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## FDR and Subcontractor Standards of Conduct

# The Health Plan's Compliance Guidance and Standards of Conduct for First Tier, Downstream and Related Entities and Mountain Health Trust Subcontractors

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## Introduction

The Health Plan is committed to providing quality health care to its members while abiding by the highest ethical standards in accordance with all applicable federal and state laws and regulations. As a result, The Health Plan has implemented a compliance program to support its commitment to compliance and promote adherence to applicable laws, rules and regulations.

The Centers for Medicare and Medicaid Services (CMS) requires The Health Plan's First Tier, Downstream and Related Entities (FDRs) to fulfill specific Medicare program compliance requirements. Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual describe in detail Medicare's expectations with respect to a Sponsor's First Tier Entities. In addition, The Health Plan's contracts with the West Virginia Bureau for Medical Services (BMS) and West Virginia Children's Health Insurance Program (WV CHIP) require The Health Plan's Mountain Health Trust Subcontractors (Subcontractors) performing delegated duties for WV Medicaid and WV CHIP enrollees to comply with its requirements.

This Compliance Guidance and Standards of Conduct for FDRs and Subcontractors (Standards of Conduct) provides information on the compliance obligations that are applicable to The Health Plan's FDRs, Subcontractors and contracted providers. While reviewing this document, FDRs, Subcontractors, contracted providers and their employees should keep in mind that ethical behavior and legal compliance begin with some basic guiding principles:

Honesty and integrity are expressed through truthfulness and the avoidance of deception or fraud. These qualities should guide behavior and decisions in any situation, whether involving day-to-day operational staff, management staff or officers of The Health Plan, its FDRs and its Subcontractors.

FDRs, Subcontractors and contracted providers have a responsibility to use the authority delegated to them in the best interest of The Health Plan and to adhere to the standards set forth in this document. Business

operations should be conducted with attention to ethics and integrity, as this fosters a continued positive relationship with The Health Plan and its members.

## Definitions

### **The Health Plan has adopted the following CMS definitions to define its FDRs:**

- A. FDR means First Tier, Downstream or Related Entity.
- B. First Tier Entity is any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization (MAO) or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare-eligible individual under the Medicare Advantage and/or Part D programs.
- C. Downstream Entity is a 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 an MAO or applicant or a Part D plan sponsor or applicant and a First Tier Entity. The written arrangements continue down to the level of the ultimate provider of both health care and administrative services.
- D. Related Entity means 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 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.

Examples of FDRs include delegates, agents, broker organizations and other individual entities such as vendors contracted with The Health Plan to provide administrative and/or health care services for its Medicare line of business.

### **The Health Plan has adopted the following definition to define its Subcontractors:**

A party contracting with the managed care organization (MCO) to perform any services related to the requirements of the contract between the MCO and BMS or the MCO and WV CHIP. Subcontractors may include affiliates, subsidiaries, and affiliated and unaffiliated third parties. Subcontractors do not include vendors contracted for the provision of utilities, mail/shipping, office space or computer hardware.

All compliance program requirements described in this document apply to FDRs and Subcontractors contracted with The Health Plan to provide administrative or health care services to THP's enrollees. Books, records and documents created and maintained for the furtherance of The Health Plan's business and supportive of the compliance obligations in this document must be accurate and properly maintained.

## Compliance with Laws and Regulations

The Health Plan expects its FDRs, Subcontractors and contracted providers to operate in accordance with all applicable federal and state laws, regulations and Medicare and Medicaid program requirements as applicable including, but not limited to, the following:

## **Title XVIII of the Social Security Act**

Title XVIII of the Social Security Act established the Medicare program, which guarantees access to health insurance for all Americans aged 65 and older, younger persons with specific disabilities, and individuals with end stage renal disease.

## **Title XIX of the Social Security Act**

Title XIX of the Social Security Act established the Medicaid program, which provides funding for medical and health-related services for persons with limited income.

## **Regulations Governing Medicare Parts C and D (42 C.F.R. §§ 422 and 423)**

- A. 42 C.F.R. §422: Medicare Advantage program. This regulation implements the Medicare Advantage program under the Social Security Act.
- B. 42 C.F.R. §423: Prescription drug program. This regulation implements the prescription drug program under the Social Security Act.

## **Federal and State False Claims Acts (31 U.S.C. §§ 3729-3733)**

The Federal False Claims Act (FCA) prohibits any person from engaging in any of the following activities:

- A. Knowingly submitting a false or fraudulent claim for payment to the United States government;
- B. Knowingly making a false record or statement to get a false or fraudulent claim paid or approved by the government;
- C. Conspiring to defraud the government by getting a false or fraudulent claim paid or approved by the government; or
- D. Knowingly making a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the government.

## **Federal Criminal False Claims Statutes (18 U.S.C. §§ 287, 1001)**

Federal law makes it a criminal offense for anyone to make a claim to the United States government knowing that it is false, fictitious, or fraudulent. This offense carries a criminal penalty of up to five years in prison and a monetary fine.

