2017 Audit Protocol Updates

Compliance Protocol Changes

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Agenda

- The 2017 CPE audit process and significant changes
- Universe Submission and Record Layout Clarifications

Audit Purpose and Guidelines

Purpose

- To evaluate a sponsor's performance with adopting and implementing an effective compliance program to prevent, detect, and correct Medicare Parts C or D program non-compliance and fraud, waste and abuse (FWA) in a timely and well-documented manner

Audit Period

- 12 months preceding and including the date of the audit engagement letter

Sponsor Disclosed Issues

- For CPE, CMS wants a list of all disclosed issues relating to a sponsor's compliance program, not issues discovered during compliance activities (such as routine monitoring or auditing).
- Examples:
  - During the audit review period, the sponsor's SIU failed to comply with a number of requests for additional information from the MEDIC and enforcement agencies.
  - A number of employees and FDRs were not checked against the OIG and GSA exclusions databases during 2 months of the audit review period.
  - Resignation or Termination of the Medicare Compliance Officer during the audit review period.

Phase 1: Universe Submission Significant Changes

2017 CPE Audits

- Implementation, outcomes, remediation and effectiveness
- 3 audit elements
- 4 Compliance Questionnaires
- 4 Record Layouts
- Tracer Summary

2016 CPE Audits

- Compliance structure and processes
- 7 audit elements
- 3 Interview Guides
- 5 Record Layouts
- Tracer PPT template

Phase 1: Universe Submission

Documentation

- CPE documentation that describe the framework and operation of the sponsor's compliance program.
  - Attachments IA – IE
  - Compliance and FWA plans
  - Formal Risk Assessments
  - Auditing & Monitoring work plans
  - Code of Conduct

Data Universes

- Data universes support the implementation of compliance activities conducted within the audit period.
  - First-Tier Entity Monitoring & Auditing (FTEAM)
  - Employees and Compliance Team (ECT)
  - Internal Auditing (IA)
  - Internal Monitoring (IM)

Phase 1: Universe Submission (cont.)

- Completed CPE Self-Assessment Questionnaire (Attachment I-A)
- Completed Compliance Officer Questionnaire (Attachment I-B)
- Customized Organizational Structure and Governance PowerPoint Presentation (Attachment I-C)
- Completed First-Tier Downstream and Related Entities (FDR) Operations Questionnaire (Attachment I-D)
- Completed Special Investigation Unit (SIU)/FWA Prevention and Detection Questionnaire (Attachment I-E)
- Standards of Conduct/Code of Conduct document (distributed to employees and FDRs during the audit review period)
- Corporate Compliance/Medicare Compliance/FWA Plan (or similar document in effect during the audit review period)
- Formal Risk Assessments and Compliance Performance Mechanisms that show the extent to which Medicare Parts C and/or D operational areas and FWA risks were identified and compliance goals were monitored during the audit review period
- Audit and Monitoring Work Plans (for internal operations and FDRs, in effect at any time during the audit review period)

Phase 1: Tracer Evaluation Significant Changes

2017 CPE Audits

- Universes Follow Up Call – Occurs within 5 business days of the engagement letter to discuss CPE universes
- Tracer samples provided to sponsor 2 weeks prior to entrance conference
- 6 tracer samples: 2 FTEAM, 2 IA, 2 IM
- Tracer Sample Follow Up Call – Occurs within 1 hour of providing the tracer sample cases to the Sponsor
- ECT Sample Selection: 20 employees provided to sponsor on first day of onsite phase

2016 CPE Audits

- Universes Follow Up Call - Optional call with sponsor to discuss CPE universes
- Tracer samples provided to sponsor 4 business days prior to entrance conference
- 6 tracer samples: 2 FTEAM, 1 IA, 1 IM, 2 FWAM
- Tracer Sample Follow Up Call – no defined timeframe for scheduling a call with Sponsor to discuss sample selection
- ECT Sample Selection: 5 employees provided to sponsor on first day of onsite phase

Phase 2: Onsite Audit of CPE Significant Changes

New for 2017 CPE Audits

- Week 2 schedule
- Day 1 – Required Operations Walkthrough/ Discussion (Infrastructure and Processes) with sponsor
- Day 1 – Compliance Interviews (CO, FDR, FWA)
- Day 2 – Employee and Compliance Team (ECT) Sample Reviews
- Day 2 -5 – Tracer Case Summary Reviews

2016 CPE Audits

- No required overview or walkthrough of the sponsor's compliance program structure and processes
- Compliance interviews and samples were scheduled throughout the duration of the onsite audit, little to no consistency across audits

