Session 410:

Medicare FDRs and Compliance Programs: What the Feds Expect and Tips for Ensuring Your Organization Satisfies the Requirements

HCCA 21th Annual Compliance Institute

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Presentation Overview

- Understand the current status of Medicare managed care compliance program requirements for "first tier" and "downstream" and "related" entities
- Learn how to effectively achieve compliance
- Gain insights for negotiating compliance program provisions in managed care agreements

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FDRs = "First tier", "Downstream" and "Related" entities

FDRs: Who is a First Tier Entity?

- First Tier Entity - A party that enters into a written arrangement with a Medicare Advantage Organization ("MAO") or Part D plan sponsor to provide:
  - Administrative services (e.g., marketing, utilization management, quality assurance, applications processing, enrollment and disenrollment functions, claims processing, adjudicating Medicare organization determinations, appeals and grievances, provider credentialing); or
  - Health care services to a Medicare eligible individual under the Medicare Advantage program or Part D program (e.g., independent practice association, hospital, PHO)

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FDRs: Who is a Downstream Entity?

- Downstream Entity – A party that enters into a written arrangement with a First Tier entity for the provision of administrative services or health care services to a Medicare eligible individual under the Medicare Advantage program or Part D program
  - Hospital within a health system that has entered into a system level agreement
  - Credentialing verification organization

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FDRs: Who is a Related Entity?

- Related Entity - Any entity that is related to the sponsor by common ownership or control and either: (1) performs some of the sponsor's management of functions under a contract of delegation; (2) furnishes services to Medicare enrollees under an oral or written agreement; or (3) leases real property or sells materials to the sponsor at a cost of more than $2,500 during a contract period

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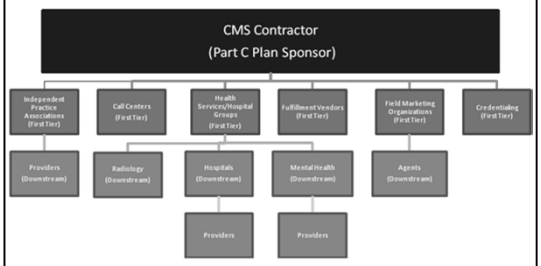
Examples



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FDR Spotting: CMS' Factors To Consider

- Impact on enrollees
- Extent of interaction with enrollees (orally or written)
- Access to PHI
- Decision-making authority

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So…..Now What?! IF FDR, THEN COMPLY WITH PART C/D COMPLIANCE PROGRAM REQUIREMENTS

What are FDRs Required to Do?

- Regulatory (and Organizational) Expectations
  - Sponsors/FDRs need to exercise oversight of subcontractor's compliance efforts (e.g., vendor management program), if Part C/D administrative, management or clinical functions are delegated
  - FDRs must maintain an effective compliance program that meets the compliance program requirements for Medicare Part C/D plans
  - FDRs much have systems in place to train employees regarding FWA (if no deemed status) and general compliance (e.g., standards of conduct, HIPAA)
  - FDRs must investigate, correct and document all instances of suspected non-compliance

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The Seven Elements: Compliance Program Requirements

CMS requires that an effective compliance program must include seven core requirements:

1. Written Policies, Procedures, and Standards of Conduct
2. Compliance Officer, Compliance Committee, and High-Level Oversight
3. Effective Training and Education
4. Effective Lines of Communication
5. Well-Publicized Disciplinary Standards
6. Effective System for Routine Monitoring, Auditing, and Identifying Compliance Risks
7. Procedures and System for Prompt Response to Compliance Issues

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Assessing Compliance

- Review CMS' audit program - Part C and D Compliance Program Effectiveness (CPE) Program
  - CPE Self-Assessment Questionnaire
  - CPE Compliance Officer Questionnaire
- Conduct a gap analysis:
  - Compare your current program against CPE requirements
  - Compare your program to your MA/Part D contracts

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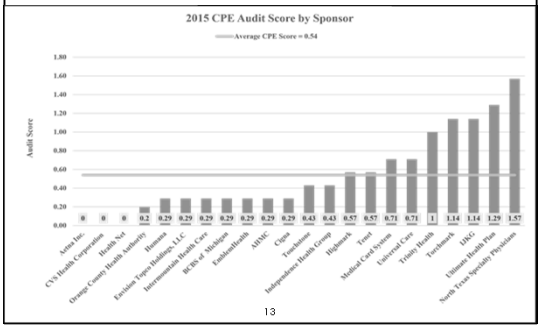
CMS Part C and D Compliance Program Effectiveness (CPE) Program Area

