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First Tier, Downstream and Related Entities (FDR) Medicare Compliance Program Guide

March 2017



I. Introduction — Aetna’s Medicare compliance program

Aetna’s reputation as an industry leader depends on our ability to deliver on our promises. For more than 160 years, we’ve been guided by the highest standards of integrity. Our relationships with our customers, business partners and suppliers are built on trust earned over time and through experience. Each day, we must remember our commitment to do the right thing for the right reason and keep the people we serve at the center of everything we do. When we act with integrity, we are living the Aetna Way.



Our Medicare compliance program helps us serve our members ethically

We’re committed to practicing business in an ethical manner. Our Medicare compliance program helps to:

- Reduce or eliminate fraud, waste and abuse (FWA)
- Make sure we comply with applicable laws, rules and regulations
- Reinforce our commitment to compliance

We use external entities to bring our members cost-effective health care solutions

Aetna Health Inc., Aetna Life Insurance Company and affiliates (Aetna) offer Medicare Advantage (MA), Medicare-Medicaid Plans (MMPs) and Medicare prescription drug plans (collectively, “Medicare plans”). We contract with several external individuals and entities as a cost-effective and efficient way of providing administrative and health care services. Some of the services provided by external entities are services that we are required to perform under our contracts with the Centers for Medicare & Medicaid Services (CMS). CMS refers to these entities as First Tier, Downstream and Related Entities (FDRs).

You’ll find specific requirements in this document

CMS also requires that Aetna’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.

The Medicare compliance program requirements described in this guide apply to MMPs. As such, the references in this guide, and in the bolded definitions of FDRs, to MA or MA organization(s), program(s), benefit(s), contract(s) or regulation(s), or to Part D or Part D sponsor(s), plan sponsor(s), program(s), benefit(s) or contract(s), shall expressly include and encompass MMPs.

It is important that you follow these requirements

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

Aetna is the brand name used for products and services provided by one or more of the Aetna group of subsidiary companies, including Aetna Life Insurance Company and its affiliates (Aetna). Aetna Better HealthSM Premier Plan is the brand name used for Medicare-Medicaid Plans (MMPs) provided by one or more of the Aetna group of subsidiary companies.

II. 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 health care services

The Medicare compliance program requirements described in this guide apply to health care providers contracted with Aetna to participate in our Medicare network. This includes physicians, hospitals and other provider types. Here are the reasons why:

- First, MA regulations and CMS rules state that providers contracted with Aetna to provide health care services to our Medicare members are "First Tier Entities."
- Second, Chapter 21 of the manual lists "health care services" as an example of the types of functions that a third party can perform that relate to an MA organization's contract with CMS. This would give third parties "First Tier Entity" status. (See last bullet point in the manual, Chapter 21 § 40.) So these requirements apply to providers that actually deliver health care services to our Medicare members.
- Third, CMS provides a chart in the manual, Chapter 21 § 40, showing that entities providing health services and hospital groups are First Tier Entities. So if we contract with a hospital group and don't have a direct contract with the group's hospitals and other providers, the hospitals and providers are Downstream Entities. This means that the hospital group is a First Tier Entity and must comply. It also must make sure its Downstream Entities comply with the CMS compliance program requirements in this guide.

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 Aetna 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.

*Under our MA contract with CMS, we're required to credential health care providers that participate in our Medicare network. We may contract with entities to perform these credentialing services on our behalf under a delegation agreement. CMS considers these delegated credentialing entities to be First Tier Entities. CMS identifies delegated credentialing entities as First Tier Entities in the manual, Chapter 11 § 100.5.

III. FDR Medicare compliance program and attestation requirements

It's 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're 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 Aetna 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:

- Effective January 1, 2016, completion of the *CMS Combating Medicare Parts C and D Fraud, Waste, and Abuse Training* and the *CMS Medicare Parts C and D General Compliance Training* modules
- Code of conduct/compliance program policy distribution
- Exclusion list screenings
- Reporting FWA and compliance concerns to Aetna
- 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 Aetna

Our actions in response to noncompliance will depend on the severity of the compliance issue. If an FDR identifies areas of noncompliance (for example, refusal of an employee to complete the required FWA training), 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 example, employee training records and CMS certificates of FWA training completion) for no less than 10 years. Also, each year, an authorized representative from your organization must attest to your compliance with the Medicare compliance program requirements described in this guide. The authorized representative is an individual who has responsibility directly or indirectly for all:

- Employees
- Contracted personnel
- Providers/practitioners
- Vendors who provide health care and/or administrative services for Aetna's Medicare plans

This could be your compliance officer, chief medical officer, practice manager/administrator, an executive officer or similar positions.

You may be asked to provide evidence of compliance

In addition to completing an attestation, Aetna and/or CMS may request that you provide evidence of your compliance with these Medicare compliance program requirements. This is for monitoring/auditing purposes.

We take these responsibilities seriously. If you have questions or concerns about these Medicare compliance program requirements, just contact your Aetna relationship manager.



What follows is a description of each Medicare compliance program requirement.

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

FWA and general compliance training

You must ensure that your applicable employees and Downstream Entities complete fraud, waste and abuse and general compliance training. Effective January 1, 2016, you/your organization must ensure their completion of the CMS **Combating Medicare Parts C and D Fraud, Waste, and Abuse Training** module, as well as the CMS **Medicare Parts C and D General Compliance Training** module. CMS may update these required training modules annually.



