



**Using  
Corporate Integrity  
Agreements (CIAs) to  
Strengthen Your Compliance  
Program**

HCCA  
Hawaii Regional Conference  
2012

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**Topics**

- Challenges of Implementing CIAs
- CIA Requirements
- How does my Compliance Program compare?

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**Challenges of Implementing CIAs**

- Relevant Covered Person
- Deadlines for Initial Implementation
- Training Requirements
- Provider Notice
- Payment-Posting Requirements
- Independent Review Organizations

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### Relevant Covered Persons

- CIAs require that companies provide specified written policies and procedures and training to individuals who meet the CIA definition of “Relevant Covered Persons.”

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### Deadlines for Initial Implementation

- CIAs typically require companies to develop and implement codes of conduct, policies and procedures, and training within specific timeframes following the effective date of the CIAs.

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### Training Requirements

- CIAs require companies to certify that they have trained all Relevant Covered Persons.

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**Health Care Provider (HCP) Notice**

- Some CIAs require companies to send HCPs a letter briefly describing the terms of the settlement between the Government and the company and the alleged misconduct at issue.

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**Payment-Posting Requirements**

- Certain CIAs require companies to track and post on company Websites information about payments made by the companies to HCPs.

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**Independent Review Organization (IRO)**

- CIAs require that companies annually retain outside IROs to conduct reviews of specified items and systems.

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**Board Resolutions and Certifications**

- CIAs may require that board members annually pass and sign a resolution confirming, if they can, that the company has implemented an effective compliance program.
- CIAs may require that boards retain outside compliance experts to independently assess the company's compliance program.

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**CIA Requirements**

Addresses the Specific Facts at Issue

- Includes:
  1. Hire a compliance officer/appoint a compliance committee
  2. Develop written standards and policies
  3. Implement a comprehensive employee training program
  4. Retain an independent review organization to conduct annual reviews
  5. Establish a confidential disclosure program
  6. Restrict employment of ineligible persons
  7. Report overpayments, reportable events and ongoing investigations/legal proceedings
  8. Provide an implementation report and annual reports to the OIG on the status of the entity's compliance activities
- Typically CIA = 5 years

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**CIA # 1**

CORPORATE INTEGRITY AGREEMENT  
 BETWEEN THE  
 OFFICE OF INSPECTOR GENERAL  
 OF THE  
 DEPARTMENT OF HEALTH AND HUMAN SERVICES,  
 AND  
 MRI RADIOLOGY NETWORK, P.A.,  
 UNIVERSITY MRI OF BOCA RATON, INC.,  
 UNIVERSITY MRI OF BOCA RATON, L.L.C.,  
 WEST BOCA OPEN MRI, INC.,  
 EXPERT RADIOLOGY RESEARCH AND EDUCATIONAL FOUNDATION, INC.,  
 UNIVERSITY MRI LEASING, L.L.C.,  
 UNIVERSITY MRI RADIOLOGY ASSOCIATES, P.L.,  
 EXPERT RADIOLOGY NETWORK, P.A.,  
 NEUROSCIENCE ACQUISITION, L.L.C.,  
 UNIVERSITY MRI RESEARCH AND EDUCATIONAL FOUNDATION, L.L.C.,  
 UNIVERSITY IMAGE GUIDED THERAPY CENTER, L.L.C.,  
 AND  
 FRED L. STEINBERG, M.D.

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**CIA # 1**

- **Issue:** Violations of the Anti-Kickback Statute or the Stark Law
- **CIA Requirements**
  - Arrangements Database
  - Internal review and approval process
  - Tracking of remuneration to and from sources of health care business or referrals

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**Arrangements Database**

- **Database Existence**
- **Keeper of the Database**
  - Management
  - Finance
  - Legal
- **Compliance Monitor**
  - Quarterly Review
    - Expired
    - Signed by both parties

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**Review & Approval Process**

- **Policies & Procedures**
  - Templates
  - Mandatory Legal Review Provider Arrangements
- **Fair Market Value**
  - Process
- **Internal Processing Form**
  - Approval
    - Senior Management
    - Legal
    - Finance

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### Tracking Remuneration

- **Gifts Policy**
  - Referral Sources
- **Tracking Methodology**
  - Existence
- **Centralized**
  - Database
    - Maintenance/Responsibility
  - Web Based System
- **Decentralized**
  - Server Database
  - Manager Responsibility

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### Arrangements Training

“at least three hours of Arrangements Training”

- Arrangements that potentially implicate the Anti-Kickback Statute or the Stark Laws
- The entities' policies, procedures and other requirements relating to Arrangements
- The personal obligation of each individual involved in the entities' Arrangements
- The legal sanctions under the Anti-Kickback Statute and the Stark Law
- Examples of violations of the Anti-Kickback Statute and the Stark Law

