



Implementation and Effectiveness of Compliance Programs and Anatomy of a Corporate Integrity Agreement

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Today's Topics

- How do you implement an effective compliance program?
- Responsibilities of Boards of Directors (or stakeholders)
- Board Training and Why?
- Appendix – Resource List and Key Questions from Guidance

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How Do You Implement An Effective Compliance Program?

WHAT ARE THE PATHS? HOW DO WE MEASURE EFFECTIVENESS? WHAT GUIDANCE EXISTS?



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Tips for Implementing an Effective Compliance Program

- Foster a Culture of Compliance
- Create Useful Policies and Procedures
- Train Your Staff
- Promote Communication
- Take Appropriate Corrective Action
- Conduct Regular Audits
- Review Your Compliance Program

OIG - HEAT Provider Compliance Training Initiative - 2011

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Measuring Effectiveness

- Develop compliance program with benchmarks and measurable goals.
- Set up a system to measure how well you are meeting those goals.
- Involve the Board in creating the program and regularly update the Board regarding compliance risks, audits, and investigations.
- If one or more goals are not met, investigate why and how to improve in the future.
- Assess whether the compliance program has sufficient funding and support.

OIG - HEAT Provider Compliance Training Initiative - 2011

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Self-Evaluative Questions

- What metrics are used to evaluate compliance? How were the metrics selected?
- How does your organization identify gaps in quality and areas for quality improvement?
- Is the organization routinely conducting internal compliance audits?
- Is the organization's response to problems sufficient? Does it track corrective action plans to make sure the proposed changes are implemented?
- Has your compliance officer identified hurdles to compliance such as resource constraints or lack of management support?

OIG - HEAT Provider Compliance Training Initiative - 2011

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DOJ and Other Guidance

- Justice Manual, Principles of Federal Prosecution of Business Organizations
- United States Sentencing Guidelines
- Benczkowski Memorandum – Oct. 2018
- Rosenstein Update to Yates Memorandum – Nov. 2018
- Original Memorandum – Sept. 2015
- DOJ Guidance Document: Evaluation of Corporate Compliance Programs, Updated: April 2019.
 - Original publication – Feb. 2017



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Examples of Questions

B. Policies and Procedures

Design – What is the company’s process for designing and implementing new policies and procedures, and has that process changed over time? Who has been involved in the design of policies and procedures? Have business units been consulted prior to rolling them out?

Comprehensiveness – What efforts has the company made to monitor and implement policies and procedures that reflect and deal with the spectrum of risks it faces, including changes to the legal and regulatory landscape?

Evaluation of Corporate Compliance Programs – DOJ Updated 2019 Guidance

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Examples of Questions

C. Analysis and Remediation of Any Underlying Misconduct

Prior Indications – Were there prior opportunities to detect the misconduct in question, such as audit reports identifying relevant control failures or allegations, complaints, or investigations? What is the company’s analysis of why such opportunities were missed?

Remediation – What specific changes has the company made to reduce the risk that the same or similar issues will not occur in the future? What specific remediation has addressed the issues identified in the root cause and missed opportunity analysis?

Evaluation of Corporate Compliance Programs – DOJ Updated 2019 Guidance

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Measuring Compliance Program Effectiveness

HCCA OIG Resource Guide - January 17, 2017

- Measuring compliance program effectiveness is recommended by several authorities (including USSG)
- Outlines suggestions about what and how to measure each compliance program element
- “One size truly does not fit all”



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HCCA – OIG Resource Guide, Example, Element 1 (Standards, Policies, and Procedures)

What to measure	How to Measure
Accessibility	<ul style="list-style-type: none"> Review link to employee accessible website/intranet that includes the Code of Conduct Survey - Can you readily access or reference policies and procedures? (Yes/No/Don't know) Survey - How and where do employees actually access policies and procedures? Test key word search (searchable) Audit and interview staff to show policies
Actual Access	<ul style="list-style-type: none"> Audit how many actual "hits" on policies and procedures
Accessible language for code, standards & policies	<ul style="list-style-type: none"> Flesch Kincaid measuring standard – no more than 10th grade reading level

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Template Matrix of the Seven Elements

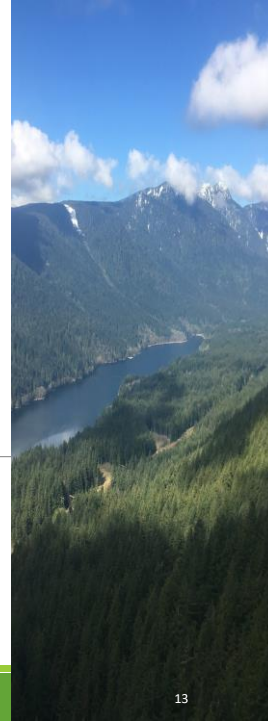
Element	Current State	Criteria/ Regulations	Gap	Action Item
Oversight	Code of Conduct	Per OIG.....	Code of Conduct is 500 pages long	Rework the Code of Conduct to make it shorter, easier to read, etc.

