

Session 602:

Medicare Managed Care Compliance Standards for FDRs: Is Your Organization's Compliance Program Adequate?

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Presentation Overview

- ✓ Understand the Medicare managed care compliance program requirements for “first tier” and “downstream” and “related” entities
- ✓ Why is this important and examples of non-compliance
- ✓ Learn how to effectively achieve compliance

Who?

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)

FDRs = "**First Tier**", "Downstream" and "Related" entities

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

FDRs = "First Tier", "**Downstream**" and "Related" entities

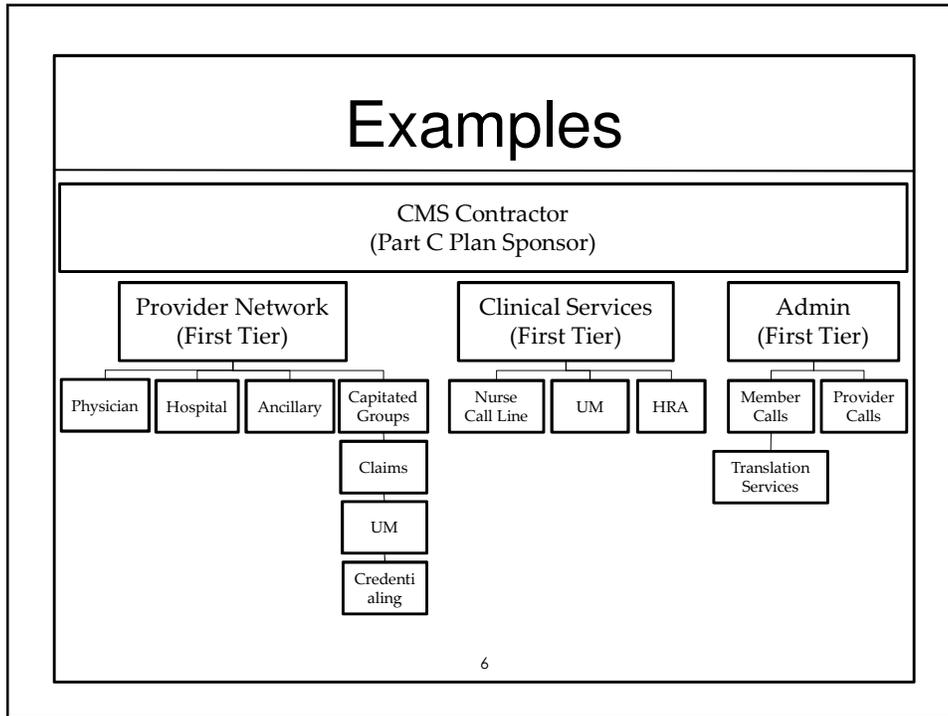
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FDRs: Who is a Related Entity?

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

FDRs = "First Tier", "Downstream" and "**Related**" entities

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- ### FDR Spotting: CMS' Factors To Consider
- Function delegated/subcontracted to be performed
 - Determination made from resources, including Sponsor contract with CMS, applicable federal regulation, and/or CMS guidance
 - Impact on enrollees' access to care
 - Interaction with enrollees (orally or written)
 - Access to PHI & PII
 - Decision-making authority
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Why?

Why is this important?

The Centers for Medicare and Medicaid Services (CMS) and other federal and state regulators requires compliance for all Sponsor delegates.

CMS and other federal and state regulators:

- Take protection of its consumers seriously, and passes that responsibility to the contractor/plan sponsor.
- Hold contractor/plan sponsor directly accountable for delegate activities and performance.
- Requires contractor/plan sponsor to perform ongoing monitoring and auditing activities to ensure delegate compliance.

