2017 Annual Conference

Compliance Program Effectiveness (CPE) Audits

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Centers for Medicare & Medicaid Services (CMS)
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Agenda

- The Evolution of Medicare Part C and D CPE Audits
- CPE Audit Process and Significant Changes
- How to Prepare For a Successful CPE Audit
  - Sponsor's Responsibilities
  - Communication with CMS
  - Universe Submission
  - Onsite activities
  - Staffing and Resources
  - Tracer Evaluation
  - Opportunities for Improvement

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 Purpose and Guidelines

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Audit Period

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

Audit Elements

- Demonstrating effective compliance controls and activities
  - Prevention
  - Detection
  - Correction

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The Evolution of Medicare Parts C & D CPE Audits

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Past	Present
• Policy and Procedure review; checklist; excessive documentation	• Tracer Evaluation; demonstrate compliance via actual activities and issues
• Compliance structures & processes	• Implementation, remediation, outcomes
• 7 audit elements	• 3 audit elements
• Interview guides and numerous employee interviews	• Transparent questionnaires & limited compliance interviews
• Separate compliance and FWA record layouts	• Consolidated record layouts
• ECT sample selection: 5 employees	• ECT sample selection: 20 employees
	• Universe and tracer selection follow-up calls/checkpoints

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The Evolution of Medicare Parts C & D CPE Audits

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Past	Present
• Optional overview of the sponsor's Medicare organization and compliance program operations	• Required walkthrough of sponsor's structure, personnel, & processes prior to start of Tracer Evaluation
• Compliance interviews were scheduled throughout the duration of onsite audit	• Week 2 onsite schedule template; Day 1 is dedicated to compliance interviews
• Tracer PPT template – limited flexibility	• Tracer Summary – maximum flexibility
• 4 business days to submit tracer cases and supporting documentation	• 2 weeks to upload tracer cases and supporting documentation to HPMS

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Evaluating Effectiveness

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How does the sponsor's compliance program, as a whole system, function in a way that is effective to address compliance and FWA issues in a timely and well-documented manner?

- What types of controls and activities are in place to **prevent** or reduce the number of potential non- compliance, FWA and regulatory violations from occurring within all Medicare business operational areas by employees and delegated entities?
- How does the MA or Part D organization **"identify and correct"** operational issues that may affect its operations and enrollee's access to health care and prescription drugs?

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Evaluating Effectiveness

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How does the sponsor's compliance program, as a whole system, function in a way that is effective to address compliance and FWA issues in a timely and well-documented manner?

- What types of internal monitors **identify** opportunities to improve the performance the Medicare business operational areas and compliance program?
- How are significant issues escalated and communicated appropriately, addressed reasonably and timely, and root causes identified to **correct** underlying problem(s)?

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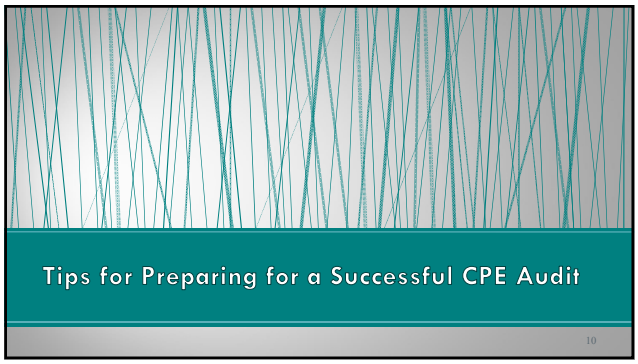

Sponsor's Responsibilities

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- Knowledgeable about laws, regulations and guidance for sponsors and FDRs, such as statutory, regulatory, and sub-regulatory changes (e.g., 42 C.F.R. §§422.503(b)(4)(vi), and 423.504(b)(4)(vi), Compliance Program Guidelines, HPMS memos)
- Review documents/protocols/webinars available on CMS Part C and Part D Compliance Policy and Program Audits website
- Be transparent during the entire audit process

