



ATRIOTM
HEALTH PLANS

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), in its 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 (CFR) outlines these requirements, and they are defined by CMS in the January 11, 2013, Compliance Program Guidelines in Chapter 21 of the Medicare Managed Care Manual (manual) and Chapter 9 of the Prescription Drug Benefit Manual. The requirements are identical in these two sources.

ATRIO is required to effectively manage and oversee our FDRs that assist us in providing administrative and/or healthcare services for our Medicare beneficiaries. Examples of FDRs include agents, providers, pharmacies, pharmacy benefits managers, claim administration vendors, fulfillment vendors and other vendors who assist us with delivering benefits. 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 its FDRs to comply with Medicare program requirements.

You received this guide because we've identified you as a First Tier Entity. This means that you must comply with these requirements.

What's an FDR?

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

First Tier Entity is any party that enters into 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 into 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 also apply to entities with which we contract to perform administrative service functions relating to our MA or Part D contracts with CMS. Some examples of administrative service functions include:

- Claims processing
- Patient management
- Credentialing

Other examples of FDRs include delegates, agents, broker organizations, pharmacies 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 manual, Chapter 21 § 40, including the Stakeholder Relationship Flow Charts

FDR Medicare compliance program and attestation requirements

It is important that our FDRs are in compliance with 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. FDRs must also ensure that their Downstream Entities, which they use for our ATRIO Medicare products, also comply with applicable laws and regulations, including the requirements in this guide.

Compliance program requirements

Your organization and all of your Downstream Entities must comply with Medicare compliance program requirements. This guide summarizes the Medicare compliance program requirements. Please review it 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/compliance program policy distribution
- Exclusion list screenings
- Reporting FWA and compliance concerns to ATRIO
- Offshore operations and CMS reporting
- Specific federal and state compliance obligations
- Monitoring and auditing of First Tier, 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 don't comply

If our FDRs fail to meet these CMS Medicare compliance program requirements, it may lead to:

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

Our actions in response to noncompliance will depend on the severity of the compliance issue. If an FDR identifies areas of noncompliance, they must 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 responsibility directly or indirectly for all:

- 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 give your employees standards of conduct

Your organization must also 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 of the elements set forth in Section 50.1 and its subsections of the Medicare Managed Care Manual, Chapter 21, and articulate the entity's 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

Also, you must retain evidence of your distribution of the standards of conduct.

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

Exclusion list screenings

Federal law prohibits Medicare, 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 and Downstream Entities performing administrative and/or health care services for ATRIO's Medicare plans aren't 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)

Also, FDRs **must maintain evidence** they checked these exclusion lists. You can use the OIG_GSA-Screening-Log we have provided, however, you must have supporting documentation available. Supporting documentation includes, but 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've screened each employee and Downstream Entity in accordance with current laws, regulations and CMS requirements. Be sure to retain evidence of the screening that was conducted including date of occurrence, the results of the screening and any actions taken if sanctioned individuals or entities were identified.

You must perform exclusion list screenings

You're not alone. We're 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 work directly or indirectly related to ATRIO's Medicare plans and notify us right away.

These exclusion list requirements are noted in § 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, and further described in the manual, Chapter 21 § 50.6.8.

Reporting FWA and compliance concerns to ATRIO

There are a number of ways to report suspected or detected noncompliance or potential FWA. Don't worry — your reports are confidential. You can find this information in ATRIO's reporting mechanism poster. You can share the poster with your employees or Downstream Entities. You can also keep it as a reference tool and use your own internal processes for reporting and collecting these issues. If you choose to use your own processes, make sure you report it to ATRIO. You can also refer back to our code of conduct for information on our reporting guidelines.

You must adopt and enforce a zero-tolerance policy for retaliation or intimidation against anyone who reports suspected misconduct. Questions or concerns can be sent to fdoversight@atriohp.com.

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) and 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.

One example provided by CMS of offshore services that trigger this attestation requirement is "offshore subcontractors that receive radiological images for reading, because beneficiary personal health information (PHI) is included with the radiological image and the diagnosis is transmitted back to the U.S."

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 didn't 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. 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:

- Contractual agreements contain all CMS-required provisions
- They comply with the Medicare compliance program requirements described in this guide
- They 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 fdroveright@atriohp.com.

Also, you/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 noncompliance.

Expect routine monitoring and audits

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 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

Fraud, waste and abuse (FWA) training and general compliance training

Although not required, it is a best practice to ensure your applicable employees complete FWA and general compliance training annually. Applicable employees include staff who are assigned to provide administrative and/or health care services for our Medicare plan(s). Employees can access trainings in a few ways:

- Complete the module on the CMS Medicare Learning network (MLN) website. The FWA training is called Combating Medicare Parts C and D Fraud, Waste, and Abuse Training. Once completed, download and retain the certificate of completion.
- You/your organization can also download or print the content of the FWA CMS training module from the MLN website to incorporate into your training materials/system.
- ATRIO can share our FWA and General Compliance Training with you which you can share or incorporate into your own training module.

Regardless of the method used, it is best practice for the training to be completed:

- Within 90 days of initial hire
- At least annually during each calendar year (January 1 – December 31) thereafter

You should maintain evidence of training completion. Evidence of completion may be in the form of certificates, attestations, training logs or other means determined by you.

Not every employee should take training. Below are examples of critical roles within an FDR that should complete training:

- Senior administrators or managers directly responsible for the FDR's contract with ATRIO (for example, senior vice president, departmental managers, chief medical or pharmacy officer)
- Individuals directly involved with establishing and administering ATRIO's formulary and/or medical benefits coverage policies and procedures

- Individuals involved with decision-making authority on behalf of ATRIO (for example, clinical decisions, coverage determinations, appeals and grievances, enrollment/disenrollment functions, processing of pharmacy or medical claims)
- Reviewers of beneficiary claims and services submitted for payment
- Individuals with job functions that place the FDR in a position to commit significant noncompliance with CMS program requirements or health care FWA

Toolbox of resources for FDRs

Code of Conduct and Compliance Policies	
Don't have your own code of conduct?	Feel free to distribute ATRIO's Code of Conduct to your employees and Downstream Entities.
Don't have your own policies?	ATRIO's compliance policies are found here. <ul style="list-style-type: none"> • Access to Facilities and Records • Centers for Medicare and Medicaid Relations • Code of Conduct and Compliance Policy Distribution • Compliance FWA and HIPAA Incident Reporting and Tracking • Compliance Program Disciplinary Standards • Conflict of Interest Policy • OIG-GSA Screening • Record Retention • Regulatory Guidance Review and Distribution
Exclusion list screenings	
Where is the OIG?	Complete OIG exclusion list screenings before hiring/contracting and monthly after that for your employees and Downstream Entities. You may use this OIG/GSA example screening log to aid in your process.
Where is the GSA's SAM?	Complete the GSA's SAM exclusion list screenings before hiring/contracting and monthly after that for your employees and Downstream Entities. You may use this OIG/GSA example screening log to aid in your process
Reporting Mechanisms	
How do I report noncompliance or potential FWA to ATRIO?	This poster provides ways for reporting issues that impact ATRIO, directly to 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 impact ATRIO.
Monitoring and oversight	
Downstream Entity oversight	You must conduct oversight of your Downstream Entities. An FDR attestation may help your Downstream Entities self-assess and report the status of their compliance to you.
Check yourself	You can use this example 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.
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Other Tools	
Offshore attestation form	Use this 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 fdoversight@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 fdoversight@atriohp.com .
FAQs	If you have a question that we didn't answer in this guide, review our frequently asked questions .