



MEDICARE FIRST TIER,
DOWNSTREAM AND
RELATED ENTITIES (FDR)
COMPLIANCE GUIDE

MEDICARE FDR COMPLIANCE GUIDE

We at ATRIO Health Plans would like to thank you for your partnership and helping us to provide exceptional service to our Medicare beneficiaries. The Centers for Medicare and Medicaid Services (CMS) regulatory guidance refers to our contracted partners as First-Tier, Downstream, and Related entities, or FDRs.

CMS requires that ATRIO's FDRs fulfill specific Medicare compliance program requirements. We describe these requirements in this document. The Code of Federal Regulations 42 CFR 422.503(b)(4)(vi), 422.504(b)(4)(vi) outlines these requirements, and they are defined further by CMS in the Medicare Managed Care Manual Chapter 21 – Compliance Program Guidelines and Prescription Drug Benefit Manual Chapter 9 – Compliance Program.

ATRIO is required to effectively manage and oversee our FDRs that assist us in providing administrative and/or healthcare services for our Medicare beneficiaries. ATRIO 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 ATRIO accountable for the failure of our FDRs to comply with Medicare program requirements.

You received this guide because we have identified you as a First Tier Downstream or Related Entity. This means that you must comply with these requirements.

What is an FDR?

We use the current CMS definitions to define First Tier, Downstream and Related Entities:

First Tier Entity is any party that enters a written arrangement, acceptable to CMS, with an MA organization or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare-eligible individual under the MA program or Part D program. (See 42 CFR §§ 422.500 and 423.501.)

Downstream Entity is any party that enters a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangement between an MA organization or applicant or a Part D plan sponsor 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. (See 42 CFR §§ 422.500 and 423.501.)

Related Entity means any entity that is related to an MA organization or Part D sponsor by common ownership or control and: 1. Performs some of the MA organization or Part D plan sponsor's management functions under contract or delegation 2. Furnishes services to Medicare enrollees under an oral or written agreement 3. Leases real property or sells materials to the MA organization or Part D plan sponsor at a cost of more than \$2,500 during a contract period (See 42 CFR §§ 422.500 and 423.501.)

FDRs providing administrative services

The Medicare compliance program requirements apply to entities with which we contract to perform (or delegate) administrative service functions relating to our MA or Part D contracts with CMS. Examples of administrative service functions include but not limited to:

- Claims processing
- Patient management
- Credentialing

Other examples of FDRs include delegates, agents, broker organizations, Pharmacy Benefit Manager and other individuals, entities, vendors, or suppliers contracted with ATRIO to provide administrative and/or health care services for our Medicare plans. You can find more information in the Managed Care Manual, Chapter 21 § 40.

FDR Medicare Compliance Program and Attestation Requirements

It is important that our FDRs follow applicable laws, rules, and regulations. Although we contract with FDRs to provide administrative and/or health care services for our Medicare plans, in the end, we are responsible for fulfilling the terms and conditions of our contract with CMS and meeting applicable Medicare program requirements. Our FDRs are responsible for complying with relevant Medicare program requirements as well. FDRs must also ensure that their Downstream Entities, which they use for our ATRIO Medicare products, comply with applicable laws and regulations, including the requirements in this guide.

Compliance program requirements

Your organization and all your downstream entities must comply with Medicare compliance program requirements. This guide summarizes those requirements. Please review to make sure that you have internal processes to support your compliance with these requirements each calendar year. These Medicare compliance program requirements include, but are not limited to:

- Code of Conduct and compliance program policies and distribution
- General compliance and FWA education and training
- Monthly exclusion list screenings for all employees and downstream entities
- Providing your employees ways to report non-compliance, including an anonymous option
- Reporting FWA and compliance concerns to ATRIO
- Offshore operations requests and reporting
- Specific federal and state compliance obligations
- Monitoring and auditing of downstream and related entities

Also, see the *“Toolbox of resources for FDRs”* at the end of this guide. It may help you meet these requirements.

What may happen if you do not comply

If our FDRs fail to meet these CMS Medicare compliance program requirements, we may require:

- Development of a corrective action plan (CAP)
- Retraining
- Termination of your contract with ATRIO

Our actions in response to non-compliance will depend on the severity of the compliance issue. If you identify areas of non-compliance, you must report it to ATRIO, take prompt action to fix the issue and prevent it from happening again.

