FDR compliance newsletter

November 2019 – Issue 23

Code of Conduct distribution

As our First Tier, Downstream or Related Entity (FDR), your organization is required to distribute a Code of Conduct (Code) to employees:

- Within 90 days of when an employee is hired or begins work on the Aetna account
- When changes are made to the Code
- Annually

You have the option of distributing either the CVS Health Code of Conduct, or your organization's own Code (if the content is comparable to the CVS' Code).

As part of our Compliance Program Effectiveness (CPE) oversight activities, we may ask you to provide evidence of the distribution of the Code to your employees. Evidence of distribution can vary by organization, but it must clearly demonstrate that your employees were provided with the Code.

Some examples of evidence of distribution include:

- Email to employees with a link to the Code of Conduct and an instruction to review it;
- Screen shot of an intranet posting with a notification to employees to review it
- Code of Conduct attestations
- Evidence of Code of Conduct training

Be sure to retain distribution evidence for 10 years.

Reporting issues of non-compliance and FWA to Aetna

Did you know, based on your organization's status of an FDR, you have an obligation to report issues of non-compliance and Fraud Waste and Abuse (FWA) to Aetna?

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Quick links

- **Archived Newsletters**
- **Aetna's FDR Guide (updated 06/2019)**
- **Medicare managed care manual**
- **Medicare prescription drug benefit manual**
- **CVS Health Code of Conduct(updated 12/2018)**

Exclusion list links:

- **OIG's list of excluded individuals and entities (LEIE)**
- **GSA's System for Award Management (SAM)**
  - *If the link does not work due to internet browser issues, please access the site directly at https://www.sam.gov/SAM/*

Aetna maintains a comprehensive Medicare compliance program. It includes communication with Aetna Medicare FDRs. Patrick Jeswald is Aetna's dedicated Medicare Compliance Officer. You can send questions or concerns to Patrick at MedicareFDR@aetna.com.

The requirement for reporting such issues can be found in the Chapter 21 — Compliance Program Guidelines, and Prescription Drug Benefit Manual Chapter 9 — Compliance Program Guidelines (Ch 9/ 21), section 50.4.2 Communication and Reporting

Mechanisms. The requirement states that the sponsor must require FDRs to report Compliance concerns and suspected or actual violations related to the Medicare program to the sponsor. We have included this requirement of our FDRs in our Medicare contracts; our FDR training packet and attestations. In addition, we test compliance as part of CPE audit processes. Refer to our FDR Program Guide for further details.

We have seen an upward trend in failures for this requirement in our CPE audits. FDRs should be aware of the requirement as well as have a written policy/procedure which demonstrates the mechanism for reporting to plan sponsors.

What type of language do we look for in your organizations written policy or procedure?

"Entity Name" will cooperate with appropriate federal, state, and local authorities who are investigating possible unlawful conduct. Additionally, "Entity Name" will report compliance issues and potential FWA, as required to the appropriate CMS Medicare Advantage Plan Sponsor.

There are several ways to report suspected or detected noncompliance or potential FWA. You can find ways to report to us on our reporting mechanism poster. This reporting mechanism poster is also available for your organizations use.

Overseeing your organization's downstream entities

Just as we audit and monitor our FDRs, your organization also has the obligation to audit and monitor FDRs that your organization contracts with to perform services for us. Here are a few questions and answers to help explain how your organization should be evaluating and overseeing your FDRs.

Q: How do we determine if a subcontractor is an FDR?

A: *Ch 9/Ch 21, Section 40, outlines areas of consideration when determining if an entity qualifies as an FDR. The chapter describes evaluating:*

- *The type of services being performed*
- *The impact of the services on beneficiaries*
- *Access to protected health information*
- *Decision-making authority*
- *The ability to commit fraud, waste, or abuse*
- *The overall risk associated with the entity*

While a specific methodology is not outlined in the chapter, your organization should have a process to consistently evaluate the FDR status of subcontractors performing services on your behalf.

What is an FDR?

FDR = First tier, downstream and related entities

A **first tier** entity is any party that enters into a written arrangement with our organization to provide administrative or health care services for our Medicare business.

A **downstream** entity is any party that enters into a written arrangement with persons or entities below the level of the first tier's arrangement with our organization. These arrangements continue down to the level of the ultimate provider of both health and administrative services.

A **related** entity is an entity that is linked to our organization by common ownership or control, and provides functions to support our Medicare business.

Q: What do I do if a subcontractor is an FDR?