Your applicable employees and Downstream Entities assigned to provide administrative and/or health care services for our Medicare plans can access these trainings in one of three ways:

- Complete the modules on the CMS Medicare Learning network (MLN) website. The general compliance course is called *Medicare Parts C and D General Compliance Training*, and 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. The certificates must be made available to Aetna and/or CMS upon request.
- You/your organization can also download or print the content of the CMS training modules from the MLN website to incorporate it into your training materials/system. The content of the CMS training modules **cannot** be changed to ensure the integrity and completeness of the training. You/your organization must retain records of completion. These must be made available to Aetna and/or CMS if requested.
- You/your organization can incorporate the content of the CMS training modules from the MLN website into written documents for providers (for example, provider guides or participation manuals).

Training requirements

Regardless of the method used, the training must be completed:

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

We request that you confirm your compliance with these requirements as part of our annual attestation process. However, you must also maintain evidence of training completion. Evidence of completion may be in the form of certificates, attestations, training logs or other means determined by you to best represent fulfillment of your obligations. If you use training logs or reports as evidence of completion, they must include:

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

Who should complete training?

Not every employee needs to take training. Below are examples of critical roles within an FDR that clearly should be required to fulfill the training requirements:

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

Not sure which employees at your organization should take the training? Then just review this **grid**. If you still have questions, you can email medicarefdr@aetna.com for help.

The only exception to this training requirement is if you/your organization is "deemed" to have met the FWA certification requirements through enrollment into Medicare Part A or B of the Medicare program or through accreditation as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). Those parties deemed to have met the FWA training through enrollment into the CMS Medicare program must still complete general compliance training.

You can find the training requirements and information about deemed status in:

- 42 CFR § 422.503(b)(4)(vi)(C) for MA
- 42 CFR § 423.504(b)(4)(vi)(C) for Part D
- Manual, Chapter 21 § 50.3

B. Code of conduct/compliance program policy distribution

You must give your employees standards of conduct

Your organization must also provide either **Aetna’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 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
- Manual, Chapter 21 § 50.1

C. 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 Aetna’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 logs or other records to document 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 Aetna’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.

D. Reporting FWA and compliance concerns to Aetna

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 **Aetna'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 Aetna. 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.

Dedicated to Aetna's Medicare compliance program is John Wells, Medicare Compliance Officer, who is based in Maryland. Questions or concerns for John and/or his Medicare compliance subject matter experts can be sent to **medicarefdr@aetna.com**.

E. 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 Aetna'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 Aetna 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, Aetna is required to submit an attestation to CMS. Therefore, you must immediately notify your Aetna 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."

F. Specific federal and state compliance obligations

Based on the services that you/your organization performs for Aetna'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 Aetna relationship manager. Aetna expects you/your organization to be compliant with all applicable federal and state laws, rules and regulations.

G. 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 Aetna'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 Aetna'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 **medicarefdr@aetna.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 Aetna's Medicare business. Also, FDRs must routinely monitor and/or periodically audit their Downstream Entities if they are used for Aetna's Medicare plans.

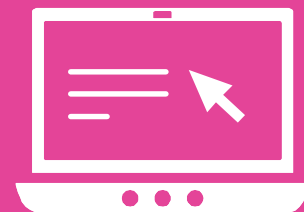
If we determine that an FDR doesn't comply with any of the requirements in this guide, we'll require the FDR to develop and submit a CAP. We can help the FDR address the identified compliance issues.

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
- Manual, Chapter 21 § 50.6.6

Questions/concerns

For compliance questions or concerns, you can email us at **medicarefdr@aetna.com**.
MMP-only FDRs can also contact:
medicaidmmpfdr@aetna.com for assistance.



Toolbox of resources for FDRs

General compliance and FWA training	
CMS general compliance training module	You can find the CMS general compliance training module on the CMS Medicare Learning Network (MLN) . It can be completed on the MLN, after registration. It is titled <i>Medicare Parts C and D General Compliance Training</i> . You can also download it and incorporate the module, unmodified, into your existing training materials/systems.
CMS FWA training module	You can find the CMS FWA training module on the MLN . It can be completed on the MLN, after registration. It is titled <i>Combating Medicare Parts C and D Fraud, Waste, and Abuse Training</i> . You can also download it and incorporate the module, unmodified, into your existing training materials/systems.
Proof of training completion	CMS requires FDRs to maintain evidence of training completion. FDRs must retain this evidence for 10 years. The CMS training completion certification is evidence of completion. This sample log also provides a way to document your employees' completion of training. If you want, you can send this log to your Downstream Entities to use for their employees' training completion.
Who should complete training?	Not every employee always needs to complete training. This grid has examples of FDR employees that do and don't need to complete it.
Code of conduct and compliance policies	
Don't have your own code?	Feel free to distribute Aetna's code of conduct to your employees.
Medicare compliance department policies	Aetna's code of conduct explains our compliance program, but these policies provide more detail about our Medicare compliance program.
Share our code and policies	Use this announcement template to share Aetna's code of conduct and compliance policies with employees and Downstream Entities. You can also use the links in this guide to access them.
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. 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. Use this OIG/GSA example screening log to aid in your process.
Reporting mechanisms	
How do I report noncompliance or potential FWA to Aetna?	This poster provides ways for reporting issues that impact Aetna, directly to Aetna. 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 Aetna.
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.

Toolbox of resources for FDRs

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 your Aetna relationship manager, medicareoffshorerequest@aetna.com or medicarefdr@aetna.com.

More tools

You can find other **resources** online. If you have ideas for tools that would help you in meeting the Medicare compliance program requirements, send an email to medicarefdr@aetna.com.

FAQs

If you have a question that we didn't answer in this guide, review our [frequently asked questions](#).