



# Lead the way

**First Tier, Downstream and Related Entities (FDR) guide**  
Delivering Medicare compliance program requirements

June 2019







# I. Introduction

Aetna refers to a subsidiary company of CVS Health, including but not limited to Aetna Health companies, Aetna Better Health companies, Aetna Life Insurance Company, Coventry Health and Life Insurance Company, Coventry Health Care companies, First Health Life & Health Insurance Company, SilverScript Insurance Company, and those joint venture entities in which a CVS Health subsidiary company has ownership interests who offers or administers, under contract with CMS, Medicare Advantage, Medicare-Medicaid Plans (MMPs), Dual Special Needs Plans (DSNPS), and Medicare prescription drug plans (PDP) ("Aetna Medicare business").

**Our reputation as an industry leader depends on the ability to deliver on our promises. For more than 160 years, we've been guided by the highest standards of integrity. We build our relationships with customers, business partners and suppliers on trust. And each day, we commit to doing the right thing for the right reason, while focusing on those we serve, treating them with respect and compassion.**

## **Who we are**

Aetna is now part of the CVS family of companies. This includes, but isn't limited to:

- Aetna Health companies
- Aetna Better Health® companies
- Aetna Life Insurance Company
- Coventry Health and Life Insurance Company
- Coventry Health Care companies
- First Health Life & Health Insurance Company
- SilverScript Insurance Company
- Joint venture entities in which a CVS Health® subsidiary company has ownership interests

## **Providing better service through partnership with you**

We collectively refer to the Medicare Advantage (MA) Plans, Medicare-Medicaid Plans (MMPs) and Medicare Prescription Drug Plans (PDPs) we offer as "Medicare plans." And we partner with external individuals and entities like you as an efficient, cost-effective way of providing the administrative and health care services that support these plans and are required under our contracts with the Centers for Medicare & Medicaid Services (CMS). CMS refers to these individuals and entities as First Tier, Downstream and Related Entities (FDRs).

## **Committed to doing things the right way**

Because we're committed to practicing business ethically:

- We work to reduce or end fraud, waste and abuse (FWA)
- We make sure to comply with applicable laws, rules and regulations
- We reinforce our commitment to compliance

## **Delivering compliance requirements**

As an Aetna FDR, you must fulfill specific Medicare compliance program requirements. The Code of Federal Regulations (CFR) outlines these requirements and we describe them in this guide. They're also defined by CMS in:

- The January 11, 2013, Compliance Program Guidelines in Chapter 21 of the **Medicare Managed Care Manual**
- Chapter 9 of the **Prescription Drug Benefit Manual**

These requirements apply to MMPs, too. So certain references in this guide (and in the bolded definitions of FDRs) also cover MMPs. These include references to:

- MA or MA organization(s), program(s), benefit(s), contract(s) or regulation(s)
- Part D or Part D sponsor(s), plan sponsor(s), program(s), benefit(s) or contract(s)





## II. What's an FDR?

## Current CMS definitions:

**A 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. These arrangements involve providing administrative or health care services to a Medicare-eligible individual under the MA program or Part D program.

**A Downstream Entity** is any party that enters into a written arrangement, acceptable to CMS, with persons or entities. These persons or entities are 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.

**A Related Entity** is one 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 (this occurs at a cost of more than \$2,500 during a contract period)

See 42 CFR §§ 422.500 and 423.501 for more information.

## Health care providers are FDRs, too

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

1. MA regulations and CMS rules state that providers contracted with Aetna to provide health care services are First Tier Entities.

2. Chapter 21 § 40 of the Medicare Managed Care Manual lists health care services as an example of the types of functions a third party can perform related to an MA organization's contract with CMS. This gives third parties "First Tier Entity" status. So CMS compliance requirements apply to providers that actually deliver health care services.

3. The flowchart in the same chapter and paragraph shows 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 the hospital group:

- Is a First Tier Entity
- Must follow the CMS compliance requirements in this guide
- Must ensure its Downstream Entities follow them, too

## What administrative services do FDRs provide?

Medicare compliance program requirements also apply to entities we contract with for administrative services for our MA or Part D contracts. Some examples of administrative functions are:

- Claims processing
- Patient management
- Credentialing\*

Additional examples of FDRs include:

- Delegates
- Agents
- Broker organizations
- Pharmacies
- Other individuals, entities, vendors or suppliers contracted with us for administrative and/or health care services for our Medicare plans

You'll find stakeholder relationship flowcharts in Chapter 21 § 40 of the Medicare Managed Care Manual.

\*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 Chapter 11 § 100.5 of the Medicare Managed Care Manual.