## **Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))**

This criminal statute prohibits anyone from knowingly and willfully receiving or paying anything of value to influence the referral of federal health care program business, including Medicare and Medicaid. Kickbacks can take many forms such as cash payments, entertainment, credits, gifts, free goods or services, the forgiveness of debt, or the sale or purchase of items at a price inconsistent with fair market value. Kickbacks may also include the routine waiver of copayments and/or co-insurance. Penalties for Anti-Kickback violations include fines, imprisonment, civil money penalties and exclusion from participation in federal health care programs.

## **The Beneficiary Inducement Statute (42 U.S.C. § 1128A(a)(5))**

This statute makes it illegal to offer remuneration that a person knows, or should know, is likely to influence a beneficiary to select a particular provider, practitioner, or supplier, including a retail, mail order or specialty pharmacy.

## **Physician Self-Referral (Stark) Law (42 U.S.C. §1395nn)**

The Stark Law prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies. Stark Law further prohibits the designated health services entity from submitting claims to Medicare for services resulting from a prohibited referral. Penalties for Stark Law violations include overpayment/refund obligations, FCA liability and civil monetary penalties. Stark Law is a “strict liability” statute and does not require proof of intent.

## **Health Insurance Portability and Accountability Act (HIPAA)**

HIPAA was developed as part of a congressional effort to reform health care. HIPAA addresses many purposes, such as the transference of health insurance, the reduction of fraud and abuse and the improvement of access to long-term care services. The regulations regarding privacy and administrative simplification of health insurance are the areas of HIPAA that have the greatest impact on MAOs, MCOs and Medicare Part D Plans.

## **Fraud Enforcement and Recovery Act (FERA) of 2009**

FERA made significant changes to the FCA. FERA makes it clear that the FCA imposes liability for the knowing retention of a Medicare or Medicaid overpayment. Consequently, a health plan or provider may violate the FCA if it conceals, improperly avoids or decreases an “obligation” to pay or refund money to the government.

## **Non-Retention of Excluded Individuals**

MAOs, MCOs, Part D Plans and Medicare/WV Medicaid/WV CHIP providers and suppliers are prohibited from employing or contracting with persons or entities that have been excluded from doing business with the federal government.

## **Sub-Regulatory Guidance**

Sub-regulatory guidance includes manuals produced by CMS such as its internet-only manuals, training materials and Health Plan Management System memos.

## **Contractual Commitments**

Violations or suspected violations of these laws or regulations should be promptly reported to The Health Plan.

# **Compliance Program Requirements for FDRs and Subcontractors**

The Health Plan is committed to assisting its FDRs, Subcontractors and contracted providers to become and remain in compliance with applicable laws, rules and regulations. Ultimately, The Health Plan is responsible for fulfilling the terms and conditions of its contract with CMS, its contract with BMS and its contract with WV CHIP and other applicable program requirements. As a result, The Health Plan requires each FDR, Subcontractor and contracted provider to comply with accepted compliance program requirements.

Failure by an FDR, Subcontractor or contracted provider to meet compliance program requirements may result in a corrective action plan, additional training, or termination of the agreement between the FDR or Subcontractor and The Health Plan. The actions taken for non-compliance will vary depending upon the severity of the non-compliance. Compliance program requirements are summarized in this section.

## **Fraud, Waste and Abuse (FWA) Training and General Compliance Training**

You or your organization is required to provide FWA and general compliance training to your employees using your own internally developed training or training materials provided by The Health Plan. Compliance and FWA training should be completed within 90 days of hire or the effective date of the contract and on an annual basis thereafter. Documentation of such training must be maintained for a period of at least 10 years.

### **Code of Conduct Distribution**

Your organization must adopt The Health Plan's Code of Conduct or a substantially similar document (Code). The Code must be distributed within 90 days of hire or the effective date of the contract, and annually thereafter. Your organization's employees must attest to the Code at least annually. Evidence of distribution and attestation must be maintained for a period of at least 10 years in a manner that demonstrates compliance with this obligation.

### **Exclusion List Screenings**

Federal law prohibits the payment by Medicare, Medicaid or any other federal health care program including CHIP for an item or service furnished by a person or entity excluded from participation in these federal programs. The Health Plan, its FDRs, Subcontractors and providers are prohibited from contracting with, or doing business with, any person or entity that has been excluded from participation in these federal programs. Prior to hire and/or contract date, and monthly thereafter, you must perform a check to confirm your employees performing administrative or health care services for The Health Plan's Medicare, WV Medicaid and/or WV CHIP lines of business are not excluded from participation in federally funded health care programs according to the Office of Inspector General List of Excluded Individuals and Entities (OIG LEIE) and the Government Services Administration System for Award Management (SAM) exclusion lists.

The OIG LEIE database can be found at: <https://exclusions.oig.hhs.gov/>

The SAM database can be found at: <https://www.sam.gov/SAM/>

In the event any of your employees are found on either exclusion list, you must immediately remove the individual from work related directly or indirectly to The Health Plan's Medicare, WV Medicaid and WV CHIP lines of business and notify The Health Plan of your findings. You should maintain evidence of your OIG LEIE and SAM database queries such as logs or other records for a minimum of 10 years.

