Frequently Asked Questions (FAQs) for First Tier, Downstream and Related Entities (FDRs)

Table of Contents

I. General questions

1. What does FDR mean?

FDR stands for first tier, downstream and related entities. If you perform administrative or health care services on behalf of Aetna's Medicare business, then you are an FDR.

Examples of FDRs include physicians, hospitals, dentists and other provider types, including dental and vision providers, contracted to provide services to our Medicare members, sales partners/agents contracted to market and sell our Medicare products, vendors providing administrative services for our Medicare members/products and delegates contracted to make decisions on our behalf for our Medicare members/products.

The Centers for Medicare & Medicaid Services (CMS) defines FDRs as:

- **First Tier Entity-** Any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization (MAO) or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare- eligible individual under the Medicare Advantage (MA) program or Part D program.
- **Downstream Entity-** Any party that enters into a written agreement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangement between an MAO or applicant or a Part D plan sponsor or applicant and a First Tier entity. These arrangements continue down to the level of the ultimate provider of both health and administrative services.
- **Related Entity-** This refers to any entity that is related to an MAO or Part D Sponsor by common ownership or control and:
    - Performs some of the MAO or Part D plan sponsor's management functions under contract or delegation.
    - Furnishes services to Medicare enrollees under an oral or written agreement; or
    - Leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than $2,500 during a contract period.

2. Are there requirements related to how long we need to retain documentation?

All Medicare documentation must be maintained for 10 years. You must have documentation to show you are compliant with each compliance program requirement. In an FDR Audit or monitoring activity, we will ask you to provide this documentation to us. Examples include, but are not limited to, policies and procedures, exclusion screening evidence, attestations, and evidence of oversight of your FDR subcontractors (if applicable).

3. What Aetna products, plans, and providers do these requirements apply to?

We offer Medicare Advantage (Part C) and Prescription Drug (Part D) coverage to Medicare members. These requirements apply to all entities that participate in of these plans:

- Medicare Advantage (MA)
- Prescription Drug (MAPD)
- Prescription Drug Plans (PDP)
- Medicare-Medicaid Plans (MMP)
- Dual Eligible Special Needs Plan (DSNP)

- Institutional Special Needs Plan (ISNP)
- Chronic Conditions Special Needs Plan (CSNP)
- Fully Integrated Special Needs Plans (FIDE)

4. I am a provider for Original Medicare (Parts A or B). Do these requirements apply to me?

If you are a provider that accepts Original Medicare (Part A or Part B) AND contracts with us to provide services to our Medicare members (including our Medicare-Medicaid members), then these requirements apply to you. This includes, but is not limited to: individual providers, ancillary providers, dentists, behavioral health, group practices, facilities, hospitals, delegated entities, etc.

These requirements apply to you if you are contracted to provide administrative or health care services to our Medicare members. If you are unsure of your contracting status with us, please refer to the **Contact Us** section on the final page of this document for contact information to assist with contracting status.

5. Am I still required to meet these compliance requirements if I do not service or accept Medicare Advantage plan members?

If your organization provides services that impact our Medicare plans, you are required to meet these requirements. For provider organizations, if your organization participates in one or more of our Medicare Advantage, Medicare/Medicaid MMP, and/or Special Needs Plans (SNP), these requirements apply to your organization, even if you do not see members in these plans.

6. Our organization received a Medicare Compliance Attestation to complete; is this the same attestation as the Council for Affordable Quality Healthcare (CAQH) attestation?

The Medicare Compliance Attestation is not related to the CAQH Attestation. The Medicare Compliance Attestation confirms you are meeting the Medicare Compliance Program Requirements as identified in our FDR program guide.

7. What is the source of these requirements?

These regulatory requirements are from CMS. They are described within the **Medicare Managed Care Manual. Chapter 21 - Compliance Program Guidelines and Prescription Drug Benefit Manual. Chapter 9 - Compliance Program Guidelines and updates in CY 2015 Final Rule CMS-4159-F published May 23. 2014 electronically on the CMS website.** The Medicare Addendum attached to your contractual agreement also is a source for these requirements.

8. Are the requirements new?

No, these requirements are not new. You should have received a similar notice about these requirements in previous years. There have been changes to these requirements since they were implemented. If you aren't familiar with the requirements, just review our FDR Guide.

9. Our organization is not complying with all the Medicare Compliance requirements. Who do we report this to? Will we be terminated?

If your organization is not meeting the requirements, you can contact your relationship manager (account manager, provider representative, Aetna liaison, etc.). Don't worry about retaliation. We enforce a zero-tolerance policy for retaliation against anyone reports concerns in good faith. You can also make reports anonymously; just refer to **our reporting poster.**

If you are willing to comply with the requirements, your contract will not be terminated. Instead, we will collaborate with you to implement a corrective action plan (CAP) to ensure you can comply.

