

**Hudson Headwaters Health Network
First-Tier, Downstream, and Related Entities (FDRs)**

Medicare Compliance Guide



To report suspected fraud, abuse or other violations of HHHN's policies, call 518-409-8642 or e-mail patientconcerns@hhhn.org



**HUDSON
HEADWATERS**
HEALTH NETWORK



OUR MISSION

To provide the best health care, and access to that care,
for everyone in our communities.

OUR VISION

To pioneer an innovative, sustainable and community-focused
health system through comprehensive primary care and diverse partnerships.

CORE VALUES

Quality: excellence in delivering care and service

Appreciation: highest regard for the worth and rights of others

Creativity: continuous improvement through innovation

Sustainability: remain viable to continue our mission

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Section I: Introduction to the FDR Compliance Guide

Hudson Headwaters Health Network (HHHN) contracts with the Centers for Medicare & Medicaid Services (CMS) to provide services under the Medicare Advantage program. HHHN works with external vendors to help fulfill its obligations to CMS and to provide health care services to our patients. CMS refers to these subcontracted vendors as First-Tier, Downstream, and Related Entities (FDRs).

Although these services are delegated, HHHN is ultimately responsible for ensuring services performed by FDRs are in accordance with the obligations of our contract with CMS. Therefore, CMS requires that FDRs fulfill specific Medicare compliance program requirements.

The purpose of this FDR Compliance Guide is to assist FDRs in understanding and meeting their compliance obligations under HHHN's Compliance Program.



Section II:

Definitions, What is a FDR, what is Fraud, Waste and Abuse?

The Centers for Medicare and Medicaid Services (CMS), in its regulatory guidance, refers to our contracted vendors as First-Tier, Downstream, and Related Entities, or FDRs (see 42 C.F.R. §423.501).

First Tier Entity – 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 – 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 – any entity related to a Medicare Advantage Organization or Part D sponsor by common ownership or control that:

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).

Examples of FDRs

- Delegates
- Agents
- Broker organizations
- Pharmacies
- Other individuals, entities, vendors or suppliers contracted with us for administrative and/or health care services.

What is Fraud, Waste and Abuse (FWA)?

Fraud: The intentional deception or misrepresentation that an individual knows to be false or does not believe to be true, knowing that deception could result in some unauthorized benefit.

Waste: Acting with gross negligence or reckless disregard for the truth in a manner resulting in any unnecessary cost or consumption of health care resources.

Abuse: Incidents that are inconsistent with accepted medical or business practices, or that are improper or excessive.

Medicare Fraud and Abuse Laws: Federal laws governing Medicare fraud and abuse include all of the following:

- Federal False Claims Act (FCA)
- Anti-Kickback Statute (AKS)
- Physician Self-Referral Law (Stark Law)
- Social Security Act

Section III: FDRs & Compliance Program Requirements

HHHN's Compliance Program is designed to do the following: eliminate fraud, waste, abuse, and inefficiencies; to ensure HHHN's compliance with applicable state and federal regulations; and to reinforce HHHN's commitment to zero tolerance for such activities. HHHN has a legal requirement to provide information and education to those individuals, entities, businesses, and providers with whom we contract. CMS, New York Office of Medicaid Inspector General (OMIG), and various other agencies provide guidance and regulatory oversight of our Compliance Program.

HHHN is committed to ensuring our FDRs are in compliance with applicable laws, rules and regulations. FDRs are expected to adhere to CMS Compliance Program requirements and HHHN's standards when conducting business on HHHN's behalf. Your organization and your Downstream Entities must comply with CMS Program Requirements.

