2025 - 2026

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

HealthPlan OF SAN MATEO

Healthy is for everyone

1

An Introduction to the Health Plan of San Mateo's Compliance Program

The Health Plan of San Mateo (HPSM) is committed to conducting its business operations in compliance with ethical standards, contractual obligations, and all applicable state and federal statutes, regulations and rules, including those pertaining to Medicare, Medi-Cal, and operations of health plans. HPSM's compliance commitment extends to its business partners and delegated entities that enable HPSM to fully meet the needs of its members.

Our Compliance Program helps us serve our members ethically

We're committed to practicing business in an ethical manner. Our Compliance Program is designed to:

- Assure compliance with all applicable federal and state laws governing HPSM
- Assure compliance with contractual obligations
- Detect violations of ethical standards
- Combat fraud and abuse
- Ensure effective education and training of staff and business partners

We use external entities to bring our members cost-effective healthcare solutions

HPSM contracts with several external individuals and entities as a cost effective and efficient way 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 CMS. The Centers for Medicare and Medicaid Services (CMS) refer to these entities as First Tier, Downstream, and Related entities (FDRs).

You'll find specific requirements in this document

CMS also requires that HPSM's FDRs fulfill specific Medicare Compliance Program requirements. We describe these requirements in this document. The Code of Federal Regulations (CFR) outlines these Medicare Compliance Program requirements and they are specifically defined by CMS in the January 11, 2013 release of the Compliance Program Guidelines found in Chapter 21 of the Medicare Managed Care Manual and Chapter 9 of the Prescription Drug Benefit Manual, which are identical.

It is important for you to follow these requirements

You received this guide because we've identified you as a First Tier Entity. This means that you must comply with these requirements.

II

What's an FDR?

We use the current CMS definitions to define First Tier, Downstream, and Related Entities:

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 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).

III

FDR Medicare Compliance Program & Attestation Requirements

It's important that our FDRs are in compliance with applicable laws, rules and regulations. Although we contract with FDRs to provide administrative and/or healthcare services for our Medicare Plans, in the end, we're responsible for fulfilling the terms and conditions of our contract with CMS and meeting applicable Medicare program requirements.

Compliance program requirements

First Tier Entities are responsible for making sure that their Downstream Entities comply with applicable laws and regulations, including the requirements in this guide. As a First Tier Entity, you/your organization and all of your Downstream Entities (if applicable) must comply with Medicare Compliance Program requirements. This guide summarizes your Medicare Compliance Program responsibilities. Please review it to make sure that you have internal processes to support your compliance with these requirements each calendar year. These Medicare Compliance Program requirements include, but are not limited to:

A. Fraud, Waste and Abuse ("FWA") training, general compliance training and Code of Conduct/compliance policy distribution
B. Exclusion list screenings
C. Reporting FWA and compliance concerns to HPSM
D. Offshore operations & CMS reporting
E. Specific federal and state compliance obligations
F. Monitoring and auditing of First Tier, Downstream and Related Entities

What may happen if you don't comply

If our FDRs fail to meet these Medicare Compliance Program requirements, it may lead to:

- Development of a Corrective Action Plan
- Retraining
- Termination of your contract and relationship with HPSM

Our actions in response to a First Tier Entity's non-compliance will depend on the severity of the compliance issue. If a First Tier Entity identifies areas of non-compliance (e.g., refusal of an employee to complete the required FWA training), the First Tier Entity must take prompt action to fix the issue and prevent it from happening again.

Attestation requirements

You must to maintain evidence of your compliance with these Medicare Compliance Program requirements (e.g., employee training records, CMS certificate of FWA training completion, etc.) for no less than 10 years. Also, each year, an authorized representative from your organization must attest to your compliance with the Medicare Compliance Program requirements described in this guide. The authorized representative is an individual who has responsibility directly or indirectly for all:

- Employees
- Contracted personnel
- Providers/practitioners
- Vendors who provide healthcare and/or administrative services for HPSM's Medicare Plans

This could be your Compliance Officer, Chief Medical Officer, Practice Manager/Administrator, Provider, an Executive Officer or similar related positions.

You may be asked to provide evidence of compliance

In addition to completing an attestation, HPSM and/or CMS may request that you provide evidence of your compliance with these Medicare Compliance Program requirements. This is for monitoring/auditing purposes.

We take these responsibilities very seriously. If you have questions or concerns about these Medicare Compliance Program requirements, contact HPSM's Compliance Department by emailing Compliance@hpsm.org. What follows is a description of each Medicare Compliance Program requirement.

