

114873.3058 COMP Website Compliance Statement Form

Health Network Laboratories believes that conscientious dedication to the highest ethical standards is essential to fulfilling our mission. Integrity governs our actions and relationships in all our interactions with others, including our employees, clients, providers and vendors. Our Code of Conduct and Corporate Compliance Plan formalizes our policies and procedures into a comprehensive program which defines the responsibilities of HNL. Our compliance efforts are designed to establish a culture that

- Facilitates discovery and education
- Promotes prevention, detection and resolution of instances of conduct that do not conform to our ethical and business policies
- Supports those structures and plans that exist to improve performance and provide a safe environment for all.

The HNL Compliance Program applies to all claims and payments for private and governmental patient services and third-party payers. Due to the breadth of requirements, complexity, cost of non-compliance and high-volume, added emphasis and priority will be brought to Medicare and Medical Assistance under this plan.

The objectives of the HNL Compliance Plan are to prevent, detect and correct inappropriate claims for patient services and thereby prevent related false claims and potential charges for civil and criminal wrongdoing. The Program demonstrates and reinforces the positive standard of conduct expected of HNL, its employees and agents, and specifies duties and responsibilities throughout HNL regarding claims and payments for services.

HNL will comply with proscribed governmental claim and payment regulations and requirements to the best of its ability and expects its employees' and agents' actions to uphold this standard.

HNL will formally train its employees and agents in Medicare and Medical Assistance billing requirements on a regular, effective basis including current and changing requirements and regulations.

HNL will create an expectation that its' employees and agents at any level will communicate with their supervisors regarding questions about appropriate claims and payment practices. Employees are expected to follow existing policies regarding compliance matters just as with other job responsibilities. Employees and agents who believe that acts of non-compliance exist after following existing policies are expected to contact the Compliance Officer. The Compliance Officer will in turn work with the reporting employee and all appropriate parties until resolution is achieved.

Corrective action, if required, will occur and will be based on the circumstances and facts of each case. Employee and agent retraining or discipline in accord with existing and customary polices, if needed will be part of the corrective action.

Duty to Report

HNL is committed to ethical and legal conduct that is complaint with all relevant laws and regulations. Each member of the organization is responsible for reporting any suspected criminal activity or illegal or unethical conduct by any colleague, physician, contractor or vendor that appears to be a violation of applicable law, regulation or policy.

Hotline/Alternative Avenues of Communication

To obtain guidance on a compliance issue or report a suspected violation, individuals may choose from several options. As with other operational matters, it is expected that if comfortable and appropriate, individuals will first discuss concerns with the immediate supervisor, or department head. If this is uncomfortable or inappropriate, another option would be to discuss concerns with another member of the management group including Human Resources, Compliance Department or the Compliance Officer. Individuals can always contact the anonymous EthicsPoint Hotline at 1-844-675-7684. HNL will make every effort to maintain, within the limits of the law, the confidentiality of the identity of any individual who reports a suspected violation or misconduct.

Non-Retaliation Policy

HNL will not impose disciplinary action or other types of retaliation against any employee who, in good faith, reports a concern to management, the Compliance Officer or the employee hotline. "Good Faith" means that an individual doesn't have to be right, but it means that an individual must be telling the truth as they believe it to be. Reporting a false accusation is a serious violation of policy and may lead to disciplinary action up to and including termination from employment.

Internal Investigations

All reported concerns will be addressed promptly and confidentially to the extent possible. The Compliance Officer will coordinate the investigation and recommend corrective action or changes that are required. Full cooperation with investigation efforts is expected of all employees and interested parties.

Federal Anti-Kickback Statute

The U.S. Department of Health and Human Services Office of Inspector General (OIG) has stated that giving free goods that have an independent value to a physician may violate the Federal anti-kickback statute if the requisite intent to induce referrals is present. The term "independent value" means that the physician may use the supply for purposes unrelated to collecting and processing a specimen for testing by the laboratory who furnishes the supply. As an example, the OIG specifically views as suspect the provisional free gloves and regular personal computers and fax machines because these items have an independent value to a physician because he/she may use them for purposes unrelated to laboratory testing. Based on the OIG's guidance, any arrangement whereby HNL furnishes free supplies in excess of a physician's need to collect and process specimens for testing by HNL may be deemed as a violation of the anti-kickback statute.