Attestation requirements

You must maintain evidence of your compliance with these Medicare compliance program requirements for no less than 10 years. In addition, each year, an authorized representative from your organization must attest to your compliance with the Medicare compliance program requirements. The authorized representative is an individual who has the authority and responsibility for:

- Employees
- Contracted personnel
- Vendors who provide health care and/or administrative services for ATRIO’s Medicare plans

This could be your Compliance Officer, Chief Medical Officer, practice manager/administrator, an executive officer, or similar positions.

You must distribute a Standard or Code of Conduct to your employees and downstream entities

Your organization must provide either ATRIO's Code of Conduct and Medicare compliance policies or your own comparable Code of Conduct/compliance policies (collectively, "standards of conduct") to all applicable employees and downstream entities who provide administrative and/or health care services for our Medicare plans. The written compliance policies and standards of conduct must contain all the elements set forth in Section 50.1 and its subsections of the Medicare Managed Care Manual, Chapter 21, and articulate your entities commitment to comply with federal and state laws, ethical behavior, and compliance program operations. You must distribute standards of conduct/policies:

- Within 90 days of hire or the effective date of contracting
- When there are updates to the standards of conduct
- Annually thereafter

You must also retain evidence of your distribution of the standards of conduct for a period of 10 years.

You can find the standards of conduct requirements in:

- 42 CFR § 422.503(b)(4)(vi)(A) for MA
- 42 CFR § 423.504(b)(4)(vi)(A) for Part D
- Medicare Managed Care Manual, Chapter 21 § 50.1

Complete Compliance and Fraud, Waste, and Abuse (FWA) education and training

FDRs are not exempt from general compliance training requirements, but you may be deemed to have met the FWA education and training requirements through one or both of the following:

- Enrollment in Parts A or B of the Medicare program
- Accreditation as a Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier

You can find the requirements for, and more information about, deemed status in:

- CMS Medicare Managed Care Manual, Chapter 21 § 50.6.61
- CMS Medicare Prescription Drug Benefit Manual, Chapter 9
- United States Code of Federal Regulations for Medicare Advantage (MA) plans: 42 CFR § 422.503(b)(4)(vi)(C) and Medicare Part D, Prescription Drug Coverage: 42 CFR § 423.504(b)(4)(vi)(C)

Required education and training must be completed:

- Within 90 days of initial hire or the effective date of contracting
- When materials are updated
- Annually thereafter

You must maintain evidence of completion for 10 years which includes:

- Employee names
- Dates of completion
- Passing scores (if captured)

Definitions of fraud, waste, and abuse:

- Fraud is an intentional deception or misrepresentation made by an individual who knows that the information is false and could result in an unauthorized benefit to him/herself, another person or the Plan.
- Waste is defined as the overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare program.
- Abuse is defined as an incident or practice that is not consistent with sound medical business or fiscal practices, which may result in unnecessary program costs, improper payment for services and directly or indirectly result in unnecessary costs to the programs that ATRIO administers.

FWA laws include:

- Anti-kickback Statute (31 U.S.C. §§ 3729-3733)
- Criminal Code (18 U.S.C. Section 1347)
- False Claims Act (31 U.S.C. §§ 3729-3733)
- Social Security Act (42 U.S.C. chapter 7)
- Stark Law (42 USC § 1395nn)

These laws state the criminal, civil and administrative remedies the federal government may impose when FWA is committed. Violating these laws may result in:

- Non-payment of claims
- Civil money penalties
- Exclusion from all federal health care programs
- Criminal and civil liability

Exclusion List Screenings

Federal law prohibits Medicare, Medicare Advantage, Medicaid, and other federal health care programs from paying for items or services provided by a person or entity excluded from participation in these federal programs. Therefore, before hiring or contracting, and monthly after that, each FDR must check exclusion lists from the Office of Inspector General (OIG) and the U.S. General Services Administration (GSA). This is to confirm that **employees, temporary employees, volunteers, consultants, members of your governing body and FDRs** are not excluded from participating in federally funded health care programs. You can use these websites to perform the required exclusion list screening:

