Lead the way

First tier, downstream or related entity (FDR)

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Inside

I. What’s an FDR?

An FDR is a U.S. Centers for Medicare & Medicaid Services (CMS) acronym that means first tier, downstream or related entity.

Current CMS definitions*

A first tier entity is any party that enters a written arrangement, acceptable to CMS, with a Medicare Advantage (MA) organization or Part D plan sponsor or applicant.

These arrangements provide 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 a written arrangement, acceptable to CMS, with persons or entities. These persons or entities are involved with the MA benefit or Part D benefit. They are below the level of the arrangement and between the following:

- An MA organization or applicant
- A Part D plan sponsor or applicant
- A first tier entity

These arrangements continue down to the level of the ultimate provider of both health and administrative services.

A related entity is any party that holds common ownership or control of an MA organization or Part D sponsor and:

- **Performs** some of the MA organization or Plan D plan sponsor's management functions under contract or delegation
- **Furnishes** services to Medicare enrollees under an oral or written agreement
- **Leases** real property or sells materials to the MA organization or Part D plan sponsor (this occurs at acost of more than $2,500 during a contract period)

For more information, review the United States Code, 42 CFR §§ 422.500 and 423.501.

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, like dentists.

Here are three reasons why:

1. CMS requires that Aetna® FDRs fulfill Medicare Compliance Program requirements. If you are contracted to provide health care and/or administrative services for any of our Medicare plans, you are an FDR.
2. Chapter 21 § 40 of the CMS Medicare Managed Care Manual lists health care services as an example of the types of functions a third party can perform. These functions are in relation to an MA organization's contract with CMS. This gives third parties first tier entity status. This means CMS compliance requirements apply to providers that provide 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. But if we contract with a hospital group and don't have a direct contract with the group's hospitals and providers, the hospitals and providers are downstream entities.

What administrative services do FDRs provide?

Some examples of administrative functions are:

- Claims processing
- Patient management
- Credentialing*

Additional examples 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

Medicare compliance program requirements also apply to entities we contract with for administrative services for our MA or Part D contracts. You'll find stakeholder relationship flowcharts in chapter 21 § 40 of the CMS Medicare Managed Care Manual.

*FOR DEFINITIONS SOURCE: The U.S. Centers for Medicare & Medicaid Services (CMS). Medicare Managed Care Manual Chapter 21 — Compliance Program Guidelines and Prescription Drug Benefit Manual Chapter 9 — Compliance Program Guidelines. CMS.gov Centers for Medicare & Medicaid Services. January 11, 2013; pages 3, 5, and 7. Available at: **CMS.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf**.

*FOR CREDENTIALING NOTE: Under our Medicare Advantage (MA) contract with the U.S. Centers for Medicare & Medicaid Services (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, section 100.5 of the 2013 CMS Medicare Managed Care Manual.

II. Partnering to do the right thing

Our partnership with you — an FDR — is important to us. We need you to help fulfill our contracts with CMS. And you can rely on us for the teamwork and support you need. Together, we'll provide quality administrative and health care services for Aetna® Medicare members.

Our Medicare plans include:

We offer several types of Medicare plans:

- Medicare Advantage (MA), Medicare Advantage Prescription Drug (MAPD), and/or Prescription Drug Plan (PDP)
- Medicare-Medicaid Plans (MMPs)
- Special Needs Plans (SNPs)

Fulfilling compliance requirements

As an Aetna® FDR, you must fulfill specific Medicare compliance requirements.* We describe those requirements in this guide.

The following references in this guide apply to all FDRs:

- The definitions for first tier entity, downstream entity and related entity on page 4
- MA organizations, plans, programs, benefits, regulations and contracts
- Part D sponsors, plans, programs, benefits and contracts

Plus, you'll find helpful resources — like the links below — in case you need to know more.

Compliance resource	How to use
Electronic Code of Federal Regulations	**Search the United States Code by title**. (The United States Code is also referred to as federal regulations.)
Compliance chapters in Medicare manuals	**Read the PDF, which includes:** • Chapter 21 of the CMS Medicare Managed Care Manual • Chapter 9 of the CMS Medicare Prescription Drug Benefit Manual

*FOR COMPLIANCE REQUIREMENTS SOURCE: U.S. Centers for Medicare & Medicaid Services (CMS). Medicare Managed Care Manual Chapter 21 — Compliance Program Guidelines and Prescription Drug Benefit Manual Chapter 9 — Compliance Program Guidelines. CMS.gov Centers for Medicare & Medicaid Services. January 11, 2013. Available at: **CMS.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf**.

