

## 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.

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### 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



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### 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

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### 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

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### 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

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**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

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**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

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**CIA Requirements**

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

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### 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](http://oig.hhs.gov/compliance/compliance-guidance/docs/Focus_on_Compliance.pdf)

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### 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

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### 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>

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### 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

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### 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

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

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### Some Ways to Measure Effectiveness

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

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

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### COMPLIANCE PRE-AUDIT TIPS

<input type="checkbox"/> Organizational Overview	<input type="checkbox"/> Compliance Committees
<input type="checkbox"/> Compliance Logs	<input type="checkbox"/> Governance
<input type="checkbox"/> Compliance Training Records	<input type="checkbox"/> Conflicts of Interest
<input type="checkbox"/> Exclusion Screening	<input type="checkbox"/> Physician Compensation
<input type="checkbox"/> Audit Process and Results	<input type="checkbox"/> Soft Factors
<input type="checkbox"/> HIPAA - Risk Assessment	<input type="checkbox"/> Compliance Policies and Code of Ethical Conduct




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## Questions



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