HNL Lab Medicine®

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Compliance Plan

Introduction

HNL Lab Medicine (HNL) is committed to maintaining compliance with all applicable laws and regulations, including the Affordable Care Act which requires a compliance program as a condition of participation in federal health-benefits programs. The Compliance Plan communicates the policies, procedures, and activities used to maintain compliance with the numerous laws, regulations, and other rules affecting the laboratory industry.

Purpose

HNL adheres to legal and ethical standards that govern its operations. HNL's Board has approved the Compliance Plan (the "Plan"), consistent with the U.S. Federal Sentencing Guidelines, the Office of Inspector General's (OIG) Compliance Program Guidance for Clinical Laboratories, and other guidance related to clinical laboratories, including but not limited to fraud alerts and advisory opinions issued by the OIG and the Centers for Medicare and Medicaid Services (CMS), Department of Justice (DOJ) guidance on Evaluation of Corporate Compliance Programs, among others.

The Plan focuses on the detection and prevention of violations of federal, state and local laws and encourages employees and others to ask questions and report concerns about behaviors or business practices that may violate laws, regulations or HNL policies.

Scope

The Plan applies to all of HNL and its wholly owned or wholly controlled subsidiaries.

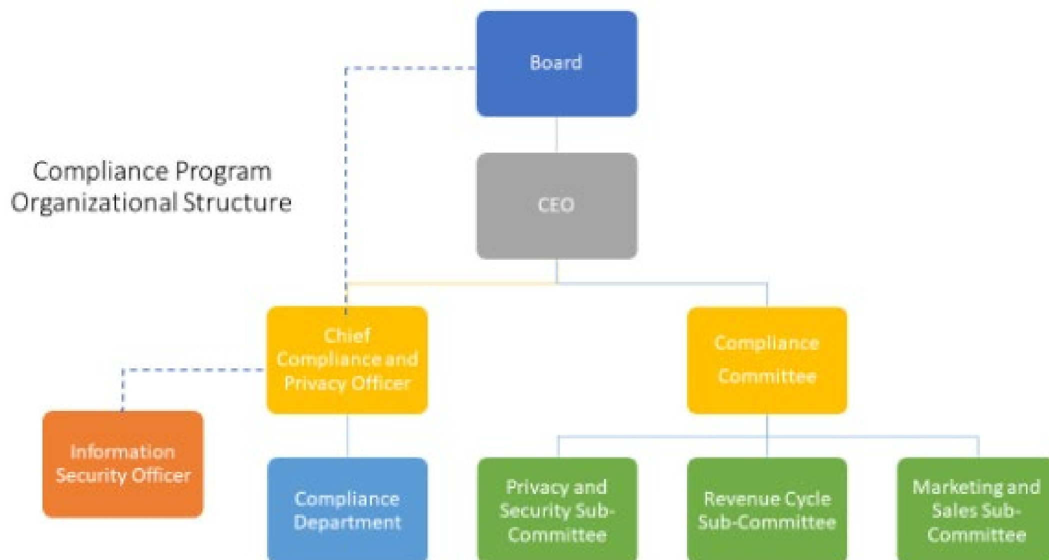
Compliance Program

Written Policies, Procedures, and Standards of Conduct

1. HNL has published a Code of Conduct, a set of guidelines and standards governing relationships with patients, providers, third party payers, subcontractors, independent contractors, vendors, consultants, competitors, and one another. A copy of the Code of Conduct can be found in HNL's document management system in the Compliance folder.
2. The Compliance program includes policies on such topics that include but are not limited to: Confidentiality, Nondiscrimination, Non-Retaliation, Screening for Excluded Individuals and Entities, Non-Monetary Compensation, Sales and Marketing Practices, Privacy and Security, and Billing and Coding.
3. Compliance policies should be reviewed every two years or more frequently in response to regulatory requirements or changes.

4. All compliance policies are maintained electronically in the laboratory's document management system. This system may be accessed via the Intranet on the MyHNL homepage.

