Health Sciences Compliance Plan

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Table of Contents

Contents

I. INTRODUCTION

The ethical and compliance foundations of Indiana University are based on the Principles of Ethical Conduct, found at http://principles.iu.edu/. The Principles are intended to serve as a high level statement of values and expectations at Indiana University. The Principles promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law and University codes, policies, and procedures.

The health sciences are a highly regulated industry with increased oversight and enforcement including access and use of health information, patient care, billing practices and research. Each health science area at Indiana University has unique characteristics involving their program. However, the primary compliance and regulatory needs are very similar and are a key compliance priority for the University.

The intent of the Health Sciences Compliance Program ("Program") is to enhance and more closely coordinate current compliance initiatives to leverage resources and best practices at the Health Science schools of Indiana University. A primary component of the Program is the Health Sciences Compliance Plan ("Plan").

The Plan establishes a framework for compliance with the laws and institutional policies that are applicable to health science schools. The Plan is not intended to set forth all the substantive programs and practices in place designed to achieve and promote compliance across the health science schools. The objectives of the Plan are to outline common goals and to share common experiences involving education, clinical care, research and/or services involving the health science schools at Indiana University.

This Plan was created by the Health Sciences Compliance Advisory Committee in conjunction with the University Compliance Office, and approved by University Clinical Affairs Council, comprised of the Deans of the Health Science schools. The Plan shall be periodically reviewed and updated, as appropriate, and shall supersede any previous or existing compliance plans at the school level.

II. SCOPE

The Plan applies to all Health Science community members, which include faculty, staff, and trainees (collectively "employees"), as well as students, of the health science schools. The Health Science schools (Schools) are currently comprised of the Schools of Dentistry, Health and Rehabilitation Sciences, Medicine, Nursing, Optometry, Public Health (Bloomington and Indianapolis) and Social Work.

III. ROLES AND RESPONSIBILITIES

The ongoing implementation and modifications of the Program shall be coordinated by:

a. University Compliance Office/ Chief Compliance Officer
The role of the University Compliance Office is to build on existing University initiatives and structures to improve the coordination, dissemination and communication of compliance information, and identify gaps in compliance.

b. Health Sciences Compliance Advisory Committee
The Health Science Advisory Committee shall provide guidance with risk identification, coordination initiatives, compliance resource assessments and recommendations regarding compliance policies and procedures involving the Program.
    1. Membership includes representation from each of the identified Schools. Health Science compliance representatives include Compliance Officers and/or those with responsibility for compliance oversight at the school level;
    2. The Health Sciences Compliance Advisory Committee shall meet at least quarterly.

While each member of the Indiana University community has a responsibility for compliance, the overall responsibility to implement this Program at each of the Schools shall be the responsibility of the respective Dean.

IV. COMPLIANCE STAFFING AT EACH SCHOOL/UNIT

Each School shall designate a representative to serve as a liaison on matters of compliance related to the Program. The responsibilities of the compliance liaison are as follows:

- Represent your School as part of the Health Sciences Compliance Advisory Committee
- Coordinate compliance activities with the University Compliance Office
- Communicate compliance requirements to your School
- Assist with the identification and development of policies and procedures as needed
- Disseminate any compliance-related policies or procedural updates
- Implement a mechanism to track your School's completion of compliance training

V. EDUCATION AND TRAINING

a. Employees
    i. All new employees shall obtain compliance orientation training no later than 90 days from the first day of their employment. Any exceptions to this timeframe shall be approved by the University Compliance Office.
        1. On a monthly basis, the University Compliance Office shall provide Health Sciences New Employee Compliance Orientation (NECO) in person and via video stream. It is *highly recommended* that employees who work at least 20 hours per week attend a NECO session in person or via video stream.
        2. In the event that attendance at these sessions is not reasonably feasible, this compliance orientation requirement may be fulfilled by other means,

at the discretion of the Dean of the School (or his/her designee) and the University Compliance Office. This may include online training options developed by the University Compliance Office. At a minimum, the content of this training shall include an Introduction to the IU Compliance Program and the Principles of Ethical Conduct. Additional compliance topics may be covered or recommended based on an employee's role, responsibilities, and/or access to University systems and data.

ii. Additional compliance training at the institutional or school level may be required annually or on a more frequent basis. This requirement shall be based on changes in regulations, institutional and affiliate policies, and/or to address any potential or current compliance risk.

iii. Each School is responsible for ensuring their employees obtain any required compliance training and shall be responsible for maintaining records of attendance as applicable. Employees should also maintain records of their training.

Each School shall be responsible for providing additional training to address any clinical, educational and/or operational initiatives that are necessary to address School-specific compliance risks and requirements. Each School shall also be responsible for the documentation, content, reporting, and maintenance of related training records.

iv. Any School that performs health care services and submits claims on behalf of the University shall provide Clinical Documentation Training (CDT) applicable to their environment.

