FDR compliance newsletter

June 2020 – Issue 25

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. We refer to these two as "Chapters 9/21." If there's an FDR audit or a monitoring activity, your organization may be asked to provide both a policy that documents a process, and evidence that demonstrates the compliance 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, as well as types of evidence 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 was 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 of Conduct or a link to the code that lists employees' names, etc.

Exclusion screenings

- **Policy** should describe the process for conducting OIG/GSA screenings before hire and monthly after that.
- **Evidence** includes providing the documentation to demonstrate that a sample of employees was screened against the OIG/GSA exclusion lists before hire and monthly after that. Evidence may vary, but could include screenshots of results from the OIG/GSA website, documentation from the 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.

In this issue:

Quick links

- **Archived Newsletters**
- **Aetna's FDR Guide (updated 06/2019)**
- **Medicare managed care manual**
- **Medicare prescription drug benefit manual**
- **CVS Health Code of Conduct (updated Nov 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 Aetna's dedicated Medicare Compliance Officer. You can send questions or concerns to Patrick at MedicareFDR@aetna.com.

Reporting Mechanisms

- **Policy** should describe at least your organization's process for reporting CVS Health/Aetna issues to CVS Health and/or Aetna, but 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, 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.

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 before contracting and monthly after that, 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.

How often should we conduct checks?

It is important to conduct exclusion checks both before employing an individual or entering into a contract with an entity, as well as monthly after that. 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 validation to ensure this occurs. Don't forget to retain documentation of exclusion checks, by maintaining screenshots or printouts, for example.

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, you must ensure that this individual or entity does not work on CVS Health and/or Aetna matters. If you find a positive match during an 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.

Standards for Business Continuity Plans

The Centers for Medicare & Medicaid Services (CMS) issued a Final Rule (42 CFR §§422.504(o) and §423.505(p)) that sets minimum standards for Business Continuity Plans effective 1/1/2016.

We must ensure our FDRs develop, implement and maintain Business Continuity Plans that meet certain minimum standards.

Minimum requirements

Business Continuity Plans must contain policies and procedures to protect the restoration of business operations following disruptions where business is not able to occur under normal conditions. Minimum Business Continuity Plan requirements include:

- Completion of a risk assessment
- Documented mitigation strategy
- Annual testing, revision and training
- Record keeping
- Identification of essential functions
- Chain of command
- Business communication plans

Essential functions

Business Continuity Plans need to address the restoration of identified **essential functions** within 72 hours of failure, as well as address CMS's minimum requirements.

Aetna has defined **essential functions** to include, at a minimum:

- Benefit authorization (if not waived) for services to be immediately furnished at a hospital, clinic, provider office, or other place of service.
- Benefit authorization (if not waived), adjudication, and processing of prescription drug claims at the point of sale.
- Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers.
- Operation of an enrollee exceptions and appeals process including coverage determinations.
- Operation of call center customer service, including translation services and pharmacy technical assistance.
- Production and mailing of essential documents including Aetna's Annual Notice of Change, Evidence of Coverage, Low Income Subsidy Rider, Multi-Language Insert, ID Cards, enrollment/disenrollment letters, formulary guides and enrollee transition supply letters.
- Support of any of the following activities: Medicare appeals, pre-service organization determinations, coverage determinations, utilization management and Medicare websites.

If you have questions, just let us know by sending an email to **MedicareFDR@Aetna.com**.

Updates to Medicare compliance policies and procedures

We recently updated our Medicare Compliance Policies and Procedures. These policies describe our process for ensuring an effective Medicare Compliance Program. FDRs should implement similar policies. These policies are also included in our initial and annual FDR training communications and are available online. Use the link above to access these policies.

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