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Compliance with attestation requirements: Tips for FDRs

» First tier, downstream, or related entities (FDRs) must build compliance frameworks to satisfy attestation requirements.
» Standards of conduct and effective communication are crucial for compliance.
» Relevant documents must be retained for ten years.
» Manage risks through a risk assessment and annual work plan.
» Report the use of offshore entities.

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Establishing a robust and comprehensive compliance program is crucial to the prevention, detection, and mitigation of risk. To assist Medicare Advantage Organizations (MAOs) and Medicare Prescription Drug Plans (Part D) with the creation of an effective compliance structure, the Centers for Medicare & Medicaid Services (CMS) has published extensive guidance on this topic.[1] Although CMS controls the compliance requirements for MAOs and Prescription Drug Plans, it does not have direct authority over a first tier, downstream, or related entity's (FDR) compliance program.[2]

Instead, CMS establishes requirements and guidance for sponsors of Part D Plans and MAOs to use regarding oversight of their FDRs. This guidance necessarily vests sponsors with discretion regarding how to effectuate and conduct FDR oversight for compliance purposes. Indeed, because sponsors that engage FDRs maintain ultimate responsibility for satisfying all Medicare program requirements, it is common for them to flow down certain compliance requirements and mandate confirmation or proof of compliance. This proof typically takes the form of an annual attestation document or certification. This article discusses the most common sponsor attestation requirements, and offers tips for how FDRs can build successful compliance frameworks.


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Develop standards of conduct, policies, and procedures

First, FDRs should develop written policies, procedures, and standards of conduct. Standards of conduct set forth the organization's commitment to follow applicable laws and regulations, and also state its dedication to ethical business practices. An effective code of conduct works in concert with the mission statement to build a strong, ethical foundation that prioritizes compliance. Policies and procedures, on the other hand, delve more specifically into the compliance program's operation and substantive risk areas. Specifically, where the code of conduct reflects

the organization's ethical philosophy, the policies and procedures highlight the organization's response to the daily risks it faces.[3] These documents help clearly communicate compliance expectations and ensure employees are aware of their compliance obligations.

Development of written policies, procedures, and standards of conduct is generally mandated by most MAOs and Part D Plan sponsors. CMS requires MAOs and sponsors to communicate their compliance expectations of FDRs, and this includes ensuring that standards of conduct, policies, and procedures are distributed to all FDRs. MAOs and sponsors retain discretion regarding distribution of these standards to FDRs and establishment of systems or procedures to ensure that FDRs implement comparable standards. Typically, the sponsor's contracts with its FDRs will determine specifics regarding communicating compliance expectations through standards of conduct.

In general, most FDRs have already adopted their own standards of conduct consistent with CMS's compliance guidelines. These entities, therefore, can demonstrate to the sponsor or MAO that compliance expectations are already being satisfied and communicated throughout the organization and to downstream companies.[4] That said, it is within the sponsor's discretion to ensure that the FDR has comparable policies, procedures, and standards of conduct to its own. If a sponsor or MAO determines that the FDR's documents are insufficient, it may require distribution of and adherence to its own policies, procedures, and standards of conduct.

Action tip: Take time to read through the code of conduct of MAOs or sponsors with which your organization contracts. Determine if there are any gaps between your organization's documents and the sponsor's documents. If so, consider what revisions you could implement to bring your standards of conduct in line with those of the sponsor organization.

Ensure appropriate distribution of standards of conduct, policies, and procedures

In addition to drafting standards of conduct, policies, and procedures, FDRs must distribute these documents to their employees. It is common for MAOs and sponsors to require distribution of the standards of conduct: (1) within 90 days of an employee being hired or the effective date of contracting; (2) when there are updates to the standards of conduct; and (3) annually thereafter.[5] FDRs should integrate these distribution requirements into their own policies and procedures to ensure full compliance.

Action tip: When distributing standards of conduct, policies, and procedures, include a removable employee signature page. This signed acknowledgment form indicates that the employee has received and reviewed the specified documents. Signature pages should be kept on file in accordance with document retention requirements to prove compliance.

Retain relevant documents for 10 years

Next, FDRs should implement a document retention system that preserves relevant documents for at least 10 years. Document retention is a crucial aspect of Medicare compliance. MAOs are required to maintain books, records, documents, and evidence of accounting procedures and practices for at least 10 years.[6] It is extremely common for MAOs and Part D Plan sponsors to flow down this requirement to FDRs. Indeed, most attestation forms require FDRs to certify that they maintain all books, records, and documents regarding any Medicare Advantage services, as well as documentation of compliance with all Medicare requirements, for 10 years.

Action tip: Consider how to develop a workable and comprehensive document

archive system. Ensure that your organization has an effective process for identifying and handling or disposing of records that are older than ten years and no longer needed for compliance purposes.