### **III. FDR Medicare compliance program and attestation requirements**

**Ultimately, we're responsible for fulfilling the terms and conditions of our contract with CMS and meeting applicable Medicare program requirements. Our FDRs are also responsible for complying with these requirements. And they must ensure their Downstream Entities also comply with applicable laws and regulations — including the requirements in this guide.**

### **Review compliance program requirements**

This guide summarizes the Medicare compliance program requirements. Be sure to review it and comply with these requirements each calendar year. They include, but aren't limited to:

- Distribute code of conduct/compliance policy
- Distribute general compliance and FWA training/education
- Complete exclusion list screenings
- Make employees aware of reporting mechanisms
- Report FWA and compliance concerns to us
- Report and request to use offshore operations
- Fulfill specific federal and state compliance obligations
- Monitor and audit First Tier, Downstream and Related Entities

### **What can happen if you don't comply?**

If you fail to meet CMS Medicare compliance program requirements, it may lead to:

- Development of a corrective action plan
- Retraining
- Termination of your contract and relationship with us

Our response to noncompliance depends on the severity of the issue. As an Aetna FDR, if you discover a compliance issue, you must take quick action to fix the issue and prevent it from happening again.

### **Confirm completion of requirements**

You must keep evidence of your compliance with these requirements for no fewer than 10 years. This evidence may include employee training records and completed exclusion list screenings.

Each year, an authorized representative from your organization must also verify your compliance with the requirements in this guide. This must be someone who has responsibility, directly or indirectly, for all:

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

This could be your compliance officer, chief medical officer, practice manager/administrator, an executive officer or someone in a similar position.

**Check out the FDR tips toolbox at the end of this guide — it can help you meet Medicare compliance program requirements.**



**Get to know each  
program requirement**



## A. Distribute code of conduct/compliance policy

As an Aetna FDR, you must also provide either our **code of conduct** and **Medicare compliance policies** to your employees and Downstream Entities or provide your own comparable versions. If you use your own versions, they must contain the elements in Chapter 21 § 50.1 of the Medicare Managed Care Manual. They must also explain your commitment to compliance with federal and state laws, ethical behavior and compliance program operations.

You must provide this material:

- 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 show proof that you provided the standards of conduct.

You'll find these 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

## B. Distribute general compliance and FWA training/education

CMS no longer requires FDRs to complete its **Medicare Parts C and D General Compliance Training** and **Combating Medicare Parts C and D Fraud, Waste, and Abuse Training**. Instead, you may complete your own version of general compliance and FWA training specific to your organizational needs.

### Who doesn't need to complete the training?

FDRs are not exempt from general compliance training requirements. But you may be deemed to have met the FWA training and education 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:

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

### When must training/education be completed?

Required training/education must be completed:

- Within 90 days of initial hire or the effective date of contracting

- When materials are updated
- Annually thereafter

If you use training logs or reports as evidence of completion, they must include:

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

### Prevent and detect FWA

As an Aetna FDR, you play an important role in protecting the integrity of the Medicare program. To combat FWA, you need to know what FWA is and how to protect your organization from engaging in abusive practices and/or civil or criminal law violations.

### What is FWA?

**Fraud** is intentionally misusing information to persuade another person or entity to part with something of value or to surrender a legal right. It could also be an act of planned deception or misrepresentation.

**Waste** is using, consuming, spending or expending resources thoughtlessly or carelessly.

**Abuse** is providing information or documentation for a health care claim in a manner that improperly uses program resources for personal gain or benefit, but without sufficient evidence to prove criminal intent.

## B. Distribute general compliance and FWA training/education (continued)

### Get to know fraud, waste and abuse laws

Federal laws governing Medicare FWA include:

- **Federal False Claims Act**
- **Anti-Kickback Statute**
- **Physician self-referral, or the “Stark law”**
- Social Security Act
- United States criminal code

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

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

The **CMS website** is a good source of additional information, including FWA training options.

## C. Complete 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 these federal programs. So before hiring or contracting, and monthly thereafter, each FDR must check exclusion lists to confirm your employees and Downstream Entities aren't excluded from participating in federally funded health care programs. Use these websites to perform your exclusion list screening:

- **General Service Administration (GSA) System for Award Management (SAM)**
- **Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE)**

You must also maintain evidence that you've checked these lists. You can use logs or other records to document that you've screened each employee and Downstream Entity. Note the date and results of the screenings and any actions taken.

### Perform screenings regularly

You must conduct screenings before hiring or contracting, and each month after that. We're required to check these exclusion lists, too, before hiring or contracting with any new:

- Employee
- Temporary employee
- Volunteer
- Consultant

- Governing body
- Member
- FDR

And we must check the lists monthly after that.

We can't check the exclusion lists for your employees and Downstream Entities. So to ensure we comply with this CMS requirement, you must confirm that your permanent and temporary employees and Downstream Entities are not on either of these exclusion lists.

### Take action with those on exclusion lists

If any of your employees or Downstream Entities are on an exclusion list, you must immediately:

- Remove them from any direct or indirect work on our Medicare plans
- Notify us

You'll find exclusion list requirements in:

- Social Security Act, § 1862(e)(1)(B)
- 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

## D. Report FWA and compliance concerns to us

There are a number of ways to report suspected or detected noncompliance or potential FWA. You'll find them on our **reporting mechanism poster**. All reports are confidential.

Share the poster with your employees and Downstream Entities. Or keep it as a reference tool and use your own internal processes for reporting and collecting these issues. If you use your own processes, make sure you include reporting it to us. Refer to our **code of conduct** for more on our reporting guidelines.