A. Fraud, Waste and Abuse ("FWA") training, general compliance training and Code of Conduct/compliance policy distribution

FWA and general compliance training

As a First Tier Entity, you/your organization must provide FWA and general compliance training to all your employees and Downstream Entities assigned to provide administrative and/or healthcare services for our Medicare Plans. To comply with this requirement, you can use the CMS Medicare Parts C & D Fraud, Waste, and Abuse Training and General Compliance Training. You can also substitute an equivalent version to satisfy these training requirements.

Compliance training requirements

Regardless of the method used, the training must be completed:

- Within 90 days of initial hire or the effective date of contracting
- At least annually thereafter

Also, you must maintain evidence of training completion. Evidence of completion may be in the form of attestations, training logs, or other means determined by you to best represent fulfillment of your obligations.

The only exception to this training requirement is if you/your organization is "deemed" to have met the FWA certification requirements through enrollment into Medicare Parts A or B of the Medicare program or though accreditation as a supplier of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). Those parties deemed to have met the FWA training through enrollment into the CMS Medicare Program don't need to complete Part 1: Medicare Parts C and D Fraud, Waste, and Abuse Training. *But, they're still obligated to complete Part 2: Medicare Parts C & D Compliance Training.*

You can find the training requirements and information regarding deemed status at:

- 42 C.F.R. § 422.503(b)(4)(vi)(C) for Medicare Advantage
- 42 C.F.R. § 423.504(b)(4)(vi)(C) for Part D
- Manual, Chapter 9 § 50.3

You must give your employees Standards of Conduct

Your organization must also provide either HPSM's Code of Conduct and Compliance Policies or your own comparable Code of Conduct/Compliance Policies to all employees and Downstream Entities who provide administrative and/or healthcare services for our Medicare Plans. You must distribute Standards of Conduct:

- Within 90 days of hire or the effective date of contracting
- When there are updates to such Standards of Conduct
- Annually thereafter

Also, you must retain evidence of your distribution of these documents. You can find these requirements in:

- 42 C.F.R. § 422.503(b)(4)(vi)(A) for Medicare Advantage
- 42 C.F.R. § 423.504(b)(4)(vi)(A) for Part D
- Manual, Chapter 9 § 50.1.1

B. Exclusion list screenings

Federal law prohibits Medicare, Medicaid and other federal healthcare programs from paying for items or services provided by a person or entity excluded from participation in these federal programs. Therefore, prior to hire and/or contract and monthly thereafter, each First Tier Entity must check the Office of Inspector General (OIG) and General Services Administration (GSA) "exclusion lists" to confirm that employees and Downstream Entities performing administrative and/or healthcare services for HPSM's Medicare Plans aren't excluded from participating in Federally-funded healthcare programs. You can use these websites to perform the required exclusion list screening:

- Office of Inspector General (OIG) List of Excluded Individuals and Entities
- General Services Administration (GSA) System for Award Management (SAM)

Also, FDRs must maintain evidence they checked these exclusion lists. You can use logs or other records to document that you've screened each employee and Downstream Entity in accordance with current laws, regulations and CMS requirements.

You must perform exclusion list screenings

You're not alone. We're also required to check these exclusion lists prior to the hiring or contracting of any new employee, temporary employee, volunteer, consultant, governing body member, or FDR, and monthly thereafter. We cannot check these exclusion lists for your employees and Downstream Entities. So, to make sure we comply with this CMS requirement, you must confirm that your permanent and temporary employees and Downstream Entities that provide administrative and/or healthcare services for our Medicare Plans are not on either of these exclusion lists.

You must take action if an employee or Downstream Entity is on the list

If any of your employees or Downstream Entities is on one of these exclusion lists, you must immediately remove them from work directly or indirectly related to HPSM's Medicare Plans and notify us right away.

These exclusion list requirements are noted in § 1862(e)(1)(B) of the Social Security Act, 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, and further described in the Manual, Chapter 9 § 50.6.8.