III. FDR Medicare compliance requirements

We're responsible for fulfilling the terms and conditions of our contract with CMS. And we must meet applicable Medicare program requirements. Our FDRs are responsible for complying with these requirements. And they must ensure that their downstream entities also comply with applicable laws and regulations. This includes the requirements in this guide.

Review compliance program requirements

This guide summarizes Medicare compliance program requirements. Be sure to review it and comply with these requirements each calendar year. Here are some of the actions you must take:

- Distribute a code of conduct or a compliance policy
- Distribute conflict of interest policy
- Distribute general compliance and FWA education and training
- 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 FDRs

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 you must 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.

Medicare Compliance performs various oversight activities each year to test your organization's compliance with the requirements outlined in this guide. In addition, we may conduct an audit, a monitoring event, or ask you to complete an attestation.

If you receive an attestation, it must be signed by someone in your organization who has responsibility, directly or indirectly, for all:

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

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

There may be other attestations that you may be required to complete based upon the services you are contracted to provide to Aetna. Not all attestation types apply to the different categories of FDRs.

Want some help?
Check out the **FDR Toolbox** at the end of this guide — it makes it easier for you to meet Medicare compliance requirements.

IV. Your compliance to-do list

A. Distribute a code of conduct or a compliance policy

As an Aetna® FDR, you must provide our **code of conduct** and our **Medicare compliance policies** (or a document of your own that's comparable to both of those documents) to your employees and downstream entities. If you provide your own comparable version, it must 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 these resources:

- CMS Medicare Managed Care Manual, chapter 21 § 50.1
- CMS Medicare Prescription Drug Benefit Manual, chapter 9 § 50.1
- United States Code

  -Medicare Advantage (MA) plans: 42 CFR § 422.503(b)(4)(vi)(A)

  -Medicare Part D, Prescription Drug Coverage: 42 CFR § 423.504(b)(4)(vi)(A)

B. Distribute a conflict-of-interest policy

A Conflict of Interest (COI) may occur when an FDR or its colleagues allow the risk of personal gain to control the way in which he or she oversees job duties and responsibilities.

Situations involving a COI may not always be clear or easy to resolve. Some situations that may present a real or potential COI include, but are not limited to:

- Outside employment
- Participation in outside organizations, including board positions
- A financial interest in a competitor
- Employment of relative

Our FDRs must have a policy and procedure that explains conflict of interest, how to report a possible COI and the actions your company takes when a COI occurs. This policy needs to be given at time of hire, or beginning to work on the CVS® account, as well as annually.

The method for distribution of COI information may vary, but some examples of distribution include:

- Electronic training that includes COI information
- Distribution of a COI policy
- Inclusion of COI in your signed Code of Conduct attestation

You must keep evidence of distribution.

C. Complete compliance and fraud, waste and abuse (FWA) education and training

CMS no longer requires FDRs to complete these trainings:

- **January 2019 Medicare Parts C and D General Compliance**
- **January 2019 Combating Medicare Parts C and D Fraud, Waste, and Abuse**

Instead, you may use and complete your own version of general compliance and FWA training. It can be 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 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 the:

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

When must education and training be completed?

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

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 it is. And you need to know how to protect your organization from engaging in abusive practices and/or civil or criminal law violations.

What are the definitions for fraud, waste and abuse?

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. However, there isn't enough evidence to prove criminal intent.

Get to know FWA laws

Federal laws govern Medicare FWA. They include:

- **Anti-kickback statute** (42 U.S.C. §1320a-7b(b))
- **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:

- 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 and includes FWA training options.

D. 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. This will help confirm that 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)**

Your organization must maintain evidence that you've screened against both lists. This includes source documentation like screenshots, input lists and/or documentation with date stamps. You may keep logs that track the dates for all screened employees and FDR. This will help track exclusion screenings. Also, make sure to keep source documentation.

