

FDR compliance newsletter

September 2021 – Issue 30

Updates to the SAM.gov website

The General Services Administration (GSA) exclusion list is maintained in the System for Award Management (SAM) database. You can find it on the **SAM.gov** website. If you manually run exclusion screenings using the **SAM.gov** website, you may have recently noticed some changes to the search functionality. If you have questions about using the new functionality, you should reach out to the SAM [Service Desk](#). You can also create a help ticket or start a live chat. The **SAM.gov Knowledge Base** also has some helpful guidance surrounding the new search functionality. For example, here is a [Knowledge Base article on searching exclusions by SSN/TIN](#). Please be sure to review the evidence of completion you are maintaining for screenings on the **SAM.gov** website. Consistent with our previous communications, CVS Health® requires documentation to include a date/timestamp of when the screenings were conducted. When reviewing the exclusion screening evidence you are maintaining, be sure that the documentation clearly includes the following:

- The full name of the individual/entity screened
- The exclusion list the individual was screened against
- Date/timestamp of completion
- Results of the screening
 - If an individual was screened as a potential match and later cleared by a secondary search using their social security number (SSN) or another method, evidence of the secondary screening should be maintained.
 - This evidence should also contain the elements listed above.
 - Be sure you enter only digits for an SSN. Don't use dashes.

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- Overseeing your organization's downstream entities
- CMS Medicare Part C and D program audit protocols
- Annual Compliance Attestation

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 doesn't 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 our Medicare FDRs. Patrick Jeswald is our dedicated Medicare Compliance Officer. You can send questions or concerns to Patrick at MedicareFDR@Aetna.com.

With the changes made to the **SAM.gov** website, you may need to update your current process. This ensures that appropriate evidence of exclusion screenings are maintained. Print to PDF or screenshots may be a helpful way to capture the information that you'll need to maintain on file as evidence of screening completion.

Overseeing your organization's downstream entities

CVS Health® audits and monitors your organization based on your status as a first tier, downstream, and/or related entity (FDR). Similarly, your organization also has the obligation to audit and monitor FDRs that your organization contracts with to perform services for CVS Health. Here are a few questions and answers to help explain how your organization should be evaluating and overseeing your FDRs.

Q: How do we determine if a downstream vendor is an FDR or just a vendor?

A: Medicare program requirements apply to FDRs to whom the sponsor has delegated administrative or health care service functions. These functions are relating to the sponsor's Medicare Parts C and D contracts. Chapter 9 of the Prescription Drug Benefit manual and Chapter 21 of the Medicare Managed Care manual, Section 40, outlines areas of consideration when determining if a vendor qualifies as an FDR. The chapter suggests evaluating the following factors when determining FDR status:

- The type of services being performed (many examples of functions that would give rise to FDR status are listed in Section 40)
- The impact of the services on beneficiaries
- The vendor's access to protected health information
- The vendor's decision-making authority
- The vendor's ability to commit fraud, waste or abuse
- The overall risk associated with the vendor

A specific methodology isn't outlined in the chapter. However, your organization should have a process that considers all the components listed above to consistently evaluate the FDR status of subcontractors performing services on behalf of CVS Health. Our FDR Guidebook also has information on identifying your FDRs. And it includes this [grid](#) of examples.

Q: If my organization determines a vendor is an FDR, what are our oversight obligations?

A: If your evaluation process determines a vendor is a downstream entity for CVS Health, be sure to let CVS Health know about this relationship. This includes if any of the FDR services are being performed offshore. Next, ensure there is an executed contractual agreement between your organization and the vendor that contains all CMS-required provisions (42 CFR 423.505(i) and 42 CFR 422.504(i)). You'll also need to ensure that processes are in place for monitoring that the vendor meets compliance and operational requirements, such as:

- Ensuring an oversight policy is in place
- Obtaining compliance attestations
- Conducting monitoring and/or auditing activities of the vendor's compliance program and performance of operational processes

When CVS Health audits your organization, we'll request evidence of oversight of your FDRs as part of the audit.

Q: What if oversight of one of our FDRs demonstrates the vendor isn't compliant with a Medicare requirement?

A: CVS Health is required to hold your organization accountable for non-compliance. And they require remediation of deficiencies. Your organization must do the same for your FDRs. Section 50.7.2 of Chapter 9 of the Prescription Drug Benefit manual and Chapter 21 of the Medicare Managed Care manual outlines key components of Corrective Plans, such as:

- Requiring the FDR to determine the root cause of the failure
- Tailoring a corrective action to specifically address the deficiency
- Validating compliance after the corrective action is in place and its importance.

If you identify a compliance or fraud, waste or abuse that impacts Aetna®, you must report it to us. Review our [reporting poster](#) for more information.

Q: What documentation do we need to retain related to oversight of our FDRs?

A: All Medicare documentation must be retained for at least 10 years. This includes contracts with your FDRs, documentation of oversight activities, evidence of corrective action plans and remediation and documentation to support your FDR evaluation process.

CMS Medicare Part C and D program audit protocols

On May 26, 2021, the Centers for Medicare & Medicaid Services (CMS) made an announcement. They announced the final audit protocols it uses to conduct the Medicare Part C and Part D program audits and the program audit protocols for Medicare-Medicaid Plans (MMPs). Collectively, these protocols and supporting data collection

instruments will be used for Medicare Parts C and D program audits and MMP audits starting in 2022.

They will be available for download at:

[CMS.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits](https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits)

Annual Compliance Attestation

We'll soon be distributing annual training to our FDRs. Training will include the CVS Health® Code of Conduct and the FDR Compliance Guidebook. While providers are no longer required to complete the Medicare Compliance Program Attestation, the attestation will be included in the annual training for all other FDRs. And it must be signed and returned to us. This attestation allows us to confirm your organizations' compliance with Medicare requirements and your receipt of the Code of Conduct and FDR Guidebook. The attestation should only be completed by the individual responsible for attesting for your organization. If you have any questions regarding the attestation you can reach out to us at **MedicareFDR@Aetna.com**. We will be happy to assist.

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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