Often Overlooked: Compliance Program Obligations Under Managed Care Agreements

Presenters

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Brief Update – NY's Compliance Regs are Final

- On December 28, 2022, the New York State Office of the Medicaid Inspector General ("OMIG") finalized a significant set of new compliance-related regulations. The rules were initially proposed on July 13, 2022.
- The **final rules contain minimal revisions** to the proposed regulations.
- **Final Changes include, but are not limited to:**
  - Clarification on the definition of "Effective compliance program" (a provider's characteristics means size, complexity, resources and culture)
  - Minor revision to Contractual Requirements (still presents many issues)
  - Disciplinary Standards – articulate standards for escalating discipline (rather than "degrees" of discipline)
  - Compliance Committee – advocate for resources (rather than ensure)
  - Reporting violations – narrowed to only when required by law, rule or regulation

Enforcement will not occur until 90 days after the effective date, March 28, 2023.

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I am in “compliance” … aren’t I?

- **Certain states have laws and regulations mandating certain providers to adopt and implement an effective compliance program.**
- **Many providers focus on the state laws and conclude:**
  - **if it does not apply to me, I do not have compliance program obligations; or**
  - **I am complying with the state law, so I have no other compliance obligations**
- **<u>Problem</u>: the majority of providers have signed agreements with Medicare Advantage Organizations (MAO); or Medicare Prescription Drug Plans (PDP) (collectively “Plan Sponsors”)**
- **Plan Sponsors have compliance obligations under agreement with CMS**
- **They push those down to the providers**

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First Tier, Downstream & Related Entity (FDR)

- **First-Tier Entity:** is any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization (MAO) or Part D plan Provider or applicant to provide administrative services ***or health care services*** to a Medicare eligible individual under the Medicare Advantage (MA) program or Part D program.
- **Downstream Entity:** is any party that enters into a written agreement, acceptable to CMS, with persons or entities involved with the MA benefit, below the level of the arrangement between an MAO or applicant or a Part D plan Provider or applicant and a first-tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.
- **Related Entity:** means any entity that is related to an MAO or Part D Provider by common ownership or control and:

  1) Performs some of the MAO or Part D plan sponsor's management functions under contract or delegation;

  2) Furnishes services to Medicare enrollees under oral or written; or

  3) Leases real property or sells materials to the MAO or Part D plan sponsor at a cost of at least $2,500 during a contract period.

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Contracting with First Tier, Downstream or Related Entities

- CMS permits Plan Sponsors to contract with FDRs to provide administrative or healthcare services.
- Under its agreement with CMS, the Plan Sponsor maintains the ultimate responsibility for overseeing FDRs and their compliance with Medicare program requirements.
- The Plan Sponsor is required to include certain contract provisions with FDRs to ensure its compliance with Medicare program requirements (access to records, exclusion checks, record retention).
- The Plan Sponsor also has freedom to impose other compliance requirements beyond what CMS requires (maintain a compliance program, training, etc.).
- In order to better understand the compliance obligations imposed on FDRs by Plan Sponsors, we will walk through the Plan Sponsor's compliance obligations to CMS.

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Compliance Program Requirements

- CMS requires Plan Sponsors to have an effective compliance program that meets the regulatory requirements (42 C.F.R. §422.503(b)(4)(vi) and 42 C.F.R. § 423.504(b)(4)(vi)).
- An effective compliance program includes the following 7 core requirements:
  - Written Policies, Procedures and Standards of Conduct;
  - Compliance Officer, Compliance Committee and High Level Oversight;
  - Effective Training and Education;
  - Effective Lines of Communication;
  - Well Publicized Disciplinary Standards;
  - Effective System for Routine Monitoring and Identification of Compliance Risks; and
  - Procedures and System for Prompt Response to Compliance Issues

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Written Policies, Procedures & Standards of Conduct

- Plan Sponsors must have written policies, procedures and standards of conduct that:
  - Articulate the Plan Sponsor's commitment to comply with all applicable Federal and State standards;
  - Describe compliance expectations & the operation of the compliance program;
  - Provide guidance on dealing with compliance issues & how to communicate them;
  - Describe how compliance issues are investigated and resolved; and
  - Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including, but not limited to, reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.
- Compliance policies and procedures and Standards of Conduct must be distributed to employees **and FDRs within 90 days of hire**, when there are updates to the policies, and annually thereafter.

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Written Policies, Procedures & Standards of Conduct-Cont'd

- Standards of conduct should:
  - Provide employees with the Plan Sponsors expectation for ethical conduct by its employees;
  - Mechanisms of proper reporting of noncompliance issues and potential FWA; and
  - Assurance that reported issues will be addressed and corrected.

