

# Medicare First Tier, Downstream and Related Entities (FDR) Compliance Program Guide

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# Introduction

Priority Health is an award-winning, Michigan based nonprofit health plan nationally recognized for improving the health and lives of more than 1 million members it serves annually. Priority Health is recognized for high integrity, quality, innovation, expertise and compassion. Our strong values guide our behaviors and actions with every interaction to do what is right. The reputation for excellence at Priority Health is built on the dedicated work and responsible conduct of the thousands who have worked with us over the years along with the external entities we have contracted with. To that end, external entities play a critical role to help us sustain our excellent reputation through ongoing vigilance in the quality services we provide.

## **Our compliance program helps us serve our members ethically**

We're committed to achieving our vision with appropriate ethical and legal standards. Our compliance program is designed to:

- Help prevent, detect and correct non-compliance and potential fraud, waste and abuse (FWA);
- Ensure we comply with applicable federal, state, and local laws, rules and regulations, program requirements; and
- Reinforce our commitment to the Spectrum Health Code of Excellence

## **We utilize external entities as cost effective healthcare solutions for our members**

Priority Health offers Medicare Advantage (Part C) and Medicare prescription drug (Part D) (collectively referred to as MAPD) plans. We contract with several external entities as a cost effective and efficient means of providing administrative and healthcare services. Some of the services provided by external entities are services that we are required to perform under our contracts with the Centers for Medicare and Medicaid Services (CMS). These

external entities that we contract with are referred to as first tier, downstream, and related entities (FDRs). Please see Appendix A for the definition of an FDR.

## **You have specific compliance program requirements as an FDR**

As a contracted FDR for Priority Health Medicare products, your organization is subject to federal laws related to the Medicare program as well as CMS regulatory guidance in the Compliance Program Guidelines in Chapter 21 of the [Medicare Managed Care Manual](#) and Chapter 9 of the [Prescription Drug Benefit Manual](#). This guide contains important information on key elements of our compliance program along with your obligations and FDR requirements including but not limited to:

- Standards of conduct and compliance policies dissemination
- General compliance and FWA training
- System for monthly screening against the Office of Inspector General List of Excluded Individuals and Entities (LEIE) and System for Award Management (SAM)
- Reporting FWA and compliance concerns to Priority Health
- Requirements related to offshore operations
- Priority Health's obligation to monitor and audit your compliance as a FDR

## **What may happen if you do not comply**

If FDRs fail to meet the CMS compliance program regulatory requirements, it may lead to:

- Development of a root cause and corrective action plan (CAP)
- Retraining or redevelopment of policies and procedures
- Termination of contract and participation status with Priority Health

# FDR regulatory requirements

## Standards of conduct

In order to communicate compliance expectations, FDRs must ensure that standards of conduct and policies and procedures are distributed to employees. As a FDR, you may either distribute your own standards of conduct and compliance policies and procedures to your employees, or you may distribute Priority Health materials. The Spectrum Health Code of Excellence, which includes compliance policies and procedures, is available on the [Vendor](#) webpage or in the [Provider Manual](#) on Priority Health's website.

*42 C.F.R. §§422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A)  
Prescription Drug Benefit Manual & Medicare Managed  
Care Manual Chapter 9/21§50.1.3*

## General compliance training and fraud, waste and abuse (FWA) training

As a plan sponsor, Priority Health must ensure that FDRs have implemented general compliance and FWA training for all its employees (including temporary or volunteer), downstream or related entities who participate in the administration or delivery of Parts C and D benefits to Medicare beneficiaries. All FDRs must ensure that:

- All employees receive training within 90 days of initial hire and annually thereafter; and
- Proof of training which may include copies of sign-in sheets, employee attestations, or electronic certifications for each employee, is maintained for no less than 10 years

Your applicable employees and Downstream Entities assigned to provide administrative and/or health care services for our Medicare plans can access FWA training in one of two ways:

- Complete the Medicare Parts C & D Compliance and FWA Training on the [Vendor](#) page

- Complete the modules on the CMS [MLN website](#)
- Complete your own customized training module

FDRs who have met the FWA certification requirements through enrollment into Parts A or B of the Medicare program or through accreditation as a supplier of DMEPOS are deemed to have met the FWA training and education requirements. The deeming exception for FWA training does not apply to general compliance training and education requirements described above. Therefore, even if you are deemed for FWA training and education, the requirement for general compliance training and education must be fulfilled.

