

Corporate Integrity Agreements HCCA—Boston

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Corporate Integrity Agreement

- General Requirements
 - Compliance Officer and Committee
 - Training and Education of Covered Persons
 - Written Policies and Procedures
 - Disclosure of Overpayments and Probable Violations of Civil, Criminal and/or Administrative Law
 - Review Procedures
 - Disclosure Program
 - Ineligible Persons Screening
 - Annual Reports

CIA – Emerging Trends

- Fewer CIAs for demonstrated effective compliance programs, but increased oversight for new CIAs
- Increasing Accountability for Board and Management
- Hiring of Compliance Experts
- Increasing Audit Scope
- Increased Samples Sizes and Frequencies
- Claw-back provisions (i.e., the executive financial recoupment program)
- Increased Focus on Risk Assessment Process
- Extrapolation



Compliance Officer's Authority



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 In 2008, Elin Baklid-Kunz raised legal concerns about doctor payments at Halifax Health. The problems weren't fixed. So she filed a whistle-blower lawsuit. Six years later the hospital has tentatively agreed to settle for \$85 million. What lessons can other hospitals learn? Page 16

CIA – What’s Reportable?

1. *Definition of Reportable Event. For purposes of this CIA, a “Reportable Event” means anything that involves:*

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

CIA- Board Responsibility

3. *Board of Directors Compliance Obligations. The Board shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board shall, at a minimum, be responsible for the following:*

- a. The Board shall meet at least quarterly to review and oversee ABCs’s Compliance Program, including but not limited to the performance of the Compliance Officer and other compliance personnel. The Board shall evaluate the effectiveness of the Compliance Program, including, at a minimum, by receiving updates about the activities of the Compliance Officer and other compliance personnel and updates about adoption and implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with applicable Federal health care program and FDA requirements.

CIA -Board Certifications

b. For each Reporting Period of the CIA, the Board shall adopt a resolution, signed by each individual member of the Board, summarizing its review and oversight of xxx's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Board of Directors has made a reasonable inquiry into the operations of xxx's Compliance Program as applicable to the CIA (including its Appendices) for the time period **[insert time period]**, **including the performance of the Compliance Officer** and the compliance personnel who are Covered Persons under this CIA. The Board has concluded that, to the best of its knowledge, xxx has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA."

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at GSK.

CIA - Management Certifications

6. *Management Accountability and Certifications:*

In addition to the responsibilities set forth in this CIA for all Covered Persons, certain officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable business unit is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA.

These Certifying Employees shall include, at a minimum, the following: President, the heads of commercial business units; Vice President, Senior Vice President, and, to the extent that a business unit performs Covered Functions and not covered by the certification of one of above listed individuals, such other executives, vice presidents, and directors of business units as would be necessary to ensure a Certifying Employee from each business unit.

CIA - Management Certifications

For each Reporting Period, each Certifying Employee shall sign a certification that states:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and GSK policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the _____ [insert name of department or functional area] of GSK is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States."

CIA - Management Certifications

If any Certifying Employee is unable to provide such a conclusion in the certification, Certifying Employee shall provide written explanation of the reasons why he or she is unable to provide the certification outlined above and steps being taken to address the issue(s) identified in the certification.

Thank You for Listening!

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