Program Structure



Compliance Officer

1. The Chief Compliance Officer (CCO) is charged with the responsibility for implementing and operating the Compliance Program in an independent and objective manner.
2. The CCO is accountable to the HNL Chief Executive Officer (CEO) with a dotted line to the HNL Board. The CCO has the authority to communicate with the Board at any time without notice to the CEO or other executive management, if necessary.
3. The CCO has the following specific responsibilities:
   a. Accountable to the CEO and responsible for the day-to-day management and implementation of the Compliance Program.
   b. Make at least quarterly and annual reports to the HNL Board and the Executive Team.
   c. Serve as Chairperson of the HNL Compliance Committee and Sub-committees.
   d. Perform periodic risk assessments to identify areas vulnerable to error or non-compliance and formulate processes that are responsive to the identified risks.
   e. Establish and communicate HNL's expectations of ethical and legal conduct by employees, agents and contractors.

f. Establish and oversee internal reporting processes including the Compliance Hotline so that employees, agents and contractors can report business ethics and compliance concerns without fear of retaliation.

g. See that concerns or allegations of wrong doing reported via the Compliance Hotline or through other means are promptly and thoroughly investigated and resolved.

h. Establish HNL training programs that convey the Program and address identified risk areas.

i. Inform HNL executive management and the Board of compliance issues that may pose significant risk to HNL.

j. Ensure action is taken when any matter requires external reporting or disclosure, such as to a regulatory or enforcement agency.

k. Conduct or authorize an independent investigation of any matter which, in the CCO's judgment, cannot adequately be investigated by an internal resource.

l. Communicate any matter deemed potentially illegal, unethical or otherwise improper to Legal Counsel, Security, Human Resources, Risk Management, or other department for review and investigation.

Compliance Committees

1. The compliance committee consists of executives and/or senior leaders in the areas of Compliance, Finance, Human Resources, Information Services, Operations, Privacy, Risk Management, Security, and Quality. The committee also includes the Chief Executive Officer, Chief Medical Officer, LVHN Compliance Officer, and representation of the Board. The HNL CCO is the chair of the committee.
    a. The committee evaluates the culture, approves new policies, reviews investigations and disciplinary matters, approves training and communication plans and auditing and monitoring plans, and reviews audit reports.
    b. The committee supports the CCO and does not interfere with the CCO's day-to-day responsibilities or report to the board.
    c. The committee meets quarterly.
2. Sub-committees will be chartered to address specific areas of risk within the organization and will report to the compliance committee through the CCO.
    a. The CCO will organize Compliance Sub-Committees who will provide advice and support to the members of the Compliance Department on compliance activities.
    b. Sub-committees will be organized to focus on areas of significant compliance risk in the clinical laboratory industry, as identified by the Office of Inspector General and other oversight bodies and will provide a regularly occurring forum in which HNL's Compliance Department receives input from leaders with subject matter expertise.

c. The sub-committees will work with the Compliance Department to identify risk areas, provide input on the annual Compliance Work Plan, identify areas appropriate for compliance training, and consider and address risks identified through the Compliance Program.

d. Sub-committees should meet at least quarterly.

HNL Management Personnel Responsibilities

1. Management personnel are required to remain current in their particular area of oversight in order to ensure compliance with applicable federal, state and local laws, regulations and rules.
2. Management personnel will insure that departmental policies and procedures under their oversight are consistent with organizational compliance policies and procedures; and that they comply with all applicable federal, state, and local laws, regulations and rules.
3. Management personnel, in coordination with the Compliance Department, are responsible for ensuring their staff complete all required compliance education and that staff understand how to report and resolve compliance issues.
4. Management personnel, in coordination with the compliance team, identify and assess risks, develop corrective action plans, and ensure employees are informed of risks and mitigation efforts impacting their work area.

