

Infirmary Health System, Inc.

Corporate Integrity Agreement (CIA)



Overview

This course provides information regarding the Corporate Integrity Agreement entered into between Infirmarium Health System, Inc. and the Office of Inspector General of the United States Department of Health and Human Services, executed and effective as of July 18, 2014.

U.S. versus Diagnostic Physicians Group, P.C

In 2011, a qui tam, or what is more commonly known as a whistleblower, suit was filed against Infirmary Health System, Inc. (IH), Infirmary Medical Clinics, P.C. (IMC), IMC – Diagnostic & Medical Clinic, P.C., and IMC – Northside Clinic, P.C., alleging false claims were submitted to the United States resulting from the financial relationship between IMC – Diagnostic and Medical Clinics, P.C. and Diagnostic Physicians Group, P.C. (an independent physician group unaffiliated with IH).

Settlement

In July 2014, IH settled the whistleblower suit and agreed to pay the sum of \$24.5 million to resolve all claims with the United States. In conjunction with the settlement, IH entered into the Corporate Integrity Agreement.

The settlement allowed IH to focus on its mission and the provision of healthcare without the distraction and expense of the lawsuit.

The settlement resulted in no admission of any wrongdoing on the part of IH and its affiliates.

Definitions

Arrangements

- ▶ Every arrangement or transaction that involves payment or receipt of anything of value between IH and any actual or potential health care referral source resulting in payments made by a Federal health care program

Definitions

Covered Persons

▶ Includes:

- a) All owners, officers, and employees of IH;
- b) All contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of IH, excluding vendors whose sole connection with IH is selling or otherwise providing medical supplies or equipment to IH and who do not bill the Federal health care programs for such medical supplies or equipment; and
- c) All physicians and other non-physician practitioners who are members of IH's active medical staff.

Definitions

Arrangements Covered Persons

- ▶ A Covered Person involved with the development, approval, management or review of IH's Arrangements and each member of the IH Board of Directors.

Corporate Integrity Agreement (CIA)

IH will operate under the CIA for five years. One focus of the CIA is on contractual arrangements. However, there are other obligations as well.

CIA Obligations

- ▶ Compliance Responsibilities
 - Compliance Officer
 - IH Executive Compliance Committee
 - IH Board of Directors
 - Senior Management
- ▶ Written Standards
- ▶ Training & Education
- ▶ Compliance with Anti-Kickback Statute & Stark Law
- ▶ Independent Review Organization
- ▶ Risk Assessment & Mitigation Process
- ▶ Disclosures Program (AKA Hotline)
- ▶ Ineligible Person Screening
- ▶ Repayment of Overpayments
- ▶ Reportable Events

Compliance Responsibilities

The CIA requires that IH have a Compliance Officer (CO) who is a member of senior management, who reports directly to the Chief Executive Officer, is not subordinate to General Counsel or the Chief Financial Officer and, who does not have job responsibilities that interfere with his ability to perform the duties of the CIA.

The Compliance Officer's responsibilities include:

- ▶ Developing policies, procedures and practices to ensure compliance with the CIA;
- ▶ Making periodic reports to the Board of Directors;
- ▶ Monitoring the day to day compliance activities engaged in by IH; and
- ▶ Reporting obligations under the CIA.

Compliance Responsibilities

As a result of the CIA, in August of 2014, the Executive Compliance Committee began meeting on a bi-monthly basis rather than quarterly. Membership on the Committee includes the Compliance Officer and numerous other members of senior management.

The Executive Compliance Committee oversees the analysis of IH's risk areas and the monitoring of internal and external audits and investigations.

Compliance Responsibilities

The IH Board of Directors is responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations under the IH CIA.

Each year the Board will submit to the OIG a resolution stating that, to the best of its knowledge, IH has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.

Compliance Responsibilities

Certain members of IH senior management (CEO, CFO, EVP Physician Services) are specifically expected to monitor and oversee activities within their areas of authority and are required to certify annually that the departments under their authority are in compliance with Federal health care program requirements and with the obligations of the CIA.

