

# Compliance Program Overview



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# **Compliance Program Effectiveness (CPE) Audits**

# Today's Topics

- Structure x Process x Outcomes
- 2016 CPE Audit Process
- Tracer Evaluation
- General Compliance & FWA Training for FDRs
- Frequently Asked Questions

# Structure x Process x Outcomes

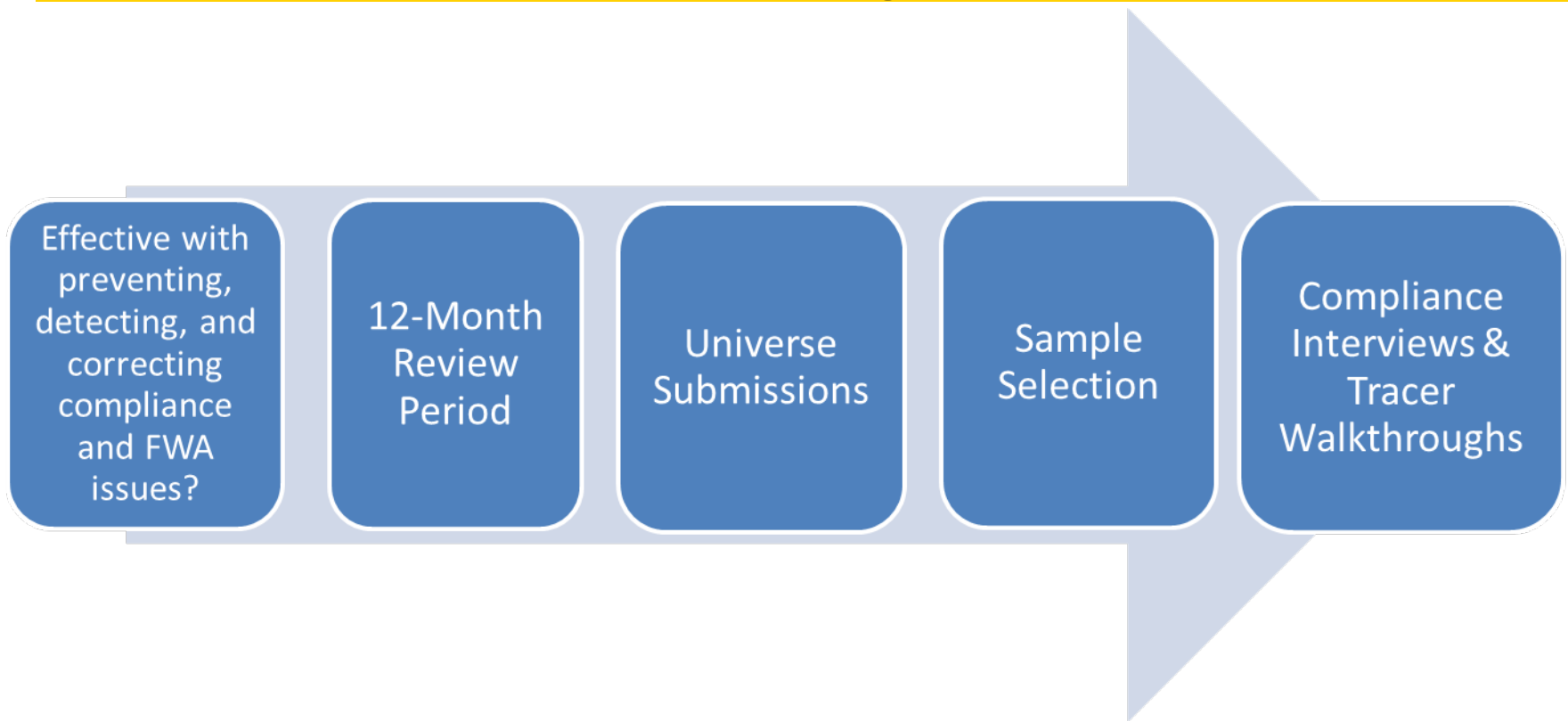
- **2010 to 2015: Structure and Process**
  - Do Medicare Advantage Organizations and Prescription Drug Plans have effective compliance programs in place?
  - Seven elements of a compliance program
  - Policies and procedures
  - Heavy documentation review

# Structure x Process x Outcomes (cont.)

- **2016: Outcomes**

- Prevent, detect, and correct controls
- Understanding the sponsor's organizational structure and risk management activities
- Business owners, FDRs, and compliance department communications
- Tracer approach for sample cases
- Streamlined documentation and discussions with compliance and operations
- Impact on Medicare beneficiaries' access to their health and drug benefits

# 2016 CPE Audit Process & Data Request



# Universes and Sample Selection



Conference call with sponsor prior to universe submission.

Once a sponsor submits universes to CMS, a completeness and accuracy check is performed.

CMS will select a sample of 6 cases from the universes to trace through the compliance program. Samples are provided to sponsor 4 business days prior to the start of Week 1.

Conference call with sponsor to review the sample selection and expectations for creating descriptive case summaries using the Tracer PPT template.

Completed Tracer PPTs and supporting documentation are due to CMS on the 1<sup>st</sup> day of Week 1.

