



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

### Introduction

Troy Health, Inc. (“Troy Health”, “Troy”, “we”, “us”, or “our”) offers a Medicare Advantage Prescription Drug Plan HMO and a Dual-Eligible Special Needs Plan (collectively, “Medicare Plans”).

We depend on you—our contracted provider, vendor, or other entity—to help us fulfill our Medicare Advantage Prescription Drug Plan (MAPD) contract with CMS. CMS refers to these entities as **First-Tier, Downstream, and Related Entities (FDRs)**.

This guide details the Medicare Compliance Program requirements that you, as a Troy Health FDR, must meet in accordance with the Code of Federal Regulations (CFR) and CMS Manuals, including the [Medicare Managed Care Manual, Chapter 21, and the Prescription Drug Benefit Manual, Chapter 9](#). You must comply with these requirements and demonstrate compliance.

### What is an FDR?

We use the current CMS regulatory definitions to define First-Tier, Downstream, and Related Entities, in accordance with 42 C.F.R. §§ 422.500 and 423.501:

- **First-Tier Entity:** any party that enters into a written arrangement, acceptable to CMS, with an MAO or Part D plan sponsor to provide administrative services or healthcare services to a Medicare eligible individual.
- **Downstream Entity:** any party that enters into a written arrangement with persons or entities involved with the Medicare Advantage or Part D benefit, below the level of the arrangement between a plan sponsor and a first-tier entity. These arrangements continue down to 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; or,
  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.



## **FDRs Providing Healthcare Services**

The requirements outlined in this guide apply to entities with which Troy Health contracts to perform administrative and health care services, including physicians, hospitals, and other provider types. CMS considers these entities First-Tier Entities as outlined in the Medicare Managed Care and Prescription Drug Benefit Manuals, Chapters 9 & 21 §40.

## **FDRs Providing Administrative Services**

The Medicare Compliance Program requirements also apply to entities with which we contract to perform administrative service functions. Examples include, but are not limited to:

- Formulary Administration
- Claims Processing
- Part C Utilization Management (Organization Determinations/Coverage Requests)
- Medical Record Reviews
- Provider and Claims Data Management
- Other examples include delegates, agents, broker organizations, pharmacies, and other vendors or suppliers.

## **FDR Resources**

- Medicare Managed Care and Prescription Drug Benefit Manuals, Chapters 9 & 21 §40 and §50.6
- Medicare Managed Care Manual, Chapter 11 §110
- 42 CFR §422.503(b)(4)(vi): Compliance Program Requirements
- 42 CFR §422.504(i): MA Organization relationship with first tier, downstream and related entities
- HIPAA: 42 U.S.C. § 1320d et al., 45 C.F.R. Parts 160 and 164
- 18 U.S.C. § 1347 – Health Care Fraud
- 18 U.S.C. § 1028(a)(7) – Identity Theft and Fraud
- Offshore Subcontracting Resources: HPMS Memos 8/15/2006, 7/23/2007, 2008 Call Letter.

## **Compliance Obligations Regarding U. S. Health Care Fraud and Identity Theft Laws**

To ensure ongoing regulatory compliance and uphold the integrity of the Medicare Advantage program, we are emphasizing the requirements of fraud and identity theft laws. **This is a shared responsibility we all bear.**

Your agreement with Troy Medicare includes language referencing your obligation to comply with "all applicable federal and state laws, regulations, CMS requirements, rules, orders, and other



requirements." This includes, but is not limited to, compliance with the following federal statutes and related health care fraud and identity theft laws:

- 18 U.S.C. § 1347 – Health Care Fraud
- 18 U.S.C. § 1028(a)(7) – Identity Theft and Fraud
- Any other applicable federal and state laws relating to health care fraud, waste, abuse, and identity theft.

**Troy Medicare reserves the following rights under the agreement:**

1. **Right to Audit:** The Company retains the right to audit, review, and inspect your organization's books, records, systems, and other relevant materials to confirm compliance.
2. **Right to Terminate:** The Company reserves the right to terminate the contractual relationship in the event of any:
  - Violation of U.S. health care fraud or identity theft laws;
  - Breach of the Company's Code of Conduct, compliance policies, or procedures; or
  - Failure to comply with the representations, undertakings, or contractual obligations related to these matters.

**Medicare Compliance Program Requirements**

Troy Health is responsible for fulfilling the terms and conditions of our contract with CMS, and our FDRs are responsible for complying with the same Medicare Compliance Program requirements. FDRs must ensure that their downstream entities comply with all applicable laws and regulations.

**Compliance Program Requirements**

These Medicare Compliance Program requirements include, but are not limited to:

- Distribute general compliance and FWA training
- Distribute a Code of Conduct or a compliance policy
- Compliance with U.S. health care fraud and identity theft laws
- Reporting FWA and compliance concerns to Troy Health
- Make employees aware of reporting mechanisms
- Conduct exclusion list screenings
- Monitoring and auditing of First-Tier, Downstream and Related Entities
- Ensure sufficient oversight (monitoring and auditing) of Downstream Entities, with timely identification and resolution of compliance deficiencies.
- Ensure timely and accurate completion of all delegated administrative and health care functions, including Part C Utilization Management and Provider Data Management.



- Report and request to use offshore operations
- Meet specific federal and state compliance obligations
- Correct identified deficiencies

### **What May Happen if You Don't Comply**

Failure of an FDR to meet these Medicare Compliance Program requirements could result in:

- Development of a corrective action plan
- Retraining
- Termination of your contract and relationship with Troy Health

The FDR must take prompt action to fix the issue and prevent it from happening again.

