Hudson Headwaters Health Network

Compliance Guide

To report suspected fraud, abuse or other violations of HHHN's policies, call 518-409-8642 or e-mail vendorcompliance@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 Compliance Guide

Hudson Headwaters Health Network (HHHN) works with external vendors to help fulfill its obligations to the Centers for Medicare & Medicaid Services (CMS), the Office of Inspector General (OIG), the Office of the Medicaid Inspector General (OMIG) and to provide health care services to our patients.

Although these services are delegated, HHHN is ultimately responsible for ensuring services performed by vendors are in accordance with the obligations to CMS, OIG and OMIG. Therefore, Vendors must fulfill specific compliance program requirements.

Compliance is not only rooted in the regulations we have to abide by. CMS, OIG and OMIG provide the foundation that compliance best practices are built upon. The purpose of this Compliance Guide is to assist vendors in understanding and meeting their compliance obligations under HHHN's Compliance Program.

Any questions pertaining to this Compliance Guide or instances of non-compliance should be reported to vendorcompliance@hhhn.org

Section II:
Definitions, What is Fraud, Waste and Abuse?

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:
Vendors & 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 that our vendors are in compliance with applicable laws, rules and regulations. Vendors 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. Vendors must provide either HHHN's Code of Conduct and Medicare Compliance Policies **(link)** 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 employees and contractors within 90 days of initial employment/contract and annually thereafter.

4. Vendors 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 Vendor's intranet, etc.).

5. A Vendor 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 Vendor 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 Vendor'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 vendor to Hudson Headwaters Health Network, 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. Vendors must be able to demonstrate that their employees and Downstream entities have fulfilled this training requirement. Vendors compliance expectations can be communicated through distribution

of the Vendor's Standards of Conduct and/or compliance policies and procedures to Vendor's 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 must receive 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. Vendors 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 Vendor 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 a Vendor's 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 Vendor 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. Vendors 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. Vendors should enforce the policy of non-intimidation and non-retaliation.

Element 5: Well-Publicized Disciplinary Standards

1. Vendors 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. Vendors 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. Vendor's Intranet site;
   ii. General compliance training; and
   iii. Posters prominently dis played throughout employ ee work and break areas.

c. Vendors must report an issue of non-compliance to HHHN that is any way associated with the services performed on HHHN's behalf.

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. Vendors 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 Administra tion (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 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. Vendors 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

6. What documentation must Vendors 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 Vendor 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 the requirements discussed in this Compliance Guide.

Element 7. Prompt Response to Compliance Issues

1. HHHN's Vendors 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 Vendors and their employees.

2. Reporting systems must maintain confidentiality, allow anonymity if desired (e.g., through anonymous hotlines or mail drop boxes), and emphasize Vendor's policy of non-intimidation and non-retaliation for good faith reporting of compliance concerns and participation in the Vendor's compliance program.

3. The methods available for reporting compliance or FWA concerns and the non-retaliation policy must be publicized throughout the Vendor's facilities.

    a. An example of such publication can be found in this guide on Appendix D: HHHN Compliance and FWA Reporting Poster.

<u>You must notify HHHN immediately if non-compliance is identified related to the functions you provide for HHHN. Instances of non-compliance should be reported to vendorcompliance@hhhn.org.</u>

Section V:
Use of Offshore Operations & Other Obligations of Vendors

Report and Request to Use Offshore Operations

1. All work performed by Vendors on HHHN's behalf should be performed within the United States and its territories (including America Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands). We refer to work being performed outside the United States and its territories as being "offshore."
2. Vendors must sign an attestation annually as to how it will oversee the offshore functions.

Other Obligations of Vendors

1. In addition to meeting the CMS Compliance Program requirements, HHHN also expects Vendors to:
    a. Maintain current federal, state and local licenses and permits required for the operation of the Vendor's business or profession.
    b. Ensure services provided for HHHN are done so in a highly ethical manner and in compliance with the Vendor'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:
Non-Compliance

Non-Compliance

1. Vendors must maintain evidence of compliance with the requirements listed in this Guide for no less than 10 years. Vendors must maintain evidence of compliance with the requirements listed in this Guide for no less than 10 years.
    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 Vendor, HHHN, CMS or any regulatory oversight agency identifies areas of non-compliance performed by a Vendor, it must take prompt action to correct the issue and prevent it from happening again.