1. The CDT shall be provided to employees involved in the preparation, documentation and/or submission of requests for reimbursement of clinical services on behalf of the University or services involving University students and personnel.
2. CDT will include, but not be limited to:
    i. The submission of accurate claims on behalf of Indiana University for healthcare services.
    ii. The obligation to ensure that the information provided by the individual (either orally or in writing) relating to the care or the services rendered to patients are properly documented.
    iii. Documentation standards of practice for providers in the teaching setting. General documentation and billing practices established by laws, regulations and guidance involving health care reimbursement.
    iv. Applicable state and federal health care program reimbursement rules and statutes, including false/fraudulent claims, the anti-kickback statute, and the Stark law.

v. The legal sanctions for the submission of false or inaccurate information, including, but not limited to, improper billings, with examples of improper billings provided.

b. Students and Residents
   i. Students and residents shall receive annual compliance training.
   ii. The forum and content shall be at the discretion of the School and consistent with the compliance training requirements set forth above.

VI. AUDITING AND MONITORING

a. Internal Review and Monitoring
   ii. Each School shall develop an internal monitoring plan to periodically assess compliance.
   iii. The University Compliance Office may implement programmatic reviews of compliance initiatives and monitoring plans of each School.

b. Clinical Documentation Review
   i. Each School that provides healthcare services shall develop a plan for conducting routine reviews of medical and billing records for a designated period in order to assess compliance with established standards of practice for documentation, coding and billing, and to provide education to providers and coders as applicable.

   ii. Reviews may also be conducted under the direction of the University Compliance Office, in consultation with the Office of the Vice President and General Counsel as necessary, for periodic risk assessment, or in response to a reported issue.

c. Key areas for monitoring and auditing that each School shall establish under this Program shall include:
   i. Privacy – Certain University information, whether in paper or electronic form, is considered sensitive. Employees that have access to personally identifiable information for students, patients, and/or employees should familiarize themselves with the applicable state laws pertaining to sensitive data, including the Family Educational Rights and Privacy Act (FERPA), the Health Insurance Portability and Accountability Act (HIPAA), the Gramm-Leach-Bliley Act (GLB), Indiana laws regarding sensitive data, and any privacy-related policies and procedures applicable to their unit. As applicable, Schools shall closely coordinate HIPAA privacy related matters with IU Health in accordance with the terms of the Support Services Agreement for HIPAA/HITECH Privacy and Security Program Management. Nothing in the Plan is meant to duplicate and/or supersede the terms of the aforementioned Support Services Agreement. Specific Indiana University guidance and policies related to privacy are accessible at http://www.iu.edu/~vpgc/compliance/hipaa-privacy-and-security/hipaa-

compliance-documents.shtml, https://protect.iu.edu/privacy/policies, and http://policies.iu.edu/.

ii. Security – Certain University information, whether in paper or electronic form, shall only be used for official University purposes. Every employee has a responsibility to maintain the security and confidentiality of University information, to prevent accidental or unauthorized disclosure, and to comply with information privacy and security policies and procedures. An employee may only access or disclose confidential information when acting within the scope of their employment, and as permitted by contract, state or federal law, regulation, and/or pursuant to an approved University Policy. The University also has specific guidance and policies related to security which may be found at https://protect.iu.edu/, http://policies.iu.edu/ and http://www.iu.edu/~vpgc/compliance/hipaa-privacy-and-security/hipaa-compliance-documents.shtml.

iii. Conflicts of Interests/Commitment/Relationship with Vendors – This is an area of risk that is especially important in the health care industry where close relationships involving third parties such as patients, vendors, payors and affiliates are common. The University promotes the principles of objectivity and impartiality in making decisions on behalf of the University. These principles require that safeguards are in place to prevent individual or institutional conflicts of interest in their assigned duties for the University. Key institutional policies include:

1. State Conflicts of Interest - http://policies.iu.edu/policies/categories/financial/purchasing/FIN-PUR-3.3-state-conflict-of-interest-for-procurement-transactions.shtml;
2. Human Resources - http://policies.iu.edu/policies/categories/human-resources/conduct/coi.pdf;
3. Research - http://policies.iu.edu/policies/categories/academic-faculty-students/conditions-academic-employment/financial-conflicts-of-interest-in-research.shtml;
4. Faculty Conflict of Commitment - http://policies.iu.edu/policies/categories/human-resources/conduct/coc.pdf

iv. Research Compliance – Regulatory oversight in the areas of human subject research, animal welfare, funding, research integrity, clinical research billing, and other related matters are coordinated through the Office of Research Compliance, http://www.researchcompliance.iu.edu/.

