

FDR compliance newsletter

September 2020 – Issue 26

Have you read our FDR Guide?

Do you have a question about the CMS Medicare compliance requirements? We want you to understand what CMS expects from you and help you understand how to comply. We have developed the FDR Medicare Compliance Program Guide, or FDR Guide, to provide your organization with a summary of the FDR compliance requirements applicable to your organization, as well as outline the compliance activities your organization will participate in as a result of your FDR status. The FDR Guide is distributed to new FDRs, to all FDRs during annual training, and at other times during the year, when needed.

The FDR Guide can help you find answers to important questions like:

- “Which subcontractors would my organization consider downstream FDRs?”
- “How often must applicable employees receive the Code of Conduct?”
- “Where are the OIG and GSA databases located and how often must I screen my employees?”
- “How can my organization demonstrate appropriate reporting mechanisms?”
- And many more!

Check out the FDR Guide and if you still have questions about compliance requirements, simply write to our Medicare Compliance FDR team at **MedicareFDR@Aetna.com**.

In this issue:

- Have you read our FDR Guide?
- Corrective Action Plans (CAPs) and Root Cause Analyses

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 \(updated Nov 2019\)](#)**

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**.

Corrective Action Plans (CAPs) and Root Cause Analyses

As an FDR to CVS Health® and/or Aetna®, your organization is required to comply with the combined Compliance Program Guidelines Chapters 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual. If an FDR does not comply with the requirements outlined in Chapters 9 and 21, a Corrective Action Plan (CAP) will be issued to the FDR. Part of the CAP process requires an FDR to conduct a root cause analysis to understand the reason the deficiency occurred.

What's a CAP?

A CAP is an organized, step-by-step action plan for fixing a non-compliance issue and preventing that non-compliance from recurring. It also provides a mechanism for monitoring your progress towards compliance.

Your CAP must be thoroughly documented and include reasonable timelines for specific achievements. To be effective, the actions outlined in your CAP must address what caused the non-compliance issue to arise in the first place. That's where the root cause analysis comes in.

What's a Root Cause Analysis?

A root cause analysis explains "why" a non-compliance issue occurred. It ensures you understand the underlying problem so you can create actions items that correct it appropriately.

How do I perform a Root Cause Analysis?

Analyze your workflows to find out the cause-and-effect chain that created the issue. A variety of problem-solving techniques can be used to do this. For example, you could form a small team of people familiar with your processes to brainstorm possible causes of the deficiency and identify the symptoms of the issue to root out its actual cause. The team's analysis could result in the discovery of multiple root causes. One "why" may actually lead to another, as there can be multiple causes for a problem.

Root Cause/CAP action examples

Problems may arise from people, processes, or systems. Some common root causes and associated CAP actions include, but aren't limited to, the following:

| People | |
|---|---|
| Root Cause | CAP Action |
| Employees weren't aware of CMS requirements or were inadequately trained. | Train staff on requirements. |
| Staffing levels were inadequate. | Hire new personnel to support process needs. |
| Downstream contractor refuses to be compliant. | Terminate contractual relationship with contractor. |

| Processes | |
|---|--|
| Root Cause | CAP Action |
| Policy was unclear or inaccurate for the CMS requirements. | Revise policy to clearly include CMS requirements and train staff on new policy. |
| There was a lack of oversight to ensure process compliance. | Develop and implement ongoing monitoring process to validate compliance with CMS requirements. |

| Systems | |
|--|--|
| Root Cause | CAP Action |
| Current system cannot support training volume. | Acquire and implement new training system that meets volume demands. |

These are just a few examples. Your Root Causes and CAPs will be specific to your deficiency and organization. It may be helpful to ask yourself "Does the Root Cause actually identify why the deficiency occurred? And, does the CAP Action actually resolve what went wrong?" If you can

answer "Yes!" to both of these questions, your organization is likely on the right path towards remediating a deficiency.

This newsletter is provided solely for your information and is not intended as legal advice. If you have any questions concerning the application or interpretation of any law mentioned in this newsletter, please contact your attorney.

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