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Compliance Officer, Compliance Committee & High Level Oversight

The Plan Sponsor must designate a compliance officer (CO) and a compliance committee (CC) to oversee the compliance program and report directly to the Plan Sponsor's chief executive or other senior management.

- The CO, is responsible for the day-to-day operations of the compliance program, must be an employee of the Plan Sponsor and **may not** be an employee of an FDR.
- The CO and the CC must periodically report directly to the Plan Sponsor's governing body about the compliance program.
- The Plan Sponsor's governing body must be knowledgeable about the compliance program and must exercise reasonable oversight with implementation and operation.

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Training & Education

- The Plan Sponsor must provide effective compliance training and education (including on FWA) for its employees, the CEO, senior administrators or managers, and the governing body members.
- **General Compliance Training:** Must occur **within 90 days** of initial hiring and **at least annually** thereafter.
- **Proof of Training**: Plan Sponsors must be able to show proof of training for their employees. (E.g. Copies of sign-in sheets, employee attestations and electronic certifications from employees).
- **Record Retention**: Plan Sponsors must maintain records for **10 years**.

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Effective Lines of Communication

- There must be established lines of communication to ensure confidentiality between CO, CC, employees, governing body and FDRs.
- The lines of communication must be accessible to all, 24 hours a day, and provide for anonymous and confidential good faith reporting of potential compliance issues.
- Plan Sponsors must have a system to receive, record, respond and track compliance questions or reports of suspected or detected noncompliance or potential FWA from employees, members of the governing body, enrollees and FDRs and their employees.
- Plan Sponsors must adopt, widely publicize, and enforce a no-tolerance policy for retaliation or retribution against any employee or FDR who in good faith chooses to report a potential FWA.

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Well-Publicized Disciplinary Standards

- Plan Sponsors must have well-publicized disciplinary standards for employees and FDRs that:
  - Articulate expectations for reporting compliance issues and resolution;
  - Identify noncompliance or unethical behavior; and
  - Provide timely, consistent, and effective enforcement when noncompliance or unethical behavior is found.
- Examples of publication methods include:
  - Newsletters
  - Presentations at department staff meetings
  - Communications with FDRs
  - General compliance training
  - Website
  - Posters prominently displayed throughout employee work and break areas

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Enforcing Disciplinary Standards

- **Enforcement:** Plan Sponsors must demonstrate that disciplinary standards are enforced in a timely, consistent and effective manner.
- **Record Retention**: **10 years** for all compliance violation disciplinary actions. The records should include:
  - Date of violation;
  - date of investigation;
  - summary of findings;
  - disciplinary action taken; and
  - date it was taken

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System for Routine Monitoring, Auditing & Compliance Risks

- Plan Sponsors must undertake monitoring and auditing to test and confirm compliance.
- Risk Areas include, but are not limited to:
  - FDR oversight and monitoring:
    - Plan Sponsors must develop a strategy to monitor and audit its first tier entities to ensure 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 Plan Sponsors' "downstream" entities).
- A monitoring and auditing work plan must be developed by the CO. The work plan includes, but is not limited to:
  - Audits to be performed (type, start/end date, announced or unannounced)
  - Audit methodology
  - Final audit report
  - Follow up activities

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System for Routine Monitoring, Auditing & Compliance Risks Cont'd

- Plan Sponsors are responsible for checking **exclusion lists** prior to hiring or contracting any new employee, temporary employee, volunteer, consultant, governing body, member or FDR.
- Monthly screening is required!
- **Exclusion lists**:
  - DHHS OIG List of Excluded Individuals and Entities
  - GSA Excluded Parties Lists System (EPLS)

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Procedures & System for Response to Compliance Issues

- A system with procedures to promptly respond to compliance issues as they are raised are required. Such system should include:
  - A **timely**, well-documented **reasonable inquiry** into any potential compliance issue or potential FWA.
    - **Timely**: No later than 2 weeks after the date the potential noncompliance was identified.
    - **Reasonable Inquiry**: includes a preliminary investigation of the matter by the CO or a delegated member of staff.
  - **Corrective actions** in response to potential noncompliance or potential FWA.
    - The corrective actions must be designed to correct the underlying problem and prevent future non-compliance.
    - Plan Sponsor must ensure the FDRs have corrected any deficiencies by conducting independent audits or review of the FDR's monitoring or audit reports.
  - **Self Reporting of FWA & Medicare Program noncompliance**
    - Plan Sponsors should self-report potential FWA discovered and potential FWA by FDRS.

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What are my compliance obligations as an FDR?

- Your obligations depend on the Plan Sponsor and your agreement.