# Week 2 – CPE Audit

- **Walkthrough of Sponsor's Infrastructure and Business Processes**
  - Organizational Structure and Governance PowerPoint Presentation
  - Overview of Compliance Program
  - Business and Compliance Relationships
  - Formal Risk Assessment Process & Monitoring/Audit Work Plans
- **Compliance Interviews**
  - Compliance Officer
  - FDR Oversight Manager(s)
  - FWA Operations – Special Investigation Unit



# Week 2 – CPE Audit (cont.)

- **Sample Case Reviews (Tracer Evaluation)**
  - 6 tracer samples
  - 1-2 hours for each sample case
  - All parties involved in the compliance activity participate in the tracer review
  - Live access and walkthrough of tracer sample case summaries and supporting documentation
  - A number of employees' names will be randomly selected from the universe to confirm receipt of required training and OIG/GSA exclusions checks

# Tracer Evaluation

- Tracer method is used to evaluate implementation of applicable compliance elements and determine whether the sponsor's compliance program, as a whole system, functions in a way that is effective to address compliance and FWA issues in a timely and well-documented manner.
- A sample of cases are selected from the CPE universes to trace the activity and sponsor's response to compliance issues.
- Examines the roles of business, delegated entities, compliance, and governance with preventing, detecting, and correcting significant issues of non-compliance and impact on access to health care for its Medicare members.
- Each sample case will not cover all elements of a compliance program.

# Tracer Evaluation (cont.)

- The CMS CPE Tracer PPT Template is a guide.
  - Do not copy & paste verbatim.
  - Do not provide “Yes or No” or duplicative responses.
- Create your own presentation using the most effective and efficient method to document the full story of how your organization identified, responded, and corrected issues of each sample case.
- In addition to using the CPE Tracer PPT as a resource, sponsors should apply a streamlined approach for documenting their actions and supporting documentation by using the following tracer case summary format.

# Tracer Evaluation (cont.)

- **Part I - Tracer Case Summary**

- Specify facts, rationale, and decisions and describe how suspected, detected, or reported compliance issues are investigated and resolved by the sponsor in chronological order
  - **Issue Overview**
    - Detailed explanation of the issue(s)
    - What was found?
    - When did the sponsor first learn about the issue?
    - Individuals and business functions involved in identifying, addressing, and resolving the issue
  - **Systems in Place Prior to Issue Occurrence**
    - Process controls
  - **Issue Identification**
    - Risk assessment
    - Monitoring/Auditing results
    - Root cause analysis

# Tracer Evaluation (cont.)

- **Part I - Tracer Case Summary**
  - **Issue Oversight, Communication, and Escalation**
    - Compliance department involvement
    - Oversight committees
    - Senior leadership and governing body
    - Communication with internal and external business process owners and FDRs
  - **Issue Remediation and Validation**
    - Specific actions taken in response to the detected issues
    - Processes and procedures affected and revised
    - Timeline of the corrective actions fully implemented or pending completion to correct issues at the sponsor or FDR levels
    - Assessment of member impact and necessary remediation
    - Validation efforts that issues no longer occur

# Tracer Evaluation (cont.)

- **Part II - Tracer Case Supporting Documentation**
  - CMS will review documentation in support of tracer summaries to determine if applicable audit elements were effectively met.
    - Evidence that compliance issues were communicated and escalated to the appropriate compliance personnel, senior management, and oversight entities
    - Evidence of communication to the affected or involved business areas regarding the compliance issues
    - Evidence of the monitoring/auditing activities that occurred as a result of the detected issues

# Tracer Evaluation (cont.)

- **Part II - Tracer Case Supporting Documentation**
  - CMS will review documentation in support of tracer summaries to determine if applicable audit elements were effectively met.
    - Evidence of appropriate accountability and oversight by the sponsor when issues are detected at the FDR level, including response and correction procedures, communication, educational requirements, and engagement with compliance department, operational areas, and any oversight entities
    - Evidence of the root cause analysis performed to determine why the issue occurred
    - Description of the beneficiary and/sponsor impact as a result of the detected compliance issues

# General Compliance & FWA Training Requirements for FDRs

- CMS is suspending review of the training certification element in the CPE program audit protocol (Element #3). Sponsors will not be required to provide the documentation requested in the 2015/2016 Part C and D CPE Audit Process and Data Request – *VII. Sponsor's Accountability for and Oversight of FDRs – Bullet #6*.
- Sponsors determine which of their vendors qualify as FDRs.
- Sponsors and/or FDRs will have three (3) options for ensuring FDRs have satisfied the general compliance training requirement.
- Sponsors should work with their FDRs to communicate and specify which positions within an FDR must complete the training. There will be certain FDRs where not every employee needs to take the training based on their duties.
- Focus on the critical roles within a FDR that are in a position to create significant non-compliance or fraud.



# Frequently Asked Questions

- CPE Universes (FTEAM, IA, IM, ECT, FWAM)
- Compliance Committee and Board of Directors Meeting Minutes and Reports
- Formal Risk Assessments
- Annual Audit of the Sponsor's Compliance Program Effectiveness
- CMS CPE Self-Assessment Questionnaire

# Questions

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