2015 CPE Audit Score by Sponsor



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2015 CPE Most Common Conditions: Condition Language	Citation Frequency 2011-Present	Percentage of Sponsors Affected 2015
Sponsor did not have an effective system to monitor first tier, downstream related entities' (FDRs') compliance with Medicare program requirements	3 out of 6	36.3%
Sponsor did not provide evidence that general compliance information was communicated to its first tier, downstream related entities (FDRs)	2 out of 6	27.2%
Sponsor did not have procedures to ensure that its first tier, downstream related entities (FDRs) are not excluded from participation in federal health care programs.	1 out of 6	27.2%

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2015 CPE Most Common Conditions: Condition Language	Citation Frequency 2011-Present	Percentage of Sponsors Affected 2015
Sponsor's compliance officer or his/her designee does not provide updates on results of monitoring, auditing, and compliance failures (i.e. Notices of Noncompliance to formal enforcement actions) to: •compliance committee, •senior executive/CEO, •senior leadership, and •governing body	3 out of 6	27.2%
Sponsor did not establish and implement a formal risk assessment and an effective system for routine monitoring and auditing of identified compliance risks.	3 out of 6	27.2%

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2017 CMS Program Audit Process

CMS will send routine engagement letters to initiate audits beginning February 21, 2017 through September 25, 2017.

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CPE Audit Process and Data Request

- 2017 Program Audit Process Overview
- Attachment I – CPE Audit Process Data Request
- Attachment I-A – CPE Self-Assessment Questionnaire
- Attachment I-B – CPE Compliance Officer Questionnaire
- Attachment I-C – CPE Organizational Structure Governance PPT
- Attachment I-D – CPE FDR Oversight Questionnaire
- Attachment I-E – CPE SIU FWA Prevention and Detection Questionnaire

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Universe Preparation & Submission

- Attachment I – CPE Audit Process Data Request
  - Appendix A – Compliance Program Effectiveness (CPE) Record Layouts
    - Table1: First-Tier Entity Auditing and Monitoring (FTEAM) Record Layout
    - Table 2: Employees and Compliance Team (ECT) Record Layout
    - Table 3: Internal Auditing (IA) Record Layout
    - Table 4: Internal Monitoring (IM) Record Layout

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Universe Preparation & Submission

- Appendix A – Compliance Program Effectiveness (CPE) Record Layout
  - Table 1: First-Tier Entity Auditing and Monitoring (FTEAM) Record Layout
    - First-tier entities that have entered into a written agreement with a sponsor to provide administrative or health care services to Medicare enrollees under the Part C and/or D program that have been audited or monitored within the audit review period.

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CPE Self-Assessment Questionnaire

- FDR Oversight Sponsor Accountability for and Oversight of FDRs
- FDR Oversight Written Policies and Procedures and Standards of Conduct
  - 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?
- FDR Oversight Effective Training and Education
- FDR Oversight Monitoring and Auditing FDRs
- FDRs: Procedures and System for Prompt Response to Compliance Issues

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CPE Compliance Officer Questionnaire

- What are some of the tools used to keep the compliance department up-to-date on tasks and assignments that have been delegated to both operational and FDRs?
- Provide an example of a compliance issue you had to deal with during the audit review period that involved a Medicare operational area and/or a first-tier, downstream or related entity (FDR) and impacted a significant number of your enrollees from receiving their health or drug benefits time in accordance with CMS requirements. Describe what happened and how you handled it.
- Provide an example of a time when communicating compliance issues to the compliance committee, senior management or governing body regarding was challenging. Briefly discuss how you handled it.

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CPE FDR Oversight Questionnaire

- How long have you been employed with the sponsor and been in involved with overseeing FDRs?
- Who or which business operations are involved with the pre-contractual assessment to ensure contractual and regulatory obligations are met.
- Describe specific examples of the types of communications that exist between the Compliance Department and FDR Oversight regarding Medicare requirements, policy updates, performance concerns or issues with FDRs, specifically the first-tier entities such as your PBM, enrollment/membership functions, coverage or claims adjudication, network management, etc.?
- Provide examples of the types of periodic monitoring reports your organization receives from FDRs?
- What are a few of the challenges or issues with effectively overseeing FDRs your organization has experienced within the audit review period (e.g., PBM, sales brokers, entities with direct member contact, provider networks, etc.).