- [OIG List of Excluded Individuals and Entities \(LEIE\)](#)
- [GSA's System for Award Management \(SAM\)](#)

You **must maintain evidence** you checked these exclusion lists for a minimum of 10 years. You can use the **OIG_GSA-Screening-Log** we provide at the end of this document. However, you must have supporting documentation available. Supporting documentation includes, but is not limited to, print screens of screening results, system reports that provide the **name, date of screening** and the **results** or other records for documentation that you have screened each employee, temporary employee, volunteer, consultant, member of your governing body and downstream entity in accordance with current laws, regulations, and CMS requirements. Be sure to also retain evidence of any actions taken if sanctioned individuals or entities were identified.

You are not alone. ATRIO is also required to check these exclusion lists before hiring or contracting with any new employee, temporary employee, volunteer, consultant, governing body member or FDR, and monthly after that. We cannot check these exclusion lists for your employees and downstream entities. So, to make sure we comply with this CMS requirement, you must confirm that your permanent and temporary employees and downstream entities that provide administrative and/or health care services for our Medicare plans are not on either of these exclusion lists.

You must take action if an employee or Downstream Entity is on the exclusion list

If any of your employees or downstream entities are on one of these exclusion lists, you must immediately remove them from working directly or indirectly related to ATRIO's Medicare plans and notify us right away.

These exclusion list requirements are noted in the following places:

- § 1862(e)(1)(B) of the Social Security Act,
- 42 CFR §§ 422.503(b)(4)(vi)(F), 422.752(a)(8), 423.504(b)(4)(vi)(F), 423.752(a)(6), 1001.1901,
- Medicare Managed Care Manual Chapter 21 § 50.6.8.

Reporting FWA and Compliance Concerns to ATRIO

There are several confidential ways to report suspected or detected noncompliance or potential FWA. You can find this information in ATRIO's reporting mechanism poster (see Toolbox on last page). If you choose to use your own processes,

make sure you report to ATRIO. You can refer to our Code of Conduct for information on our reporting guidelines.

You must adopt and enforce a policy for non-retaliation and non-intimidation against anyone who reports suspected misconduct.

Offshore Operations and CMS Reporting

To help make sure we comply with applicable federal and state laws, rules and regulations, you are required to request permission to perform offshore services or to use an individual or entity (offshore entity) to perform services for ATRIO's Medicare plans when the individual or entity is physically located outside the United States or one of its territories (that is, American Samoa, Guam, Northern Marianas, Puerto Rico and Virgin Islands). The only approval is made by an authorized ATRIO representative in advance and in writing for the use of such offshore individual or entity.

Notify us immediately if you plan to use an offshore entity.

If you perform services offshore or use an offshore entity to perform services involving the receipt, processing, transferring, handling, storing, or accessing of Medicare member protected health information (PHI) we must approve the arrangement. ATRIO is required to submit an attestation to CMS, and CMS requires an annual audit to ensure compliance with the applicable laws. Therefore, you must immediately notify your ATRIO relationship manager if you engage in offshore services yourself or through an offshore entity.

Specific Federal and State Compliance Obligations

Based on the services that you/your organization performs for ATRIO's Medicare plans, you may be subject to other federal and state laws, rules, and regulations that we did not describe in this guide. If you have questions about the Medicare requirements for the services that you/your organization performs, consult your ATRIO relationship manager or contact compliance@atriohp.com. ATRIO expects you/your organization to be compliant with all applicable federal and state laws, rules, and regulations.

Monitoring and Auditing of First Tier and Downstream Entities

CMS requires that we develop a strategy to monitor and audit our first tier entities. This helps ensure that our first tier entities comply with all applicable laws and regulations and that our first tier entities must monitor the compliance of their downstream entities. Therefore, if you choose to subcontract with other individuals/parties to provide administrative and/or health care services for ATRIO's Medicare plans, you must make sure that these downstream entities abide by all laws and regulations that apply to you as a first tier entity. This includes ensuring:

- Notification to ATRIO prior to contracting with downstream entities
- Contractual agreements contain all CMS-required provisions
- Downstream entities comply with the Medicare compliance program requirements described in this guide
- Downstream entities comply with any applicable Medicare operational requirements

Not every subcontractor is considered a downstream entity. Only those entities who provide administrative or health care services for ATRIO's Medicare Advantage and Prescription Drug Plan products may be downstream entities. Review this [grid](#) to help you determine who is a downstream entity for your organization. If you have additional questions, feel free to contact us for assistance at compliance@atriohp.com.

