

FDR compliance newsletter

September 2022 – Issue 34

Annual Training Distribution and Attestations

Centers for Medicare and Medicaid (CMS) requires Plan Sponsors to distribute training materials to First Tier Downstream and Related Entities (FDRs) within 90 days of contracting and annually thereafter. For our 2022 annual distribution, CVS Health® will begin distributing annual materials in the third quarter of this year. Training materials include:

- CVS Health Code of Conduct
- FDR Guidebook
- Model of Care (MOC) Training, if contracted as DSNP

Along with distributing the training materials, CVS Health requires certain FDRs to complete an annual attestation as part of our continuous oversight for compliance. The attestation provides the CMS compliance requirements that each FDR should be following themselves. If you are asked to complete a 2022 Annual Compliance Attestation, please make sure to complete it timely. Your completed attestation allows us to confirm your organizations' compliance with Medicare requirements. Some of these requirements are as follows:

- Distribution of Code of Conduct and/or Compliance Policies to your staff within 90 days of hire and annually
- Screen employees against the OIG and GSA exclusion lists prior to hire and monthly
- Ensure you have a process in place to report FWA and compliance concerns to CVS Health
- Request to use offshore operations
- Have oversight of any Downstream entities you are using to support CVS Health

In this issue

- Annual Training Distribution and Attestations
- The Relationship Between Policies and Evidence in an Audit
- Why are Exclusion Checks so Important?

Quick links

- [Archived newsletters](#)
- [Aetna FDR guide \(updated July 2021\)](#)
- [Medicare managed care manual](#)
- [Medicare prescription drug benefit manual](#)
- [CVS Health® Code of Conduct \(updated May 2022\)](#)

Exclusion list links:

- [OIG list of excluded individuals and entities \(LEIE\)](#)
- [GSA System for Award Management \(SAM\)](#)

Links not working? Go to [SAM.gov/SAM/](https://www.sam.gov/SAM/) to access the site directly.

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

If you have any questions regarding the annual training requirements, please contact us at MedicareFDR@aetna.com.

The Relationship Between Policies and Evidence in an Audit

As an FDR to CVS Health® and/or Aetna, your organization must be able to demonstrate compliance with the requirements outlined in Chapter 9 of the Medicare Prescription Drug Benefit Manual/Chapter 21 of the Medicare Managed Care Manual (hereafter “Chapters 9/21”).

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In the event of a FDR Compliance Program audit or a monitoring activity, your organization may be asked to provide both a policy that documents your process, and based upon sample selection, evidence that demonstrates the compliant process is in place.

Here are some of the most common policies that an FDR should expect to provide in a FDR Compliance Program Audit or monitoring activity, as well as types of evidence/examples that will be requested to support the policy:

- **Code of Conduct Distribution**
 - **Policy** should describe the process for distribution of the Code of Conduct within 90 days of hire and annually thereafter.
 - **Evidence** includes providing the actual Code of Conduct that was distributed to employees, as well as evidence that a sample of employees were provided the Code of Conduct within 90 days of hire, annually, and when updates were made. Examples of evidence include: screenshots from your training system, reporting with training dates, an email with the Code or a link to the Code that shows the employees name that received, etc.
- **Exclusion Lists**
 - **Policy** should describe the process for conducting exclusion list screenings prior to hire and monthly thereafter.
 - **Evidence** includes providing the documentation to demonstrate that a sample of employees were screened against the exclusion lists prior to hire and monthly thereafter. Examples of evidence could include: screenshots of results from the applicable website (with the date of screening), documentation from an external entity that conducts screenings on your behalf (if applicable), screenshots from exclusion database files and the record of employees screened as well as the results, etc.
- **Reporting Mechanisms**
 - **Policy** should describe your organization's requirement for reporting CVS Health/Aetna issues to CVS Health and/or Aetna but may also describe other processes related to reporting mechanisms and non-retaliation.
 - **Evidence** includes documentation of how your organization actually communicated the process for employees to report compliance concerns, that employees have an obligation to report compliance issues, and that your organization has a non-retaliation policy. This information must be widely available and/or displayed throughout your facility, such as a poster, Code of Conduct, internal intranet site, etc.
- **Downstream Oversight**
 - **Policy** should, as applicable, describe how your organization oversees any downstream entities to support CVS Health and/or Aetna Medicare business. Topics that should be covered in the policy include required contractual terms and how your organization:
 - conducts exclusion screening of the entity,
 - ensures these entities conduct exclusion screenings of their employees,
 - oversees the operations of the downstream entity, and
 - manages corrective action and/or disciplinary actions, when appropriate.
 - **Evidence** includes documentation that your organization screened your downstream entities prior to contracting and monthly thereafter, examples of your oversight activities, and other documentation that demonstrates the oversight activities your organization performs.

Why Are Exclusion Checks So Important?

The Office of the Inspector General (OIG) prohibits payment by a federal program, such as Medicare or Medicaid, for items or services provided by an excluded individual/entity or at the direction or prescription of an excluded individual/entity. The List of Excluded Individuals/Entities (LEIE,) along with the System for Award Management (SAM), provides information related to individuals/entities that are or may be excluded from participation in federal programs. Depending on the services being performed, some FDRs, such as provider organizations and certain health care vendors, are also required to screen against the CMS Preclusion List—review your contractual agreement if you are unsure if your organization has an obligation to screen against the Preclusion List.

Why Conduct Exclusion Checks?

Failure to conduct exclusion checks may result in termination of your agreement with CVS Health and/or Aetna, as well as potential imposition of civil monetary penalties by the OIG of up to \$10,000 for each item or service furnished by an excluded individual/entity. In addition, you may be fined by the OIG up to three times the amount claimed to a federal government program for services provided by the excluded individual/entity. In some cases, your company could even face exclusion from participation in federal health care programs.

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”).

[Aetna.com](https://www.aetna.com)

How Often Should We Conduct Checks?

It is important to conduct exclusion checks both prior to employing an individual or entering into a contract with an entity, as well as monthly thereafter. Your initial check is a snapshot in time, so you may find something new in a follow up exclusion check that wasn't there in the initial check. CVS Health and Aetna require ongoing screenings to be conducted monthly. The Medicare FDR Oversight team may conduct an audit or monitor to ensure this occurs. Don't forget to retain documentation of exclusion checks, such as by maintaining screen shots or print outs.

What Happens if a Check Reveals a Positive Match?

If you find a positive match during your initial pre-screening and you choose to move forward with hiring the individual or contracting with the entity, your organization must ensure that this individual or entity does not work on CVS Health and/or Aetna matters. If you find a positive match during monthly exclusion screening, you must disclose your finding to CVS Health and/or Aetna.

Conducting monthly exclusion checks is an essential part of an effective Compliance Program. Exclusion checks will help you protect the integrity of your company and your relationship with CVS Health and/or Aetna by validating that your employees and Downstream or Related entities meet federal requirements.