FDR compliance newsletter

March 2020 – Issue 24

The origin of the compliance Program

As a First Tier, Downstream or Related Entity (FDR), you're required to have an effective compliance program that meets the requirements of Chapter 9 — Medicare Prescription Drug Benefit Manual and Chapter 21 — Medicare Managed Care Manual (Ch 9/21). Compliance program requirements aren't new. In fact, the basics of the "7 Elements" outlined in Ch 9/21 were actually developed almost 30 years ago.

The elements of an effective compliance program were originally developed by the United States Sentencing Commission in 1991. They're to help all types of businesses self-police their conduct by providing a structure for preventing and detecting criminal conduct.

In 1997, the Office of the Inspector General (OIG), a department of Health and Human Services, began applying the elements described in the sentencing guidelines to health care organizations. Today, the OIG has compliance program guidance for many health care organizations, including provider organizations, durable medical equipment (DME) suppliers, clinical laboratories and more.

The Centers for Medicare and Medicaid Services (CMS) adopted the same guidelines in Ch 9/21. These are the requirements the Medicare Compliance Team uses to assess your organization's compliance program during audit and monitoring events. For more information on the essential elements of a compliance program, review Ch 9/21.

Updates to our Code of Conduct

We recently updated our Code of Conduct. We give it to our FDRs during their initial orientation, and each following year. To request a copy, just email us at **MedicareFDR@Aetna.com**.

In this issue:

Quick links

- **Archived newsletters**
- **Aetna's FDR guide (updated 6/2019)**
- **Medicare managed care manual**
- **Medicare prescription drug benefit manual**
- **CVS Health Code of Conduct (updated 11/2019)**

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 **SAM.gov/SAM***

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

2019 audit trends update

At the end of 2019 compliance program audits and monitoring, we saw a variety of deficiencies. Below is a summary of some of the frequently identified deficiencies, and a self-check suggestion that will help your organization avoid the same findings in 2020 audit and monitoring activities.

Frequently identified deficiency	Self-check suggestion
Failure to perform OIG and GSA screenings on employees and governing body members	Validate that you have a written process (which you are following) for screening employees, including governing body members, against **both** the OIG and GSA lists. If you screen manually, be sure you are spelling names properly. Make sure you have screenshots with date/time stamps.
Failure to oversee downstream entities that perform services for CVS Health or Aetna, as applicable	If your organization contracts with downstream entities to perform services for Aetna® or CVS Health® business, validate that your organization can demonstrate oversight of their work. This includes documentation like an FDR oversight policy, collection of compliance attestations, evidence of auditing and monitoring activities, and/or documentation of oversight of performance. Also be certain that Aetna and/or CVS Health is aware of this relationship and of any offshore services that the entity may perform. For more information related to notifying Aetna of offshore services, refer to the First Tier, Downstream and Related Entities (FDR) Guidebook.
Failure to perform OIG and GSA screenings on downstream entities, as applicable	If your organization contracts with downstream entities to perform services for Aetna or CVS Health business, validate that you have a written process (which you are following) for screening these entities against **both** the OIG and GSA lists both prior to contracting with them, and then monthly thereafter. If you screen manually, be sure you are spelling the names of the entities properly, and that you maintain screenshots with date/time stamps.
Failure to report noncompliance, fraud, waste, and/or abuse to CVS Health and/or Aetna	Make sure your organization has a policy (which you are following) that states that your organization will report compliance, fraud, waste and/or abuse, as required by CMS, to plan sponsors. Be sure your employees are aware of reporting mechanisms, such as the CVS Ethics Line, and that mechanisms are widely publicized within your facility.

You have been selected for an audit — now what?

CVS Health and Aetna conduct regular audits of FDRs to confirm compliance with Ch 9/21. As an FDR, your organization is likely to receive an audit engagement notice at some point. Here are some highlights of what to expect if your organization receives an audit announcement.

The auditor will give your organization a list of documents needed to assess your compliance program. You'll also get a request for a list of the employees that perform services for CVS Health and/or Aetna. Be sure to review the requests and coordinate with your internal compliance organization and any other teams to give or help gather the requested documents and the employee list. There's a deadline for submitting documents to the auditor, so begin collecting documents right away. Don't wait to ask for clarification from the auditor if you have any questions.

The auditor will review the documents you provide. If any potential findings are identified, you'll get a deadline to provide additional documentation to prove compliance. Once all documents are reviewed, the auditor will schedule a meeting with your organization to review the audit findings. At this point the audit will close. If corrective action is needed, your organization will continue to work with the auditor until all deficiencies are satisfied and closed.

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