10. What will happen if I don't comply with the requirements?

If you are willing to comply, we partner with you to resolve the issue. You will be given training and education on the requirements and we will make sure that you develop a comprehensive corrective action plan (CAP). We ask for you to provide a written CAP that addresses the issue and outlines when actions will be completed.

If you refuse to comply or fail to implement your CAP, there could be ramifications, up to and including contract termination.

11. Why did our organization receive a Medicare Compliance Attestation to complete?

Your organization has been identified as a first tier entity because of your contractual relationship with us. Medicare Compliance performs various oversight activities each year to test your organization's compliance with Medicare Compliance requirements. We may conduct an audit, a monitoring event, and/or require an attestation be completed.

12. I have no employees. Do I have to complete an attestation?

Yes. If we send you an attestation to complete, it must be completed even if you have no employees.

13. Does each staff member have to complete the attestation?

No. An authorized representative can submit an attestation on behalf of your organization.

14. What documentation must I keep?

You must have documentation to show you are compliant with each requirement. Examples Include: policies and procedures, training logs, and attestation.

15. Who do I contact if I have more questions?

If you have any questions about the Medicare Compliance requirements that are not addressed in our **FDR Guide,** please refer to the **Contact Us** section on the last page of this documents.

II. Standards of Conduct and compliance policies

16. What are Standards of Conduct?

A Standards of Conduct are also known in some organizations as the "Code of Conduct." A Code of Conduct states the overarching principles and values by which the company operates and defines the framework for the compliance program.

17. How often must the Standards of Conduct be distributed?

Your Standards of Conduct and/or compliance policies must be distributed to employees: Within 90 days of hire, Each Calendar year, and When changes are made If you don't have your own Standards of Conduct and compliance policies, you can distribute Aetna's. Aetna is a CVS Health Company and complies with the **CVS Health Code of Conduct**. We also have **Medicare Compliance Policies** that describe how our Compliance Program operates.

18. Can I use my own Standards of Conduct?

Yes, you can use your own Standards of Conduct and compliance policies. They must contain the elements set forth in Section 50.1 and its subsections of **Chapters 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual.** They must also articulate the entity's commitment to comply with federal and state laws, ethical behavior and compliance program operations.

If you don't have your own Standards of Conduct and compliance policies, you can use Aetna's. Aetna is a CVS Health Company and complies with the **CVS Health Code of Conduct**. We also have **Medicare Compliance Policies** that describe how our Compliance Program operates.

III. Conflict of interest

19. What is a conflict of interest?

A conflict of interest occurs when an individual's personal or financial interests interfere with their ability to make objective decisions in the best interest of Aetna and its members. This includes situations where an individual, or their close family members, could gain an unfair advantage or influence business decisions for personal benefit.

20. Who is required to disclose potential conflicts of interest?

All First Tier, Downstream, and Related Entities (FDRs), including their employees, contractors, and subcontractors involved in Aetna-related operations, must disclose any potential or actual conflicts of interest.

21. What are some examples of conflicts of interest?

- Financial Interests: Owning stock, investments, or financial stakes in a competitor.
- Outside Employment: Working for or consulting with a competitor, vendor, or provider while engaged in Aetna-related duties.
- Employment of relatives: Having close personal or family ties with individuals in decision-

making roles that could influence business transactions.

22. How often should I distribute the Conflict of Interest (COI) policy?

COI disclosures should be distributed at the time of hire and annually thereafter. Additionally, updates must be submitted whenever a new potential conflict arises or if there are significant changes in personal, financial, or professional circumstances.

IV. Reporting mechanisms

23. What is Fraud, Waste & Abuse (FWA)?

Fraud: Intentional misuse of information in order to persuade another to part with something of value or to surrender a legal right. It could also be an act of planned deception or misrepresentation.
Waste: To use, consume, spend or expend thoughtlessly or carelessly.
Abuse: Providing information or documentation for a health care claim in a manner that improperly uses program resources for personal gain or benefit, yet without enough evidence to prove criminal intent.

Medicare Fraud and Abuse Laws: Federal laws governing Medicare fraud and abuse include all the following:
Federal False Claims Act (FCA)
Anti-Kickback Statute (AKS)
Physician Self-Referral Law (Stark Law)
Social Security Act
United States Criminal Code

Please refer to the **FDR Guide** for more detail.

24. Do we have to report noncompliance and FWA to Aetna?

Yes. Your organization must have a process to report concerns to Aetna. You must notify Aetna about actual and potential noncompliance and FWA if it impacts our Medicare Business.

