

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

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**HEALTH PARTNERS PLANS, Inc.**

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**Health Partners** Plans

Health Partners Plans (HPP) relies on our contracted delegated vendors and providers to help us meet the needs of our membership according to The Centers of Medicare and Medicaid Services' (CMS) Medicare Advantage/Medicare Prescriptions Part D program requirements. These individuals and organizations are considered First Tier, Downstream, and Related Entities ("FDRs"). FDRs are individuals or entities to which HPP has delegated administrative or health care service functions under HPP's Medicare Advantage contract with CMS. The contractors are an integral part of the HPP Medicare Advantage program and have specific responsibilities under Medicare guidelines. The purpose of this FDR Compliance Guide is to assist FDRs in understanding and meeting their compliance obligations under HPP's Compliance Program.

## Medicare FDR Compliance Guide

We at Health Partners Plans (HPP) would like to thank you for your partnership with HPP and helping us to provide exceptional service to our Medicare beneficiaries. The Centers for Medicare and Medicaid Services (CMS), in its regulatory guidance, refers to our contracted partners as First-Tier, Downstream, and Related entities, or FDRs.

HPP is required to effectively manage and oversee our FDRs that assist us in providing administrative and/or healthcare services for our Medicare beneficiaries. Examples of FDRs include field marketing organizations, agents, providers, pharmacies, pharmacy benefits managers, claim administration vendors, fulfillment vendors and other vendors who assist us with delivering benefits.

HPP maintains the ultimate responsibility for fulfilling the terms and conditions of its contract with CMS, and for meeting the Medicare program requirements. Therefore, CMS may hold HPP accountable for the failure of its FDRs to comply with Medicare program requirements.

### Description of a First Tier, Downstream, and Related Entity

First Tier Entity: any party that enters into a written arrangement, acceptable to CMS, with an MAO or Part D plan sponsor or applicant to provide administrative services or healthcare services to a Medicare eligible individual under the MA program or Part D program. (See, 42 C.F.R. § 423.501).

**Downstream Entity:** any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangement between an MAO 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.

**Related Entity:** any entity that is related to an MAO or Part D sponsor by common ownership or control and

- 1) Performs some of the MAO or Part D plan sponsor's management functions under contract or delegation;
- 2) Furnishes services to Medicare enrollees under an oral or written agreement; or
- 3) Leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than \$2,500 during a contract period.

There are several requirements that FDRs must satisfy on behalf of HPP, which we track through submitted attestations.

As an FDR, you are required to comply with the CMS Medicare Compliance Program requirements provided below. Additionally, you must complete the HPP FDR Compliance Program Attestation.

### FDR Compliance Requirements and How to Meet Them

#### Code of Conduct/ Compliance Policy/ Conflict of Interest Policy

(Medicare Managed Care Manual Ch. 21 §50.1.3)

The Code of Conduct, also known as the "Standards of Conduct", state the overarching principles and values by which the organization operates, and defines the underlying framework for the compliance policies and procedures. The Code of Conduct and compliance policies describe your organization's expectations that all employees conduct themselves in an ethical manner; that issues of noncompliance and potential Fraud, Waste, and Abuse (FWA) are reported through appropriate mechanisms; and

that reported issues will be addressed and corrected.

The Code of Conduct communicates to employees of your organization and those of your downstream and related entities that compliance is everyone's responsibility from the top to the bottom of the organization. As an FDR who contracts with HPP to provide administrative or healthcare services for our Medicare business, you are required to distribute the Code of Conduct and any additional compliance policies and procedures to all of your organization's employees and those of your downstream and related entities who provide services for HPP within **90 days of hire or contracting and annually** thereafter.