The seven elements below ensure that your program meets CMS' standards:

Element 1: Written Policies, Procedures and Standards of Conduct

Element 2: Designating a Compliance Officer and Oversight of Compliance Program

Element 3: Effective Training and Education

Element 4: Effective Lines of Communication

Element 5: Well-Publicized Disciplinary Standards

Element 6: Effective System for Routine Monitoring and Identification of Compliance Risks

Element 7: Prompt Response to Compliance Issues



Section IV:

Compliance Program Requirements Explained

Element 1. Distribute Policies, Procedures and Standards of Conduct

1. FDRs must provide either HHHN's Code of Conduct ([link](#)) and Medicare Compliance Policies ([link](#)) (pgs. 5-11) or your own comparable code of conduct/compliance policies to all employees and Downstream Entities who provide services as part of your contract with HHHN.
2. The written compliance policies and standards of conduct must contain all of the elements set forth in Section 50.1 and its subsections of Manual, Chapter 21, of the Medicare Managed Care Manual ([link](#)) and re-iterate the organization's commitment to comply with federal and state laws, ethical behavior and compliance program operations.
3. Such information must be distributed to FDR employees and contractors within 90 days of initial employment/contract and annually thereafter.
4. FDRs can determine the most effective method of distributing the policies and procedures or Standards of Conduct (e.g., via hardcopy at the time of hire/contract, via electronic copy, posting a copy on the FDR's intranet, etc.).
5. A FDR must maintain documentation (i.e. attestations, logs, etc.) that demonstrates the information was distributed, read and understood by each employee and contractor that received it.

Element 2. Designating a Compliance Officer and Oversight of Compliance Program

1. A FDR must designate a senior level

employee to act as the Compliance Officer for its organization.

1. The Compliance Officer must maintain responsibility for the implementation of the FDR's Compliance Program, including responding to reports of potential fraud, waste and abuse (FWA) and non-compliance.
1. The Compliance Officer also ensures documentation is maintained related to the Compliance Program and is responsible for overseeing, developing, and monitoring corrective action plans.

Element 3. General Compliance and Fraud, Waste and Abuse Trainings

1. As a FDR, your organization is responsible for providing general compliance training (Medicare Managed Care Manual Ch. 21 §50.3.1) as well as FWA training (Medicare Managed Care Manual Ch. 21 §50.3.2) to all of your employees and Downstream Entities that provide administrative and/or health care services in relation to your contract with HHHN.
 - a. *Refer to Appendix B: Who should complete General Compliance and FWA training? within this guide for additional information.*
2. General Compliance and FWA Training
 - a. General Compliance and FWA training must be formally conducted within 90 days of initial contract/employment, when materials are updated and annually thereafter.
 - b. FDRs must be able to demonstrate that their employees and Downstream entities have fulfilled this training requirement. FDRs compliance expectations can be communicated through distribution of the

FDRs Standards of Conduct and/or compliance policies and procedures to FDRs' employees.

3. Privacy and Security Training

- a. FDRs are required to protect all HHHN Patient information. This not only includes Protected Health Information (PHI), but also includes Personally Identifiable Information (PII).
- b. Employees that have access to PHI and/or PII must receive HIPAA Privacy and Security training within 90 days of initial contract/employment and annually thereafter.
- c. Privacy and Security training should address topics such as:
 - i. Federal and state laws governing the confidentiality of PHI and PII
 - ii. When PHI and PII may be accessed, used and disclosed
 - iii. Safeguards for protecting the integrity, confidentiality, and availability of PHI and PII
 - iv. Validation of Training Completion

4. Training Records

- a. FDRs must retain records of training completion on the topics listed previously. Evidence may include sign-in sheets/training logs, certificates, attestations, electronic acknowledgements, etc.
- b. To validate training completion, please ensure the following information is retained for a minimum of 10 years per CMS requirements:
 - i. Employee names
 - ii. Dates of employment
 - iii. Dates of Hire
 - iv. Results of test scores (if relevant)
 - v. Title of training
 - vi. Training content

- c. An example of a training log that fulfills this

requirement can be found in this guide on Appendix C: General Compliance & Fraud, Waste, and Abuse Training Log.

