Frequently Asked Questions (FAQs) for First Tier, Downstream and Related Entities (FDRs)

These FAQs were developed for ATRIO's FDRs. They summarize common questions and answers about the Medicare compliance requirements. The ATRIO FDR Guide explains each requirement in more detail. There's also a toolbox of resources for FDRs, to help them meet these requirements.

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1. General questions

What does FDR mean?

FDR stands for first tier, downstream and related entities. Examples of FDRs include sales partners/agents contracted to market and sell our Medicare products, vendors providing administrative services for our Medicare members/products and delegates contracted to make decisions on our behalf for our Medicare members/products.

The Centers for Medicare & Medicaid Services (CMS) defines FDRs as:

- **First Tier Entity:** Any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization (MAO) or Part D plan sponsor 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:** Any party that enters into a written agreement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangement between an MAO or applicant or a Part D plan sponsor or applicant and a first tier entity. These arrangements continue down to the level of the ultimate provider of both health and administrative services.
- **Related Entity:** This refers to any entity that is related to an MAO or Part D Sponsor 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 an oral or written agreement; or
    3. Leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than $2,500 during a contract period.

What ATRIO products and plans do these requirements apply to?

We offer Medicare Advantage (Part C) and Prescription Drug (Part D) coverage to Medicare members. These requirements apply to all entities that are contracted to provide administrative or health care services for our Part C and/or Part D Medicare products:

- Medicare Advantage (MA) plans
- Medicare Advantage Prescription Drug (MAPD)
- Prescription Drug Plans (PDP)
- Medicare-Medicaid Plans (MMP)

What is the source of these requirements?

These regulatory requirements are from CMS.

They are codified in Federal Regulations 42 CFR 422.503(b)(4)(vi), 422.504(b)(4)(vi) and are described in more detail within the Medicare Managed Care Manual, Chapter 21 – Compliance Program Guidelines and Prescription Drug Benefit Manual, Chapter 9 – Compliance Program Guidelines, and updated periodically by Final Rules.

Are the requirements new?

No, these requirements are not new. You should have received a similar notice about these requirements in previous years. There have been changes to these requirements since they were implemented.

Training Requirements

Effective 2018, CMS updated the requirements regarding General Compliance and Fraud, Waste, and Abuse (FWA) training. FDRs are still required to train their staff, but they are no longer required to use specific training from ATRIO or from CMS. If you aren't familiar with the guidance, just review our FDR Guide.

We don't meet all of the Medicare Compliance requirements on the attestation so we can't attest. Who do we report this to? Will we be terminated?

If your organization is not meeting the requirements, contact ATRIO Compliance at fdroversight@atriohp.com. We will collaborate with you to create a corrective action plan (CAP) to ensure you meet the requirement(s). If you are willing to comply with the requirements, your contract will not be terminated.

What will happen if I don't comply with the requirements?

We will collaborate with you to create a corrective action plan (CAP) to ensure you meet the requirement(s). If you are willing to comply with the requirements, your contract will not be terminated.

Why am I receiving a notice to complete an attestation?

You were identified as a first tier entity because of your contractual relationship with us. We collect attestations to confirm that you understand and are complying with the requirements.

I have no employees. Do I have to complete an attestation?

Yes, you should submit an attestation even if you have no employees. This includes solo practitioners, sales partners, agents, etc.

Does each staff member have to complete the attestation?

No. An authorized representative can submit an attestation on behalf of your organization. We describe who might be an authorized representative in the FDR Guide. For Sales Partners/agents, we track attestation completion by National Producer Number (NPN).

What documentation must I keep?

You must have documentation to show you are compliant with each requirement. Examples include: policies and procedures, logs and attestations.

Who do I contact if I have more questions?

If you have any questions about the Medicare Compliance requirements that are not addressed in our FDR Guide, please email fdroversight@atriohp.com.

2. Code of Conduct and compliance policies

What is a Code of Conduct?

A Code of Conduct is also known in some organizations as the "Standards of Conduct." It states the overarching principles and values by which the company operates, and defines the framework for the compliance program.

How often must the Code of Conduct be distributed?

A Code of Conduct and/or compliance policies must be distributed to employees annually, as well as within 90 days of hire and when changes are made. FDRs can distribute ATRIO's Code of Conduct and Medicare Compliance Policies or comparable documents.

Can I use my own Code of Conduct?

Yes, you can use your own Code of Conduct and compliance policies. They must contain the elements set forth in Section 50.1 and its subsections of Chapters 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual. They must also articulate the entity's commitment to comply with federal and state laws, ethical behavior and compliance program operations.

If you don't have them, you can use ATRIO's Code of Conduct.

3. Reporting mechanisms

Do we have to report noncompliance and FWA to ATRIO?

Issues that impact ATRIO's Medicare business must be reported to ATRIO. You can have employees report directly to ATRIO. Or you can train employees to use your own internal mechanisms for reporting noncompliance and FWA.

If you use your own reporting mechanisms, your internal processes must include a process to report concerns to ATRIO. We enforce a zero-tolerance policy for retaliation or retribution against anyone who reports suspected misconduct.

What can I do if I suspect FWA or noncompliance?

You must report the issue to us so we can investigate and respond to it immediately. A few of the ways you can report issues are on this poster. Others are outlined in our Code of Conduct.

Don't worry about retaliation. We enforce a zero-tolerance policy for retaliation or retribution against anyone who reports suspected misconduct.

4. Exclusion lists screening

What are the exclusion lists?

There are 2 exclusion lists:

- Office of Inspector General (OIG) List of Excluded Individuals/Entities
- General Services Administration (GSA) System for Award Management (SAM)

What is the difference between the OIG and GSA SAM?

GSA SAM includes exclusion and debarment actions taken by various federal agencies. The OIG only contains the exclusion actions taken by the OIG. You must screen both.

What are the requirements related to exclusion list screenings?

FDRs must review both the OIG and GSA SAM exclusion lists. Review both of these lists before hiring or contracting and monthly thereafter. This ensures employees and downstream entities are not excluded from participating in federal health care programs. We explain the requirement in more detail within the FDR Guide.

How often do the exclusion list screenings have to be completed?

Both the OIG and GSA SAM exclusion lists must be checked before hiring/contracting and **monthly** thereafter.

What evidence must I keep to show that these checks are completed?

The documentation may vary depending on how you complete screenings. If you perform these checks using an automated system or program, your documentation may be based on the information available within that system.

Regardless of how you do these checks, your documentation should show:

- What exclusion list was checked
- The name of the entity or individual checked
- Date completed
- Result

What if an individual or entity is identified as excluded?

If you employed or contracted with an excluded individual or entity you must report this to ATRIO. You must also remove them from directly or indirectly servicing ATRIO's Medicare products.

5. Record retention

How long do I need to maintain records?

Keep records of your Medicare compliance program requirements (for example, exclusion list screenings) for at least 10 years.

6. Downstream entity oversight

Why are you asking about my downstream entities (i.e., subcontractors)?

We are accountable to CMS for all of our FDRs. If you are subcontracting, then we need to ensure you are doing appropriate oversight of your downstream entities.

What requirements apply to downstream entities?

Downstream entities must comply with all applicable regulatory requirements that apply to the Medicare Parts C & D program. This includes the compliance program requirements explained in our FDR Guide.

What oversight is expected for my downstream entities?

If you use downstream entities you must have adequate oversight of their compliance and performance. This includes testing the compliance and performance of your downstream entities through audits or monitors and imposing corrective actions when deficiencies are identified.

7. CONTACT US

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