Perform screenings regularly

The following individuals and entities must be screened before hiring or contracting and then monthly thereafter:

- Employees
- Temporary employees
- Volunteers
- Consultants
- Members of your governing body
- FDRs

To comply with CMS requirements, your organization needs to check both the OIG and the GSA exclusion lists. This will ensure these individuals and entities aren't excluded.

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:

- CMS Medicare Managed Care Manual, chapter 21 § 50.6.8
- CMS Medicare Prescription Drug Benefit Manual, chapter 9 § 50.6.8
- Social Security Act, § 1862(e)(1)(B)
- United States Code
  - 42 CFR §§ 422.503(b)(4)(vi)(F)
  - 422.752(a)(8)
  - 423.504(b)(4)(vi)(F)
  - 423.752(a)(6)
  - 1001.1901

E. 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. Refer to our code of conduct for more on our reporting guidelines.

If you use your own code of conduct or compliance policies, you must include a process for reporting all compliance and FWA issues that impact Aetna®.

Enforce a zero-tolerance policy for retaliation

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

Have questions or concerns?

Send an email to Patrick Jeswald, Medicare Compliance Officer at **MedicareFDR@Aetna.com**. He and his team of experts are dedicated to the Medicare Compliance program.

F. If you conduct offshore business

Offshore term definitions

Here's what we mean when we talk about offshore business. It's an individual or entity physically located outside the United States or one of its territories, like American Samoa, Guam, Northern Marianas, Puerto Rico and the Virgin Islands. Some examples of offshore countries include Mexico, Canada, India, Germany and Japan. Offshore subcontractors can be American-owned companies with portions of their operations outside of the U.S. Or they can be foreign-owned companies with operations outside of the U.S. Offshore subcontractors provide services performed by workers located in offshore countries, regardless of whether they're employed by American or foreign companies.

Protected health information (PHI) refers to the types of personal information listed in the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. Examples of PHI include:

- Beneficiary name
- Birth date
- Address
- Social Security number
- Health insurance claim number
- Patient identifier
- Medical diagnosis
- Medical history
- Treatment records
- Type of provider visited
- Use of health care services
- Payment information
- Evidence of insurance coverage
- Any information that could reasonably identify a beneficiary

Offshore services means the offshore entity will or may receive, process, transfer, handle, store or access the PHI — in oral, written or electronic form — of Aetna® Medicare Advantage members and Prescription Drug Plan members.

If your activities involve PHI, we will submit an attestation of that fact to CMS.

Examples of offshore entities

Here are a couple examples of how U.S. businesses might work with offshore subcontractors:

- An offshore radiologist who receives radiological images, reads them and transmits diagnoses back to the U.S.
- A billing company that performs services

Already use an offshore entity?

If you already use an offshore entity, tell us right away.

Offshore requirements

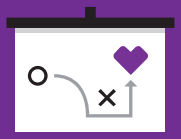
1. Get written approval before you perform services

An authorized Aetna representative must grant you offshore written approval before you can:

- Perform offshore services for our Medicare plans
- Use an individual or entity to perform offshoreservices for our Medicare plans

2. Keep this information updated

If there are material changes with a previously approved offshore entity (for example, change in location, scope of services), you must submit a new Offshore Services Attestation form with the new information for review and approval.



How to request offshore permission:
Send an Offshore Services Attestation form to us.

G. Fulfil federal and state compliance obligations

You may be subject to other federal and state laws, rules and regulations. You'll still need to fulfill these, but they 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, simply email us at **MedicareFDR@Aetna.com** or ask your Aetna® relationship manager.

H. Monitor and audit FDRs

CMS requires us to develop and implement 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 it ensures 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.

If you fail to comply with the requirements in this guide, we'll expect you to submit a corrective action plan. And 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:

- All the contractual agreements between youand the downstream entity contain all CMS-required provisions
- The downstream entity complies with the Medicare compliance program requirements described in this guide
- The downstream entity complies 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. Email us at **MedicareFDR@Aetna.com** if you have any questions.