- d. Each FDR is responsible for conducting their own FWA, General Compliance and Privacy & Security trainings. If your organization does not have a Compliance/FWA training program or Privacy & Security program you can utilize a nationally recognized training program. The compliance trainings should be relevant to your organization's line of business and compliance needs.
- e. HHHN may request evidence of FDRs employee training. If you are deemed and exempt from FWA training requirements, you must retain evidence of your deemed status.
 - a. Refer to Appendix B of this guide: Exceptions to the Training Requirement for further details.

Element 4. Effective Lines of Communication

1. A FDR must communicate the name and contact information of its Compliance Officer and communicate the information to any Downstream Entities.
 - a. Communication lines to the Network Compliance Officer or designee should be accessible to all employees, officers, agents, and Board Members, to allow compliance issues to be reported.
 - b. FDRs must adopt a policy of non-intimidation and non-retaliation of employees, including whistleblowers, for good faith reporting of concerns regarding non-compliance or FWA. FDRs should enforce the policy of non-intimidation and non-retaliation.

Element 5: Well-Publicized Disciplinary Standards

1. FDRs must require participation in the Compliance Program by their affected employees.
 - a. Policies should outline expectations for reporting compliance issues and assisting in their resolution. The policies should outline

- actions for failing to report suspected problems, participating in non-compliant behavior, and/or encouraging, directing, facilitating, or permitting, either actively or passively, non-compliant behavior.
 - b. Such disciplinary policies must be fairly and firmly enforced. FDRs should be able to demonstrate that disciplinary standards are enforced timely, consistently, and effectively. Some examples of the types of publication methods for disciplinary standards include:
 - i. FDR's Intranet site;
 - ii. General compliance training; and
 - iii. Posters prominently displayed throughout employee work and break areas.
 - c. FDRs must report an issue of non-compliance to HHHN that is any way associated with the services performed on HHHN's behalf.
- and GSA SAM?
 - a. GSA SAM includes exclusion and debarment actions taken by various federal agencies.
 - b. The OIG only contains the exclusion actions taken by the OIG.
 - 3. FDRs must confirm that permanent and temporary employees and Downstream Entities are not on either of these exclusion lists.
 - 4. If any of your employees or Downstream Entities are on an exclusion list, you must immediately remove them from any direct or indirect work on our contracts and notify HHHN.
 - 5. A list of exclusion requirements is found in:
 - a. Social Security Act, § 1862(e)(1)(B)
 - b. 42 CFR §§ 422.503(b)(4)(vi)(F); 422.752(a)(8); 423.504(b)(4)(vi)(F); 423.752(a)(6); 1001.1901
 - c. Medicare Managed Care Manual, Chapter 21 § 50.6.8

Element 6: Effective System for Routine Monitoring and Identification of Compliance Risks

1. Exclusions: Federal law prohibits Medicare, Medicaid and other federal health care programs from paying for items or services provided by an individual or entity excluded from participation in these federal programs. FDRs must perform exclusion screenings before hiring, contracting and monthly thereafter, of employees and Downstream Entities to ensure they are not excluded from participating in federally funded health care programs.
 - a. These websites can be used to perform exclusion screenings:
 - i. General Service Administration (GSA) System for Award Management (SAM) [\(link\)](#)
 - ii. Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE) [\(link\)](#)
2. What is the difference between the OIG LEIE
6. What documentation must FDRs keep to show that these checks were completed?
 - a. Which exclusion list(s) were checked
 - b. Date the check was completed
 - c. Names of the individuals and entities that were checked
 - d. Results of the check, and
 - e. Action taken if sanctioned individuals or entities were identified
7. To validate exclusion check monitoring, please ensure the above information is retained for a minimum of 10 years per CMS requirements.
8. Ongoing Monitoring & Auditing
 - a. As a FDR that contracts with HHHN, you must ensure that compliance is maintained by your organization as well as your Downstream Entities that provide administrative or health care services to HHHN.

- b. 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.