Written Standards

Revisions to the IH Business and Professional Standards of Conduct were required within 120 days of entering into the CIA. The revisions include:

- IH's commitment to compliance with Federal health care program requirements;
- Requirement that all IH Covered Persons are expected to comply with Federal health care program requirements and IH policies and procedures;
- IH covered persons are expected to report suspected violations of any Federal health care program requirements or IH policies and procedures to the Compliance Officer or to the Corporate Compliance Department; and

Written Standards

- ▶ The right of all IH covered persons to use the Compliance Hotline and Confidential Intranet Email and IH's commitment to non-retaliation, and to maintain as appropriate confidentiality and anonymity with respect to disclosures.
- ▶ The IH Business and Professional Standards of Conduct were revised and adopted by the IH Board of Directors in August 2014.
- ▶ The CIA requires that IH Policies and Procedures include policies that address compliance with Anti-Kickback Statute and Stark Law. The policies must be distributed to Covered Persons and must be reviewed annually and revised as appropriate.

Training & Education

IH has developed a written Compliance Training Plan that outlines the steps that IH will take to ensure that:

- ▶ All Covered Persons receive adequate training regarding IH's CIA requirements, IH's Compliance Program, and Code of Conduct.
- ▶ All Arrangements Covered Persons receive adequate training in:
 - Arrangements that potentially implicate Anti-Kickback Statute or Stark Law
 - IH policies and procedures regarding Arrangements and Focus Arrangements
 - Personal obligation of each individual involved in development, approval, management or review of IH Arrangements
 - Legal sanctions under the Anti-Kickback Statute and Stark Law, and
 - Examples of Anti-Kickback Statute and Stark Law

Compliance with Anti-Kickback Statute & Stark Law

The CIA requires that IH design procedures to ensure that existing and new contracts and arrangements do not violate the Anti-Kickback Statute or Stark Law, including a method of monitoring contracts and arrangements for compliance and written certifications that parties to contracts and arrangements will not violate the Anti-Kickback Statute and Stark Law with respect to the performance of the arrangement.

Legal Independent Review Organization (IRO)

IH was required to engage a law firm as an IRO to perform an arrangements review and to prepare a written report of the findings to the OIG annually during the term of the CIA. The IRO chosen by IH is The Sanders Law Firm, P. C.

Risk Assessment and Mitigation Review

IH is required to develop and implement a centralized annual risk assessment and mitigation process to identify and address risks associated with Arrangements.

The review must include a process for:

- ▶ Identifying and prioritizing risks;
- ▶ Developing remediation plans in response to those risks; and
- ▶ Tracking results to assess the effectiveness of the remediation plans.

Compliance Disclosures

The CIA requires that IH establish a disclosure program that includes a mechanism to report any suspected violations of Federal health care programs associated with IH's policies, conduct, practices or procedures. The CIA also requires that the disclosure process must allow individuals reporting to remain anonymous and must emphasize IH's non-retribution and non-retaliation policy toward any individuals using the disclosure process.

Ineligible Person Screening

IH is required to implement policies and procedures to ensure that all prospective and current Covered Persons are not ineligible to participate in federally funded programs.

All Covered Persons were screened against the OIG's List of Excluded Individual/Entities (LEIE) and the General Services Administration's System for Award Management (SAM) exclusion lists within 90 days after entering into the CIA. Thereafter, the LEIE must be screened monthly and the SAM screening must occur annually.

Repayment of Overpayments

IH was required to develop and implement policies and procedures regarding identification, quantification and repayment of Overpayments received from any Federal health care program. Overpayments should be repaid within 60 days after identification of the overpayment and steps should be taken to prevent similar overpayments within 90 days after identification of same.

Reportable Events

Events that must be reported to the OIG within 30 days include:

- ▶ Substantial overpayments
- ▶ Probable violation of any Federal health care program requirements
- ▶ Employment or contracting with a Covered Person who is an Ineligible Person
- ▶ Filing of bankruptcy
- ▶ Sale of business, business unit or location
- ▶ Change or closure of business, business unit or location
- ▶ Purchase or establishment of new business, business unit or location

Additional Information

- ▶ The complete CIA can be found at http://oig.hhs.gov/fraud/cia/agreements/Infirmary_Health_System_07182014.pdf
- ▶ You may contact Danny Harrison, IH Compliance Officer, at danny.harrison@infirmaryhealth.org if you have additional questions.