Your organization must conduct sufficient oversight (that is, auditing and monitoring) to test and ensure that your employees and downstream entities are compliant. You must retain evidence of oversight completion, ensure root cause analysis is conducted for any deficiencies, and implement corrective actions or take disciplinary actions such as contract termination, as necessary, to prevent recurrence of non-compliance.

We routinely monitor and periodically audit our FDRs. This helps us ensure compliant administration of our contracts with CMS to offer Medicare plans, as well as applicable laws and regulations. Each FDR must cooperate and participate in these monitoring and auditing activities. If an FDR performs its own audits, we may ask for the audit results affecting ATRIO's Medicare business. In addition, FDRs must routinely monitor and/or periodically audit their downstream entities if they are used for ATRIO's Medicare plans.

If we determine that an FDR does not comply with any of the requirements in this guide, we will require the FDR to develop and submit a Corrective Action Plan (CAP). We can help the FDR address the identified compliance issues.

These monitoring and auditing requirements are noted in:

- 42 CFR § 422.503(b)(4)(vi)(F) for MA
- 42 CFR § 423.504(b)(4)(vi)(F) for Part D
- Medicare Managed Care Manual, Chapter 21 § 50.6.6

Toolbox of Resources for FDRs

Code of Conduct and Compliance Policies	
Do not have your own Code of Conduct?	Feel free to distribute ATRIO's Corporate Code of Conduct to your employees and Downstream Entities.
Do not have your own policies?	ATRIO's compliance policies are found here. • Access to Facilities and Records • Centers for Medicare and Medicaid Relations • Compliance Program and Compliance Policies Distribution • Compliance Program Disciplinary Standards • Compliance, Fraud Waste Abuse, and HIPAA Mandatory Training • Conflict of Interest Policy • Incident Reporting, Tracking and Resolution • Non Intimidation Non Retaliation Policy • OIG-GSA Screening • Record Retention • Regulatory Guidance Review and Distribution
Exclusion list screenings	
Where is the OIG?	OIG List of Excluded Individuals and Entities (LEIE) You may use this example OIG GSA Screening Log to track OIG exclusion list screenings before hiring/contracting and monthly after that for your employees and downstream entities.
Where is the GSA's SAM?	GSA's System for Award Management (SAM) You may use this example OIG GSA Screening Log to track the GSA's SAM exclusion list screenings before hiring/contracting and monthly after that for your employees and downstream entities.
Reporting Mechanisms	
How do I report non-compliance or potential FWA to ATRIO?	This Compliance Poster provides ways for reporting directly to ATRIO any issues that impact ATRIO. Feel free to share this throughout your organization so that your employees know how to report concerns. Remember, you must report suspected or detected noncompliance or potential FWA that impacts ATRIO.

Monitoring and oversight	
Downstream entity oversight	You must conduct oversight of your downstream entities. An FDR Attestation of Compliance may help your downstream entities self-assess and report the status of their compliance to you.
Check yourself	You can use this Medicare Compliance Program self-assessment tool to assess your compliance with the Medicare compliance program requirements. Your organization can also modify the tool to assess compliance of your downstream entities.
Which subcontractors are downstream entities?	Not every subcontractor is a downstream entity. This grid has examples of downstream entities.

Other Tools	
Offshore attestation form	Use this Offshore Services form to request permission for you or your subcontractor to use an offshore individual or entity to perform services that involve the processing, transferring, handling, storing or accessing of Medicare member PHI. Return the completed form to compliance@atriohp.com .
More tools	If you have ideas for tools that would help you in meeting the Medicare compliance program requirements, send an email to compliance@atriohp.com .
FAQs	If you have a question that we didn't answer in this guide, review our frequently asked questions