Risks of Non-Compliance

- Laws, Rules and Regulation Violations
- Industry Reputation
- Public Enforcement Actions (CMPs and Sanctions)
- Sponsor Actions (CAP, Contract Loss)
- Operational disruption, costs of responding to audits and addressing noncompliance

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Non-Compliance Examples

Healthcare Breaches Cannot Be Ignored

Lawyers: [REDACTED] envelope window reveals patients' HIV status

Originally published August 24, 2017 at 8:45 am

In late May 2016, [REDACTED] that 4,300 dental patient records were stolen. According to [REDACTED], these records were not stored on their systems, but instead stolen from the network of a third-party vendor—[REDACTED]—that assists the hospital in managing dental

We signed on with a terrific new call center. All was going well until we found out the complaint volume had spiked. We didn't have good service level reporting. We couldn't get answers and apparently our related vendor outsourced to some overseas locations and we couldn't quite figure out where they all were or who was overseeing them.

What?

FDR Compliance Basics

- Learn the FDR Requirements and 7 Elements of an Effective Compliance Program and assess your program
- Establish a strong and transparent contractor/plan sponsor delegate relationship and communication channels
- Ensure strong and transparent communication channels within your organization
- Implement internal auditing and monitoring for performance and compliance program requirements
- Report and remediate gaps/deficiencies

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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FDR Compliance Requirements

- Code of Conduct Policy Awareness
- Fraud, Waste and Abuse (FWA) & General Compliance Training
- Exclusion Checks - Office of Inspector General (OIG) and GSA System for Award Management (SAM)
- Document Retention
- Offshoring Notification
- Monitoring and/or auditing subcontracted delegates

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FDR Requirements

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 must 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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How?

Compliance Resources

- **OIG Compliance Guidance and Resources**
<https://oig.hhs.gov/compliance/compliance-guidance/index.asp>
- **Review CMS' audit program - Part C and D Compliance Program Effectiveness (CPE) Program**
 - CPE Self-Assessment Questionnaire
 - CPE Compliance Officer Questionnaire
 - CPE FDR Oversight Questionnaire

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Getting Started

- **Get a copy of the relevant rules 42 C.F.R. § 422.503 and 42 C.F.R. § 423.504 and Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual, Compliance Program Guidelines**
- **Obtain and review copies Part C/D contracts and/or exhibits/attachments describing compliance expectations and obligations**
- **Conduct a gap analysis:**
 - Compare your current program against CPE requirements
 - Compare your program to your MA/Part D contracts

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CPE Self-Assessment Questionnaire

Written Policies and Procedures and Standards of Conduct				
42 CFR §422.503(b)(4)(vi)(A); 42 CFR §423.504(b)(4)(vi)(A)				
No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)	Responsible Part or Department
1.	Do you have written policies and procedures (Ps & Ps) and/or Standards of Conduct that: (A through G)			
A.	Articulate the organization's commitment to comply with all applicable Federal and State standards?			
B.	Describe compliance expectations as embodied in the standards of conduct?			
C.	Implement the operation of the compliance program?			
D.	Provide guidance to employees and others on dealing with potential compliance issues?			
E.	Identify how to communicate compliance issues to appropriate compliance			

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CPE Compliance Officer Questionnaire

Example Questions:

- 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 was challenging. Briefly discuss how you handled it.

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CPE FDR Oversight Questionnaire

Example Questions:

- Describe specific examples of types of communications that exist between the Compliance Department and FDR Oversight regarding Medicare requirements, policy updates, performance concerns or issues with FDRs, specifically first-tier entities such as your PBM, enrollment/membership functions, coverage or claims adjudication, network management, etc.?
- Provide examples of types of periodic monitoring reports your organization receives from FDRs?
- What are a few 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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Implementation Challenges

Common Implementation Challenges

- Training – who, scope of/actual content, tracking
- Battle of the Forms – code of conduct, compliance policies
- Operationalizing managed care contract obligations into current compliance efforts
- Offshoring provisions
- Managing attestation process

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Compliance Training

Confirm adherence to compliance training requirements:

- Currently, FDRs must complete the general compliance and/or FWA training modules located on the CMS MLN
- 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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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.
 - 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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Who to Train Examples