The Centers for Medicare and Medicaid Services (CMS) has declared that laboratories may only give their customers supplies that may be used solely for the collection, processing, storage, or transport of specimens sent to the laboratory that provided such supplies. If a customer is able to use a supply for other purposes, the laboratory may not provide the supply.

In addition, laboratories may only give customers quantities of permitted supplies that are reasonably related to the number of specimens the client sends to the laboratory for testing. For example, laboratories cannot provide customers with gloves.

HNL does and will continue to utilize reasonable controls to help ensure that we provide only the appropriate quantities of these permitted supplies. We have a commitment to comply with all laws and regulations that affect our business. Our policies and practices are developed to safeguard both HNL and you, as a valued customer, from potential violations of these laws and regulations. Should you have any additional questions, please contact our Compliance Department at 484-425-8150.

Federal and State Laws Pertaining to Civil or Criminal Penalties for False Claims and Statements

The federal Civil False Claims Act, the Program Fraud Civil Remedies Act and Pennsylvania's Medicaid Fraud and Abuse Control Law are important laws in the prevention and detection of fraud, waste and abuse in federal and state health care programs.

Federal Civil False Claims Act (42 U.S.C. § 3729 et seq.)

The federal Civil False Claims Act ("FCA") is a law aimed at preventing fraud against the federal government, including fraudulent billing and submission of claims to all federal health care programs (e.g., Medicare and Medicaid). In general, the FCA prohibits any person or entity from:

- Knowingly presenting, or causing to be presented, a false or fraudulent claim, record or statement to the government for payment or approval;
- Conspiring to defraud the government by getting a false or fraudulent claim allowed or paid;
- Using a false record or statement to avoid or decrease an obligation to pay the government; or
- Committing any other fraudulent acts detailed in the FCA.

The term "knowingly" means that the person has actual knowledge of the information, acts in deliberate ignorance of the truth or falsity of the information or acts in reckless disregard of the truth or falsity of the information. No proof of a specific intent to defraud the government is required. The U.S. Attorney General may bring civil actions for violations of the FCA. A private person also may file a FCA suit in the name of the United States for false or fraudulent claims submitted by individuals or entities. Commonly known as "qui tam" actions, such lawsuits by a private person are commenced when a "relator" (also referred to as a "whistleblower") files a civil complaint in federal court, under seal, and discloses material evidence to the U.S. Attorney General. Whistleblowers who file a qui tam action may receive a reward of 15-30 percent of the monies recovered for the government, plus attorneys' fees and costs. (This amount may be reduced, however, if, for example, the court finds the whistleblower planned and initiated the violation.)

FCA Whistleblower Protections

Whistleblowers are afforded certain protections against retaliation for bringing an action under the FCA. An employee who is discharged, demoted, suspended, threatened, harassed or confronts discrimination in furtherance of such an action or as a consequence of whistleblowing activity is entitled to all relief necessary to make the employee whole. Such relief may include reinstatement, double back pay, and compensation for any special damages, including litigation costs and reasonable attorneys' fees.

The Program Fraud Civil Remedies Act of 1986 (31 U.S.C. § 3801 et seq.)

The Program Fraud Civil Remedies Act ("PFCRA") provides for administrative remedies against persons or entities that make, or cause to be made, a false claim or written statement to certain federal agencies, including the U.S. Department of Health and Human Services. The conduct prohibited by the PFCRA is similar to that prohibited by the FCA. The PFCRA makes it unlawful for any person or entity to make, present or submit or to cause to be made, presented, or submitted, a claim that the person or entity knows or has reason to know:

- Is false, fictitious, or fraudulent;
- Includes or is supported by any written statement which asserts a material fact which is false, fictitious, or fraudulent;
- Includes or is supported by any written statement that omits a material fact; is false, fictitious, or fraudulent as a result of such omission; and is a statement in which the person or entity making, presenting, or submitting such statement has a duty to include such material fact; or
- Is for payment for the provision of property or services which the person or entity has not provided as claimed.

