

# Mock Audit



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# Purpose

- To provide an extensive walkthrough of the audit process

# Overview

- Audit Conferences
- Audit Areas
  - Formulary Administration (FA)
  - Coverage Determinations Appeals & Grievances (CDAG)
  - Organization Determinations Appeals & Grievances (ODAG)
  - SNP – Model of Care (MOC)
  - Compliance Program Effectiveness (CPE)

# AUDIT CONFERENCES

# Audit Conferences

- Engagement Letter Follow-up Call
- Entrance Conference
- Pre-Exit Conference
- Exit Conference

# Engagement Letter Follow-up Call

- Topics
  - Engagement Letter discussion
  - Confirmation of necessary staff needed to complete audit
  - Universe request explanation
  - Discuss CMS' universe analysis

# Engagement Letter Follow-up Call (cont.)

- Topics (cont.)
  - Verify Sponsor will be able to show internal systems necessary for CMS to complete review
  - Self-disclosure explanation
  - EFT/HPMS
  - Webinars
  - FDR/PBM discussion
  - Logistical Items

# Entrance Conference

- Topics
  - Introductions
  - Overview of the Audit Process
  - Pass/Fail Transparency
  - Logistical Items
  - Sponsor Presentation (if applicable)



# Pre-Exit Conference

- The purpose of the pre-exit conference is to clearly identify each preliminary condition from week 1 of the audit.
- Sponsors will be provided with a list of the findings prior to the start of this conference.
- Immediate corrective actions and best practices are also identified during this conference.

# Exit Conference

- The purpose of the final exit conference is to clearly identify each preliminary condition from week 2 of the audit.
- Sponsors will be provided with a list of the findings prior to the start of this conference.

# Exit Conference (cont.)

- Updates on pending cases from week 1 are provided during this conference.
- Next steps regarding post audit activities are discussed.

# AUDIT AREAS

# **Formulary Administration (FA)**

# FA Webinars

- Formulary Administration
- Transition Review

# **FA Webinars:**

## **Formulary Administration**

- Samples uploaded 1 hour prior to Webinar
- Identify findings/conditions for each case
- Determine Observation, Corrective Action Required (CAR), or Immediate Corrective Action Required (ICAR)
- Clearly state reason for pending
- Sponsor uploads screenshots of all cases with findings/conditions

# **FA Webinars:**

## **Formulary Administration (cont.)**

- Order of Review
  - Verify beneficiary name, HICN, and DOB
  - Beneficiary eligibility information
  - Rejected claim in question: drug quantity, days supply, detailed rejection messaging
  - Look at beneficiary claim history to see if there are any paid claims for this drug



# **FA Webinars:**

## **Formulary Administration (cont.)**

Condition found in FA review:

- Failing to properly administer its CMS-approved formulary by applying unapproved quantity limits.

# FA Webinars:

## Transition Review

Condition found in Transition review:

- Failing to provide a new beneficiary a transition supply of a medication with a CMS-approved step therapy requirement.

# **Coverage Determinations Appeals & Grievances (CDAG)**

# CDAG Webinars

- Clinical Decision Making (CDM) Review
- Grievances Review

# **CDAG Webinars**

## **Clinical Decision Making Review**

- Order of Review
  - Beneficiary name and eligibility date
  - Request receipt date and time
  - Incoming fax
  - Call notes
  - Standard or Expedited notation

# **CDAG Webinars**

## **Clinical Decision Making Review (cont.)**

- Order of Review (cont.)
  - Request review process and case notes
  - Clinical reviewer title
  - Denial date and time
  - Denial letter sent to the Beneficiary

# **CDAG Webinars**

## **Clinical Decision Making Review (cont.)**

- Samples uploaded 1 hour prior to Webinar
- Identify findings/conditions for each case
- Determine Observation, CAR, or ICAR
- Clearly state reason for pending
- Sponsor uploads screenshots of all cases with findings/conditions

# **CDAG Webinars**

## **Clinical Decision Making Review (cont.)**

- **Conditions found in CDM review:**
  - Sponsor did not appropriately notify the beneficiary, or their prescriber, of its decision within 24 hours of receipt of the expedited coverage determination request, or, for an exceptions request, the physician's or other prescriber's supporting statement.
  - Sponsor did not appropriately auto-forward a coverage determination exceeding the CMS required timeframe to the IRE for review and disposition.



