speaking and project clearly and confidently
- When accessing any system for the first time, provide the auditor with a brief description of the application
- Do not perform any research on the screen with the auditors- pause the screen
- Everyone speaking should be near the phone, and support should be in the back of the room
- Do not speak or whisper at all in the background and mute unless speaking

Do’s and Don’ts During a Webinar

- Portray confidence
- Speak slowly, clearly and concisely
- Allow silence
- Use active listening
- Be courteous, cooperative and professional
- Ask questions about anything requiring clarification
- Answer only the questions asked by the auditors
- Address cases in chronological order
- Once an issue/error is identified, acknowledge it, take notes, and prepare to provide a root cause/impact analysis
- Be mindful of body language for audit fieldwork on-site

- Leave auditors on hold for a long time
- Provide any unnecessary, unrequested information
- Over-explain
- Appear defensive with the auditor
- Speak quickly
- Seem unprepared
- Answer questions if you are not sure
- Root cause on the fly
- Create excuses/make up possible reasons something occurred
- Use words of uncertainty (i.e., I believe, often, sometimes, frequently)
- Use acronyms

Thank you!

BluePeak ADVISORS

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