Pennsylvania's Medicaid Fraud and Abuse Control Law (62 P.S. § 1407)

Pennsylvania's Medicaid Fraud and Abuse Control Law ("Medicaid Fraud Control Act") provides a criminal remedy for the submission of false or fraudulent claims to Pennsylvania's medical assistance (i.e., Medicaid) program. The Medicaid Fraud Control Act prohibits any person from, among other things:

- Knowingly or intentionally presenting for allowance or payment any false or fraudulent claim or cost report for furnishing services or merchandise under the Medicaid program;
- Knowingly presenting for allowance or payment any claim or cost report for medically unnecessary services or merchandise under the Medicaid program;
- Knowingly submitting false information, for the purpose of obtaining greater compensation than that to which he or she is legally entitled for furnishing services or merchandise under the Medicaid program; or
- Knowingly submitting false information for the purpose of obtaining or furnishing services or merchandise under the Medicaid program.

Pennsylvania Whistleblower Protections

The Pennsylvania Whistleblower Law (43 P.S. §§ 1421-1428) provides protection from discrimination and retaliation to any person who witnesses or has evidence of wrongdoing or waste while employed by a public body (e.g., state, county or city agency, department, division or council, etc.) and who makes a good faith report of the wrongdoing or waste, verbally or in writing, to one of the person's superiors, to an agent of the employer or to an appropriate authority. No employer may discharge, threaten or otherwise discriminate or retaliate against an employee regarding the employee's compensation, terms, conditions, location or privileges of employment because the employee, or a person acting on behalf of the employee, makes a good faith report or is about to report, verbally or in writing, to the employer or appropriate authority an instance of wrongdoing or waste.

HNL Whistleblower Protections

Consistent with the FCA and the Pennsylvania Whistleblower Law, HNL's policy is to protect employees from any retaliation or retribution for reporting suspected violations of the law to law enforcement officials or to HNL's management or for filing "whistleblower" lawsuits on behalf of the government. Specifically, HNL's Policy, False Claims and Fraud Prevention, prohibits retaliation in any manner or retribution against an employee who has made or intends to make a report of an activity, practice or arrangement that the employee believes violates or may violate a law (including the FCA), a regulation, or Compliance Program Standards of Conduct or Policies or Procedures.

Questions?

Questions regarding the FCA, the PFCRA, Pennsylvania's Medicaid Fraud Control Act, related whistleblower protections or HNL's commitment to preventing fraud, waste and abuse in federal and state health care programs, should be directed to HNL's Compliance Officer. Any employee/contractor or vendor who has knowledge or information of any potential false claims or other wrongdoing has a duty under the HNL Compliance Program to report such suspected misconduct to the Compliance Officer, to the employee's direct supervisor, or through HNL's toll-free Customer Care Hotline at (877) 402-4221. Information may be reported through the Compliance Hotline anonymously.

Laboratory Complaints

A complaint is any concern that you may have about a laboratory's operation. Examples include violations of laws or regulations, violations of policies, procedures, or the HNL Code of Conduct, concerns about accreditation standards, quality of testing, licensing, conflicts of interest, workplace safety, illegal or unethical conduct, business conduct, criminal activity, confidentiality of patient information, or laboratory personnel qualification or responsibility issues.

Complaints can be reported by anyone including but not limited to, patients, patient's relatives, the public, physicians and any personnel working in a laboratory. You may contact the Centers for Medicare & Medicaid Services (CMS) Central Office, Division of Laboratory Services (CLIA), in Baltimore, Maryland at (410) 786-3531 or toll free at (877) 267-2323, extension 63531.

You may also call, write or e-mail your complaint to any of the following:

- Directly to Health Network Laboratories Compliance Office
- CMS Regional Office
- The State Agency or State Department of Health where the laboratory is located
- The laboratory's State licensure program

When making a complaint, the following information may be requested:

- Name and Address of laboratory
- Complete description of your concern
- View of the frequency and pervasiveness of issue
- Your name, address and telephone number
- Who has been affected or involved
- Date(s) & Time(s) of the incident(s)
- Name of other agencies you have contacted
- Any other details or documentation

Contact information for the following:

- Health Network Laboratories Corporate Compliance Officer - HNL Compliance Office (484) 425-8150
- [State Agency and Regional Office CLIA Contacts](#)
- [Accreditation Organizations and Exempt States](#)