# **CDAG Webinars**

## **Clinical Decision Making Review (cont.)**

- Conditions found in CDM review (cont.):
  - Denial letters did not include an adequate rationale or contained incorrect information specific to the denial.
  - Sponsor failed to properly administer its CMS-approved formulary by applying unapproved utilization management practices.
  - Sponsor made an inappropriate denial when processing a coverage determination.

# **CDAG Webinars**

## **Grievances Review**

- Order of Review
  - Beneficiary's name
  - Receipt date of grievance
  - Letter for written requests
  - Call Note for verbal requests

# **CDAG Webinars**

## **Grievances Review (cont.)**

- Order of Review (cont.)
  - Processing
  - Related Coverage Determination
  - Resolution date and time
  - Resolution letter to Beneficiary

# **CDAG Webinars**

## **Grievances (GRV) Review**

- Conditions found in GRV review:
  - Sponsor failed to notify the beneficiary of the resolution of the GRV as expeditiously as the enrollee's case required (as the beneficiary was out of medication).

# **CDAG Webinars**

## **Grievances (GRV) Review (cont.)**

- Conditions found in GRV review (cont.):
  - Sponsor's quality of care grievance resolution letter failed to provide the beneficiary with written notice of their right to file with, and the contact information for, the QIO.
  - Sponsor did not take appropriate action, including appropriately addressing all issues raised in the grievance.

# **Organization Determinations Appeals & Grievances (ODAG)**

# ODAG Webinars

- Clinical Decision Making review
- Grievances Review

# ODAG Webinars

## Clinical Decision Making

- Order of Review
  - Beneficiary name and eligibility date
  - Receipt date of request
    - For written request – incoming fax
    - For oral request – call notes
  - Verify type of request
    - Standard or expedited notation
    - Claim payment or service request
    - Reconsideration or overturned reconsideration



# **ODAG Webinars**

## **Clinical Decision Making (cont.)**

- Order of Review (cont.)
  - Request review process and case notes
  - Denied date and time
  - Denial letter sent to beneficiary
  - Appointment of Representative (AOR), when applicable

# **ODAG Webinars**

## **Clinical Decision Making (cont.)**

- Samples uploaded 1 hour prior to Webinar
- Identify findings/conditions for each case
- Determine observation, CAR, or ICAR
- Clearly state reason for pending
- Sponsor uploads screenshots of all cases with findings/conditions

# **ODAG Webinars**

## **Clinical Decision Making (cont.)**

- **Conditions Cited in CDM Case Example:**
  - Sponsor failed to provide a written denial letter for a standard or expedited organization determination request.
  - When Sponsor denied a request for payment from a non-contracted provider, the remittance advice/notice did not state the specific reason for the denial nor did it provide a description of the appeals process.

# **ODAG Webinars**

## **Grievances Review**

- **Order of Review**
  - Beneficiary name and eligibility date
  - Receipt date of grievance
    - For written request – incoming fax/letter
    - For oral request – call notes
  - Identify beneficiary issue

# ODAG Webinars

## Grievances Review (cont.)

- **Order of Review (cont.)**
  - Does the grievance also involve:
    - An expedited request
    - Quality of Care concern
    - A request for an organization determination

# **ODAG Webinars**

## **Grievances Review (cont.)**

- **Order of Review (cont.)**
  - Request case notes to determine how the grievance was resolved
  - Date and time of grievance resolution letter
  - Appointment of Representative (AOR), when applicable

# **ODAG Grievance**

## **Example Resolution Summary**

Member had colon surgery, on his intestines and colon. However, he states while in the hospital, the nurses failed to keep the surgical site clean and as a result has suffered complications. He also stated he has a hernia and has to go back in for more surgery. He said the doctor did all he could and that it's not his fault, but the quality of care at the hospital after surgery was lacking.

# **ODAG Grievance**

## **Example Resolution Summary (cont.)**

Member stated he also had surgery for an obstruction but was still blocked after surgery. Member is concerned about hernia surgery. CSR assured member hernias are minor and common and then closed the grievance.



# ODAG Grievance

- **Conditions Cited in GRV Case Example**
  - Sponsor did not take appropriate action, including a full investigation, and/or appropriately addressing all issues raised in the grievance.
  - Sponsor did not respond to a quality of care grievance in writing as required. Sponsor failed to provide the beneficiary with written notice of their right to file with, and the contact information for, the QIO.