Any questions pertaining to this Compliance Guide or instances of non-compliance should be reported to vendorcompliance@hhhn.org

Section VII: Deficit Reduction Act, OIG Training Resources and HIPAA

Title 18 of the New York Codes, Rules and Regulations (18 NYCRR) § 521-1.4(a)(2)(ix) states all Required Providers shall comply with the provisions of 42 USC 1396a(a)(68). This addendum identifies the requirements of the DRA and the detailed information that OMIG looks for in a Required Provider's written Policies and any employee handbook when assessing if a compliance program meets statutory and regulatory requirements.

The Centers for Medicare and Medicaid Services issued the Deficit Reduction Act frequently asked questions that provides guidance on the DRA requirements and is available at DRA 6032 - Employee Education About False Claims Recovery - Frequently Asked Questions 3-20-07.

DEFICIT REDUCTION ACT (DRA) REQUIREMENTS

18 NYCRR § 521-1.4(a) requires inclusion of Title 42 United States Code § 1396-a(a)(68), also known as the DRA, which states:

Any entity… as a condition of receiving [Medicaid] payments, shall:

(A) establish written policies for all [affected individuals], that provide detailed information about the False Claims Act established under sections 3729 through 3733 of title 31, administrative remedies for false claims and statements established under chapter 38 of title 31, any State laws pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under such laws, with respect to the role of such laws in preventing and detecting fraud, waste, and abuse in Federal health care programs (as defined in section 1320a–7b(f) of this title);

(B) include as part of such written policies, detailed provisions regarding the entity's policies and procedures for detecting and preventing fraud, waste, and abuse; and

(C) include in any employee handbook for the entity, a specific discussion of the laws described in subparagraph (A), the rights of employees to be protected as whistleblowers, and the entity's policies and procedures for detecting and preventing fraud, waste, and abuse.

A. Written Policies should include detailed information about the topics listed below for each law:

1. Federal False Claims Act, Title 31 United States Code §§ 3729 to 3733, excluding § 3730(h):
   a. liability,
   b. damages and penalties,
   c. the knowledge requirement, and
   d. the qui tam provisions.

2. Federal administrative remedies for false claims and statements, Title 31 United States Code §§ 3801 to 3812:
   a. liabilities,
   b. civil penalties and damages, and
   c. periodic adjustment to civil penalties by Congress.

3. NYS False Claims Act (https://ag.ny.gov/sites/default/files/2022-08/nyfca.pdf), NYS Finance Law §§ 187 to 194, specifically §§ 187 to 190 and 192 to 194:
   a. liability,
   b. damages and penalties,
   c. false claims and reverse false claims,

and
d. the qui tam provisions.

4. NYS laws pertaining to civil liabilities, penalties, and administrative sanctions for false claims and statements:
   a. Social Services Law § 145-b—False Statements; actions for treble damages, and
   b. Social Services Law § 145-c—Sanctions.

5. NYS laws pertaining to criminal liabilities and penalties for false claims and statements:
   a. Social Services Law § 145—Penalties,
   b. Social Services Law § 366-b—Penalties for Fraudulent Practices,
   c. Penal Law Article 155—Larceny,
   d. Penal Law Article 175—Offenses Involving False Written Statements,
   e. Penal Law Article 176—Insurance Fraud, and
   f. Penal Law Article 177—Health Care Fraud.

6. Federal and state whistleblower protections, including application, protections, prohibited actions, and available remedies:
   a. Federal False Claims Act (31 U.S.C. § 3730(h)),
   b. NYS False Claims Act (State Finance Law § 191—Remedies),
   c. NYS Labor Law § 740, and
   d. NYS Labor Law § 741.

B. OMIG considers the written policies and detailed provisions regarding an entity's policies and procedures for detecting and preventing fraud, waste, and abuse, that are required by Title 42 United States Code § 1396-a(a)(68), to be equivalent to the written Policies required by 18 NYCRR § 521-1.4(a).

C. The Required Provider need not create an employee handbook if one does not already exist. The Required Provider's employee handbook, if applicable, should include a specific discussion of:

1. the laws described above,
2. the rights of employees to be protected as whistleblowers, and
3. the entity's policies and procedures for detecting and preventing fraud, waste, and abuse (i.e., the Required Provider's compliance program).