Element 7. Prompt Response to Compliance Issues

1. HHHN's FDRs must have a system in place to receive, record, respond to and track compliance questions or reports of suspected or detected noncompliance or potential FWA from employees, members of the governing body, and FDRs and their employees.
2. Reporting systems must maintain confidentiality, allow anonymity if desired (e.g., through anonymous hotlines or mail drop boxes), and emphasize FDR's policy of non-intimidation and non-retaliation for good faith reporting of compliance concerns and participation in the FDR's compliance program.
3. The methods available for reporting compliance or FWA concerns and the non-retaliation policy must be publicized throughout the FDR's facilities.
 - a. An example of such publication can be found in this guide on Appendix D: HHHN Compliance and FWA Reporting Poster.

You must notify HHHN immediately if non-compliance is identified related to the functions you provide for HHHN.



Section V:

Use of Offshore Operations & Other Obligations of FDRs

Report and Request to Use Offshore Operations

1. All work performed by FDRs on HHHN's behalf must be performed within the United States and its territories (including America Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands). A FDR may request approval in advance from HHHN to utilize employees or contractors located outside the United States. We refer to work being performed outside the United States and its territories as being "offshore."
2. If HHHN approves a requested offshore arrangement, HHHN must self-disclose the offshore arrangement to CMS. CMS requires HHHN to provide attestations to CMS within 30 calendar days after an offshore subcontract is signed. In the event that HHHN approves an offshore subcontract, to ensure that any applicable attestations are provided to CMS timely, HHHN requires that all necessary information be provided to HHHN within a timeframe not to exceed 15 calendar days from the date the contract is signed.
3. FDRs must also sign an attestation annually as to how it will oversee the offshore functions.

Other Obligations of FDRs

1. In addition to meeting the CMS Compliance Program requirements, HHHN also expects FDRs to:
 - a. Maintain current federal, state and local licenses and permits required for the operation of the FDR's business or profession.
 - b. Ensure services provided for HHHN are done so in a highly ethical manner and in compliance with the FDR's Code of Conduct.
 - c. Ensure that services provided for HHHN are performed in a competent, timely, efficient, professional, and skillful manner as well as in compliance with applicable laws, regulations and the terms of its agreement with HHHN.

Section VI: FDR Attestation & Non-Compliance

FDR Attestation Requirements

1. FDRs must maintain evidence of compliance with the requirements listed in this Guide for no less than 10 years.
 - a. Each year, an authorized representative from your organization must attest to your compliance with these requirements.
 - i. A FDR's authorized representative is an individual who is ultimately responsible for assuring your organization provides services for HHHN in a complaint manner. An authorized representative could include your Compliance Officer, a Chief Executive Officer, Chief Operations Officer or someone in a similar position.
 - b. Your organization will receive instructions from HHHN when an attestation must be completed.

Non-Compliance

1. If a FDR fails to meet any of these Compliance Program requirements, this puts HHHN at risk and may lead to:
 - a. Development of a corrective action plan (CAP)
 - b. Additional monitoring/auditing
 - c. Monetary penalties
 - d. Termination of your contract(s) with HHHN
2. HHHN's response to issues of non-compliance will depend on the severity of the compliance issue. If a FDR, HHHN, CMS or any regulatory oversight agency identifies areas of non-compliance performed by a FDR, it must take prompt action to correct the issue and prevent it from happening again.



Appendix A:

FAQ

1. Why am I receiving a notice to complete an attestation from HHHN?

If your organization is asked to complete a FDR Annual Compliance Attestation, then we have identified you as a FDR because of your contractual relationship with HHHN. CMS requires us to have oversight of our FDRs and to collect an attestation to confirm that you understand and are complying with Medicare compliance program requirements.

2. I don't have any employees; do I have to complete an attestation?

Yes, you should submit an attestation even if you have no employees. This includes solo practitioners, sales agents, partners, etc.

3. How often do I have to complete the attestation?

The Medicare FDR Annual Compliance Attestation is due annually each year as part of our oversight of FDRs.