Participate in effective training and education programs

In addition to developing written standards of conduct and ensuring document retention, FDRs must participate in effective training and education in at least two areas: (1) general compliance; and (2) fraud, waste, and abuse. These trainings should be made part of the orientation process, and must be completed within 90 days of initial hire or contract, and annually thereafter.[7] MAOs and sponsors generally are responsible for establishing and providing these trainings to their employees and FDRs, and may specify the types of training required. Over time, this has caused FDRs to complain about the burden of complying with multiple sponsoring organizations' compliance trainings.

Given CMS's proposed rule, it is unclear how FDR training and education requirements will change in the future.

In 2014, CMS attempted to resolve these concerns by developing its own web-based standardized compliance training modules. Effective January 1, 2016, FDRs were required to complete the web-based CMS training for both general compliance and fraud, waste, and abuse.[8] However, on November 28, 2017, CMS issued a proposed rule intending to delete the regulatory provisions that require use of the CMS-developed training for FDRs.[9] CMS explained that the broad requirement that Plan sponsors provide compliance training to their FDRs no longer promotes the effective administration of the Medicare Advantage and Prescription Drug programs. Indeed, CMS has proposed to remove FDRs from the compliance training requirement altogether.

Given CMS's proposed rule, it is unclear how FDR training and education requirements will change in the future. These entities may be excluded from the training and education requirements; however, good compliance practices counsel against avoiding these topics altogether. FDRs should continue to develop and implement their own training and education programs on compliance topics that are relevant to their organizations. Additionally, until CMS publishes a final rule, FDRs must continue to complete the CMS web-based training programs.

Action tip: FDRs should monitor the legal and regulatory landscape and keep abreast of new CMS rules. Completion of CMS's web-based training program is still a requirement until a final rule stating otherwise is passed. However, FDRs should supplement this training with their own education programs specific to their organizational needs.

Establish effective lines of communication

Further, FDRs must establish effective lines of communication. MAOs and sponsors typically require FDRs to have at least one anonymous mechanism for employees to report suspected non-compliance or fraud, waste, and abuse. This reporting mechanism must be accessible to all parties. Use of multiple communication methods, including hotlines, is encouraged. The available methods for reporting non-compliance must be widely publicized throughout the FDR's facilities, and the MAO or sponsor should also have reporting mechanisms that FDRs can access.

To create effective lines of communication, FDRs should focus on ensuring that multiple channels of reporting are available to its employees. For example, an organization may operate a hotline, maintain an e-mail account for the receipt of compliance reports, and encourage reporting to a supervisor or the chief compliance officer. These reporting methods should be detailed in the code of conduct or employee handbook and posted throughout the organization. Additionally, make sure that employees are aware of the non-retaliation policy for good faith reporting of compliance concerns. Your organization may also want to endeavor to maintain the confidentiality of all individuals who report violations, regardless of whether the individual uses anonymous reporting.

Moreover, FDRs may be required to report suspected non-compliance or legal violations related to the Medicare program directly to the MAO or sponsor. Make sure your organization understands its reporting obligations to all entities with which it holds a contract. The reporting mechanisms and contacts at each MAO may vary, so it is important to understand your reporting obligations and how to satisfy those obligations up front, before an incident occurs.

Action tip: Ensuring that employees know how and to whom to report compliance concerns is crucial. Delayed reporting can increase organizational and reputational harm. Consider including a training module on the available reporting mechanisms in your general compliance training curriculum.

Develop risk identification, monitoring, and response strategies

The identification and remediation of compliance risks is critical to the functioning of an effective compliance program. To ensure their FDRs maintain robust compliance programs, MAOs and sponsors may require FDRs to create and maintain an established process or procedure for risk identification and response/remediation. This process must be used on a routine basis and may include auditing and monitoring. The purpose of auditing and monitoring is to test and confirm the organization's compliance with legal standards and the written compliance policy. Effective monitoring and auditing can result in early identification of operational weaknesses and risks, which may reduce exposure to government investigations or *qui tam* claims.

The requirement for effective auditing and monitoring can be met by developing an internal monitoring and auditing work plan that is prioritized by risk. Risks that are identified through this process must be prioritized for resolution. FDRs should document their risk identification and response processes in case of an audit from the MAO or sponsor. Indeed, specific monitoring of FDRs is required, and a sponsor may perform its own risk assessment to identify and audit its highest risk first-tier entities.[10]

Action tip: Conducting an annual risk assessment and developing an annual work plan can be effective tools for risk mitigation. The work plan should be based on the risk assessment and can help the organization focus on key risk areas.

Manage downstream entity relationships

In addition to ensuring the strength of its own compliance program, a first-tier entity must apply appropriate compliance program requirements and monitor the compliance of any downstream entities with which it contracts. MAOs and sponsors may include an attestation requirement that the first-tier entity appropriately applies compliance program requirements to downstream entities and monitors such compliance. Accordingly, it is important for your organization to ensure it has a process in place to verify downstream

compliance. The exact process will differ by organization, but oversight should include, at a minimum, testing the compliance of downstream entities through monitoring and auditing and imposing corrective action if deficiencies are discovered.