In addition to the Code of Conduct and compliance policies, you must ensure that all of your employees and those of your downstream and related entities who provide services for HPP have reviewed either the HPP Conflict of Interest policy or your own equivalent version. Any potential conflicts of interest as they relate to administering or delivering Medicare benefits on behalf of our organization must be disclosed to senior management within your organization and HPP. If necessary, your organization must promptly address all conflicts of interest by any of the following:

- Determine that the potential conflict does not impact administering or delivering Medicare benefits
- Eliminating any potential conflicts
- Remove anyone who has a conflict of interest from administering or delivering Medicare benefits

## **Medicare Parts C & D Fraud, Waste, and Abuse (FWA) Training and General Compliance Training**

(Medicare Managed Care Manual Ch. 21 §50.3.1 & §50.3.2)

As a First Tier, Downstream or Related entity who provides administrative or healthcare services to Medicare beneficiaries on behalf of HPP, you must at a minimum, provide any new employee, temporary employee, volunteer, consultant, governing body member or delegated vendors Fraud, Waste, and Abuse training and General Compliance training within **90 days of initial hiring and annually** thereafter. To reduce the potential burden on FDRs, CMS has developed and provided a standardized FWA training and education module. You must use the Medicare Parts C & D Fraud, Waste, and Abuse and General Compliance Training that was created by CMS.

- Laws and regulations related to MA and Part D FWA (i.e., False Claims Act, Anti-Kickback statute, HIPAA/HITECH, etc.);
- Obligations of FDRs to have appropriate policies and procedures to address FWA
- Processes for employees of your organization or those of any of your downstream and related entities to report suspected FWA to the appropriate area within your company, who in turn will notify HPP; or they may directly report suspected FWA to HPP
- Protections for employees of your organization or those of any of your downstream and related entities who report suspected FWA; and
- Types of FWA that can occur in your organization or those of any of your downstream and related entities work environment

### **How to Comply:**

You can either distribute your organization's own Code of Conduct and compliance policies and procedures to your employees and downstream entities, or you may distribute HPP's Code of Conduct/ Medicare Compliance Program. HPP makes its Code of Conduct/ Medicare Compliance Program available to FDRs on the Medicare FDR Information web page at the below link:  
<https://medicare.healthpartnersplans.com/medicare-fdr-information>

You must retain evidence of your distribution of the Code of Conduct.

### How to Comply:

Take the CMS Standardized General Compliance and FWA Trainings available at the following:

- HPP Medicare FDR Information web page <https://medicare.healthpartnersplans.com/medicare-fdr-information>
- CMS Learning Management Network and Product Ordering System <https://learner.mlnlms.com/Default.aspx>

FDRs that are “deemed” to have met the FWA training and education requirements are NOT exempt from the general compliance training requirements. You **MUST** take the general compliance training.

HPP provides FWA and General Compliance information to providers through the following method:

HPP Provider web page (Provider Manual)  
<https://www.healthpartnersplans.com/providers/resources>

### Office of Inspector General (OIG)/ System for Award Management (SAM) Exclusion Screening

(Medicare Managed Care Manual Ch. 21 §50.6.8)

Medicare payment may not be made for items or services furnished or prescribed by an excluded provider or entity. HPP is responsible for ensuring that we do not use federal funds to pay for services, equipment or drugs prescribed or provided by a provider, supplier, employee or FDR excluded by the DHHS Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE list) and the System for Award Management (SAM) Excluded Parties List System (EPLS).

As a First Tier, downstream or related entity that provides administrative or healthcare services to Medicare beneficiaries, your organization is required to review the OIG’s LEIE & SAM’s EPLS. These checks must be performed prior to the hiring or contracting of any new employee, temporary employee, volunteer, consultant, governing body member, or delegated vendors and monthly thereafter, to ensure that none of these persons or entities are excluded or become excluded from participation in federal programs. After entities

are initially screened against the entire LEIE and SAM at the time of hire or contracting, at minimum, you must review the LEIE supplement file provided each month, which lists the entities added to the list that month, and review SAM updates provided during the specified monthly time frame

### How to Comply:

Review the Department of Health and Human Services (DHHS) Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE) prior to hiring or contracting and monthly thereafter. The LEIE is available at: <http://www.oig.hhs.gov/exclusions/index.asp>.

Review the General Service Administration (GSA) System for Award Management (SAM) prior to hiring or contracting and monthly thereafter. The SAM is available at: <http://www.sam.gov>.