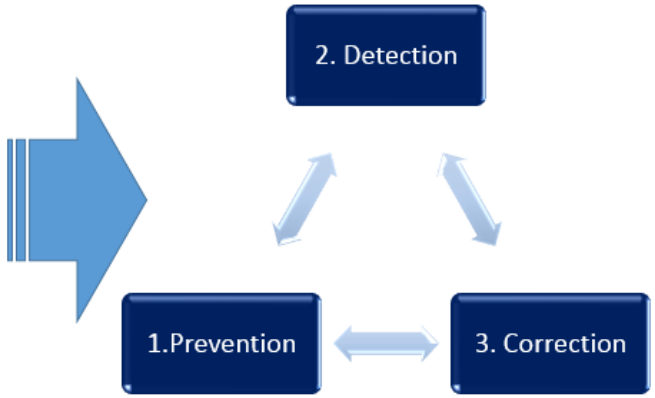
Audit Elements – Significant Changes

7 Audit Elements vs. 3 Audit Elements

Seven Elements of an Effective Compliance Program

- Standards of Conduct/ Policies and Procedures
- Compliance Officer/ Compliance Committee/Senior Management/Governing Body
- Education/ Training
- Lines Of Communication/Reporting
- Well Publicized Disciplinary Standards/Enforcement
- Risk Assessment/ Auditing & Monitoring/FDR Oversight
- Timely Response to Issues Of Non-Compliance & FWA

Three Elements of an Effective Compliance Program



Audit Elements – Significant Changes

I. Prevention Controls & Activities

Compliance Standards

- Standards of Conduct and Policies and Procedures
- Compliance Officer/ Compliance Committee
- Senior Leadership and Governing Body
- Compliance Issue Reporting Structure
- Training and Education
- Monitoring for Non-Compliance and FWA Prevention

Evaluates effectives of internal controls in place to reduce the potential for non-compliance issues.

Audit Elements – Significant Changes

II. Detection Controls & Activities

Compliance Standards

- System in place for reporting compliance concerns
- Risk Assessments performed
- Internal Auditing / Monitoring
- OIG/GSA Exclusion Checks
- Monitoring for FWA Detection
- Auditing/ Monitoring of FDRs
- Effective Communication

Evaluates effectiveness of internal controls in detecting non-compliance issues and activities.

Audit Elements – Significant Changes
III. Correction Controls & Activities

Compliance Standards

- Reasonable Corrective Action Taken In a Timely Manner
- Corrective Actions for Detected FDR Issues Implemented In a Timely Manner

Evaluates effectiveness of processes to respond to compliance issues that have been identified.

Universe Submissions and Record Layouts

CPE Record Layouts

Table 1: First-Tier Entity Auditing and Monoitoring (FTEAM)
Table 2: Employees and Compliance Team (ECT)
Table 3: Internal Auditing (IA)
Table 4: Internal Monitoring (IM)

CPE Record Layout Table 1

Field Name/Description:

"Component"

Clarifying Guidance:

Provide the name of the internal department that performed the auditing or monitoring activity for the first-tier entity. Please be consistent in the name of component to aid in filtering (e.g. A/B vs. Agent Broker vs. Agent/Broker).

CPE Record Layout Tables 1, 3 & 4

Field Name/Description:

“Compliance or FWA”

Clarifying Guidance:

In situations where the activity can be compliance and FWA related, please respond by choosing the better of the 2 options. During the universe validation process, you will have an opportunity to discuss and resolve any issues or questions with the CMS Audit Team.

CPE Record Layout Table 1 (cont.)

Field Name/Description:

“Activity Frequency”

Clarifying Guidance:

Do not include daily activities, but rather roll them up into an aggregate time period such as weekly or monthly.

CPE Record Layout Table 1 (cont.)

Field Name/Description:

"Description of Deficiencies"

Clarifying Guidance:

When completing the description of deficiencies, list them out in a 1:1 correlation. For example, in column M (as in Mike), if you have indicated there were 5 deficiencies, please list each deficiency separately. For example, deficiency 1 was _____; deficiency 2 was _____; and so on.

CPE Record Layout Table 1 (cont.)

Field Name/Description:

“Corrective Action Description”

Clarifying Guidance:

Provide a summary of the corrective action(s) implemented by the sponsor and FTE in response to the noncompliance or potential FWA, including any root cause, timeframes for specific achievements, and any ramifications for failing to implement the corrective action satisfactorily.

CPE Record Layout Table 1 (cont.)

Field Name/Description:

"Corrective Action Description"

Clarifying Guidance:

For an audit or monitoring activity that identified multiple issues, separate the corrective actions implemented for each issue by a number as needed.

1. Employee coaching was completed between 2017/02/01 and 2017/02/15 for the errors identified during the 2017/01/01 pharmacy mail order monitoring activity, 2. Member remediation was conducted for 50 members that never received their approved medication.