# **Special Needs Plan (SNP) – Model of Care (MOC)**

# SNP-MOC Webinars

- Enrollment Verification (EV) Review
- Health Risk Assessment (HRA), Inter-disciplinary Care Team (ICT) and Individualized Care Plan (ICP) Review

# SNP-MOC Webinars

## EV Review

- Samples uploaded Wednesday prior to Webinar
- Identify findings/conditions for each case
- Determine Observation, CAR, or ICAR
- Clearly state reason for “pending” status
- Sponsor uploads screenshots of all cases with findings/conditions

# SNP-MOC Webinars

## EV Review (cont.)

- Order of Review
  - Verify beneficiary name
  - Verify enrollment receipt date
  - Verify beneficiary's eligibility date
  - Verify beneficiary's enrollment date
  - A verification of the beneficiary's eligibility for SNP
  - Verify beneficiary eligibility is re-evaluated

# **SNP-MOC Webinars**

## **EV Review (cont.)**

- Sponsor did not re-verify the beneficiary's dual eligibility in a timely manner

# **SNP- MOC Webinar HRA/ICT/ICP Review**

- Order of Review
  - Verify beneficiary name
  - Verify beneficiary enrollment date
  - Verify date of initial health risk assessment
  - Verify completion of ICP

# **SNP- MOC Webinars HRA/ICT/ICP Review**

- **Conditions:**
  - Sponsor administered the initial health risk assessment to a beneficiary more than 90 days after their enrollment.
  - Sponsor did not include measurable outcomes to ICP.



# **Compliance Program Effectiveness (CPE)**

# **Compliance Program Effectiveness (CPE)**

## **Pre-Audit Activities**

- Perform CPE universe validation (i.e. ensure CPE team actually received what we asked for in universe request).
- Review Sponsor Self-Assessment Questionnaire (SAQ).

# **Compliance Program Effectiveness (CPE)**

## **Pre-Audit Activities (cont.)**

- Select samples and submit sample documentation request to sponsor the Thursday before week 1 of audit. Samples include:
  - A list of personnel to interview
  - Compliance Program policies and procedures
  - HPMS memos
  - Disciplinary actions taken

# **Compliance Program Effectiveness (CPE)**

## **Pre-Audit Activities (cont.)**

- Select samples and submit sample documentation request to sponsor the Thursday before week 1 of audit. Samples include:
  - Monitoring and auditing activities
  - First Tier Downstream and Related Entities (FDR) records
  - Incidents of non-compliance and Fraud Waste and Abuse (FWA)

# **Compliance Program Effectiveness (CPE)**

## **Pre-Audit Activities (cont.)**

- Submit documentation request for any documents not provided in universe as requested.
- Finalize interview schedule for the week 2 onsite activities.

# CPE Audit Team Activities

## Week 1

- Conduct desk review of sample documentation provided by sponsor.
- Review Daily Summaries from other audit program areas (e.g., CDAG, ODAG, etc.).
- Listen in on webinar sessions for other audit program areas.

# **CPE Audit Team Activities**

## **Week 1 (cont.)**

- Gather intelligence and identify areas of concern to focus on while on-site during week 2.
- Develop list of clarifying questions to ask Sponsor while on-site during week 2.

# CPE Audit Team Activities

## Week 2

- **Conduct on-site interviews:**
  - **CEO/Sr. Leader of Medicare C/D Plan** to determine how involved Sr. Management is engaged with the Medicare compliance program.
  - **Special Investigation Unit (SIU)/Fraud Waste & Abuse (FWA) Director** to learn how the sponsor conducts surveillance, interviews and other methods of investigation relating to potential FWA.



# CPE Audit Team Activities

## Week 2 (cont.)

- **Conduct on-site interviews:**
  - **Dir./Mgr. of Oversight for First-Tier, Downstream or Related Entities (FDRs)** to gain an understanding of the compliance program specific to FDR oversight.
  - **Employees involved with Medicare operations** to determine whether employees are knowledgeable about compliance program requirements.
  - **Governing Body Member** to gain an understanding of his/her knowledge of the effectiveness of the compliance program.

# CPE Audit Team Activities

## Week 2 (cont.)

- **Conduct on-site interviews:**
  - **Compliance Officer** to gain insight to his/her responsibilities as they relate to the compliance program:
    - Implementation of the Compliance Program
    - Compliance Program structure
    - Educational requirements
    - Reporting
    - Complaint Mechanisms
    - Response and correction procedures
    - Compliance expectations of personnel and FDRs
    - Monitoring and Auditing

# **Compliance Program Effectiveness (CPE) Audit - Week 2**

- Conduct two tracer sample sessions to determine whether the Sponsor's compliance program functions in a way that is effective in preventing, correcting and detecting Medicare program non-compliance and FWA.