### **Reporting FWA and Compliance Issues to The Health Plan**

The Health Plan believes it is the duty of every person who has knowledge of a compliance issue or potential FWA to promptly report such issue to the appropriate party. This reporting obligation applies even if the individual with the information is not in a position to mitigate or resolve the issue.

There are various ways to report instances of non-compliance including suspected or actual misconduct or FWA. Methods for reporting non-compliance and FWA include:

**Website:** <https://fraud.healthplan.org/> (allows anonymous reporting)

**Hotline:** 1.877.296.7283       (allows anonymous reporting)

**Email:** [compliance@healthplan.org](mailto:compliance@healthplan.org) or [SIU@healthplan.org](mailto:SIU@healthplan.org)

Information on how to report non-compliance or suspected FWA is illustrated in the attached poster. You may distribute this poster within your organization to your employees and Downstream Entities. You may also use it as a reference to help you custom design your own internal poster for reporting. Reports of non-compliance

and suspected FWA can be made anonymously. The Health Plan has adopted, and all FDRs and Subcontractors of The Health Plan must adopt, a zero-tolerance policy for intimidation or retaliation against anyone who reports suspected or actual misconduct.

## **Offshore Operations and CMS Reporting**

To promote compliance with applicable federal and state laws, rules and regulations, you must notify The Health Plan prior to using any offshore individual or entity, including, but not limited to, any employee, contractor, downstream subcontractor, agent, representative or other individual or entity, to perform any service for The Health Plan's Medicare line of business if the individual or entity is physically located outside of the United States. WV Medicaid and WV CHIP generally prohibit the use of offshore operations. For offshore subcontractors that provide services for The Health Plan's Medicare line of business you must complete and attest to the following:

- A. The offshore subcontracting arrangement has policies and procedures in place to ensure that Medicare beneficiary protected health information (PHI) and other personal information remains secure.
- B. The offshore subcontracting arrangement prohibits the subcontractor's access to Medicare data not associated with the sponsor's contract with the offshore subcontractor.
- C. The offshore subcontracting arrangement has policies and procedures in place that allow for immediate termination of the subcontract upon discovery of a significant security breach.
- D. The offshore subcontracting arrangement includes all required Medicare Parts C and D language (e.g., record retention requirements, compliance with all Medicare Parts C and D requirements).
- E. You will conduct an annual audit of the offshore subcontractor.
- F. The audit results will be used by you to evaluate the continuation of your relationship with the offshore subcontractor.
- G. You agree to share the offshore subcontractor's audit results with The Health Plan and CMS, upon request.

## **Monitoring and Auditing of FDRs and Subcontractors**

CMS requires The Health Plan develop a process to monitor and audit our FDRs and Subcontractors to promote compliance with all applicable laws and regulations, and to ensure our FDRs and Subcontractors are monitoring their Downstream Entities for adherence with all applicable laws and regulations pertaining to Medicare Parts C and D, WV Medicaid and WV CHIP. You or your organization are required to conduct sufficient oversight to test that your employees and Downstream Entities (if applicable) are compliant with applicable law. You should retain evidence of this monitoring and implement corrective actions or take disciplinary actions as necessary to prevent recurrence of non-compliant activities. Documentation of such activities must be maintained for at least 10 years.

The Health Plan will audit a sample of its FDRs and Subcontractors on an annual basis. In addition, all The Health Plan's FDRs and Subcontractors must complete an annual compliance attestation. FDRs and Subcontractors must cooperate fully and participate in the monitoring and auditing activities conducted by The Health Plan's staff or those conducted by federal, state and local government agencies. If an FDR or Subcontractor performs its own audits, The Health Plan may request a copy of the audit results. FDRs are encouraged and expected to routinely monitor and periodically audit their Downstream Entities.

If it is determined an FDR, Subcontractor or contracted provider is not compliant with the requirements contained within this notice, the FDR, Subcontractor or contracted provider will be required to develop and

submit a corrective action plan. The Health Plan will provide assistance to the FDR, Subcontractor or contracted provider in addressing identified issues of non-compliance.

## **Violations of These Standards of Conduct**

Suspected violations of these Standards of Conduct must be reported to The Health Plan immediately. Serious deficiencies may result in contract termination and/or notification to the appropriate enforcement agency.

**These Standards of Conduct summarize your Medicare, WV Medicaid and WV CHIP compliance program responsibilities. You should take steps to meet these requirements on an ongoing basis. As an FDR, Subcontractor or contracted provider you are required to retain evidence of your compliance with compliance program requirements (e.g., employee training records, exclusion screening logs, Code of Conduct attestations) for a minimum of 10 years.**

**The Health Plan's FDRs and Subcontractors are required to complete a compliance attestation on an annual basis. An authorized representative from your organization is required to complete the attestation. An authorized representative is an individual who has responsibility, directly or indirectly, for all employees and contracted personnel who provide delegated services for The Health Plan's Medicare, WV Medicaid and/or WV CHIP plans. Examples of an authorized representative include your compliance officer, executive officer or similarly situated individual.**

See also THP's [Code of Conduct](#).

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