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### CIA # 2

CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
TENET HEALTHCARE CORPORATION

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### Clinical Quality Department

- **Personnel**
  - Chief Medical Officer
  - Senior Officers
  - Clinical Quality Staff
- **Monitor clinical quality at all Tenet Hospitals**
  - Commitment to quality program
  - Clinical audits
  - Physician credentialing
  - Privileging
  - Peer Review
  - Utilization Management and Review
  - Quality metrics/scorecard/performance standards

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### Quality, Compliance and Ethics Committee of the Board of Directors

- **Directors**
- **Review and oversight**
- **Meeting frequency**
- **Responsibilities**
  - Staff performance
  - Departments
  - Compliance program effectiveness
  - Resolution
    - Reasonable inquiry
  - Independent expert

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### Written Standards

- **Code of Conduct**
- **Clinical Quality**
  - Documentation in medical records
  - Measuring, analyzing and tracking
  - Monitoring effectiveness
  - Performance improvement priorities
    - High-risk
    - High-volume
    - Problem-prone
  - Medical errors
  - Quality assessments/audits
  - Reporting

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### Compliance Education

- **Two hours of general training**
- **Three hours of clinical quality training**
  - All clinical quality covered persons
- **Certification**
  - Written
  - Electronic

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### CIA Site Visit by the OIG

- **Primary purpose of a site visit is to provide the OIG with an opportunity to observe the daily operations of the entity and its compliance program.**

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### CIA Site Visit by the OIG

- **Presentation by the entity:**
  - An overview of the entity's corporate structure and operational organization
  - An overview of the entity's coding and billing systems
  - An overview of the entity's compliance efforts
  - A discussion of compliance efforts specific to coding, billing and medical record documentation
- **Tour of the pertinent portions of the facility**
- **Review**
  - Disclosure log
  - Training sign-in sheets
  - Ineligible persons screening results and other pertinent documentation

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### CIA Site Visit by the OIG

- **Employee Interviews**
  - Regarding the entity's compliance program
  - Adherence to the terms of its CIA or integrity agreement
- **Discussions**
  - The entity's annual report
  - CIA deficiencies
  - Corrective actions
  - The OIG's site visit observations

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### Comments from Compliance Officers with CIAs

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### Compliance Officer # 1

- **What were the positive effects of having a CIA?**
  - "The CIA got the Board's attention, a new structure was created at the Senior Management level and the position reports directly to the Board with a dotted line to the CEO.
  - Formal Board, leadership and management education was developed and has continued with greater appreciation.
  - A greater focus was placed on disclosure and "getting it right" vs. getting it done. After five years, employees, management and the majority of physicians understand the value."

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**Compliance Officer # 1**

- **What were the negative effects?**
  - Our local newspaper added a statement on every positive article, "and by the way, is under a settlement agreement or CIA and paid millions of dollars in fines."

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**Compliance Officer # 1**

- **What effect did the CIA have on management's opinion of the compliance program?**
  - "The stigma of bureaucratic imposition to understanding the logical value based on a proactive approach has been the greatest improvement in opinion."

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**Compliance Officer # 1**

- **How did the community react to the CIA?**
  - "The community reacted very negatively.
  - Patients were skeptical when they received bills, middle management in the community were skeptical.
  - We invited the press into our organization in about the third year of our CIA to combat the negative press and inform them of "lessons learned" in a positive article; however they refused."

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**Compliance Officer # 2**

- **What were the positive effects of having a CIA?**
  - “It meant that I was just the messenger....If we don’t do this we’ll have to report it to the OIG.
  - It also forces a focus on resolving problems that you don’t have otherwise. When you have 30 days to investigate and report an issue to the IG and have to certify at the end of the period that you lived up to the requirements of the CIA....You get it done.”

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**Compliance Officer # 2**

- **What were the negative effects?**
  - “Not necessary a negative, but I don’t think that CIAs have an effect on the culture of the organization. In fact in some cases they may make affecting the culture more difficult.”

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**Compliance Officer # 2**

- **What effect did the CIA have on management's opinion of the compliance program?**
  - “I’ve seen the most impact on management’s opinion of the compliance program in situations where I’ve been able to help the organization avoid some or all components of a CIA.
  - I am not sure the CIA is a good thing for affecting the culture....It does, however, force your hand as far as getting things done and this is a good thing from a standpoint of getting management buy in. You don’t have a choice.”

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**Compliance Officer # 2**

- **How did the community react to the CIA?**
  - "Don't think that they know or care, honestly."

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How does my Compliance Program compare? Have I done enough?

- <http://www.youtube.com/watch?NR=1&v=aeHIE-Zn-Ig&feature=endscreen>

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**QUESTIONS**



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