As a CVS Health Company, Aetna's FDRs can make reports using the mechanism found in the **CVS Health Code of Conduct** including calling the CVS Health Ethics Line at 877-287-2040 (877-CVS-2040). If you don't have internal reporting mechanisms, you can share our **reporting poster** with your employees and downstream entities so they can report directly to us. We prohibit retaliation against individuals who raise concerns in good faith or who cooperate in an investigation. All calls are treated confidentially, and you may request to remain anonymous.

25. What can I do if I suspect FWA or noncompliance?

You must report the issue to us so we can investigate and respond to it immediately. **Our reporting poster** describes a few of the ways you can make reports. As a CVS Health Company, Aetna's FDRs can make reports using any of the mechanism listed in the **CVS Health Code of Conduct.** Don't worry about retaliation. We enforce a zero-tolerance policy for retaliation against anyone who reports suspected misconduct.

V. Exclusion lists screening

26. What are the exclusion lists?

There are 2 exclusion lists:

a. **Office of Inspector General (OIG) List of Excluded Individuals/Entities**
b. **General Services Administration (GSA) System for Award Management (SAM)**

27. What is the difference between the OIG and GSA SAM?

The **GSA SAM** includes exclusion and debarment actions taken by various federal agencies. The **OIG** only contains exclusion actions taken by the OIG. You must screen both.

28. What are the requirements related to exclusion list screenings?

FDRs must review both the **OIG** and **GSA SAM** exclusion lists. Review both of these lists before hiring or contracting and monthly thereafter. We explain the requirement in more detail within the **FDR Guide.**

Regular screenings ensure that your employees and downstream entities are not excluded from participating in federal health care programs. Federal money cannot be used to pay for services provided or prescribed by an excluded individual or entity.

29. How often do the exclusion list screenings have to be completed?

Both the **OIG** and **GSA SAM** exclusion lists must be checked before hiring/contracting and monthly thereafter.

30. What evidence must I keep showing that these checks are completed?

The documentation may vary depending on how you complete screenings. If you perform these checks using an automated system or program, your documentation may be based on the information available within that system. Regardless of how you do these checks, your documentation should show:

- which exclusion list(s) were checked,
- the date the check was completed,
- names of the individuals and entities that were checked, and
- results of the check.

If you do screenings manually, you can download our screening log and use it to capture the required information. Be sure to also maintain the source documentation to support your screenings, such as input sheets, screenshots, and documentation with date stamps.

31. What if an individual or entity is identified as excluded?

If you find a potential hit during a screening, be sure to verify that your employee is actually the individual who has the exclusion. You can do this by verifying the social security number in the database you searched.

If you confirm your employee is excluded, you should immediately stop them from doing any

work on Aetna Medicare business and report this to Aetna through your Relationship Manager, or directly to the Aetna **MedicareFDR mailbox**. If you confirm the excluded individual is your employee, it is a best practice to review their work for potential FWA. If you confirm that the excluded individual is not actually your employee, maintain evidence showing that the exclusion was reviewed, and it was confirmed that the excluded person identified in the search was not your employee.

VI. Downstream entity oversight

32. Which of my subcontractors should be considered downstream entities?
Not every subcontractor is considered a Downstream Entity. Only those entities who provide administrative or health care services for Aetna's Medicare business are Downstream Entities. FDRs should have processes in place to identify and classify subcontractors as Downstream Entities. To help you, we have a **grid** that lists examples of Downstream Entities.

33. Why are you asking about my downstream entities (i.e., subcontractors)?
We are accountable to CMS for all our FDRs. If you are subcontracting, then we must ensure that you are overseeing your downstream entities.

34. What requirements apply to downstream entities?
Downstream entities must comply with all applicable regulatory requirements that apply to the Medicare Parts C & D program. This includes the compliance program requirements explained in our **FDR Guide**.

35. What oversight is expected for my downstream entities?
If you use downstream entities, you must have acceptable oversight of their compliance and performance. This includes testing compliance and performance of your downstream entities through audits or monitors, and requesting corrective actions when deficiencies are identified.

VII. FDR Audits and Monitoring Activities

36. What is the scope of an FDR Audit or Monitoring event?
The purpose of a compliance audit or monitoring event is to review the effectiveness of your organization's compliance program, as outlined in Chapters 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual. as well as components of your organization's contract with us, including the Medicare Addendum. We may also review operational processes outlined in contractual documents or policies.

During an FDR Audit, we will take a comprehensive look at your compliance program and review a range of documents and evidence. In a monitoring event, we will take a focused approach and look at one or two key issues.