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Sponsor's Responsibilities

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- Ensure CMS audit team understands your Medicare organization (key staff, operations& FDRs, decision-making authorities/processes, reporting, unique situations, etc.)
- Identify the Sponsor's CPE Lead to CMS audit team
- Ask clarifying and concise questions
- Comply with deadlines and document requests
- Provide accurate and timely universes/documentation in an organized manner

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Universe Submission

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- Thoroughly review and complete the Audit Submission Checklist with the engagement letter
- CPE universes follow-up call within 5 business days of engagement letter
- Many opportunities for a sponsor to ask questions about document requests
- Failure to produce complete universes and documents by the due date may delay sample selection and shorten tracer preparation time

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Universe Submission

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- For each respective CPE universe, sponsors should include both compliance and FWA activities
- Pay close attention to the "include" and "exclude" sections of each record layout
- Do not create any of the requested documentation (e.g. risk assessments, work plans, compliance plan) for this audit
- Questionnaires responses should be detailed and reflective of actual processes – general/canned responses are not helpful and will lengthen the duration of the compliance interviews

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Onsite Activities – Week 2

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- Welcome Meeting
  - Introductions of key individuals vested in Medicare operations and compliance program
  - Executive officers, senior management team and compliance department encouraged to attend
- Tour of Facilities (Optional)
- Compliance Program Walkthrough
- Employee and Compliance Team (ECT) sample selection provided to sponsor

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Onsite Activities – Week 2

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- Compliance Interviews (Compliance Officer, FDR Oversight, Special Investigations Unit/FWA)
- Tracer Evaluation and ECT sample reviews
- Evaluation of Reporting Mechanisms
- Exit Conference

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Onsite Activities – Week 2

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Audit Year and Sponsor's name:		2017				
Entrance Conference Date:		Tuesday, October 10, 2017				
Exit Conference Date:		Friday, October 20, 2017				
AIC			TIME ZONE applying to all events below:	Eastern		
		CMS				
			Week 2			
Audit Area	Meeting Name	Monday, October 16, 2017	Tuesday, October 17, 2017	**********	Thursday, October 19, 2017	Friday, October 20, 2017
COMPLIANCE	Team Setup	8:30 am - 9:00 am				
	Webinar Meeting	9:00 am - 10:00 am				
	Walkthrough Documentation and Processes IN ECT Sample Submission to Sponsor	10:30 am - 12:00 pm				
	Tracer Sample Review 1		8:30 am - 11:30 am			
	Tracer Sample Review 2			8:00 am - 10:30 am		
	Tracer Sample Review 3			10:30 am - 12:30 pm		
	ECT Sample Review				8:30 am - 11:30 am	
	Tracer Sample Review 5				12:00 pm - 1:00 pm	
	Lunch	12:00 pm - 1:00 pm	12:00 pm - 1:00 pm	12:30 pm - 1:30 pm		
	Tracer Sample Review 2		1:30 pm - 4:30 pm			
	Tracer Sample Review 4			2:00 pm - 4:30 pm		
	Tracer Sample Review 6				1:30 pm - 4:30 pm	
	Interview – Compliance Officer	1:30 pm - 2:30 pm				
	Interview – SIU/FWA Oversight	2:30 pm - 3:30 pm Meeting Password:	<mark>[Webinar Link (WILL BE UPDATED WITH WEBINAR LINK)]</mark>			
	Interview – FDR Oversight	3:30 pm - 4:30 pm				
	Team Review	4:30 pm - 4:45 pm	4:30 pm - 4:45 pm	4:30 pm - 4:45 pm	4:30 pm - 4:45 pm	8:30 am - 9:30 am
	Daily Wrap-Up with Sponsor	4:45 pm - 5:00 pm	4:45 pm - 5:00 pm	4:45 pm - 5:00 pm	4:45 pm - 5:00 pm	

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Compliance Program Walkthrough (Infrastructure & Processes)