*42 C.F.R. §§422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)  
Prescription Drug Benefit Manual & Medicare Managed  
Care Manual Chapter 9/21§50.3.1-2*

## Exclusion Screening

As a FDR, you are prohibited from employing or contracting with persons or entities that have been excluded from doing business with the federal or state government. Upon hiring or contracting and monthly thereafter, you are required to verify your employees (including temporary and voluntary) against the Office of Inspector General List of Excluded Individuals and Entities (LEIE) and System for Aware Management (SAM), or any individual state provider exclusion or sanction list or database. Monthly screening is essential to prevent inappropriate payment to providers, pharmacies, and other entities that have been added to exclusion lists since the last time the list was checked.

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Links to OIG and SAM Exclusions Databases

- LEIE via the [OIG Website](#)
- [SAM](#)

If any of your employees or downstream entities are on one of these exclusion lists, you must immediately remove them from work and notify Priority Health immediately.

42 C.F.R. §§422.503(b)(4)(vi)(F), 422.752(a)(8), 423.504(b)(4)(vi)(F), 423.752(a)(6), 1001.1901

*Prescription Drug Benefit Manual & Medicare Managed Care Manual Chapter 9/21 §50.6.8*

### Reporting compliance and FWA concerns to Priority Health

Priority Health promotes and provides mechanisms to receive, record, respond and track compliance questions or reports of suspected or detected noncompliance or potential FWA. As a FDR, you are encouraged to proactively ask questions to prevent mistakes and ensure compliance. FDRs always have the opportunity and obligation to report actual or potential violations by telephone or in writing to the compliance officer at:

- Compliance HelpLine at 800.560.7013  
Toll Free, 24 hours a day, 7 days a week; or
- Cindy Rollenhagen  
Director, Compliance Officer  
Priority Health  
1231 East Beltline NE, MS 3230  
Grand Rapids, MI 49525; or  
[PHCompliance@spectrumhealth.org](mailto:PHCompliance@spectrumhealth.org)

You may also report FWA concerns at:

- Special Investigations Unit  
Priority Health  
1231 East Beltline NE, MS 3175  
Grand Rapids, MI 49525  
[SIU@priorityhealth.com](mailto:SIU@priorityhealth.com)

The process to report actual or potential noncompliance violations is designed to ensure that confidentiality is maintained, and anonymity is protected. All persons

making a report are assured that confidentiality will be maintained at all times insofar as is legal, practical and consistent with a reasonable investigation. Priority Health obtains a policy of non-intimidation and non-retaliation for good faith participation for reporting potential issues. This policy protects an individual who reports a concern in good faith from any type of intimidation or retaliation, regardless if the report is ultimately substantiated.

If you choose to use your own reporting procedures, you must have a process to ensure suspected or detected noncompliance, fraud, waste or abuse are reported to Priority Health. You can also refer back to our Code of Excellence for information on our reporting guidelines.

42 C.F.R. § 422.503(b)(4)(vi)(D), 423.504(b)(4)(vi)(D)  
*Prescription Drug Benefit Manual & Medicare Managed Care Manual Chapter 9/21 §50.4.2*

### Offshore operations

In order to comply with applicable federal and state laws, rules and regulations, as an FDR you are required to request permission from Priority Health to perform offshore services or to use an individual or entity that is physically located outside the United States or one of the United States Territories (i.e., American Samoa, Guam, Northern Marianas, Puerto Rico and Virgin Islands). Approval to utilize offshore services can only be made by an authorized Priority Health representative.