HNL Employee Responsibilities

1. The effectiveness of the Program depends on each employee's commitment to ethics and compliance.
2. Each employee has a responsibility to understand compliance policies and risks applicable to their job and to HNL as a whole.
3. Each employee has a DUTY to report compliance concerns, and should report concerns to his/her direct supervisor.
4. Alternative avenues for communication include other individuals in the employee's direct reporting line, the Vice President of Human Resources or the CCO.
5. It is recommended that dissatisfaction concerning interpretation or application of work-related policy by management, supervisors, or other employees should be handled in accordance with the Issues Resolution Policy whenever possible prior to reporting this category of concerns through the Compliance Hotline.
6. Questions about compliance concerns or reports of potential or actual violations may also be made through the toll-free Compliance Hotline at 1-844-675-7684 or via the web form at www.healthnetworklabs.ethicspoint.com.
7. Employees who know of compliance violations and willfully fail to report such violations can be subject to corrective action.

8. Each employee is expected to abide by the Code of Conduct and comply with applicable laws, regulations, and HNL's policies.

Training and Education

1. Compliance personnel will provide an introduction to Compliance, Privacy, and Security for new hire orientation.
2. Annual and new hire training should be completed within 30 days of assignment. All employees will receive on-line compliance training covering General Compliance Training; Overview of Fraud, Waste, and Abuse Laws; HNL's Code of Conduct; HIPAA Privacy and Security Basics.
3. Some roles require more in-depth training related to arrangements and medical necessity. Courses are issued upon hire and annually, and cover topics including, but not limited to, CPT/HCPCS codes, ICD-10 codes, local and national coverage decisions, valid test orders, standing orders, panels and profiles, authorized persons, reflex testing, crediting orders, advanced beneficiary notices, and inducements and kickbacks.
4. Management personnel will complete on-line or instructor led training: Creating a Culture of Compliance; EthicsPoint User Training; Disclosures - Conflicts, Gifts, Political Contributions; HIPAA Access Monitoring; HIPAA Q&A; Risk Assessment. These courses should be completed within twelve months of rollout or new leader start date, whichever is later.
5. The CCO shall provide training to the board at least annually.
6. Posters, emails, videos, and compliance week messaging and games are some of the ways in which the compliance department endeavors to improve awareness of the compliance program.
7. The compliance department staff is available to attend department or other meetings upon request.

Open Lines of Communication and Reporting

1. HNL maintains an open door policy and encourages employees and others to directly seek guidance, ask questions or report suspected or actual misconduct. Individuals may do so confidentially, and without fear of retaliation or retribution. Refer to HNL's Compliance Hotline Policy for more information.
2. Individuals should report their concerns through their department reporting structure whenever possible. It is recommended that dissatisfaction concerning interpretation or application of work-related policy by management, supervisors, or other employees should be handled in accordance with the Issues Resolution Policy whenever possible prior to reporting this category of concerns through the Compliance Hotline.
3. If however, an employee or other individual is not comfortable reporting directly, communications may be made anonymously through the toll-free Compliance Hotline 1-844-675-7684 or via the web form at www.healthnetworklabs.ethicspoint.com.

4. Staff may use any communication channel they deem appropriate to report compliance issues.
5. To the extent practical or allowed by law, persons addressing information received through the hotline protect the confidentiality or anonymity of staff when requested.
6. Quality concerns may be reported to the College of American Pathologists (CAP) hotline: 1-866-236-7212. CAP is HNL's accrediting body. Although this reporting option is available, HNL strongly encourages internal reporting as a first option to give the organization an opportunity to self-correct any quality issues.

