

Corporate Integrity Agreement Design and Enforcement: How to Mitigate Liability

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Disclaimer

- The materials and views expressed in this presentation are the views of the presenters and not necessarily the views of the North Shore-LIJ Health System, Dignity Health or the OIG.

GOALS OF THE PRESENTATION

- What compliance officers and attorneys can learn from CIAs
- How to effectively manage a CIA
- How to work successfully with your OIG monitor
- Review trends and developments in CIAs
- Tips for assessing compliance program effectiveness



What is a Corporate Integrity Agreement ?

- Agreement with DHHS-OIG in connection with civil health care fraud settlement
- Requires entity to implement (or continue) certain integrity obligations for a period of years
- Obligations are based on 7 elements of an effective compliance program
- In exchange for release of the OIG's permissive exclusion authority

Purpose of CIAs

“Corporate integrity agreements [provide] the OIG with a mechanism to advise hospitals concerning what it feels are acceptable practices to ensure compliance with applicable Federal and State statutes, regulations and program requirements.”

- 63 FR 8991 (February 23, 1998)

“CIAs are designed to put the entity at the frontline of promoting compliance.”

- Gregory E. Demske, Chief Counsel to the IG, OIG Outlook 2013 audio podcast

CIA Structure

- Most CIAs have common elements, but each is tailored to address the specific facts at issue (*e.g.*, a CIA for a pharmaceutical manufacturer is generally different than a CIA for a hospital)
- Often attempt to accommodate and recognize the elements of any pre-existing voluntary compliance program
- Typically lasts 5 years

CIA Requirements

- Compliance Program Elements
 - ✓ Compliance Officer and Committee
 - ✓ Code of Conduct/Policies and Procedures
 - ✓ Training and Education
 - ✓ Review Procedures
 - ✓ Disclosure Program
 - ✓ Ineligible Persons Screening

CIA Requirements

- Notification of government investigations/legal proceedings
- Repayment of identified overpayments within 60 days
- Reportable events
- Changes to business units/locations (successor liability issues)
- Implementation/Annual Reports

CIA Requirements

- OIG inspection, audit, and review rights
- Document and record retention
- Disclosures under FOIA
- Breach and Default
 - Stipulated Penalties
 - Exclusion for Material Breach

OIG Roundtables

- Pharmaceutical Compliance Roundtable (February 23, 2012)
<http://oig.hhs.gov/compliance/compliance-guidance/docs/Pharmaceutical-Compliance-Roundtable.pdf>
- Focus on Compliance: The Next Generation of Corporate Integrity Agreements
http://oig.hhs.gov/compliance/compliance-guidance/docs/Focus_on_Compliance.pdf

CIA – Recent Developments

- Board of Directors Compliance Obligations
- Management Certifications
- Training Plan
- Review Procedures – Larger Sample Size, Risk-Based Reviews, Extrapolation
- Risk Assessment
- Employee and executive incentive compensation
- Executive financial recoupment program

OIG Compliance Resources

- Compliance Education Materials
<http://oig.hhs.gov/compliance/101/index.asp>
- CIA Compliance Resources
<http://oig.hhs.gov/compliance/corporate-integrity-agreements/resources.asp>
- Compliance Program Guidance
<http://oig.hhs.gov/compliance/compliance-guidance/index.asp>
- Compliance Resource Material
<http://oig.hhs.gov/compliance/compliance-guidance/compliance-resource-material.asp>

Tips for Effectively Managing a CIA

- Identify a core team of individuals from compliance, legal, and other departments to manage and oversee CIA obligations
- Schedule weekly or monthly meetings to track CIA implementation
- Begin working immediately (even before the CIA has been executed)
 - The first 120 days are critical

Tips for Effectively Managing a CIA

- Engage in open dialogue with your monitor
 - If a particular obligation is extremely challenging or unworkable, explain the challenge and suggest alternatives that may satisfy the overall intent
 - When in doubt, ask your monitor
- Thoroughly vet IRO candidates

Practical Tips for Working With Your OIG Monitor

- Make sure you are familiar with the requirements of the CIA
- Keep lines of communication as open as possible from the very beginning
- If you need clarification or modification, ask and explain why

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Practical Tips for Working With Your OIG Monitor

- Err on the side of transparency
- Don't wait until the last minute to request an extension of time
- Provide narrative/context with any disclosures or reports submitted
- Allow IRO to be independent but manage the process for potential obstacles, delays, etc.