# Compliance Program Effectiveness (CPE) Audit - Week 2 (cont.)

- In each session a selected operational issue is traced through the seven elements of an effective compliance program.
  - **Tracer Sample #1** – Issue from week 1 operational area audit in which sponsor is non-compliant. The issue may be relatively new.

# Compliance Program Effectiveness (CPE) Audit - Week 2 (cont.)

- **Tracer Sample #2** – Issue from the audit period which may be selected from a variety of sources including but not limited to:
  - Notices of Non-Compliance, Warning Letters, Issues identified by Account Manager etc.
  - Audit conducted by the Sponsor (or outside auditor) that yielded poor results
  - Operational areas experiencing high rate of beneficiary complaints relative to total number of beneficiary complaints.

# **Compliance Program Effectiveness (CPE) Audit - Week 2 (cont.)**

- Conduct On-site operational facility walk-through
  - Depending on the size of the organization typically lasts 30 to 45 min.
  - Observe the activities of Medicare operations.
  - Observe signage related to compliance information (i.e. compliance messages, compliance hotline, posters, information on personnel desks)

# **Compliance Program Effectiveness (CPE) Audit - Week 2 (cont.)**

- Conduct On-site operational facility walk-through (cont.)
  - Be cordial (i.e. introduce yourself) and ensure not to interrupt operations.
  - Observe personnel as they go about daily activities related to Medicare operations.

# **Sample CPE Audit Conditions**



# **Element I: Policies & Procedures and Standards of Conduct**

**Condition 1:** Sponsor did not provide evidence that general compliance information was communicated to its FDRs.

**SAQ Question: #66**

# Element I: Policies & Procedures and Standards of Conduct (cont.)

ATTACHMENT V  
MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS  
SELF-ASSESSMENT QUESTIONNAIRE

	<i>42 CFR §422.503(b)(4)(vi)(A) and 42 CFR §423.504(b)(4)(vi)(A)</i>				
	<u>Description</u>	<u>Yes</u>	<u>No</u>	<u>Documentation</u>	<u>Responsible Party or Department</u>
66.	Do you ensure that either your Standards of Conduct and Ps & Ps or comparable Standards of Conduct and Ps & Ps are distributed to FDR's employees within 90 days of hire / contracting and annually thereafter?	X		FDR Policy; contractual requirements	Compliance Department. Operational Department

# **Element I: Policies & Procedures and Standards of Conduct (cont.)**

- The Sponsor answered “yes” to the question; however, in reviewing supporting documentation and conducting the interview sessions with the Compliance Officer and FDR Oversight Manager, the audit team noted that there was no evidence demonstrating that the Standards of Conduct or Ps & Ps had been provided to the FDRs during the audit period.

# **Element VI: Monitoring and Auditing of FDRs**

**Condition 2:** Sponsor did not conduct monitoring of its FDRs to ensure that that they fulfill CMS compliance requirements.

**SAQ Question: #73**

# Element VI: Monitoring and Auditing of FDRs (cont.)

## ATTACHMENT V MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS SELF-ASSESSMENT QUESTIONNAIRE

<b>FDR Oversight</b>					
<b>Element VI: Monitoring and Auditing of FDRs</b>					
<i>42 CFR §422.503(b)(4)(vi)(F) and 42 CFR §423.504(b)(4)(vi)(F)</i>					
	Description	Yes	No	Documentation	Responsible Party or Department
A.	Ensuring that they are in compliance with Medicare Parts C and D requirements?	X		FDR Policy; Medicare Auditing and Monitoring Policy	Compliance Department
B.	Ensuring that they are monitoring their downstream entities?	X		FDR Policy; Medicare Auditing and Monitoring Policy	Compliance Department
73.	Do you monitor and audit your related entities?	X		FDR Policy; Medicare Auditing and Monitoring Policy	Compliance Department

## **Element VI: Monitoring and Auditing of FDRs (cont.)**

- The Sponsor answered “yes” to the question; however, in reviewing supporting documentation and conducting the interview session with the FDR Oversight Manager, the audit team noted that there was no documentation demonstrating that Sponsor had been auditing or monitoring related entities during the audit period.

# Summary

- Today we covered:
  - What to expect during the Audit Conferences
  - Audit steps for the following areas:
    - FA
    - CDAG
    - ODAG
    - SNP – MOC
    - CPE

# Questions?