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 forany deficiencies
- Implement corrective actions, including disciplinary actions, like contract termination, to prevent recurrence of noncompliance

You'll find these requirements in:

- CMS Medicare Managed Care Manual,chapter 21 § 50.6.61
- CMS Medicare Prescription Drug Benefit Manual,chapter 9 § 50.6.61
- United States Code

  -Medicare Advantage (MA) plans:
  42 CFR § 422.503(b)(4)(vi)(F)

  -Medicare Part D, Prescription Drug Coverage:
  42 CFR § 423.504(b)(4)(vi)(F)

We’re here to help

Email us at **MedicareFDR@Aetna.com** for FDR-related questions.

Email us at **MedicaidMMPFDR@Aetna.com** for MMP-only FDR-related questions.

V. FDR toolbox

Use this tool to help your organization meet Medicare compliance requirements.

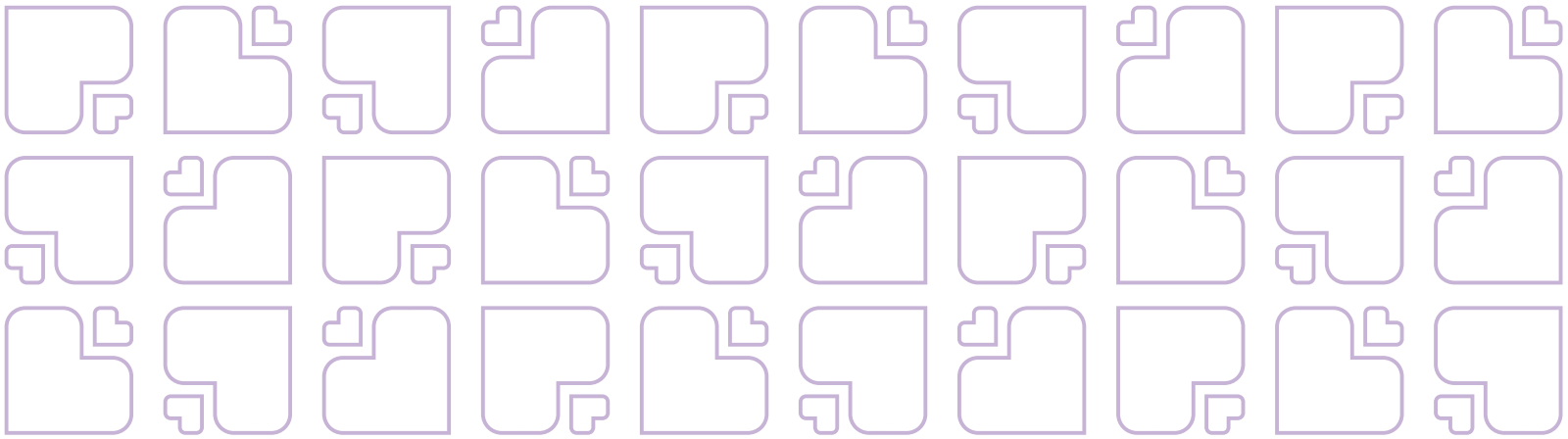
Frequently Asked Questions (FAQ)	
Have questions?	Find answers in our **FDR FAQ**.
Code of conduct and compliance policies	
Don't have your own code?	Feel free to distribute our **code of conduct** to your employees.
You can use our Medicare policies	Feel free to distribute our **Medicare compliance policies** to your employees, too.
Exclusion list screenings of conduct and compliance policies	
The U.S. Department of Health and Human Services (HHS) Office of Inspector General (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. Don't forget that you need to also maintain source documentation of your screenings, like screenshots and input lists.
General Service Administration (GSA) System for Award Management (SAM)	Complete the **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 to report noncompliance or potential fraud, waste and abuse (FWA)	Remember, you must report suspected or detected noncompliance or potential FWA to us. This **poster** shows you how. Feel free to share it throughout your organization so your employees know how to report any 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 tool	You can use this **Check Yourself tool** to assess how you fulfill Medicare compliance program requirements. Your organization can modify the tool to assess compliance of your downstream entities.
Which subcontractors are downstream entities?	Not every subcontractor is a downstream entity. Read **downstream entity requirements** for examples of those that are.

More tools

Offshore Services Attestation form	Use this **Offshore Services Attestation 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 **MedicareFDR@Aetna.com** and note "New offshore submission" in the subject line.

Have a question we didn't answer in this guide?

Remember, you can always review our **FDR FAQs**.



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