OIG Training Resources

Please find the Officer of Inspector General HEAT Provider Compliance Training videos at https://oig.hhs.gov/compliance/provider-compliance-training/videos/

- For further clarification, review any of the following videos for your reference:
- Reporting Fraud to the OIG (1:21)
- Updated Self-Disclosure Protocol (5:39)
- Importance of Documentation (4:12)
- Tips for Implementing an Effective Compliance Program (4:26)
- Compliance Program Basics (3:58)
- Advisory Opinions, Compliance Program Guidance, and Other Guidance (6:34)
- Physician Self-Referral Law (4:21)
- False Claims Act (4:17)
- Federal Anti-kickback Statute (4:46)
- Exclusion Authorities & Effects of Exclusion (4:25)

HIPAA Privacy Rule

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule is a federal regulation in the United States that protects the privacy and security of individuals' health information. The key points of the HIPAA Privacy Rule are as follows:

1. Protected Health Information (PHI): The rule applies to individually identifiable health information held or transmitted by covered entities and their business associates. PHI includes information related to an individual's physical or mental health, treatment, and payment for healthcare services.

2. Covered Entities: The Privacy Rule applies to healthcare providers (e.g., doctors, hospitals), health plans, and healthcare clearinghouses that electronically transmit health information. It also

covers their business associates who handle PHI on their behalf.

3. Privacy Rights: Individuals have several rights under HIPAA, including the right to access their PHI, request corrections to their records, and receive a notice of privacy practices from covered entities.

4. Uses and Disclosures: Covered entities can use or disclose PHI for treatment, payment, and healthcare operations without patient consent. Other uses and disclosures require patient authorization, unless otherwise permitted by law.

5. Minimum Necessary Standard: Covered entities must limit the use or disclosure of PHI to the minimum necessary to achieve the intended purpose.

6. Safeguards: Covered entities must implement administrative, physical, and technical safeguards to protect PHI from unauthorized access, use, or disclosure. This includes secure electronic systems and workforce training.

7. Notice of Privacy Practices: Covered entities are required to provide patients with a notice explaining how their PHI will be used and disclosed, as well as their privacy rights.

8. Breach Notification: Covered entities must notify individuals and relevant authorities in the event of a breach of unsecured PHI. The timing and content of these notifications are specified in the rule.

9. Penalties: Violations of the HIPAA Privacy Rule can result in civil and criminal penalties, depending on the severity of the violation.

10. Enforcement: The U.S. Department of Health and Human Services (HHS) is responsible for enforcing the Privacy Rule and ensuring compliance through investigations and audits.

Any privacy concerns should be reported to vendorcompliance@hhhn.org.

Appendix A: FAQ

1. What is a Downstream Entity?
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).

2. How long do I need to maintain records?
Vendors 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.

3. 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. Vendors should have processes in place to identify and classify subcontractors as Downstream Entities.

4. 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 Compliance Guide.

5. What oversight is expected for my downstream entities?
Any Vendors 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 Vendor, your entire staff is not necessarily subject to the training requirement. Examples of the critical roles within an organization that are required to fulfill the training requirements are as follows:

1. Senior administrators or managers directly responsible for the Vendor's contract with HHHN (e.g., Senior Vice President, Departmental Managers, Chief Medical or Pharmacy Officer);
2. Individuals involved with decision-making authority on behalf of the Vendor
3. Individuals with job functions that place the Vendor in a position to commit significant noncompliance with CMS program requirements or health care FWA.

Exceptions to the Training Requirement:
The only exception to the training requirement is that Vendors 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. Vendors 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 Vendors to track training completion by employees. Additionally, Vendors 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 Vendors employees and downstream entities who are contracted to perform services for HHHN.

Medicare Fraud, Waste and Abuse (FWA)
and General Compliance Training Log

Name of Entity: _____

List all training materials provided & attach a copy or copies to this log:

_____

_____

Training Information Provided to:

Name of Attendee	Title	Date of Hire	Date of Training

_____ _____

Signature of Authorized Representative Date

_____

Authorized Representative printed name and title

SAMPLE

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

HHHN.org

HUDSON HEADWATERS
HEALTH NETWORK

Hudson Headwaters Health Network
9 Carey Road
Queensbury, NY 12804

Hudson Headwaters Health Network is a 501(c)(3) nonprofit and Federally Qualified Health Center (FQHC) funded in part through a grant from the U.S. Department of Health and Human Services and generous community support. Hudson Headwaters Health Network is a Health Center Program grantee under 42 U.S.C. 254b, and a deemed Public Health Service employee under 42 U.S.C. 233(g)-(n).

HUDSON HEADWATERS
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