

FDR compliance newsletter

June 2021 – Issue 29

Reporting issues of noncompliance and FWA to CVS Health®

Did you know? Based on your organization's status as a Medicare First Tier, Downstream and/or Related Entity (FDR), you have an obligation to report issues of noncompliance and Fraud Waste and Abuse (FWA) to plan sponsors (like Aetna® or CVS Health).

The requirement for reporting such issues can be found in the Medicare Managed Care Manual Chapter 21 — Compliance Program Guidelines. And the Prescription Drug Benefit Manual Chapter 9 — Compliance Program Guidelines, [section 50.4.2](#) Communication and Reporting Mechanisms. It says that the sponsor must require FDRs to report Compliance concerns, as well as suspected or actual violations related to the Medicare program, to the sponsor. CVS Health has included this requirement of our FDRs in our Medicare contracts and addendums, and our FDR training packet and compliance attestations. We also test compliance as part of Compliance Program Effectiveness (CPE) audit processes. You can refer to the [First Tier, Downstream and Related Entities \(FDR\) guide](#) for more details.

CVS Health has seen an upward trend in failures for this requirement in our CPE audits.

FDRs should know the requirement and make sure that a written policy/procedure is in place. It should show the mechanism for reporting to plan sponsors. Here is sample language that could be included in your organization's 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*

In this issue:

- Reporting issues of noncompliance and FWA to CVS Health®
- Self-review: Preparing for CVS Health FDR auditing and monitoring activities in 2021
- Time-saving tips
- 2020 audit trends update

Quick links:

- [Archived newsletters](#)
- [Aetna® FDR guide \(updated 6/2019\)](#)
- [Medicare managed care manual](#)
- [Medicare prescription drug benefit manual](#)
- [CVS Health Code of Conduct \(updated 3/21\)](#)

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, you can access the site directly at SAM.gov/SAM/

We maintain 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 Patrick at MedicareFDR@Aetna.com.

appropriate Centers for Medicare & Medicaid Services Medicare plan sponsor.

There are a number of ways to report suspected or detected noncompliance or potential FWA.

- CVS Health® Ethics Line: **1-877-287-2040**
- CVS Health Online Ethics Line CVSHealth.com/EthicsLine
- Write us: Chief Compliance Officer, CVS Health One CVS Drive, Woonsocket, RI 02895



Self-review: Preparing for CVS Health FDR auditing and monitoring activities in 2021

CVS Health may schedule an audit with, or conducts a monitoring activity on, FDRs. The primary purpose is to validate compliance with Chapter 9 Prescription Drug Benefit Manual and Chapter 21 Medicare Managed Care Manual, as well as contractual obligations existing between the FDR and CVS Health. The following **five** items are key examples of the requirements we may look at in an audit or monitoring event. Conduct a self-review by marking “YES” or “NO” after each.

1. **Code of Conduct:** My organization distributes either the CVS Health Code of Conduct or our own Code of Conduct (which has substantially similar content) to applicable employees within 90 days of when an employee is hired or begins work on the CVS Health 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. It 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 CVS Health account. 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 Chapter 9 of the Prescription Drug Benefit Manual or Chapter 21 of the Medicare Managed Care Manual) to perform services on behalf of CVS Health 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 action plans (CAPs):** My organization **EITHER** has not been issued a CAP by CVS Health. **OR** we have been issued a CAP and we have corrected and maintained compliance. And we 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!

Time-saving tips

Wondering how to save time and ensure efficiency when working with CVS Health on an audit or a monitoring activity? Here are a few time-saving tips.


Please do:

- Ensure that all evidence is legible. Documents that have been scanned or faxed often become distorted and cannot be used to show compliance.
- Ensure that all evidence is clearly labeled. Documentation is crucial in any audit or monitoring activity we perform. Including a description when you send back documentation helps make sure we’re reviewing the information supplied as intended.

Please do not:

- Send restricted data such as Social Security numbers (SSNs), or any mention of them, when providing requested audit or monitor evidence. We cannot accept any documentation that contains restricted data. We’ll request that you redact the documents and send back the evidence without this information.



Did you know that you can view the CVS Health Code of Conduct anytime at: CVSHealth.com/sites/default/files/cvs-health-code-of-conduct.pdf 

2020 audit trends update

At the end of the 2020 compliance program audits and monitoring activities, we saw a variety of deficiencies. Below is a summary of some of the frequently identified deficiencies. You'll also see a self-check suggestion that will help your organization avoid the same findings in 2021 audit and monitoring activities.

Frequently identified deficiency	Self-check suggestion
Failure to perform OIG and GSA screenings on employees and governing body members	Confirm 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. Ensure 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.
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. Screen against 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 screen shots with date/time stamps.
Failure to report non-compliance, fraud, waste, and/or abuse to CVS Health® and/or Aetna®	Ensure 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. Make sure that your employees are aware of reporting mechanisms, such as the CVS Ethics Line, and that they're widely publicized within your facility.

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.

"Aetna" refers to a subsidiary company of CVS Health, including but not limited to Aetna Health companies, Aetna Better Health companies, Aetna Life Insurance Company, Coventry Health and Life Insurance Company, Coventry Health Care companies, First Health Life & Health Insurance Company, SilverScript Insurance Company, and those joint venture entities in which a CVS Health subsidiary company has ownership interests who offer or administer, under contract with CMS, Medicare Advantage, Medicare-Medicaid Plans (MMPs), Dual Special Needs Plans (DSNPS), and Medicare prescription drug plans (PDP) ("Aetna Medicare business").