4. How long do I need to maintain records?

FDRs must maintain records of Medicare compliance program requirements. Examples include employee training records, distribution of the Code of Conduct or compliance policies, and exclusion list screenings, for a minimum of 10 years.

5. Which of my subcontractors should be considered downstream entities?

Not every subcontractor is considered a Downstream Entity. Only those entities who provide contracted services on behalf of HHHN are Downstream Entities. FDRs should have processes in place to identify and classify subcontractors as Downstream Entities.

6. What requirements apply to downstream entities?

Downstream entities must comply with applicable regulatory and sub regulatory requirements that apply to the Medicare Program. This includes the compliance program requirements further explained in this Medicare FDR Compliance Program Requirements Guide.

7. What oversight is expected for my downstream entities?

Any FDRs that utilize Downstream Entities to perform services on HHHN's behalf, must have acceptable oversight of the Downstream Entities' compliance. This includes testing compliance program requirements and performance.

Appendix B:

Who Should Complete General Compliance and FWA training?

As an FDR, your entire staff is not necessarily subject to the training requirement. CMS has provided “examples of the critical roles within an FDR that should clearly be required to fulfill the training requirements”.

1. Senior administrators or managers directly responsible for the FDR’s contract with the Sponsor (e.g., Senior Vice President, Departmental Managers, Chief Medical or Pharmacy Officer);
2. Individuals directly involved with establishing and administering the Sponsor’s formulary and/or medical benefits coverage policies and procedures;
3. Individuals involved with decision-making authority on behalf of the Sponsor (e.g., clinical decisions, coverage determinations, appeals and grievances, enrollment/dis-enrollment functions, processing of pharmacy or medical claims);
4. Reviewers of beneficiary claims and services submitted for payment; or,
5. Individuals with job functions that place the FDR in a position to commit significant non-compliance with CMS program requirements or health care FWA.

Exceptions to the Training Requirement:

The only exception to the training requirement is that FDRs are deemed to have met the FWA training requirements through enrollment into the Medicare program or accreditation as a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Those parties deemed to have met the FWA training are still obligated to complete the general compliance training requirement. FDRs who are deemed to have met the FWA training requirements will need to provide HHHN proof of deemed status.



Appendix C:

General Compliance & Fraud, Waste, and Abuse Training Log

This example is intended to be used by FDRs to track training completion by employees. Additionally, FDRs can provide this log to Downstream Entities to use in monitoring training. Fraud, Waste and Abuse and General Compliance Training is required within 90 days of hire/contracting and annually thereafter for all of FDRs employees and downstream entities who are contracted to perform services for HHHN.

2021 Fraud, Waste and Abuse & General Compliance Training Log

Organization Name: _____

Training Included:

CMS Medicare Parts C and D Fraud, Waste, and Abuse Training

CMS Medicare Parts C & D Compliance Training

Name of Attendee	Title	Date of Hire	Date/Time of Training	Score (If applicable)

Appendix D: HHHN Compliance and FWA Reporting Poster

PATIENT CONCERNS

At Hudson Headwaters, we are committed to a high standard of care and take patient concerns very seriously.

HOW TO REPORT YOUR CONCERNS

If you have questions or concerns about the quality of care, policies, privacy, billing, or other areas of Hudson Headwaters' operations, we urge you to contact the Hudson Headwaters Risk Management & Compliance Department



518-409-8642

Please leave your name, telephone number and a detailed message about your concern. A member of our team will return your call within 3 business days.



patientconcerns@hhhn.org



Hudson Headwaters Risk Management & Compliance
9 Carey Road
Queensbury, NY 12804

PLEASE LET US KNOW:

WHO was involved (employee, provider, patient, etc.)

WHAT happened (a complete detail of the event)

WHEN it happened (date and time)

WHERE it happened (what health center or administrative office)

Any other details that may help with the investigation

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HEALTH NETWORK

Hudson Headwaters Health Network
9 Carey Road
Queensbury, NY 12804

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