Infirmary Health System, Inc.

Corporate Compliance Plan

Plan Purpose:

Infirmary Health (“IH”) acknowledges the risks that are involved when fraud, abuse and waste occur in the health care environment. In an effort to detect and minimize these risks within the System, IH has adopted a Corporate Compliance Plan. The Plan was developed based on guidance provided by Federal health care authorities.

The IH Corporate Compliance Plan includes the elements outlined in the Health and Human Services, Office of Inspector General's Model Plan, the 2005 OIG Supplemental Compliance Guidance, Federal Sentencing Guidelines issued in 2004, and the Deficit Reduction Act of 2005. The elements are:

- High-level Oversight of Compliance Responsibilities
- Compliance Standards and Policies
- Due Care in Retaining Trustworthy Individuals Throughout IH
- Education and Training
- Monitoring, Auditing and Reporting
- Enforcement and Discipline
- Response and Prevention
- Risk Assessment
- Federal and State False Claims Acts

The IH Compliance Officer, Danny Harrison, directs the operation of the Compliance Plan. Any questions or concerns regarding this Plan should be brought to his attention.

The Executive Compliance Committee provides direction and guidance, such as ensuring that the IH mission, vision, and goals are aligned with regulatory requirements.

The Executive Compliance Committee works with the Compliance Department and provides assistance by prioritizing compliance requirements and providing leadership for the implementation of plans.

Infirmiry Health System, Inc.

Business and Professional Standards of Conduct

Introduction

The Infirmary Health System Business and Professional Standards of Conduct provide guidance for us in the workplace.

These Standards apply to every person associated with IH, including officers, employees, board members, physicians, non-physician practitioners, volunteers, vendors, contractors, subcontractors, and agents. These persons are referred to as Covered Persons.

IH and all Covered Persons are obligated to understand and comply with these Business and Professional Standards of Conduct and must commit to full compliance with all Federal health care program requirements and IH Policies and Procedures.

Regulatory Compliance

IH will not tolerate activities of fraud and abuse related to its operations and relationships with outside third parties. Some examples of activity that are considered fraud or abuse are:

- ▶ Illegal patient referrals
- ▶ Filing claims for services not rendered
- ▶ Duplicate billings
- ▶ Billing the wrong codes
- ▶ Providing unnecessary services
- ▶ Improper business relationships with third parties
- ▶ Noncompliant arrangements and contracts with potential or actual referral sources of health care business

Regulatory Compliance

Compliance with federal and state laws requiring submission of bills, statements, and reports and other information to the government is a condition of employment.

All Covered Persons are required to make good faith reports of any identified issues or questions associated with IH's policies, conduct, practices, or procedures with respect to Federal or State health care programs believed by the individual to be a potential violation of criminal, civil, or administrative law. These reports can be made to the Compliance Officer, Compliance Hotline, or any member of Executive Leadership.

Regulatory Compliance

Covered Persons are also required to recognize and adhere to all federal and state laws that prohibit the submission of false claims and statements and to acknowledge the commitment of IH to be compliant with federal and state laws.

Disclosure Program

IH has established a disclosure program that includes a confidential Compliance Hotline and a mechanism to send confidential emails to the Compliance Office via the IH Intranet.

The confidential Compliance Hotline numbers are (251) 435-2006 and toll free at 1(800) 431-2590.

Disclosure Program

To send a Confidential email to the Compliance Department, access the IH Intranet, select the Compliance–HIPAA–HITECH tab on the left hand side of the screen under “My Applications”, then select “Corporate Compliance” and then “Compliance Issue Submission.” Send the email by following the directions on the screen.

When using the Compliance Hotline or Confidential Compliance Email, you do not have to give your name and you will be protected against retaliation.

Non-retaliation & Non-retribution

IH prohibits retaliation, retribution or any form of harassment against any Covered Person who makes a good faith report of a compliance issue. Anyone who is involved in any act of retaliation or retribution against an employee who has reported a suspected violation is subject to disciplinary action.

Any concerns about possible retaliation, retribution or harassment should be brought to the attention of the Compliance Officer or reported through the Compliance Hotline or Confidential Compliance Email.