v. Waste, Fraud and Abuse – The elimination of waste, fraud and abuse is the responsibility of all University employees. Federal fraud and abuse laws seek to promote efficiency and avoid waste in federally funded programs, such as health

care programs like Medicare and Medicaid, and research programs supported by the U.S. Public Health Service.

vi. Other regulatory risks applicable to the health sciences as determined by Health Sciences Compliance Advisory Committee.

vii. High-level resources for compliance stakeholder include:

1. The University Policy website at http://policies.iu.edu/, which serves as a comprehensive source for current University-wide policies, as well a place to view policies under review or provide policy-related feedback.
2. The Compliance Matrix, available at http://www.higheredcompliance.org/matrix/, was created as part of the Higher Education Compliance Alliance and provides a comprehensive list of federal laws and regulations with which colleges and universities must comply, serving to illustrate the scope of the regulatory framework surrounding higher education.

VII. REPORTING SYSTEMS AND COMMUNICATION

a. Reporting Obligations

The University maintains an "open door" policy with respect to information regarding suspected non-compliance. Employees have an obligation to report any activity which they believe is in violation of any policy, regulation, or other legal requirement to one or more of the following persons: a supervisor or any member of management at the University, Compliance liaison or representative for their School, the Dean of their School, the Chief Compliance Officer and/or the Office of the Vice President and General Counsel.

b. Notification/Hotlines

The University has established the following forms of communication that may be used to report compliance issues or possible violations of compliance standards and policies.

- The University Compliance Office can be reached at (317) 274-2667 or comply@iu.edu.
- Anonymous reports can be made by calling IU's Anonymous Reporting Hotline through EthicsPoint: 888-236-7542; or online at: https://secure.ethicspoint.com/domain/en/report_custom.asp?clientid=17361

Though confidentiality cannot be assured, calls to the "hotline" remain confidential and anonymous to the extent possible. The "hotline" is operated in a manner to encourage candid disclosure by the caller of information such as a particular description of the activity in question, the area in which it has taken place, and the identity of the people who may have knowledge of the relevant facts. A record is maintained of any complaints made, and each complaint will be reviewed and/or investigated as appropriate.

c. Non-Retaliation

Indiana University prohibits retaliation against any individual who reports, in good faith, actual or suspected violations of the laws, regulations, or policies. See the University's Whistleblower Policy at http://policies.iu.edu/policies/categories/administration-operations/whistleblower/whistleblower.shtml. Though confidentiality cannot be assured, all reported violations will be handled with an appropriate level of confidentiality to ensure that the identity of the reporting individual (when known), and the person or persons involved in the suspected violation, is only given to those persons with a need to know.

VIII. CORRECTIVE ACTION

a. Corrective action plans shall be designed to address not only the specific issue identified, but also to mitigate the likelihood of similar problems occurring in the future. Corrective action plans may require certain activities to be handled in a designated way; that certain training or re-training be conducted; that restrictions be placed on the processes used by particular employees; or that the matter be disclosed to persons or entities outside the School or unit. Sanctions or discipline of individuals, up to and including termination, will be in accordance with University rules.

b. Each School is responsible for tracking compliance incidents and shall submit to the University Compliance Office a report on an annual basis for tracking and trending purposes. The annual report shall contain the date that the compliance issue or incident took place and/or was reported, a brief summary of the incident or issue, whether the issue is resolved or unresolved, and a summary of any corrective action taken.

IX. CONTACT FROM A GOVERNMENT OFFICIAL, AUDITOR, OR REGULATOR

Indiana University's commitment to compliance includes cooperation with all lawful inquiries, audits, inspections, and investigations by agencies of the federal, state and local government.

In the event of an unannounced audit or inspection or other non-routine Regulatory Review, your supervisor, the Compliance Officer for your department or school, and the University Compliance Office should be notified. Timing is of the essence as most Regulatory Reviews require responses be made within a short time frame. Therefore, providing notice regarding any unannounced and/or non-routine Regulatory Review is essential in the coordination of these efforts.

In the event an auditor or authorized official shows up unannounced at your office, here are key tips to remember:

a. Be cordial – let the auditor/agent know that the University's intent is to cooperate with the request.
b. Verify credentials – ask for official identification and note down in writing the name of the individual(s), firm or agency name, and firm or agency contact information.
c. Ask the auditor/authorized official if they can provide information regarding the nature of the request, audit or inspection.

d. Inform your supervisor and the Compliance Officer for your department or school and contact the University Compliance Office immediately.

The Office of the Vice President and General Counsel should be notified if a search warrant, subpoena, legal-related demand for information, complaint or other legal document (other than a routine request for patient records) is received.