

**HCCA**  
**Nashville Conference**  
 Medicare Advantage Organizations' Attestation  
 Requirements and Implications

**November 18, 2016**

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**So Many Certifications . . . So Little Time**

- EHR Meaningful Use Certifications
- Provider-Based Certifications
- Corporate Integrity Agreement Certifications
  - Executive Management
  - Board
  - Compliance Officer
- Cost Report Certifications
- Credit Balance Certifications
  - Medicare
  - Medicaid
- **Medicare Managed Care Compliance Attestations**
- Many Others

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**Goals of Session**

- Overview of Medicare Advantage Organization (MAO) Compliance Requirements
- Explore Practical Strategies for Complying with Key Medicare Advantage Compliance Obligations
  - Training
  - Offshore Contractors Accessing protected health information (PHI)
  - Auditing and Monitoring
- Discuss Medicare Advantage Contract Negotiation Strategies
- Questions

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## Overview of Medicare Advantage Compliance Requirements

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## Medicare Advantage Compliance Expectations

- Compliance Program requirements are outlined in Chapter 21 of the Medicare Managed Care Manual.
  - Issued in 2012 by CMS
- Required elements track OIG’s seven elements of an effective compliance program.
  - Also requires a risk assessment.
- Expectation that a MAO’s compliance program should be tailored to each MAO’s unique organization, operations and circumstances.
- CMS makes clear that “a compliance program will not be effective unless sponsors devote adequate resources to the program.”

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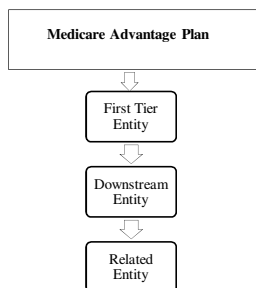
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## Role of FDRs

- CMS recognizes that sponsors may enter into contracts with entities (referred to as First Tier, Downstream, and Related Entities (FDRs) to provide administrative or healthcare services for enrollees on behalf of the sponsor.



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### FDRs: Defined

- **First Tier entity** refers to a party that enters into a written arrangement with an MAO (or contract applicant) “[t]o provide administrative services or health care services for a Medicare eligible individual.” 42 C.F.R. § 422.500.
- **Downstream entity** refers to a party that enters into a written arrangement “[b]elow the level of the arrangement between an MA organization (or contract applicant) and a first tier entity.” 42 C.F.R. § 422.500.

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### FDRs: Defined (Cont'd)

- **Related entity** refers to an entity that is related to the MAO “[b]y common ownership or control” and:
  - “Performs some of the MA organization’s management functions under contract or delegation”;
  - “Furnishes services to Medicare enrollees under an oral or written agreement”; or
  - “Leases real property or sells materials to the MA organization at a cost of more than \$2,500 during a contract period.” 42 C.F.R. § 422.500.

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### CMS’s Expectations

- CMS requires MAOs to ensure that their FDRs remain compliant with applicable law.
- “The *sponsor maintains the ultimate responsibility for fulfilling the terms and conditions of its contract with CMS*, and for meeting the Medicare program requirements. Therefore, *CMS may hold the sponsor accountable for the failure of its FDRs to comply with Medicare program requirements.*” (Medicare Managed Care Manual, Ch. 21, Section 40)
- “*Medicare program requirements apply to FDRs* to whom the sponsor has delegated administrative or health care service functions relating to the sponsor’s Medicare Parts C and D contracts.” (Medicare Managed Care Manual, Ch. 21, Section 40)

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### **CMS's Expectations (Cont'd)**

- MAOs **must** develop procedures to ensure that all FDRs are in compliance with relevant laws.
- MAOs **must** implement a system to monitor their FDRs' compliance.
- MAOs **have discretion** over the types of monitoring methods they use to ensure FDRs comply with requirements.

CMS, Medicare Managed Care Manual, chapter 21 (Jan. 11, 2013), available at <https://www.cms.gov>.

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### **MAO Oversight Authority: Contractual Authority**

- Payor agreements may provide additional insight regarding compliance expectations and the MAO's authority to push compliance obligations to the FDR.
- MAO regulations require certain compliance-related provisions be included in an MAO's contract with FDRs.
  - Regulator access to MA-related documents (42 CFR 504(i)(2)(i))
  - "Payment in full" obligations (42 CFR 422.504(i)(3)(i))
  - Consistency between FDR-MAO contract and MAO-CMS contract (42 CFR 422.504(h)(iii))

CMS, Medicare Managed Care Manual, chapter 21 (Jan. 11, 2013), available at <https://www.cms.gov>.

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### **Impact on FDRs**

- MAOs push compliance obligations to FDRs.
- As pressure on the MAOs to demonstrate compliance program effectiveness increases, the pressure on FDRs to demonstrate compliance also increases.
  - *FDRs may be subject to burdensome audits.*
- MAOs require annual attestations certifying compliance with the Medicare Advantage compliance requirements.
  - Scope of certification may vary by MAO
  - What if an FDR is unable to certify that it has satisfied a requirement?

