Procedure

DEPARTMENT: Compliance	
TITLE: Regulatory Compliance Auditing	**VERSION:** 1.0
APPROVED BY: Sandra Ferguson	**DATE:** 09/28/2021
DEPENDENCIES: *Routine Monitoring, Auditing, and Identifying Compliance Risks Policy; Response to Deficiencies*	

Contents

Purpose

The purpose of this policy is to demonstrate the process for identification, investigation, response, creating, and tracking Corrective Action Plans (CAPs) in response to known noncompliance or potential issues of non-compliance or suspected Fraud, Waste, and Abuse, and the development of action plans to remediate the issues.

Definitions, Abbreviations, and Acronyms

Acronym	Meaning
AAH	AllyAlign Health
CAP	Corrective Action Plan
CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
FDR	First Tier Entity, Downstream Entity, or Related Entity
FWA	Fraud, Waste and Abuse
PA	Perennial Advantage
RCA	Root Cause Analysis
SME	Subject Matter Expert

Procedure

1. Each year, the Medicare Compliance Officer, or designee, will create the annual Audit Work Plan for: 1) First Tier, Downstream and Related Entities (FDRs) for which Perennial Advantage Medicare Advantage (PA) has responsibility to perform direct oversight activities, including AllyAlign Health (AAH) and Navitus; and 2) Activities performed by Perennial Advantage.
    - Perennial Advantage will direct annual FDR Oversight Audit Work Plans for FDRs for which the Plan has responsibility to perform direct oversight activities, including the Pharmacy Benefit Manager and downstream entities to which the Plan has delegated core functions.
    - Those FDRs determined to be high risk will be scheduled for an annual oversight audit of all delegated core functions, including the FDR's compliance program.
    - Functional areas determined to be high risk will be audited based on the annual risk assessment.
    - For-Cause audits may be conducted and added to the Audit Work Plan should suspected compliance issues arise throughout the year, in response to reported issues or identified deficiencies that require a more comprehensive review to determine root cause or potential non-compliance or FWA.

2. Once the Audit Work Plans have been finalized, the Compliance Officer will present the Audit Work Plans to the Perennial Advantage Compliance Committee for review and approval.
3. The Compliance Officer, or designee, will direct or perform audits in accordance with the Audit Work Plan.
    a. The Compliance Officer, or designee, will utilize the appropriate audit tool(s) and resources for the particular audit being conducted as follows:
        - Current existing CMS audit tools, where available.
        - CMS Audit Protocols along with CMS Best Practices and Common Findings memos and Job Aids.
        - Previous CMS audit tools updated to reflect the current requirements.
        - Previously updated internal tools.
        - Creation of new tools when none of the above tools listed exist.
    b. The Compliance Officer, or designee, will gather universes and documentation as required for the audit. Where available and appropriate, the Compliance Officer will use available data and documentation sources to gather and/or verify information related to the audit.
        i. At the start of the audit, an audit engagement notice will be provided to the FDR/PA functional area contact. Audit engagement notices will include but are not limited to the scope of review, methodology, references to rules/regulations to be assessed, preliminary document request list and tentative audit milestones and deliverable dates.
            1. For FDRs, audit notification will be issued in accordance with requirements outlined in the contract or delegation agreement with the FDR or as agreed upon.
            2. If requested, the Compliance Officer, or designee, will work with the FDR/ PA functional area to schedule a pre-audit conference call to discuss the audit process, including, as applicable, the scope of the audit, universe and documentation requests.
        ii. If documentation is needed from the FDR/ PA functional area, the Compliance Officer, or designee, will include with the audit announcement document request(s) with expected due date(s).
            o Documentation requests may include, but are not limited to, policies and procedures, process documents, training materials, self-reports, universes, supporting documentation for sample selections, beneficiary impact analyses, documentation of quality activities related to delegated functions and documentation to demonstrate compliance with its contractual requirements and/or CMS and other applicable regulatory requirements.

- The Compliance Officer, or designee, will work with the designated FDR/ PA functional area contacts throughout the audit if additional documentation and/or clarification is needed.
- Generally, due dates for responses will be set as follows:
  - Universes – 10 calendar days from request.
  - Sample and/or Supporting Documentation – 10 calendar days from request.
  - Response to Questions and/or Additional Documentation requests during audit – 5 calendar days from request.
  - Due dates may be adjusted based on the nature and/or timing of the request.
  - The FDR/ PA functional area may also request adjustments to due dates prior to expiration of the response timeframe. The Compliance Officer will adjust due dates based on the reasonableness of the request.

c. Once the review is complete, the Compliance Officer, or designee, will complete an audit summary that outlines the scope, methodology and results of the audit.

i. Prior to finalizing the audit results, the Compliance Officer will provide a draft audit summary for review to the FDR/ PA functional area with a request to respond within 7 calendar days. The FDR/operational area is provided an opportunity to either concur, non-concur or discuss any of the potential deficiencies.

1. If further discussion is requested, the Compliance Officer, or designee, will work with the FDR/ PA functional area to schedule a meeting to review the audit outcomes.
2. If the FDR/ PA functional area does not concur with the audit findings, the FDR/ PA functional area will submit an explanation and/or additional documentation to support their position.
   a. The Compliance Officer, or designee, will review and respond to any non-concurrence and, if warranted, will adjust the audit summary as needed and forward the revised copy to the FDR/ PA functional area contact.
   b. If no response is received or the FDR/ PA functional area contact concurs with the results, the Compliance Officer, or designee, will finalize the audit summary as drafted.

ii. Once the audit results are finalized, the Compliance Officer, or designee, will send the final Audit Summary to the FDR/ PA functional area and request a root cause analysis be completed for any identified deficiencies as outlined in the *Response to Deficiencies* procedure.

4. Perennial Advantage will maintain documentation related to the audit.

- For Perennial Advantage audits, the Compliance Officer, or designee will maintain documentation in the Compliance Operations folder on the Plan SharePoint site.
- For oversight audits of FDRs, audit documentation will be stored and maintained in the appropriate FDR folder on the Plan SharePoint site.
  - The Compliance Officer, or designee, will upload documentation created and/or retrieved by Perennial Advantage Medicare Advantage, including, but not limited to, document requests, audit summaries, audit tools, universes, sample documentation and sample selections.

5. The Compliance Officer and team will report the results of auditing activities to the Perennial Advantage Compliance Committee and the Board of Directors. The Compliance Officer will include in the meeting materials the results of audits completed by the Compliance Officer or other functional areas when applicable.

Change Log

Document Version	Major or Minor Revision?	Date	Name	Comments
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