### **Attestation Requirements**

Each year, an authorized representative (e.g., practice manager/administrator, compliance officer, or executive officer) from your organization must attest to your compliance with the Medicare Compliance Program requirements. You must keep evidence of your compliance with CMS requirements for no less than 10 years.

### **Compliance Record Retention Summary**

FDRs must retain evidence of compliance for all mandated requirements for **no less than 10 years** from the date of creation or completion. This includes, but is not limited to:

- The annual FDR Compliance Attestation and evidence of underlying compliance with all CMS requirements.
- Evidence of General Compliance and FWA Training completion (e.g., training logs, certificates).
- Evidence of Code of Conduct/Compliance Policy distribution.
- Documentation of all monthly Exclusion List Screenings (OIG and GSA).

### **You May Be Asked to Provide Evidence of Compliance**

Troy Health and/or CMS may request that you provide evidence of your compliance to test your processes. We may also conduct an audit, monitoring event, or ask you to complete an attestation.



## **General Compliance and FWA Training**

As an FDR, your organization must provide general compliance and FWA training to all employees and downstream entities assigned to provide administrative and/or health care service for Troy Medicare plans.

Troy Health permits you to use and complete your own general compliance and FWA training, provided it is comparable to the CMS model training.

## **Fraud, Waste, and Abuse (FWA) Defined**

FWA includes actions that cause a financial loss to the Medicare Program.

- Fraud: Intentional deception or misrepresentation made for financial gain (e.g., billing for services not rendered).
- Waste: Over-utilization of services or misuse of resources (e.g., conducting excessive diagnostic tests).
- Abuse: Actions resulting in unnecessary costs to the Medicare Program (e.g., improper billing practices).

## **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
- When training materials are updated

You must retain evidence of training completion for 10 years. If your organization is "deemed" to have met the FWA training requirements (enrolled into Medicare Part A or B or accredited as a supplier of DMEPOS), you will still need to complete the general compliance training.

## **Standards of Conduct and Compliance Policy Distribution**

Your organization must provide either Troy Health's Code of Conduct and applicable Compliance Program policies or your own comparable Code of Conduct and Compliance Program policies to all employees and downstream entities who are assigned to work on Troy Health Medicare business. You must distribute these policies:

- Within 90 days of hire or the effective date of contracting



- When there are updates to such Standards of Conduct
- Annually thereafter

You must retain evidence of your distribution of the Code of Conduct for 10 years.

### **Reporting Violations to Troy Medicare**

You have an obligation to report all suspected violations of the Compliance Program Guide or any law or regulation, whether involving your employees and/or downstream entities. FDRs must ensure all employees know how to report compliance concerns and suspected misconduct, either through your own anonymous reporting mechanisms or by referring them to Troy Health's Compliance & Ethics Hotline.

### **Ways to report suspected or detected noncompliance or potential FWA:**

- Call your Troy Medicare contact
- Visit Troy Medicare's Compliance & Ethics reporting portal: [ethics-hotline.troymedicare.com](https://ethics-hotline.troymedicare.com)
- Send an email to Troy Medicare's Compliance Department at [Compliance@troymedicare.com](mailto:Compliance@troymedicare.com)

There can be no retaliation against anyone reporting in good faith.

### **Exclusion List Screenings**

Prior to hire and/or contract and monthly thereafter, each FDR must check the Office of Inspector General (OIG) and General Services Administration (GSA) "exclusion lists" to confirm that employees and downstream entities are not excluded from participating in federally-funded healthcare programs. You must maintain evidence for 10 years that you have checked these lists.

If any employee or downstream entity is on an exclusion list, you must immediately:

- Remove them from work directly or indirectly related to Troy Health's Medicare Plans and
- **Notify us right away** ([compliance@troymedicare.com](mailto:compliance@troymedicare.com))

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

CMS requires us to develop a strategy to monitor and audit our FDRs. Each FDR must participate and contribute in these monitoring and auditing activities. If we determine that an FDR doesn't comply with any of the requirements in this guide, we will require the FDR to develop and submit a Corrective Action Plan (CAP).



## Monitor compliance of downstream entities

If you subcontract with other parties, you are responsible for the compliance of your downstream entities. This includes ensuring that:

- All contractual agreements contain all CMS-required contract provisions.
- The downstream entity complies with the Medicare compliance program requirements described in this guide.
- The downstream entity complies with any applicable Medicare operational requirements.

You must conduct sufficient oversight (monitoring and auditing) to test and ensure your employees and downstream entities are compliant, and you must implement corrective action plans or take disciplinary actions, as necessary, to prevent reoccurrence of noncompliance.

## Offshore Operations & CMS Reporting

If you perform services offshore or use an offshore subcontractor that will or may receive, process, transfer, handle, store or access Protected Health Information (PHI) of Troy MAPD members (offshore services), you must:

- Complete the Offshore Services Attestation and submit to Troy Compliance.
- Receive **written approval from us before** you can use an offshore entity.
- Notify us right away if there are material changes to offshore services information.

## Specific Federal and State Compliance Obligations

You may be subject to other federal and state laws, rules, and regulations not described in this guide. Consult Troy Health's Compliance Officer if you have questions about the Medicare compliance requirements for the services you perform.

## Questions/Concerns

For compliance questions or concerns, you can email Troy Health Compliance department: [Compliance@troymedicare.com](mailto:Compliance@troymedicare.com).

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