Enforcement of Standards; Well Publicized Disciplinary Guidelines

1. Development of corrective action plans will typically be delegated to subject matter experts or the responsible department. All corrective action plans must be approved by the compliance department and will be approved by legal counsel if determined necessary by the CCO and/or CEO.
2. Enforcement action determination includes an assessment of the level of severity of the violation and will be made consistent with the Human Resources Employee Counseling and Discipline Policy, the Compliance Program Discipline Policy, the Privacy Sanctions Policy, and any specific enforcement guidance included in the applicable policy governing the non-compliance.
3. Records of disciplinary actions are maintained by Human Resources in the employee's personnel files.
4. Corrective and disciplinary actions may also extend to vendors, contractors, and other agents and may including suspension or termination of physical or network access, or of a contract. Purposeful violations will result in termination of the business relationship or contract, as applicable, unless termination would have a negative impact on patient care, safety, or quality. In this case, alternatives should be identified within 30 days and a selection must be made with 180 days. Risk of further violations must be prevented and mitigation should be implemented immediately and until an alternative can be implemented.
   a. Vendors - The CCO and the Materials Management Director will respond to noncompliance in accordance with the Vendor Code of Conduct.
   b. Contractors - The CCO and the Vice President of Human Resources or the Vice President of Facilities will respond to noncompliance, as applicable.
   c. Other Agents - The CCO, in coordination with the responsible administrator or executive, will respond to noncompliance.

Internal Auditing and Monitoring

1. HNL conducts periodic auditing and monitoring of business operations, systems for testing internal controls, confirming compliance with applicable laws and HNL standards, and detecting violations of such laws and standards. Compliance risks are monitored to evaluate effectiveness in preventing and detecting violations of law. HNL promptly responds to detected program deficiencies and ensures appropriate corrective action is promptly implemented.
2. Auditing and monitoring activities are reported to the Compliance Committee and significant initiatives and findings are reported to the President and CEO, and the Board. Refer to the Auditing and Monitoring policy for more information on HNL's Auditing and Monitoring program.

Investigations

1. HNL is committed to a policy of thoroughly investigating and taking all reasonable steps to respond appropriately to any and all credible allegations of misconduct regarding applicable laws and the standards of conduct enunciated under HNL's Code of Conduct. Refer to HNL's Compliance Investigations Policy which governs the conduct of investigations.
2. HNL will cooperate with any external audit or government investigation of wrongdoing consistent with its obligations to comply with the law and to protect the rights of HNL and its employees. Please refer to the Response to Government Investigations Policy and Procedure documents for more information on government investigations.

Excluded Individual and Entity Screening

1. HNL will not knowingly arrange or contract (by employment or otherwise, with or without compensation), with an excluded person or entity, for the direct or indirect provision of items or services for which payment may be made by a Federal Health Care Program (as defined in 42 U.S.C. § 1320a-7b(f) or in any other government payment program).
2. HNL has established policies, procedures, and processes to ensure the completion of initial and routine screening of employees, vendors, contractors, suppliers, referral sources, students, and board members.
3. Should any of the processes set forth result in the determination that any individual/entity is, or has been, an Excluded individual/entity, there are procedures in place governing notification, suspension of billing or payment, and internal investigation and corrective action (e.g., termination of contract or service, removal from responsibility).
4. Refer to HNL's Excluded Individual and Entity Policy for more information.

Risk Assessment

1. Federal Sentencing Guidelines and other authorities require or recommend periodic assessment of risk and that organizations implement measures to mitigate the identified risks. Performance of a risk assessment is expected to improve the effectiveness of the compliance program.

2. HNL's Risk Assessment policy describes identification, measurement, and prioritization of risks, and the development and implementation of compliance work plans related to the identified risks. The risk assessment will be scheduled annually, however, the risk assessment process is ongoing in response to newly discovered or emerging risks (e.g., pandemic, new law or regulation).