### **Enforce a zero-tolerance policy for retaliation**

There can be no retaliation against or coercion of anyone reporting suspected misconduct.

### **Have questions or concerns?**

Just reach out to Patrick Jeswald, Medicare Compliance Officer. He's dedicated to our Medicare compliance program. You can email Patrick and his team of experts at **[medicarefdr@aetna.com](mailto:medicarefdr@aetna.com)**.

## E. Report and request to use offshore operations

You must request permission to perform offshore services or to use an individual or offshore entity to perform services for our Medicare plans. "Offshore entity" refers to an individual or entity physically located outside the United States or one of its territories. The only acceptable approval is from an authorized Aetna representative obtained in advance and in writing.

Offshore subcontractors that receive radiological images for reading are an example of services that trigger submission of an attestation. That's because beneficiary PHI is included with the radiological image and the diagnosis is transmitted back to the U.S.

### **Notify us before using an offshore entity**

If you already use an offshore entity, let us know right away. To request permission to perform offshore services, submit an **offshore attestation** to us. If your activities involve personal health information (PHI), we must also submit an attestation to CMS.



## F. Fulfill federal and state compliance obligations

You may be subject to other federal and state laws, rules and regulations that you must also fulfill but aren't covered in this guide. We expect your organization to comply with all applicable federal and state laws, rules

and regulations. If you have questions about the compliance obligations for the services your organization performs, just ask your Aetna® relationship manager. Or simply email us at [medicarefdr@aetna.com](mailto:medicarefdr@aetna.com).

## G. Monitor and audit First Tier and Downstream Entities

CMS requires us to develop a strategy for monitoring and auditing our First Tier Entities. This helps ensure they comply with all applicable laws and regulations.

### Expect routine monitoring and audits

We routinely monitor and periodically audit our FDRs. This helps us ensure compliant administration of our CMS contracts and compliance with applicable laws and regulations. Each FDR must take part in these monitoring and auditing activities. If you do your own audits, we may ask for the results affecting our Medicare business. Also, you must routinely monitor and periodically audit your Downstream Entities.

If you fail to comply with the requirements in this guide, we'll expect you to submit a Corrective Action Plan. We can help you address the identified issues.

### Monitor compliance of Downstream Entities

You must also monitor the compliance of your Downstream Entities. If you choose to subcontract with other parties for services for our Medicare plans, you must make sure they abide by all laws and regulations that apply to you as a First Tier Entity. This includes ensuring that:

- 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 a Downstream Entity

Only subcontractors that provide administrative or health care services for our 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, just email us at [medicarefdr@aetna.com](mailto:medicarefdr@aetna.com).

### Take action to ensure compliance

You must conduct enough oversight (auditing and monitoring) to test and ensure your employees and Downstream Entities are compliant.

You must:

- Retain evidence of this oversight
- Ensure that root cause analysis is conducted for any deficiencies
- Implement corrective actions, including disciplinary actions, like contract termination, to prevent recurrence of noncompliance

You'll find these requirements 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



# We're here to help

If you have questions, simply email us at [medicarefdr@aetna.com](mailto:medicarefdr@aetna.com).

If you're an MMP-only FDR, you can also email us at [medicaidmmpfdr@aetna.com](mailto:medicaidmmpfdr@aetna.com).

# References for you

## FDR tips toolbox

Use this toolbox to help ensure your organization is meeting Medicare compliance program requirements.

### Frequently asked questions (FAQs)

Refer to our [FAQ document](#) for answers to many common questions.

#### Code of conduct and compliance policies

**Don't have your own code?** Feel free to distribute our [code of conduct](#) to your employees.

**Medicare compliance department policies** These [policies](#) provide more detail about our Medicare compliance program.

#### Exclusion list screenings

**Where is the OIG exclusions database?** Complete [OIG](#) exclusion list screenings before hiring or contracting, and each month thereafter, for your employees and Downstream Entities. This [sample log](#) provides a way to track your screenings.

**Where is the GSA SAM?** Complete the [GSA SAM](#) exclusion list screenings before hiring or contracting, and each month thereafter, for your employees and Downstream Entities. This [sample log](#) provides a way to track your screenings.

#### Reporting mechanisms

**How do I report noncompliance or potential FWA to Aetna?** Remember, you must report suspected or detected noncompliance or potential FWA that affects Aetna. This [poster](#) shows you how. Feel free to share it throughout your organization so your employees know how to report concerns.

#### Monitoring and oversight

**Downstream Entity oversight** You must conduct oversight of your Downstream Entities. An FDR [attestation](#) may help your Downstream Entities self-monitor and report the status of their compliance to you.

**Check yourself** You can use this [sample tool](#) to assess how you follow 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 ones who are.



## Other tools

### Offshore attestation form

Use this **form** to request permission for you or your subcontractor to use an offshore individual or entity. Request to perform any of these services for Medicare member PHI:

- Processing
- Transferring
- Handling
- Storing
- Accessing

Email your completed form to **[medicareoffshorerequest@aetna.com](mailto:medicareoffshorerequest@aetna.com)**.



Have a question we didn't answer in this guide? Remember, you can always review our **FAQs**.