3.4 **Compliance.** Provider agrees to comply with [redacted] policies and procedures including [redacted], payment, billing and reimbursement policies, the MA Provider Manuals, [redacted] contractual obligations to CMS, and all applicable federal, state and local laws, rules and regulations, now or hereafter in effect including Medicare laws, regulations, reporting requirements and CMS instructions, including, Member appeal and dispute resolution procedures related to Covered Services provided to a Member. To the extent that Provider

3.20 **Compliance Plan.** Provider shall have a compliance plan that includes: (1) measures to detect, correct, and prevent fraud, waste, and abuse; and (2) written policies, procedures, and standards of conduct articulating Provider's commitment to comply with all applicable federal and state standards; (3) the designation of a compliance officer and compliance committee accountable to senior management and responsible for high level oversight of Provider's compliance plan; (4) effective training and education for Provider's compliance officer and Provider's employees, Governing Body members, and Downstream Entities, including training on FWA; (5) effective lines of communication between the compliance officer and [redacted] and the compliance officer and Provider's employees, Governing Body members, and Downstream Entities; (6) enforcement of standards through well-publicized disciplinary actions; (7) procedures for effective and routine internal monitoring and auditing; and (8) procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives related to any evidence of fraud and misconduct.

3.21 **Compliance and FWA Concerns.** Provider shall, and shall require its Downstream Entities to, within five (5) business days of becoming aware of an actual, suspected, or potential compliance concern or actual, suspected, or potential fraud, waste, and abuse by Provider, Provider's Governing Body members, employees, contractors, agents, or Downstream Entities, report such compliance and FWA concerns to [redacted] These reports may be made to the

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What are my compliance obligations as an FDR?

Most Sponsor Plans we looked at take a more measured approach and use a annual certification form as part of its FDR oversight. Here is what you should expect to be doing:

1. Distribute Code of Conduct & Compliance Policies: You can circulate the Plan Sponsor's documents or use your own if it comparable. Within 90 days of hire and annually thereafter.
2. Compliance and FWA Training: Within 90 days of initial hire and annually thereafter. Caveat on "deemed" status.
3. Exclusion Checks: Federal Healthcare Programs cannot pay for items or services furnished or prescribed by an excluded provider or entity. FDRs must check exclusion databases monthly.
4. Reporting Awareness: Make employees aware of FWA reporting mechanisms.
5. Reporting FWA: Report FWA and compliance concerns to Plan Sponsors.
6. Monitoring and Auditing: Self-auditing and of first tier, downstream and related entities.
7. Offshore Operations: Report and request to use offshore operations (discussed later).

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Record Retention, Attestations & Consequences

- Must maintain proof for 10 years. On audit, you will be asked for proof of:
  - Distribution of policies
  - Training and education
  - Exclusion checks (need to be time stamped)
  - Corrective Action Plans for self and downstream entities
  - Reporting compliance issues
  - Offshore subcontracting arrangements
- Complete Annual Attestation. You will certify to the Plan Sponsor that you/your entity is in compliance with various requirements.
- Failure of a FDR to meet the CMS requirements could result in one of the following:
  - Development of a correction action plan (CAP)
  - Retraining
  - Termination of an FDR's contract

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Offshore Business Services Reporting

This is about ensuring PHI is protected.

FDRs are required to notify and obtain approval from Plan Sponsors before engaging in offshore business.

This requirement is triggered when an offshore entity will receive access to PHI for a Plan Sponsor (examples include billing and coding services, storage of medical records, offshore physicians reading scans/images).

An offshore subcontractor is a FDR located outside of one of the fifty U.S. states, the District of Columbia, or one of the United States Territories (American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands).

Offshore outsourcing is permitted however an Attestation must be submitted and include information concerning the terms of the agreement and security measures the offshore business must adhere to.

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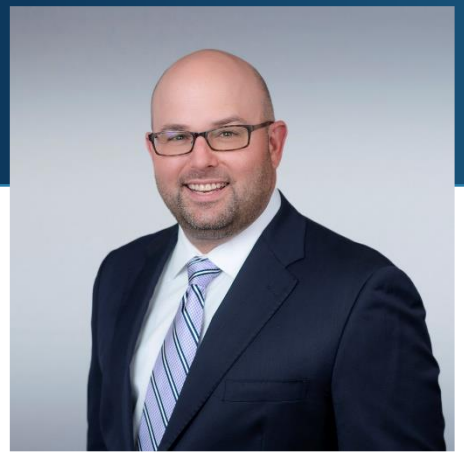
THANK YOU!

Thank you for joining us.

Contact Information



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