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Methods to Assess a Compliance Program

Method	Pros	Cons
Self-Assessment	<ul style="list-style-type: none"> • Cost effective • Knowledgeable • Easier to organize 	<ul style="list-style-type: none"> • Lack of independence • Potential bias • Trend towards external
Peer Review	<ul style="list-style-type: none"> • Cost effective • Practical guidance • Learning opportunity 	<ul style="list-style-type: none"> • Difficult to find partner • Confidentiality • Potential bias if co-peer
Outside Consultant	<ul style="list-style-type: none"> • Breadth of client base • Independence • Credible if reputable firm used 	<ul style="list-style-type: none"> • Cost • Increase in process time • “Specific organization” operational expertise
Government Review	<ul style="list-style-type: none"> • Free if voluntary • Government insight • Good enough for government, good enough for us! 	<ul style="list-style-type: none"> • Costly if an investigation • Not all government agencies view issues the same • Risk if program fails • Disclaimer on “effective”

Some Ways to Measure Effectiveness

Item	2014 Results
<ul style="list-style-type: none"> ▪ Active Compliance Help-Line 	<ul style="list-style-type: none"> ▪ Over [X] calls ▪ Within industry average ▪ All issues resolved
<ul style="list-style-type: none"> ▪ Effective compliance training program 	<ul style="list-style-type: none"> ▪ ~ [XX]% completed the training ▪ Won national award ▪ ~ [XX]% of employees found it effective ▪ [XX]% of employees received a passing test score
<ul style="list-style-type: none"> ▪ Strong voluntary disclosure program*** 	<ul style="list-style-type: none"> ▪ [X] disclosures - ~ \$X million
<ul style="list-style-type: none"> ▪ Robust audit function ▪ Implemented new data mining tools 	<ul style="list-style-type: none"> ▪ Conducted [X] coding audits ▪ Confirmed [X]’s focus is correct ▪ Decreased error rate by [X] ▪ All CAPs completed
<ul style="list-style-type: none"> ▪ Written policies, procedures, standards of conduct 	<ul style="list-style-type: none"> ▪ [XX]% completed annual Code of Conduct certification ▪ [X] revised or new compliance policies

Some Ways to Measure Effectiveness	
Item	2014 Results
<ul style="list-style-type: none"> ▪ Employees Awareness of Compliance Program 	<ul style="list-style-type: none"> ▪ [X]% employees knows the Compliance Officer by name ▪ [X]% of employees know how to contact the compliance office ▪ [X]% do not fear retaliation
<ul style="list-style-type: none"> ▪ Risk Assessment and Work Plan Process 	<ul style="list-style-type: none"> ▪ Formal semi-annual review ▪ Interviewed and surveyed [X] employees and managers
<ul style="list-style-type: none"> ▪ Exclusion Screening Process 	<ul style="list-style-type: none"> ▪ Monthly review ▪ [X] findings ▪ Audit of this process was favorable
<ul style="list-style-type: none"> ▪ Favorable benchmarking against similar area providers 	<ul style="list-style-type: none"> ▪ Outside firms' praise
<ul style="list-style-type: none"> ▪ Outside validation by government agencies 	<ul style="list-style-type: none"> ▪ Government conducted [X] audits ▪ [X]% Financial error rate compared to revenue audited

COMPLIANCE PRE-AUDIT TIPS

- Organizational Overview
- Compliance Logs
- Compliance Training Records
- Exclusion Screening
- Audit Process and Results
- HIPAA - Risk Assessment

- Compliance Committees
- Governance
- Conflicts of Interest
- Physician Compensation
- Soft Factors
- Compliance Policies and Code of Ethical Conduct

AUDIT CHECKLIST
 Audit Satisfactory
 Nonconformances Found
 Observations Made

Questions



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