### Reporting FWA and Compliance Concerns

(Medicare Managed Care Manual Ch. 21 §50.4.2)

HPP takes compliance concerns and suspected or actual violations related to the Medicare program very seriously. As an FDR that contracts with HPP, you must ensure that all of your employees and those of any of your downstream entities are informed of how to report compliance concerns and suspected misconduct. HPP will perform an internal investigation of each concern after your organization reports any incidents.

Good faith reporting of suspected non-compliance or fraud, waste and abuse is expected and accepted behavior. Anyone who in good faith reports a violation is referred to as a “whistleblower” and is protected from any retaliation by any organization. A number of laws contain whistleblower protection, including the False Claims Act. You are expected to cooperate with any investigation resulting from a report. We have various reporting mechanisms for your use

to ensure confidentiality when reporting compliance concerns and/or suspected or actual misconduct.

**File a report through  
[www.healthpartnersplans.ethicspoint.com](http://www.healthpartnersplans.ethicspoint.com).**

Reports filed through this webpage will be handled by a third party vendor on behalf of HPP. An option for anonymous reporting is provided on the webpage.

**Medicare Compliance:**  
[compliance@hplans.com](mailto:compliance@hplans.com)

Please note, email is not considered anonymous however, your reports will be handled in confidence to the fullest extent possible.

**HIPAA Compliance:**  
[compliance@hplans.com](mailto:compliance@hplans.com)

Please note, email is not considered anonymous however, your reports will be handled in confidence to the fullest extent possible.

**Compliance Hotline:** 1-866-477-4848

If you wish to remain anonymous, you may do so by using the Compliance hotline.

**Special Investigations Unit:**  
1-866-HPSIU4U (1-866-477-4848)

The SIU hotline is anonymous, does not have any call back mechanisms and is received by an outside entity. You will be prompted to leave a message. Your referral to this hotline will be sent to our SIU without your identity being disclosed (unless you did so). All reports are treated as confidential and privileged to the fullest extent permitted by law.

**SIU email:**

- Email compliance concerns to [compliance@hplans.com](mailto:compliance@hplans.com)
- Email suspected or actual fraud, waste and abuse concerns to [SIUtips@hplans.com](mailto:SIUtips@hplans.com)

Please note, email is not considered anonymous however, your reports will be handled in confidence to the fullest extent possible.

**How to Comply:**

Distribute HPP's FWA and Compliance Reporting Posters to your employees or post it in your facility. HPP's Reporting Posters provide the required notifications regarding the availability of an anonymous reporting method. The HPP Reporting Posters are available on the Health Partners Plans Medicare FDR Information Web Site at <https://medicare.healthpartnersplans.com/medicare-fdr-information>.

The hotline is an anonymous reporting method; HPP policies prohibit retaliation or retribution against anyone who reports suspected violations in good faith.

Notify your employees that they are protected from retaliation for False Claims Act complaints, as well as any other applicable anti-retaliation protections.

You can also keep this reporting information as a reference tool and use your own internal processes for reporting and collecting these issues. If you choose to use your own processes, make sure you have a process to report issues to HPP.

**Offshore Subcontractor Reporting**

(CMS Memo dated August 28, 2008: Offshore Subcontractor Data Module in HPMS)

As an FDR that contracts with HPP, you must ensure that your downstream or related entities do not engage in offshore operations for any of HPP's Medicare-related work without first having received expressed consent from an authorized representative at HPP. CMS requires HPP to provide attestations to CMS within 30 calendar days after an offshore subcontract is signed. In the event that HPP approves an offshore subcontract, to ensure that any applicable attestations are provided to CMS timely, HPP requires that all necessary information be provided to HPP within a timeframe not to exceed **15 calendar days** from the date the contract is signed. The term "offshore" refers to any country that is not one of the fifty United States or one of the United States Territories (American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands). Examples of countries that meet the definition of "offshore" include Mexico, Canada, India, Germany, and Japan. Subcontractors that are considered offshore can be either American---owned

Companies with certain portions of their operations performed outside of the United States or foreign-owned companies with their operations performed outside of the United States. Offshore subcontractors provide services that are performed by workers located in offshore countries, regardless of whether the workers are employees of American or foreign companies.