Answer TBD if corrective measures have yet to be determine for an ongoing activity. Answer N/A if corrective action was not taken or determined unnecessary by the sponsor for any of the identified issues.

CPE Record Layout Table 2

Field Name/Description:

- “Employee’s Organizational Component”
- “Physical Location”
- “Medicare Compliance Department Employee?”
- “Compliance Committee Member’s Role”

Clarifying Guidance:

Indicate NA if the individual is a governing body member and the field is not applicable.

CPE Record Layout Table 2 (cont.)

Field Name/Description:

- “Medicare Compliance Department Employee?”
- “Compliance Department Job Description”

Clarifying Guidance:

Indicate if the individual named in the universe is an employee of the Medicare Compliance Department. If they are, please indicate their job title under “Compliance Department Job Description.”

CPE Record Layout Table 2 (cont.)

Field Name/Description:

- “Compliance Committee Member?”
- “Compliance Committee Member’s Role”

Clarifying Guidance:

Indicate if the individual named in the universe is an employee of the Medicare Compliance Department. If they are, please indicate their job title under “Compliance Department Job Description.”

CPE Record Layout Tables 3 & 4

Field Name/Description:

“Component”

Clarifying Guidance:

Provide the name of the internal business unit who conducted the audit or monitoring activity.

CPE Record Layout Tables 3 & 4 (cont.)

Field Name/Description:

- "Auditor Type"
- "Monitor Type"

Clarifying Guidance:

Provide the name/position of the individual who conducted the audit or monitoring activity. If it was an external auditor, please state "external auditor." If it was an internal individual, name the individual and his/her position.

Contact Us

- **Audit Mailbox:** part_c_part_d_audit@cms.hhs.gov
- **CPE Policy Mailbox:** parts_c_and_d_cp_guidelines@cms.hhs.gov
- **Part C and Part D Compliance and Audits Website:** https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/index.html

2017 Audit Protocol Updates

MMP Audits and Coordination

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Agenda

- Background on the Financial Alignment Initiative
- MMPs and the 2016 Medicare Program Audits
- 2017 MMP Audit Protocols
  - Release of Final Protocols
  - Protocol Highlights
  - Audit Process
  - Program Areas (Elements, Universes)

Financial Alignment Initiative

Background:

- A longstanding barrier to coordinating care for Medicare-Medicaid enrollees is the financial misalignment between Medicare and Medicaid.
- In 2011, CMS announced new models to integrate the service delivery and financing of both Medicare and Medicaid through federal-state demonstrations to better serve the population.

Goal:

- Increase access to quality, seamlessly integrated services for Medicare-Medicaid enrollees

Financial Alignment Initiative (cont.)

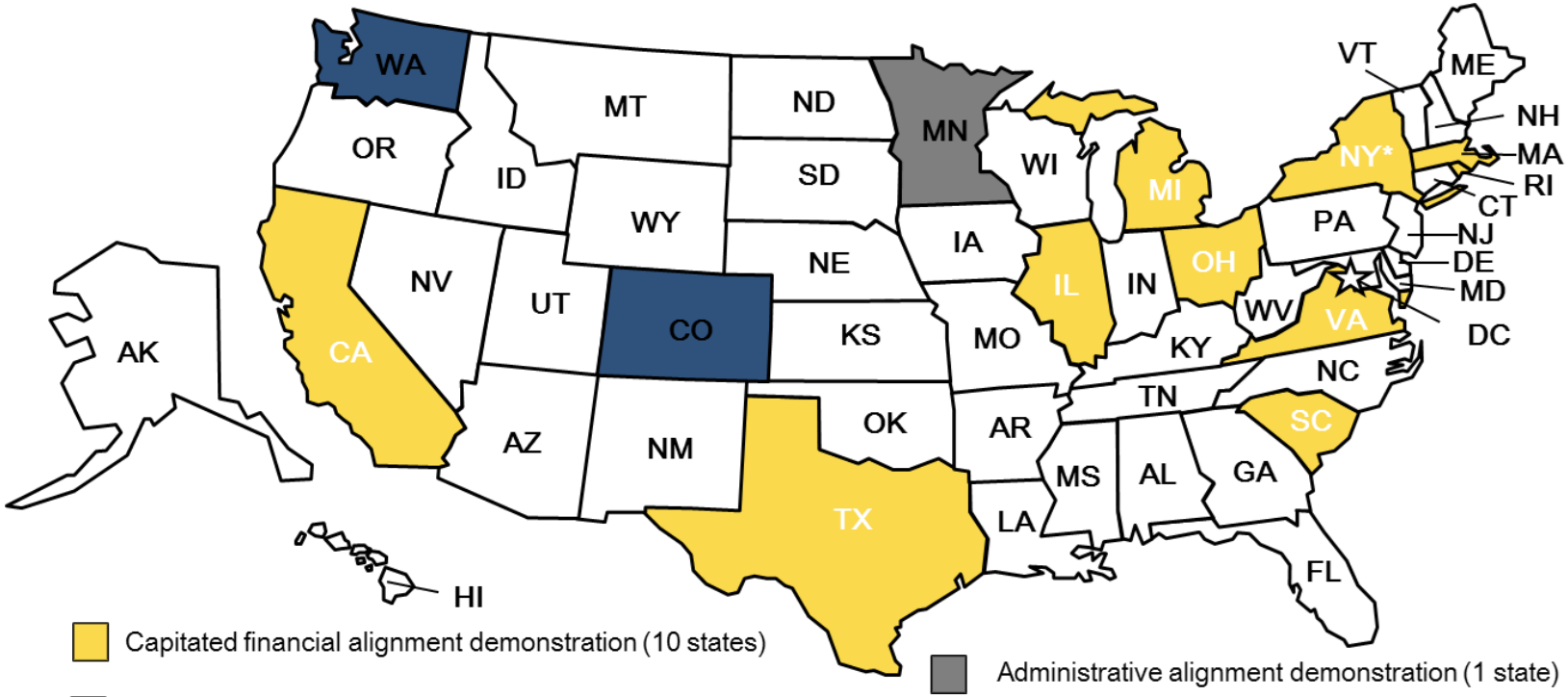
FAI Demonstration Models:

- **Capitated Model:** Three-way contracts among states, CMS, and health plans to provide comprehensive, coordinated care in a more cost-effective way
- **Managed Fee-for-Service (FFS) Model:** Agreements between states and CMS under which states would be eligible to benefit from savings resulting from initiatives to reduce costs in both Medicaid and Medicare

Alternative Model:

- Agreement to integrate care for Medicare-Medicaid enrollees building on the state's current infrastructure (MN)

FAI Participating States



2016 Medicare Program Audits

- CMS conducted Medicare program audits on 37 Parent Organizations (POs) and 168 contracts in 2016.
- These Medicare program audits included:
  - 8 POs with 19 Medicare-Medicaid Plans
  - Spanned 7 demonstrations
- Any MMP-specific findings were included in the final reports as observations; requests were made for corrective action plans; but these findings did not factor into audit scores.

Differences between MA and MMP Requirements

- Appeals and Grievances Standards
  - Expedited
  - Standard
- Covered Services
- Health Risk Assessment Completion
- Individual Care Plan Completion

Development of MMP Audit Protocols

- Released drafts of the MMP audit protocols – February 23, 2017
- Received comments from – MMPs, D-SNPs, Industry and Advocacy groups, and a PBM
- Released final MMP audit protocols – April 28, 2017

Final 2017 MMP Audit Protocols Released

- MMP Service Authorization Requests, Appeals and Grievances (SARAG)
- MMP Care Coordination and Quality Improvement Program Effectiveness (CCQIPE)

2017 MMP Audit Protocol Highlights

- CMS will pilot the protocols for contract year 2017 audits
  - MMP Audit Scoring
  - Final Reports
  - Corrective Action
  - Validation
- Standardized with ODAG and SNP-MOC protocols
- Reduced the amount of data elements for universes

MMP Audit Process

- Engagement Letter
- Timing of Audit Fieldwork
- Format of Audit
- The MMP Protocols and other Program Area Audit Protocols

SARAG Overview – Elements

- Timeliness – Service Authorization Requests, Appeals and Grievances
- Appropriateness of Clinical Decision-Making & Compliance with SARA Processing Requirements
- Grievances and Misclassification of Requests

SARAG Overview – Universes

- 12 Universes
  - Standard/ Expedited Service Authorization Requests
  - Provider Payment Requests
  - Standard/Expedited Plan Level Appeals
  - State Fair Hearing Decisions Overturns
  - MMP IRE Cases Requiring Effectuation (including payment cases)
  - MMP ALJ and MAC Cases Requiring Effectuation
  - MMP Standard/ Expedited Grievances
  - MMP Call Logs

SARAG Overview – Universes (cont.)

- Part B Point of Sale Drugs
- Part D Drugs
- Concurrent Review

CCQIPE Overview – Elements

- Care Coordination
- Quality Improvement Program Effectiveness

CCQIPE Overview – Universes

- Medicare-Medicaid Plan Members (MMPM)
- Quality Improvement Program Effectiveness (QIPE)

Questions?

Please contact:

Medicare Part C & D Audit Mailbox:
part_c_part_d_audit@cms.hhs.gov

OR

Medicare-Medicaid Coordination Office:
MMCOCapsReporting@cms.hhs.gov