

# FDR Compliance Newsletter

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Archived FDR Newsletters

<https://www.mercycareaz.org/providers/advantage-forproviders/fdr>

This newsletter is provided solely for informational purposes and is not intended as legal advice. Questions concerning the application or interpretation of any law mentioned in this newsletter should be discussed with your attorney.



## The relationship between policies and evidence during an FDR audit or monitoring activity

As an FDR, your organization must be able to demonstrate compliance with the requirements outlined in Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual. During 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.

*(continued)*

# The relationship between policies and evidence during an FDR audit or monitoring activity

## Exclusion screenings

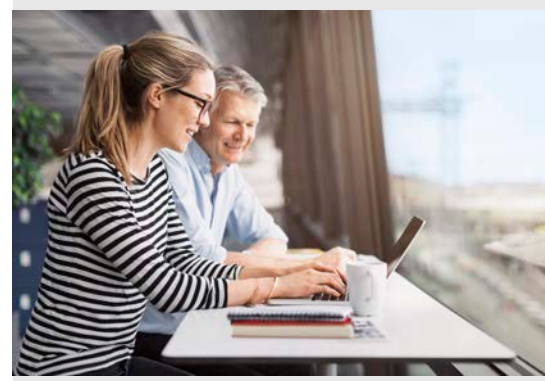
- **Policy** should describe the process for conducting OIG/GSA screenings before hire and monthly after that. This screening continues to be a requirement even though CMS has excluded the OIG/GSA verification element from Program Audits.
- **Evidence** includes providing the documentation to demonstrate 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.

## Reporting Mechanisms

- **Policy** should describe your organization's process for reporting issues to Mercy Care but may also describe other processes related to reporting mechanisms.
- **Evidence** includes documentation of how your organization 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 Mercy Care 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.



## Business Continuity Plans (BCPs)

CMS has set minimum requirements for Business Continuity Plans. At Mercy Care, we maintain a Business Continuity Plans and must ensure our FDRs develop, implement, and maintain Business Continuity Plans that meet certain **minimum standards**:

- ✓ 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

Business Continuity Plans need to also address the restoration of identified **essential functions** within 72 hours of failure, such as:

- ✓ 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.
- ✓ Operation of call center customer service, including translation services and pharmacy technical assistance.
- ✓ Production and mailing of essential documents and letters.
- ✓ Support of any of the following activities: pre-service organization determinations, coverage determinations and utilization management.



## 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 Mercy Care or Mercy Care Advantage, 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. Mercy Care and Mercy Care Advantage require ongoing screenings to be conducted monthly. The Medicare Compliance 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 Mercy Care or Mercy Care Advantage matters. If you find a positive match during an exclusion screening, you must immediately disclose your finding to the Mercy Care Compliance contacts.

As previously mentioned, this screening continues to be a requirement even though CMS has excluded the OIG verification element from Program Audits. 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 Mercy Care and Mercy Care Advantage by validating that your employees and Downstream or Related entities meet federal requirements.