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Compliance Training

- Two types of required training: (1) General Compliance; and (2) Fraud, Waste and Abuse ('FWA")
- Must be completed within 90 days and annually thereafter
- FDRs must maintain certificates or documentation of training completion and must furnish to CMS upon request
- Deemed status:
  - FDRs that have met the FWA certification requirements through enrollment in the Medicare program are deemed to have met the FWA training requirement
  - Still need to complete the general compliance training

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Compliance Training Options

- **February 10, 2016** CMS Memo – "Additional Guidance – Compliance Training Requirements and Audit Process Update
- Now three options for training:
  (1) FDRs can complete the general compliance and/or FWA training modules located on the CMS MLN
  (2) Sponsors and FDRs can incorporate the content of the CMS standardized training modules from the CMS website into their organizations' existing compliance training materials/systems
  (3) Sponsors and FDRs can incorporate the content of the CMS training modules into written documents for providers (e.g. Provider Guides, Participation Manuals, Business Associate Agreements, etc.)

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Who Needs to Be Trained?

- MA plans should work with FDRs and specify which positions within the FDR must complete the training.
- FDRs (e.g. hospitals, labs, providers) should contact the sponsor's compliance officer and discuss the December 28, 2015 and February 10, 2016 " Additional Guidance – Compliance Program Training Requirements and Audit Process Update" memorandums to determine the critical roles within an FDR that are subject to the compliance training requirement.

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Who Needs to Be Trained?

- Examples of critical roles that should clearly be required to fulfill the training requirements:
  - Senior administrators or managers directly responsible for the FDR's contract with the Sponsor.
  - Individuals directly involved with establishing and administering the Sponsor's formulary and/or medical benefits coverage policies and procedures.
  - Individuals involved with decision-making authority on behalf of the Sponsor (e.g. clinical decisions, coverage determinations, etc.).
  - Reviewers of beneficiary claims and services submitted for payment; or
  - Individuals with job functions that place the FDR in a position to commit significant noncompliance with CMS program requirements or health care FWA.

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Examples of Who to Train:

- Providers (e.g. Physicians, Chiropractors, Dentists)
- Nurses and nurses' aides
- Laboratory and radiology technicians
- Pharmacists and pharmacy technicians
- Therapists
- Social Workers
- Home Health Aides
- Medical coding staff
- Medical records staff
- Medical directors
- Billing staff, including certified coders, and pharmacy or medical claims processors

Aetna, June 2016

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Examples of Who Not to Train:

- Housekeeping and custodial staff
- Cafeteria workers
- Grounds and maintenance workers
- General receptionists and front desk coordinators (without access to PHI/member ID cards)
- Retail staff (e.g., gift shops, pharmacy)
- Non clinical administrative and clerical staff (e.g. human resources, payroll, administrative assistants)
- Machine repairmen
- Purchasing agents/assistant or logistics coordinators

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CPE Audit Process

- Tracer Evaluation
  - Sample Selection
  - Tracer Case Summary
  - Supporting Documentation
- Audit Elements
  - Prevention Controls and Activities (1.1 – 1.6)
  - Detection Controls and Activities (1.1 – 1.7)
  - Correction Controls and Activities (1.1 – 1.2)

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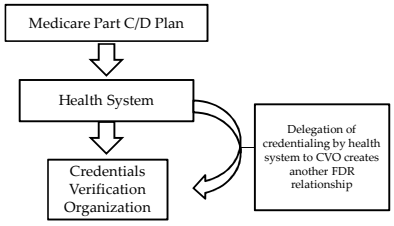
What ELSE are FDRs Required to Do?

- Manage their FDRs!