Examples of Who <u>to</u> Train	Examples of Who <u>not to</u> Train
Providers (e.g. Physicians, Chiropractors, Dentists, Therapists)	General receptionists and front desk coordinators (without access to PHI/member ID cards)
Nurses and Nurses' Aides	Cafeteria workers
Laboratory and Radiology Techs	Grounds and maintenance workers
Pharmacists and Pharmacy Techs	Housekeeping and custodial staff
Home Health Aides	Retail staff (e.g. gift shops, pharmacy)
Medical Directors	Machine repairmen
Billing Staff, including medical coders, certified coders, pharmacy or medical claims processors, records staff	Non clinical administrative and clerical staff (e.g. human resources, payroll, administrative assistants)

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Training Proposed Changes

- If adopted, changes would apply to Contract Year 2019 (CMS-4182-P) posted to the Federal Registrar 11/28/2017
 - Remove requirement to accept CMS' training as meeting the compliance training requirements
 - Retain requirement to train MA and Part D sponsors, their employees, chief executives or senior administrators, managers, and governing body members
 - Pros/Cons: provides flexibility to sponsoring organizations and FDRs, but may increase variation in training requirements across various plans, thereby increasing FDR compliance burden

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Other Training Considerations

- 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 critical roles within an FDR that are subject to the compliance training requirement.

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Battle of the Forms

- Code of conduct - some sponsors require use/dissemination of their code of conduct in their contracts
- FDR considerations:
 - 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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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, non-retaliation and prompt response to compliance issues
- Review compliance reporting mechanisms to ensure required reporting to sponsor occurs
- Document exclusion checks

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Offshoring

- Most sponsors require approval to offshore PHI
- Lack of CMS guidance and available guidance regarding sponsor obligations to monitor FDRs who offshore potentially onerous
- FDR Considerations:
 - Ensure part of contract negotiation
 - Consider specifying process, requesting guidance from sponsor
 - Know whether your vendors offshore, and ensure ongoing communication with IT

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Compliance Attestations

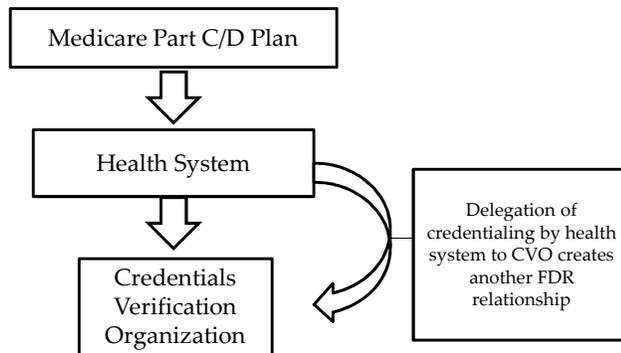
- Most sponsors have an annual attestation process as part of vendor management and/or delegate oversight.
- FDR Considerations:
 - Consider identifying an individual (by title) to whom the attestation will be sent
 - Consider requesting form of attestation in advance

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But wait, there's more...

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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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 a 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
 - Primary contacts for managing the relationship between the organization and the vendor
 - Distribution of performance metrics
 - Frequency of performance meetings
 - Communication protocols for compliance concerns
 - Escalation process for risks and issues

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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.
 - Establish a process to get information for regulatory audits after relationship ends
 - Reputational Risk
 - Unnecessarily providing monetary compensation to vendor once contract ends

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In Closing

- ✓ Understand the Medicare managed care compliance program requirements for FDRs
- ✓ Understand the importance of the compliance program requirements
- ✓ Learned how to effectively achieve compliance

Proactively be Audit Ready

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Questions?



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Resources

Resource Name	Link/Reference
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
2019 CMS Proposed Changes - Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503 and 423.504)	https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare
CPE Self-Assessment Questionnaire	https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/Compliance-Program-Effectiveness-Self-Assessment-Questionnaire.pdf
CPE Compliance Officer Questionnaire	https://www.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/Compliance_Institute/2017/410handout5.pdf
CPE FDR Oversight Questionnaire	https://www.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/Compliance_Institute/2017/410handout6.pdf

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