Compliance Risks

1. It is important to differentiate compliance risks from other risks to ensure the compliance program focuses resources appropriately and is effective. Compliance risks can be organizational risks due to their impact on reputation, finances, etc.; however, compliance risks are typically more focused on ethical misconduct and noncompliance with laws, regulations and organizational policies. Organizational risks have an impact on strategic objectives, operations, finances, and reputation. An example might be the consideration of a law that prevents a healthcare entity from participating in a certain business practice. The likelihood of the law being passed and in what timeframe will inform the decision to engage in the practice.
2. Risks impacting laboratories may be found in several places including the Office of Inspector General's (OIG) Compliance Program Guidance for Clinical Laboratories, published in 1998; the OIG's Annual Work Plan; OIG Enforcement Actions published on the OIG website; Advisory Opinions and Special Fraud Alerts, in Corporate Integrity Agreements (CIAs) which are used to enforce fraud and abuse laws; and in industry publications.
3. Risk areas specific to laboratories are numerous and fall within the two key categories of medical necessity and arrangements. Topics in these categories include but are not limited to licensure/records management, lab test requisition design, specimen processing procedures, repeat testing, test crediting procedures, prevention of duplicate billing, billing for referral testing, billing for end stage renal disease (ESRD) testing, use of CPT/HCPCS codes and modifiers, reflex testing, notices to physicians, pricing for equipment and services provided, written and verbal test order authorization, standing orders, diagnosis coding, proper use of advanced beneficiary notices and related billing, test utilization trends and unusual ordering patterns, compensation arrangements, equipment and space lease arrangements, and supplies to clients.

Risk Prioritization

1. Risks are assessed to determine risk exposure taking into account severity, with respect to financial, legal/regulatory, and reputational factors; and likelihood as it relates to probability of occurrence and its detectability. Controls in place to mitigate risk are evaluated to assess effectiveness, whether they are operating as intended and driving improvement.
2. Risks should be prioritized based on score; however, risks with lower scores which are raised frequently in interviews, are hard to detect, or have a high likelihood of occurrence may be given a higher priority. Additionally, a risk with a low score may become the subject of government focus, indicating it should be re-prioritized.

Annual Work Plan

1. The CCO has the authority and responsibility to develop an annual Compliance Work Plan, subject to input and approval of the Compliance Committee based on the risk assessment process.
2. The Compliance Work Plan shall be included in the compliance report at least annually, which shall be submitted to the President and CEO, the Compliance Committee, and the Board.
3. A Work Plan is intended to provide the organization with a list of vulnerabilities on which it should focus in a given year. The Work Plan also serves as an assessment of the compliance program in that it should offer insight on adequate budget, staffing, tools/technology, and effectiveness.
4. The Annual Work Plan will be based upon several sources, including the Risk Assessment, instances of previous noncompliance, the OIG Work Plan, Corporate Integrity Agreements, other recent enforcement actions, employee surveys, exit interviews, and others. The Work Plan is subject to change in response to current events.
5. The Compliance Committee will be accountable for the Work Plan including its approval and monitoring of progress. The CCO will be responsible for coordinating with subject matter experts and communicating the Work Plan status to the Committee, the CEO, and the Board.

Questions

Questions about this Plan or any compliance related topic may be directed to the CCO in person, by phone, or in writing, to:
Brandy Frey
794 Roble Road
Allentown, PA 18109
484-425-8008
brandy.frey@hnl.com

Reporting

1. A report of a suspected violation may be made in person, by phone, or in writing, to:
    a. A supervisor or department manager
    b. HNL Compliance Department
    c. Information Security Officer
    d. Human Resources
    e. Compliance Hotline (EthicsPoint): 1-844-675-7684 or via the web form at www.healthnetworklabs.ethicspoint.com.

2. HNL makes every effort to maintain, within the limits of the law, the confidentiality of any individual who reports a concern or potential misconduct. If a colleague reports an actual or potential compliance issue in good faith, no discipline or retribution shall be taken or threatened against the individual in retaliation for making the report. "Good faith" means that an individual does not have to be right, but it does mean that the information is truthful to the best of their knowledge.
3. Reporting a false allegation is a serious violation of policy and will be handled in accordance with the Disciplinary Guidelines mentioned above.

Approved by Compliance Committee: April 2021