Action tip: Depending on the number of contracts your organization has with downstream entities, it may not be possible to conduct a full-scale audit of each downstream entity every year. Use monitoring and spot audits to help identify which downstream entities pose the highest risk of non-compliance. Additionally, if you see non-compliant trends across entities, consider how best to address those on a global scale.

Check the OIG and GSA exclusion lists

A separate component of the sponsor's monitoring obligations is the implementation of fraud, waste, and abuse safeguards to identify excluded providers and entities. Sponsors and MAOs are prohibited from employing or contracting with an individual or entity that is excluded from participation in Medicare. Accordingly, MAOs and sponsors must review the Department of Health & Human Services' OIG List of Excluded Individuals and Entities and the General Services Administration (GSA) Excluded Parties Lists System prior to hiring a new employee or contracting with an FDR and monthly thereafter.[11] MAOs and sponsors can delegate the responsibility to perform this administrative function to FDRs. In fact, it is quite common for this duty to be delegated. As such, FDRs must make sure they have a process in place to confirm that they—and all employees, board members, consultants, volunteers, providers, and contractors that are involved in the administration or delivery of Medicare services—are not on the OIG and GSA exclusion lists prior to hiring and on a monthly basis thereafter. If an FDR discovers that an employee or contractor is on the exclusion list, it must remove that individual from any work directly or indirectly related to federal healthcare programs.

Action tip: Consider which department is best suited to handle routine checking of the exclusion lists. Some organizations house this requirement in the Compliance department, but others assign it to the Human Resources department. Determine what works best for your compliance framework.

> ...CMS has expressed concern about offshore organizations' accountability for personally identifiable information.

Report use of offshore entities

Finally, in addition to requiring MAOs and sponsors to establish robust compliance programs, CMS limits the use of offshore entities for Medicare functions. Particularly, CMS has expressed concern about offshore organizations' accountability for personally identifiable information.[12] Sponsors and MAOs that work with offshore subcontractors for Medicare-related work that uses personally identifiable health information are requested to provide CMS with specific offshore contractor information and complete an attestation regarding protection of beneficiary health information.

Given CMS's policy on offshore entities, numerous MAOs and sponsors have adopted a general policy that prohibits the offshore delegation of Medicare services. Accordingly, these MAOs and sponsors require FDRs to certify that they do not use or employ offshore entities for Medicare Advantage programs. If an FDR does contract with an offshore entity,

it generally must disclose the identity of that organization to the MAO or sponsor and detail what services that entity performs.

Action tip: If your organization uses offshore entities for Medicare services, review your MAO or sponsor contract obligations carefully. Some sponsors and MAOs may strictly prohibit use of offshore entities. Also, carefully consider whether your organization can protect the personally identifiable health information that is sent overseas.

Conclusion

Compliance with sponsor attestation requirements is an undeniable reality of the healthcare regulatory environment for FDRs. However, because CMS does not directly control or regulate an FDR's compliance program, there is confusion regarding which compliance program elements apply to FDRs. It is a best practice for FDRs to adhere to all seven elements of an effective compliance program described by CMS. Such adherence demonstrates a firm organizational commitment to compliance and ethics, and can be an important tool in preventing illegal or non-compliant behavior.

That said, sponsor attestation forms tend to focus broadly on certain categories of FDR compliance, including: (1) written policies, procedures, and standards of conduct; (2) document retention; (3) training and education; (4) effective lines of communication; (5) risk identification, monitoring, and mitigation; (6) managing downstream entity compliance; (7) OIG exclusion lists; and (8) offshore entities. FDRs seeking to build or strengthen their compliance programs may wish to focus on these categories, but should also review the specific attestation forms they will be required to sign for additional insight into structuring their compliance programs.

1. Centers for Medicare & Medicaid Services (CMS): *Medicare Managed Care Manual* Chapters 9 and 21. January 11, 2013. Available at https://go.cms.gov/2sf79Ub
2. CMS: "Questions and Answers Supplement to the Compliance Program Guidelines Focused Training Element 1: Written Policies, Procedures, and Standards of Conduct" January 30, 2013. Available at https://go.cms.gov/2qFi71E
3. Office of Inspector General & American Health Lawyers Assoc.: Corporate Responsibility and Corporate Compliance: A Resource of Health Care Boards of Directors. Available at https://bit.ly/2C0MhzZ
4. Ibid, Ref #1, § 50.1.3.
5. Idem.
6. 42 C.F.R. §§ 422.504(d)-(e), 423.505(d)-(e).
7. Ibid, Ref #1, § 50.3.1.
8. See 42 C.F.R. §§ 422.503(b)(4)(vi)(C)(3), 423.504(b)(4)(vi)(C)(4).
9. 82 Fed. Reg. 56336, 56429-30 (Medicare Program, Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program) November 28, 2017.
10. Ibid, Ref #1, § 50.6.6.
11. 42 C.F.R. § 422.503(b)(4)(vi)(F).
12. CMS: Sponsor Activities Performed Outside of the United States (Offshore Subcontracting). July 23, 2007. Available at https://bit.ly/2HGc1WV