A: If your evaluation process determines an entity is a downstream entity for Aetna, be sure to let us know about this relationship. If any of the services will be performed offshore you will need to request permission to perform offshore services, through an offshore attestation.

Q. What are oversight obligations for these subcontractors?

A: You need to ensure effective oversight of the compliance and operational requirements for the services the FDR is performing. This includes executing a contractual agreement that contains the CMS required provisions. Your organization can accomplish this through an oversight policy, compliance attestations, monitoring and/or auditing activities. When we audit your organization, we will request evidence of oversight of your FDRs as part of the audit.

Q: What if oversight of our FDRs demonstrates they are not compliant with a Medicare requirement?

A: Just as we are required to hold your organization accountable for non-compliance and require remediation of deficiencies, your organization must do the same for your FDRs. Ch 9/Ch 21, Section 50.7.2 outlines key components of Corrective Plans, such as the root cause of the failure, tailoring the corrective action to specifically address the deficiency, and the importance of validating compliance after the corrective action is in place.

Q: What documentation do we need to retain related to oversight of our FDRs?

A: You must retain Medicare documentation for at least 10 years. This includes:

- *Contracts with your FDRs*
- *Documentation of oversight activities*
- *Evidence of corrective action plans and remediation*
- *Documentation to support your FDR Evaluation Process*

Exclusion screening: Why are you required to screen using both GSA SAM and OIG Lists?

Ch 9/Ch 21, Section 50.6.8, requires plan sponsors and FDRs to screen all new employees, temporary employees, volunteers, consultants, governing body members, and FDRs prior to hire/contracting and monthly thereafter using both of the following:

- The Office of Inspector General for the Department of Health and Human Services ("HHS-OIG") List of Excluded Individuals and Entities ("LEIE")
- The exclusion list maintained by the General Services Administration ("GSA") in the System for Award Management ("SAM") database.

Why must we review both lists for exclusions? *Neither database alone provides all the exclusion information you need.*

The LEIE database is maintained by HHS-OIG to identify individuals/entities that have been excluded from Medicare and other federal healthcare programs.

The General Services Administration (GSA) maintains the GSA List that identifies exclusions related to individuals/entities excluded from Federal procurement. The GSA List includes exclusions related to health care programs. It does not include every excluded provider on the LEIE and may not be immediately updated with LEIE exclusions.

While there is some overlap, these lists are maintained by different agencies for different purposes and are updated in different ways. Not only does CMS require both lists be used, but practically speaking, both lists MUST be used in order to identify all pertinent exclusions.

Two questions to test your process:

1. Does your organization's exclusion screening process review BOTH the LEIE and the GSA lists?
2. Does your organization retain documentation of your results for at least 10 years?

If you answered 'yes' to both, that's great! If not, it's time to update your process.

Self-review: Preparing for FDR auditing and monitoring activities in 2020

When we schedule an oversight activity on FDRs, the primary purpose is to validate compliance with Ch 9/Ch 21 and your contractual obligations. The following items are examples of the requirements we may look at.

Conduct a self-review of these each element to check your compliance:

1. Code of Conduct: My organization distributes either the CVS Health Code of Conduct or our own Code (which has substantially similar content), to applicable employees within 90 days of when an employee is hired or begins work on the Aetna account, when changes are made, and annually.
   YES___ NO___

2. Exclusion screenings: My organization screens applicable employees and downstream entities against the OIG and GSA exclusion lists and maintains evidence that demonstrates the result of the screening, as well as the date of screening, for at least 10 years. My organization promptly removes any excluded employees from working on the Aetna accounts. We have a policy that describes how our screening process meets these requirements.
   YES___ NO___

3. Record retention: My organization has a policy for retaining Medicare documents for at least 10 years.
   YES___ NO___

4. Oversight of downstream vendors: My organization EITHER does not use any vendors that would meet the definition of "FDR" (as described in Ch 9/Ch 21) to perform services on behalf of Aetna Medicare business, OR we use FDRs and are able to provide documentation of effective oversight (such as an FDR oversight policy, compliance attestations, evidence of auditing and monitoring activities, and/or documentation of oversight of performance).
   YES___ NO___

5. Corrective Actions Plans (CAPs): My organization EITHER has not been issued a CAP by Aetna, OR we have been issued a CAP and we have corrected and maintained compliance and can demonstrate ongoing compliance through documented evidence.
   YES___ NO___

How did you do? If you were not able to answer 'YES' to every element, make corrections to your processes today — this may save you from a corrective action plan tomorrow!

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