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### Breadth of MAO Attestation Expectations

- Certification elements may include (certification requirements may vary by MAO):
  - FDR training
  - Adoption and dissemination of relevant policies and procedures (including Code of Conduct)
  - Downstream entity monitoring
  - Exclusion checks
  - Use of offshore contractors accessing PHI
  - Maintenance of records to demonstrate compliance
  - Compliance with federal healthcare program requirements generally

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### Enforcement Considerations

- Potential requirement for corrective action plans.
- The MAO may revoke the contract with an FDR if the FDR does not perform its services satisfactorily and if the reporting and disclosure requirements are not fully met in a timely manner.
- The government may take action against MAOs and FDRs for failing to comply with applicable laws.
- MAO referral of an FDR to CMS, OIG and/or law enforcement.
  - “While no bright line definition exists as to what is a “significant” or “serious” incident that should be reported, [MAOs] *should err on the side of over-reporting* rather than under-reporting.”
- Whistleblower considerations for “false” certifications.

CMS, Medicare Managed Care Manual, chapter 11 (Apr. 25, 2007), available at <https://www.cms.gov>.

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### Practical Strategies: Complying with Medicare Advantage Compliance Requirements

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### Discussion of Key Medicare Advantage Requirements

- Training Obligations
  - General Compliance
  - Fraud, Waste and Abuse (FWA)
- Offshore Contractors Accessing PHI
- Auditing and Monitoring Obligations

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### Overview of Training Requirements: FDRs

- Annual training
  - General Compliance Training
  - FWA
- **Exception:** There is an exception to the FWA training if the organization is “deemed” to have met the FWA certification requirements through enrollment into Medicare Parts A or B of the Medicare program. 42 C.F.R. § 422.503(b)(4)(vi)(C)(2).
  - *FDRs deemed to have met the FWA training and education certification requirements through enrollment into Parts A or B of the Medicare program or through accreditation as a supplier of DMEPOS are NOT exempt from the general compliance training requirement.*
- CMS does not expect an FDR’s entire staff would necessarily be subject to the training requirements.

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### General Compliance Training

- **June 2015:** CMS announced changes to its general compliance training effective January 1, 2016.
  - Those changes were initially designed to *reduce administrative burden* on FDRs.
  - However, CMS acknowledged that the changes may have in fact *increased the administrative burden*.
- **February 2016:** CMS revised its expectations for completion of the general compliance training to attempt to reduce burden on FDRs.
  - CMS also announced that it was suspending review of the training certification element in the MAO Compliance Program Effectiveness program audit protocol.
    - *Temporary suspension.*

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### Practical Strategies: Training Obligations

- Is the organization exempt from FWA training?
  - How is the exemption documented?
- What stakeholders are required to take the training?
  - Is the approach to identifying the relevant universe of stakeholders disclosed to the MAO?
  - Use other guidance to define the population (e.g. Covered Persons definition)?
- How is the compliance training disseminated?
  - Must consider CMS's new guidance.
- How is the training documented?
  - Student info, Date of Time, Name of Course, etc..

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### Offshore Subcontractors Accessing PHI

- CMS requires MAOs using offshore subcontractors that handle PHI to submit specific information on these contractors and an attestation that the MAO has taken steps to address the potential risks to PHI.
- The attestation includes information related to:
  - The offshore subcontractor's name and function;
  - Description of the PHI provided to the offshore subcontractor;
  - The safeguards adopted to protect PHI; and
  - Audit requirements for the offshore subcontractor.
- CMS does *not* require pre-approval of MAO offshore contractors.
- *However, MAO plans may attempt to impose more stringent requirements on an FDR's use of an offshore contractor accessing PHI.*

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### Offshore Subcontractors Accessing PHI (Cont'd)

- The ability of an FDR to use offshore subcontractors (accessing PHI) may be dependent on the FDR's contract with the MAO.
  - For example, some MAOs may attempt to *prohibit* the organization's use of offshore subcontractors or may require the organization to obtain *pre-approval* from the MAO before using offshore subcontractors.
- Medicare Advantage compliance attestations typically include a reference to the offshore contractor requirements.

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### Practical Strategies: Offshore Contractor Obligations

- How does the FDR compile an inventory of all offshore vendors that potentially access PHI?
  - How is this maintained and updated?
  - Is pre-approval from the MAO obtained before contracting with these vendors?
- What safeguards are taken to protect PHI?
- What internal monitoring/auditing of these vendors is performed?
- Consider potential need for sub-certifications from vendors to demonstrate compliance with the MAO requirements.

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### Auditing and Monitoring Considerations

- Multiple auditing and monitoring considerations.
  - CMS audits of MAO plans.
  - MAOs obligation to audit first tier entities.
  - First tier entities obligations to audit downstream and related entities.
- CMS indicates that “[i]t is a best practice for [MAOs] to use a combination of **desk** and **on-site audits**.”

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### Auditing and Monitoring

- MAOs are required to develop a strategy to audit and monitor their first tier entities to ensure that:
  - The first tier entities are compliant with the law; and
  - The first tier entities are monitoring the compliance of their downstream entities.
- Sponsors must also monitor any related entities to ensure those entities are compliant with all applicable laws and regulations.