37. **What documents will my organization be expected to provide in an FDR Audit or Monitoring event?**
    During an FDR audit, we will take a comprehensive look at your compliance program and review a range of documents and evidence, such as policies and procedures, training records, and monitoring reports. In a monitoring event, we will take a focused approach and examine one or two key compliance areas. To assist your organization in ensuring compliance with Medicare compliance program requirements, the Self-Assessment Tool will help you evaluate your program's effectiveness and identify any areas for improvement.

38. **How do we know what Medicare compliance requirements will be looked at in an audit?**
    You can review the sample tool which outlines the requirements that are part of an audit in the **FDR Toolbox** section of the **FDR Guide**. You can use this tool to conduct a self-assessment of your organization's compliance program, as well as to assess your subcontractor FDRs' compliance programs (if applicable).

39. **What happens if we can't show you certain evidence in an audit because it is proprietary or confidential?**
    When we review employee screening and Code of Conduct distribution, you must provide the employee first and last name to maintain employee confidentiality. For policies and other documentation, you have the option to redact proprietary or confidential information, or to present information over webinar.

    Additionally, the self-assessment tool provided in the **FDR Toolbox** section of the **FDR Guide** and ensure that you have evidence that can be shared for each item. If you don't, consider creating an Aetna specific policy that can be shared which details your compliance program processes. Keep in mind that during an audit, we can only review what you provide to us, so ensuring you have evidence that can be shared for each item in the self-assessment tool will help your organization avoid deficiencies.

40. **We already had an audit that requested similar documentation, so can we give you that audit and skip this review?**
    No. While your organization is welcome to submit such a report, the audits we conduct require independent validation of documentation to ensure compliance with CMS requirements. We cannot depend on audits conducted by other entities. We appreciate your collaboration during the audit process and will do our best to ensure the process moves quickly.

VIII. Corrective Action Plan

41. **What happens if Aetna identifies a deficiency during an audit or monitoring activity?**
    As a result of a compliance audit or monitoring activity, Aetna may observe an issue that

must be corrected. When this happens, we will require a corrective action plan (CAP) from your organization. As part of this process, you will complete a CAP Response Form in which you will identify the root cause of the deficiency and describe the plans you have for remediating the issue.

42. I'm not sure of what a CAP Response Form would look like-can I see a sample?

Yes, a sample is located in the **FDR Toolbox** section of the **FDR Guide.**

43. How do we identify the root cause of an issue?

Root cause refers to the underlying reason for a deficiency and allows you to determine what went wrong and why. Without an accurate understanding of the root cause of a problem, it is difficult to prevent the deficiency from occurring again. You should ask yourself when determining the root cause of an issue:

- Is this a new issue or a recurrence of a previously identified issue?
- If the issue was previously identified, why did the issue occur again?
- Are there multiple contributing factors that caused the issue?
- Who was involved?
- What happened and when did it happen?
- Where was the failure and why did it occur?

44. How do we identify solutions for remediating an issue?

Solutions for fixing a deficiency vary depending on the nature of the CAP. Your organization may need to implement a new process, update an existing process, create or update a policy. Consider the following questions as you reflect on possible solutions for remediating a deficiency:

- Does my CAP address the root cause of the deficiency and thoroughly solve the problem?
- Does my CAP address both short-term and long-term needs?
- What timeframe is needed to resolve this issue?
- How will employees involved in the process be notified/trained on the new policies or processes?

45. We completed the CAP remediation process. Is there anything else we need to do?

Once a CAP is closed, your organization must continue to monitor your improvements to ensure ongoing compliance and to verify that your improvements actually corrected the deficiency. You may need to make additional updates to your process based on your ongoing monitoring.

Be sure to ask yourself the following questions as you continue to monitor your improvements:

- Did the solution in the CAP actually solve the problem?
- Are additional enhancements or changes to the process needed to maintain compliance?

Is an auditing, monitoring, and/or process control point needed to further improve the process?

ATTACHMENT A: CONTACT US

Medical Providers- Contact our Provider Service Center

Follow these steps ONLY for Medicare Questions

1. Dial 1-800-624-0756 (TTY: 711) for Aetna Medicare Advantage plans and HMO-based plans
2. Enter your Provider ID number
3. At the prompt for patient ID number, dial “O” or say "representative"
4. At the prompt for patient ID number, say "general question"
5. Your call will be opted out to a customer service representative

You can email us via CONTACT US ONLINE

Sales Partners/Agents- Contact our Broker Services Department

Phone: 1-866-714-9301
Fax number: 1-724-741 -7285
Email: brokersupport@aetna.com
You may also contact your Account Manager/Sales Director directly.

Vendor/Suppliers

Please contact your Relationship Manager/Contract Liaison directly.