If Medicare member PHI data is determined by Priority Health to be in the scope of offshore access or storage, a CMS Offshore Attestation form will be required. This process is part of the Priority Health vendor risk assessment to ensure pre-contract due diligence by our organization and to mitigate risks associated with sharing beneficiary information with such subcontractors. Attestations and documentation required by CMS must be submitted by Priority Health via the Health Plan Management System (HPMS) Subcontractor Data Module within 30 calendar days after the contract with the offshore subcontractor is signed. Attestations are required for offshore entities that receive, process, transfer, handle,

store or access protected health information (PHI) in oral, written or electronic form.

45 C.F.R. § 164.308(a)(1)(ii)(B)

*CMS Center for Beneficiary Choices HPMS memos  
7/23/2007, 9/20/2007, and 8/26/2007*

### Monitoring and auditing FDRs

CMS requires Priority Health to develop a strategy to monitor and audit its first tier entities (FTEs) to ensure they are in compliance with all applicable laws and regulations, and to ensure that the FTEs are monitoring the compliance of the entities with which they contract (downstream entities). Therefore, as an FTE, if you choose to subcontract with other individuals/entities to provide administrative and/or health care services for Priority Health, you must ensure that these downstream entities abide by all laws and regulations that also apply to you.

As an FDR, you are responsible for conducting sufficient oversight through monitoring and auditing as well to test and confirm your employees and downstream entities are meeting compliance requirements. This includes ensuring root cause analyses and corrective action plans are implemented (including any applicable disciplinary actions) to correct any issues of noncompliance.

Priority Health routinely monitors and audits FDRs to ensure compliance to our contract with CMS as well as other applicable laws and regulations. As an FDR, you should be aware and expect to receive notice from Priority Health to be included in routine compliance audits on an annual basis. Also, you should expect to receive requests for your own internal monitoring and auditing results which affect Priority Health's Medicare business. If Priority Health determines that an FDR is not complying with the compliance program requirements through our monitoring or auditing, we will require you to submit a formal root cause analysis and corrective action plan and we will assist you in addressing any issues of noncompliance.

42 C.F.R. § 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

*Prescription Drug Benefit Manual & Medicare Managed Care Manual Chapter 9/21 §50.6.6*



# Appendix A: What is an FDR?

**First tier entity** is any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization or Part D plan sponsor or applicant to provide administrative services or healthcare services to a Medicare eligible individual under the Medicare Advantage program or Part D program. (See 42 C.F.R. §§ 422.500 & 423.501).

**Downstream entity** is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Medicare Advantage benefit or Part D benefit, below the level of the arrangement between a Medicare Advantage Organization or applicant or a Part D plan sponsor or applicant and a first-tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. (See 42 C.F.R. §§ 422.500 & 423.501).

**Related entity** means any entity that is related to a Medicare Advantage Organization or Part D sponsor by common ownership or control and:

1. Performs some of the Medicare Advantage Organization's or Part D plan sponsor's management functions under contract or delegation; or
2. Furnishes services to Medicare enrollees under an oral or written agreement; or
3. Leases real property or sells materials to the Medicare Advantage Organization or Part D plan sponsor at a cost of more than \$2,500 during a contract period. (See 42 C.F.R. §§ 422.500 & 423.501).

## **FDRs providing administrative or healthcare services**

The Medicare Compliance Program requirements apply to entities which Priority Health contracts with to perform administrative and health care services relating to MAPD contracts with CMS. Services provided by FDRs include but are not limited to:

- Sales and marketing
- Utilization management
- Quality improvement
- Applications processing
- Enrollment, disenrollment and membership functions
- Claims administration, processing and coverage adjudication
- Appeals and Grievances
- Licensing and Credentialing
- Pharmacy Benefit Manager
- Customer Service
- Provider Network Management
- Health Care Services

You can find more information in the Medicare Managed Care Manual, Chapter 9, § 40, including the Stakeholder Relationship Flow Charts.