Medicare related work encompasses what offshore subcontractors do when they receive, process, transfer, handle, store, or access beneficiary Protected Health Information (PHI) while helping organizations such as HPP fulfill their Medicare Part C and Part D contract requirements. For example, the term “Medicare-related work” includes offshore subcontractors that receive radiological images for reading, because beneficiary PHI is included with the radiological image and the diagnosis is transmitted back to the U.S. More examples of Medicare-related work include claims processing, claims data entry services, scanning paper claims to create electronic records, receipt of beneficiary calls, and any situation where the offshore subcontractor may have access to beneficiary PHI.

#### How to Comply:

Notify HPP if your organization or if any of your organization’s subcontractors delegate functions to an offshore entity.

HPP requires that all necessary information be provided to HPP within a timeframe not to exceed **15 calendar days** from the date the contract is signed.

You as a delegated vendor to HPP will be required to:

- Verify that any contractual agreements with those entities include all required Medicare Part C and D language.
- Conduct annual audits of offshore subcontractors and make audit results available upon request from CMS.

## Ongoing Monitoring and Auditing

(Medicare Managed Care Manual Ch. 21 §50.6.1)

As an FDR that contracts with HPP, you must ensure that compliance is maintained by your organization as well as your downstream entities that provide administrative or healthcare services to HPP’s Medicare business. To ensure ongoing compliance with State and Federal regulations, your organization must perform ongoing oversight to ensure that your organization and your downstream entities, if applicable, comply with the above stated requirements and any additional regulations related to the services you/they provide to HPP.

To ensure that HPP has proper auditing and monitoring controls in place, HPP and/or CMS reserve the right to request that you provide evidence of your compliance with these requirements or other requirements within the scope of our delegation to you. If you fail to comply with the Medicare Compliance program requirements, HPP will request remedial action. The remedial action will depend upon the severity of your noncompliance and may include requiring a corrective action plan, or contract termination.

## Downstream Entities

(Medicare Managed Care Manual Ch. 21 §50.6.6)

HPP is responsible for the administration of the Medicare Parts C and D benefit under their contracts with CMS, regardless of whether we elect to delegate some of that responsibility to FDRs. CMS expects that the plan sponsor develop a strategy to monitor and audit its first tier entities to ensure that they are in compliance with all applicable laws and regulations.

HPP presumes that first tier entities that are contracted with HPP ensure that they are auditing and monitoring the compliance of their entities (downstream) with which they delegate any administrative or health care function.

**How to Comply:**

If your organization subcontracts with other entities to perform any of the services contractually delegated to your organization on behalf of HPP and that relate to HPP's CMS contract.

Your organization **must** distribute materials and information to those downstream entities. In addition, your organization **must** monitor and audit your downstream entities' performance to ensure they also comply with all applicable CMS requirements and the requirements discussed in this Compliance Guide.

**\*\*Note to the FDRs**

An authorized representative from your organization is required to complete the HPP FDR Compliance Program Attestation (on behalf of your organization) upon contracting and on an annual basis thereafter. Your organization will receive instructions from HPP on which attestations they must complete. In doing so, you attest to your organization's compliance with these Medicare Compliance Program requirements.

For the purposes of these attestations, an authorized representative is an individual who has responsibility directly or indirectly for all employees, contracted personnel, providers/practitioners, and delegated vendors who provide administrative and/or healthcare services for HPP; this would include the Compliance Officer, Chief Medical Officer, Chief Operating Officer, an Executive Officer or similar related positions.

Since we at HPP are dedicated to ensuring we meet the Medicare program requirements, we provide you with the following information on the public website:

- Medicare Parts C & D Fraud, Waste, and Abuse Training and General Compliance Training that was created by CMS
- HPP's Code of Conduct/Medicare Compliance Program
- Reporting Concerns Posters
- Sample Training Log
- Compliance Attestation for Existing Vendors
- Compliance Attestation for New Vendors (contracted in current calendar year)
- Downstream Entity Form
- Offshore Subcontractor Attestation
- Provider Compliance Attestation
- Frequently Asked Questions (FAQs)