C. Reporting FWA and compliance concerns to HPSM

There are a number of ways to report suspected or detected non-compliance or potential FWA. HPSM has established a confidential Compliance Hotline for HPSM Employees, Providers, Members, FDRs, and other interested persons to report any violations or suspected violations of law and/or HPSM's Compliance Program. This can include, but is not limited to:

- Incidents of fraud and abuse
- Criminal activity (fraud, kickback, embezzlement, theft, etc.)
- Conflict of interest issues

HPSM currently uses a national hotline organization to administer its Compliance Hotline. The Compliance Hotline is accessible 24 hours a day, 365 days a year, excluding designated holidays (when callers will be routed to a voice mail message alerting them to call back during established hours of operation). All callers to the Compliance Hotline can report issues anonymously. All reports will be referred to HPSM's Compliance Officer and investigated. The toll-free Compliance Hotline is **1-844-965-1241.** You must adopt and enforce a zero-tolerance policy for retaliation or intimidation against anyone who reports suspected misconduct.

Dedicated to HPSM's Medicare Compliance Program is Ian Johansson, Chief Compliance Officer. Questions or concerns for Ian and HPSM's Compliance Department can be directed to Compliance@hpsm.org.

D. Offshore operations & CMS reporting

To help make sure we comply with applicable federal and state laws, rules and regulations, you're prohibited from using any individual or entity (Offshore Entity) to perform services for HPSM's Medicare Plans if the individual or entity is physically located outside of one of the fifty United States or one of the United States Territories (i.e., American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands). The only exception to this is if an authorized HPSM representative agrees in advance and in writing to the use of such Offshore Entity.

Notify us immediately if you plan to use an Offshore Entity

If you perform services offshore or use an Offshore Entity to perform services involving the receipt, processing, transferring, handling, storing, or accessing of Medicare Member protected health information (PHI) and we approve the arrangement, we must submit an attestation to CMS. One example provided by CMS of offshore services that trigger this attestation requirement is "offshore subcontractors that receive radiological images for reading, because beneficiary personal health information (PHI) is included

with the radiological image and the diagnosis is transmitted back to the U.S." Therefore, you must immediately notify HPSM if you plan to use an Offshore Entity.

E. Specific federal and state compliance obligations

Based upon the services that you/your organization performs for HPSM's Medicare plans, you may be subject to other federal and state laws, rules and regulations that we didn't describe in this guide. If you have questions about the Medicare compliance requirements for the services that you/your organization perform, please contact HPSM's Compliance Department by emailing Compliance@hpsm.org.

F. Monitoring and auditing of First Tier and Downstream Entities

CMS requires that we develop a strategy to monitor and audit our First Tier Entities. This helps ensure compliance with all applicable laws and regulations and that our First Tier Entities monitor the compliance of their Downstream Entities. Therefore, if you choose to subcontract with other individuals/parties to provide administrative and/or healthcare services for HPSM's Medicare Plans, you must make sure that these Downstream Entities abide by all laws and regulations that apply to you as a First Tier Entity. This includes the Medicare Compliance Program requirements described in this guide.

Also, you/your organization must conduct sufficient oversight to test and ensure that your employees and Downstream Entities are compliant with applicable laws, retain evidence of completion, conduct root cause analysis and implement corrective action plans or take disciplinary actions, as necessary, to prevent recurrence of non-compliance with applicable laws.

Expect routine monitoring and audits

We routinely monitor and periodically audit First Tier Entities. This helps us ensure compliant administration of our contracts with CMS to offer Medicare Plans, as well as applicable laws and regulations. Each First Tier Entity must cooperate and participate in these monitoring and auditing activities. If a First Tier Entity performs its own audits, we may request the audit results affecting HPSM's Medicare business. Also, we expect First Tier Entities to routinely monitor and periodically audit their Downstream Entities.

If we determine that an FDR doesn't comply with any of the requirements in this guide, we'll require the FDR to develop and submit a Corrective Action Plan (CAP). We can help the FDR address the identified compliance issues.

These Monitoring and Auditing requirements are noted in 42 C.F.R. § 422.503(b)(4)(vi)(F) for Medicare Advantage and 42 C.F.R. § 423.504(b)(4)(vi)(F)for Part D, and further described in the Manual, Chapter 9 § Section 50.6.6.

Quick Reference

Medicare Program Requirements	
CMS Managed Care Manual Chapter 21 – Compliance Program Guidelines	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019326.html
CMS Prescription Drug Benefit Manual	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019326.html
CMS Provider Compliance Resources – Medicare Fraud & Abuse	https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html

Exclusion Checklist Resources	
Office of Inspector General List of Excluded individuals and Entities	http://oig.hhs.gov/exclusions
General Services Administration (GSA) System for Award Management	https://sam.gov/content/home

Questions/Concerns

If you have compliance questions or concerns, you can contact the HPSM Compliance Department at:

801 Gateway Boulevard, Suite 100
South San Francisco, CA 94080

Compliance@hpsm.org