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Elements of an Effective Vendor Oversight Program

- Structured Procurement Process
- Proper Identification and Classification
- Communication Strategy
- Training and Education
- Risk Management
- Vendor Off-Boarding

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3/8/2017

Structured Procurement Process

- Effective oversight begins with formal procurement processes including accountability for sourcing, contracting and purchasing goods and services from vendors
- Processes may include:
  - Formal engagement policies and procedures
  - Formal sourcing review
  - Formal contractual agreement between the organization and the vendor
  - Use of a structured contract management system

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Proper Identification and Classification

- Organizations should have formal process to properly identify and classify vendors
- Processes may include:
  - Designations of the specified delegated service
  - Cost of delegated service
  - Impact and level of access to the end consumer
  - Access to Personally Identifiable Information (PII), Personal Health Information (PHI), or Payment Card Industry (PCI)
  - Relationship to government contracts

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Communication Strategy

- Effective communication between the organization and the vendor is critical to ensure a successful relationship
- Processes may include:
  - Your organization's code of conduct
  - Policies and procedures directly related to the specified delegated service
  - Main contracts for managing the relationship between the organization and the vendor
  - Distribution of performance metrics
  - Frequency of performance meetings
  - Communication protocols for compliance concerns
    - Compliance Liaison

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Training & Education

- When an organization delegates administrative functions to a vendor, they are not simply delegating a task … they are sharing their organization expectations around culture, mission and values
- Materials should include:
  - Organization's Code of Conduct
  - General compliance expectations/information
  - How to report suspected Fraud, Waste, Abuse and other compliance concerns
  - Operational performance metrics/expectations
  - Scope of delegated functions

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Risk Management

- Vendor performance must be monitored similar to business performance to ensure delegated functions are being performed as expected/contracted
- Types of Monitoring:
  - Vary dependent on delegated services
  - Key performance measures
  - Compliance with contractual requirements
  - Consider survey/attestations
- Remediation:
  - Reporting and escalation process
  - Validate and test corrective actions
  - Consequences in contract for non-compliance

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Vendor Off-Boarding

- While effective on-boarding is important – don't forget a check list when off-boarding
- Risks to Monitor
  - Exposure to PHI, etc.
  - Need to get information for regulatory audits after relationship ends
  - Reputational Risk
  - Unnecessarily providing monetary compensation to vendor once contract ends

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Effectively Negotiating Compliance Program Provisions in Part C/D Agreements

Ensure Legal/Compliance Staff Involved in Negotiation and Operationalization of Compliance Provisions

- Need process in place for managed care staff to coordinate with legal/compliance before negotiating/executing Part C/D contracts
- Need process in place to identify downstream entities and ensure required contractual provisions included
- Need process to review attestations and process any questionnaires related to compliance requirements
- Consider sample provisions regarding code of conduct, policies and procedures and training requirements (including who will be trained)

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Whose Code of Conduct?

- Many sponsors require use/dissemination of their code of conduct in their contracts
- FDR response:
  - CMS does not require that FDRs adopt the sponsors code of conduct
  - Effective compliance program cannot have multiple codes of conduct
  - Training efforts tailored to organization's code of conduct

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Who needs to be trained?

- Many sponsors have broad language regarding application of compliance training requirements
- FDR Response:
  - Limit training program to those critical roles within the FDR (others may not be subject to the compliance training requirement)
  - Refer sponsor to December 28, 2015 and February 10, 2016 " Additional Guidance – Compliance Program Training Requirements and Audit Process Update" memorandums for support

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Audit Response Provisions

- Many sponsors include broad audit rights in contract
- FDR Response:
  - Consider time/manner/scope of audit requirements
  - Consider allocation of audit costs

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Compliance Attestations

- Many sponsors have annual attestation process as part of vendor management
- FDR Response:
  - Consider identifying individual (by title) to whom attestation will be sent
  - Consider requesting form of attestation in advance (attachment to agreement)

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Operationalizing the Agreement

- Remember that final agreement requirements must be operationalized
  - Document completion of required training
  - Institute processes for downstream entity monitoring, if needed
  - Review policies and procedures regarding general compliance, FWA, nonretaliation and prompt response to compliance issues
  - Review compliance reporting mechanisms to ensure required reporting to sponsor occurs
  - Document exclusion checks

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Questions?

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Resources

- Regulatory Requirements: 42 C.F.R. § 422.503 and 42 C.F.R. § 423.504
- Compliance Guidance: http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/CompliancePrograMPolicyandGuidance.html
- Training Materials: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html

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