

FDR compliance newsletter

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Exclusion screening: why are both GSA SAM and OIG lists required?

Chapter 9 of the Medicare prescription drug benefit manual/chapter 21 of the Medicare managed care manual (section 50.6.8) requires plan sponsors and first tier, downstream or related entities (FDRs) to screen all new:

- Employees
- Temporary employees
- Volunteers
- Consultants
- Governing body members
- FDRs

Screening is required prior to hire/contracting and monthly thereafter. And it uses both the office of inspector general for the department of health and human services (HHS-OIG) list of excluded individuals and entities (LEIE), as well as the exclusion list maintained by the general services administration (GSA) in the system for award management (SAM) database.

You may ask yourself “why must we review both lists for exclusions?” The answer is: neither database alone provides all of the exclusion information you need.

The LEIE database is maintained by HHS-OIG. It identifies individuals/entities that have been excluded from Medicare and other federal health care programs by HHS-OIG. In other words, individuals/entities excluded from other programs, or excluded by entities other than HHS-OIG, will not be included on LEIE. The GSA list, on the other hand, is maintained by the general services administration. It identifies exclusions related to individuals/entities excluded from federal procurement. While the GSA list includes exclusions related to health care programs, it does not include every excluded provider on the LEIE. It

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- [Archived newsletters](#)
- [Aetna® FDR guide \(updated 7/2021\)](#)
- [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 doesn't work due to internet browser issues, you can access the site directly at [SAM.gov/SAM/](https://www.sam.gov/SAM/)

We maintain a comprehensive 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 Patrick at MedicareFDR@Aetna.com

also may not be immediately updated with LEIE exclusions.

It's important to keep in mind that while there is some overlap, these lists are maintained by different agencies for different purposes. And they are updated in different ways. CMS requires both lists be used. Both lists must be used in order to identify all pertinent exclusions.

SELF CHECK: Does your organization's exclusion screening process review both the LEIE and the GSA lists? 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.

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”). In the event of an FDR audit or a monitoring activity, your organization may be asked to provide the following:

- A policy that documents a process
- Actual 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 an FDR Audit or monitoring activity. This includes the 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, annually and when updates are made.
- **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. Evidence may vary but could include:

- Screenshots from your training system
- Reporting with training dates
- An email with the code
- A link to the code that lists the employees name, etc.

Exclusion screenings

- **Policy** should describe the process for conducting OIG/GSA screenings prior to hire and monthly thereafter.
- **Evidence** includes providing the documentation to demonstrate that a sample of employees were screened against the OIG/GSA exclusion lists prior to

hire and monthly thereafter. Evidence may vary, but could include:

- Screenshots of results from the OIG/GSA website including the date
- Documentation from the external entity that conducts screenings on your behalf (if applicable)
- Screenshots from exclusion database files
- The record and results of employees screened

Reporting mechanisms

- **Policy** should describe at least your organization’s process for reporting CVS Health/Aetna issues to CVS Health and/or Aetna. It may also describe other processes related to reporting mechanisms.
- **Evidence** includes documentation of how your organization actually communicated the process for employees to report compliance concerns. Employees have an obligation to report compliance issues. Your organization also has a non-retaliation policy. This information must be widely available and/or displayed throughout your facility.

Downstream oversight

- **Policy** should describe oversight of downstream entities if your organization uses 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.

What is the Medicare compliance FDR guide?

Do you have a question about the Centers for Medicare and Medicaid Services (CMS) Medicare compliance requirements? It is outlined in Chapter 9 of the Medicare prescription drug benefit manual/chapter 21 of the Medicare managed care manual. We want you to understand what CMS expects from you. And we want to help you understand how to comply. We've developed a [FDR Medicare compliance guide](#) (FDR guide). It provides your organization with a summary of the FDR compliance requirements applicable to your organization. And it outlines the compliance activities your organization will participate in as a result of your FDR status with CVS Health® and/or Aetna. The FDR guide is distributed to new FDRs,

FDRs during annual compliance training distribution and at other times during the year, when needed.

The FDR guide was updated this year. It may have a new look and feel. However, no requirements have been updated or changed. 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?”
- Do I need to retain source documentation of exclusion screenings?
- “How can my organization demonstrate appropriate reporting mechanisms?”
- And many more!

Check out our FDR guide. If you still have questions about compliance requirements, simply write to our Medicare Compliance FDR team. You can reach them at [**MedicareFDR@Aetna.com**](mailto:MedicareFDR@Aetna.com)

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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