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### Auditing and Monitoring

- As part of its monitoring and evaluation efforts, CMS requires MAOs to confirm that ***“the first tier entities are applying appropriate compliance program requirements to downstream entities with which the first tier contracts.”***
- “Although first tier entities may perform their own internal auditing, the sponsor remains obligated to perform its own auditing of first tier entities.”
- “When FDRs perform their own audits, ***it is a best practice for [MAOs] to obtain a summary of the audit work plan and audit results*** that relate to the services the FDR performs.”

CMS, Medicare Managed Care Manual, chapter 21 (Jan. 11, 2013), available at <https://www.cms.gov>

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### Practical Strategies: Auditing and Monitoring

- Routine Monitoring is required of FDR’s
  - Develop an annual monitoring process
    - Possible collection of attestations from each vendor
- Periodic Auditing of FDR’s
  - Develop an audit plan looking at high risk vendors
    - Make the audit simple but effective
    - Utilize other published audits (e.g. SOC2 Audits)
      - IT may already be auditing or collecting data you can utilize
- Establish and track necessary corrective actions

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### Practical Strategies: Auditing and Monitoring

- Response strategies for MAO audit requests.
  - What information is being requested?
  - How often?
  - How are the results shared with the first tier entity?
- Documentation likely requested by MAOs to demonstrate a first tier entity’s oversight of its downstream entities.
- Read the MAO contracts which your organization participates
  - Usually there will be language requiring compliance with a provider manual and policies and procedures
- Communicate with Managed Care Contracting Staff

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**Medicare Advantage  
Contract Negotiation Strategies**

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**Pre-Negotiation Considerations:  
Conduct a Status Check**

- Understand your organization’s current practices in key areas that will be the subject of negotiation.
  - Requires significant lead time, especially when there are numerous vendors.
  - Prepare for surprises: “How is it that we didn’t know that our collection agency’s call center was in Ireland?”
  - Know ahead of time what types of requirements with which the organization cannot comply – don’t be in immediate breach the moment you sign the agreement!

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**Pre-Negotiation Considerations:  
Who’s on the negotiation “team”?**

- Business lead.
- Compliance officer(s).
- Counsel – often brought in too late, or not at all.

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**The Negotiation: Nuts and Bolts**

- MAO contracts typically have a “regulatory appendix” or some other stand-alone exhibit that includes attestation/regulatory requirements.
- If MAO uses a template that MAO represents cannot be altered, add an exception appendix.
- Don’t wait until the end of the negotiation to tackle the regulatory appendix -- lowest ebb of negotiating power for both parties.

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**The Negotiation: Nuts and Bolts**

- Everything is negotiable
  - Exceptions are typically possible.
  - Start at the baseline required by the regulations and negotiate from there (as opposed to starting at the MAO’s template requirements and scaling back).
  - Can’t agree on language? State in the agreement that “the parties will comply with the following regulation,” and then quote the regulation.
  - Beware of “regulation bleed” -- MA requirements being applied to commercial business.

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**The Negotiation:  
Training Requirements**

- MAO proposes language that requires FDR to certify that it and its downstream contractors provide fraud, waste and abuse training.
  - If FDR is enrolled in Medicare Part A or Part B, FWA training not required. FDRs who have met the FWA certification requirements through enrollment into Parts A or B of the Medicare program or through accreditation as a supplier of DMEPOS are deemed to have met the FWA training and education requirements.
  - No requirement that “deemed” status be obtained through accrediting organization (e.g. The Joint Commission).

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### The Negotiation: Offshoring Requirements

- Three flavors:
  - No offshoring permitted.
  - Offshoring permitted with MAO approval.
  - Offshoring permitted with no approval.
- Under all three scenarios, organization needs to understand its current practices.

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### The Negotiation: Offshoring Requirements

- Options for language:
  - FDR will not offshore.
  - FDR doesn't currently offshore, but will notify the MAO if it starts to offshore, and will submit information needed for MAO to complete CMS attestation.
  - FDR offshores, and will submit information needed for MAO to complete CMS attestation.
  - FDR will seek MAO approval before offshoring\*\*

\*\* CMS does not require pre-approval of offshore contractors.

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### The Negotiation: Auditing/Monitoring Downstream

- MAO proposes language that requires FDR to *audit* downstream entities' compliance with CMS requirements, and to certify their compliance.

- This is more rigorous than required by CMS. The Medicare Managed Care Manual, Ch. 21, provides as follows:

"[MAO] must develop a strategy to monitor and audit its first tier entities to ensure that they are in compliance with all applicable laws and regulations, and to ensure that the first tier entities are monitoring the compliance of the entities with which they contract (the sponsors' "downstream" entities)."

- "Audit" v. "Monitor" is a meaningful distinction under according to CMS: "Audit is a formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures." (Medicare Managed Care Manual, Ch. 21, Section 20)

"Monitoring Activities are regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective." (Medicare Managed Care Manual, Ch. 21, Section 20)

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**Questions?**

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