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- Extremely important to the success of the CPE audit (2-3 hours)
- Attachment I-C guides the discussion
- Corporate Governance & Accountability
- Org charts, department interactions, reporting structures, decision-making bodies, business committees
- Interpretation and tracking CMS regulations and guidance
- Market trends and significant changes made since last CMS audit

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Compliance Program Walkthrough (Infrastructure & Processes)

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- Development of risk assessments, work plans and corrective action plans
- Communications between Compliance and Operations
- Pre-Audit Disclosures
- Issue escalation and remediation processes
- Clarifying questions related to supporting documentation submitted with universes (Attachments I-A, I-C, performance mechanisms, compliance goals)

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Tracer Evaluation

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- A tracer is a single compliance activity or issue used to evaluate a sponsor's comprehensive approach to detecting, correcting and/or preventing compliance issues.
- 6 cases (2 FTEAM, 2 IA, 2 IM)
- Tracers may not touch all compliance program elements.
- Related organizational structure and operating procedures should be detailed in the tracer summaries.

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Tracer Evaluation

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- Examples of Tracer Cases
  - Monthly review of expedited organization determinations
  - Audit performed by sponsor's first-tier entity to a downstream entity to whom functions were delegated to a triage call center
  - Sales agents oversight (training, education, enrollments)
  - Annual evaluation of sponsor's PBM compliance with contractual and regulatory requirements
  - Audit of SNP Model of Care (Health Risk Assessment & Model of Care)
  - Monthly review of pharmacy department's collaboration with the PBM to ensure errors were identified, corrected and adjudicated timely.

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Tracer Evaluation

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- Tracer Case Summary and Documentation Reviews
  - Refer to 2.1 and 2.2 of Tracer Evaluation – CPE Audit Process and Data Request
  - Written summary and supporting documentation for each tracer
  - Document facts of each tracer using the most efficient method for your business
  - Be prepared to share the story of the issue from beginning to end in chronological order
  - PowerPoint and Word documents
  - Screenshots or embed supporting documentation into summaries for real time review

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Tracer Evaluation

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- Who should be in attendance?
  - Director & staff level
  - Knowledgeable about the details of the compliance issue/activity (who, what, when, how, and why)
  - Compliance & Business areas
  - 3-5 people
  - 1 person designated as a lead presenter
  - 1 individual to locate documents or obtain additional information in real time

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Tracer Evaluation

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Presentation Format 1 (Best Practice)

- Table of Contents
- Summary Overview
- Issues: Audit Process and Data Request 2.1 bullets
- Prevention
- Detection
- Correction
- Compliance Standards
- Elements (7 core elements)

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Tracer Evaluation

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Presentation Format 2 (Best Practice)

- Table of Contents
- Summary /Overview
- Prevention
  - Compliance Standards
  - 7 core elements
  - Data request 2.1 bullets
- Detection
  - Compliance Standards
  - 7 core elements
  - Data request 2.1 bullets
- Correction
  - Compliance Standards
  - 7 core elements
  - Data request 2.1 bullets

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Opportunities for Improvement

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- Monitoring and Auditing Activities (Medicare Operations & FDRs)
  - Identifies specific monitoring and audits of FDR operations with dates, type of activity, methodology, individual/business area involved, process for responding to all monitoring and auditing deficiencies

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Opportunities for Improvement

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- Risk Assessments (Medicare Operations & FDRs)
  - Must take into account all Medicare business operational areas
  - Identify highest risk first-tier entities; indicators of why FDR is high risk
  - Enterprise-wide and detailed level are acceptable
  - Demonstrate how the risk assessment influenced audit and monitoring work plans

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Opportunities for Improvement

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- Root Cause Analyses
  - Written description of the issue
  - Duration of the problem (beginning date and end date)
  - Impacted groups or individuals (FDRs, employees, enrollees)
  - Number of groups or individuals impacted
  - Root cause of non compliance (*unaware of CMS requirements is not sufficient)
  - Any remediation efforts that have been taken to correct problem

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Contact Us

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- **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

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