Use this tool to assist in developing an action plan with dates of completion

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Responsibilities of Boards of Directors (or stakeholders)



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Board Responsibilities for Implementing Effective Program

- Board oversight of a compliance program is one of three key Board responsibilities. Oversight includes:
 - Diversifying areas of expertise
 - Staying informed on risk areas and compliance issues
 - Attending compliance training and speaking to staff
 - Adapting to changing health care delivery and reimbursement risks
 - Board must be engaged and active, raise questions, and be “skeptical”.

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Board Responsibilities for Measuring Effectiveness

- Board's duty to inquire and make sure organization has an effective compliance program flows out of the traditional Board duties of care, loyalty, and obedience.
- Board must exercise its oversight to ensure "a corporate information and reporting system exists and the reporting system is adequate to assure the Board that appropriate information relating to compliance with applicable laws will come to its attention timely and as a matter of course.
- Board's responsibilities include self-assessing the Board and its committees, including:
 - Composition of compliance and quality committees
 - Board responses to systemic failures or lapses

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Compliance Infrastructure

- How does the Board encourage compliance in daily decision-making?
- Have compliance-related responsibilities been assigned across the appropriate levels of the organizations?
- Are goals periodically adjusted?
- Board has responsibility for protecting Compliance Officer's independence

OIG - HEAT Provider Compliance Training Initiative - 2011

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Compliance Accountability

Compliance Program Size and Structure

- Each health care entity's compliance program must be tailored to the specific needs, size, and complexity of the organization.

Audit, Compliance and Legal Functions

- Clearly define the roles, structure, and reporting relationships of the audit, compliance, and legal functions within the organization.

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Compliance Accountability

Board Reports

- Receive regular reports regarding the organization's risk mitigation and compliance efforts

Auditing Process

- Work with management to ensure the adequacy of the organization's auditing process

Compliance Culture

- Exercise creativity in implementing programs to ensure that compliance is a "way of life"

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Board Training and Why

HOW DO WE HELP OUR BOARD AND/OR STAKEHOLDERS UNDERSTAND HOW TO IMPLEMENT AN EFFECTIVE COMPLIANCE PLAN?



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How Does Board Training Help With Effectiveness?

- Demonstrates culture of compliance
- Demonstrates “fairness,” support for the program, and support for individual (in-house or outside experts) implementing and assisting with program
- Provides Board with practical tools to assess program effectiveness, e.g.,
 - Meetings with managers in lagging business units on strategies for improvement
 - Personal appearances by Board members at staff meetings
- Fulfills duty of care obligations

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What Should Your Board know?

- Board's Oversight Role
- Structural and Operational Information
- OIG CIAs as additional guidance source
- Focus on the 7 elements of compliance programs as specifically applied to the organization
- Not one size fits all

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Board's Oversight Role

Board needs to understand:

- Major risks to the organization
- How the Compliance Program functions
- That the Compliance Program is adequate to the task

How do they obtain that understanding?

- Education (like this)
- Questions from leaders
- Get regular reports from Compliance Officer
- Consider outside evaluation of effectiveness of the Compliance Program

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Board's Oversight Role *(cont.)*

- Direct communication with the compliance officer (CO) is critical.
- Generally, CO will report more regularly to compliance/audit committee and its committee chair.
- Some “executive sessions” are advisable.
(Keep eye on CMS Mandatory Compliance Plan requirements)

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Structural Information

1. How is Board structured to oversee compliance issues?
2. How frequently does Board receive reports about compliance issues?
3. Goals – what are the inherent limitations in the compliance program?

And how does the organization address the limitations?

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Structural Information *(cont.)*

4. Significant risks of the organization?
 - How were those risks determined?
 - How are new compliance risks identified and incorporated into the program?
5. What level of resources necessary to implement the compliance program envisioned by Board?
 - How has management determined the adequacy of the resources dedicated to implementing and sustaining the compliance program?

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Operational Information

- A. Code of Conduct
 - How has the Code of Conduct incorporated into corporate policies across organization?
 - How do we know Code understood and accepted?
 - Has management taken affirmative steps to publicize the importance of Code?

Management Support of Compliance Program is
Key.



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Operational Information *(cont.)*

B. Policies and Procedures

- Has organization implemented policies and procedures address compliance risk areas?
- Has organization established internal controls to counter those vulnerabilities?

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Operational Information *(cont.)*

C. Measures to Prevent Violations

1. Scope of compliance education and training across organization?
 - Has the effectiveness been assessed?
 - Policies/measures to enforce training requirements and to provide remedial training as warranted?
2. How is Board kept apprised of significant regulatory and industry developments affecting the organization's risk?

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Operational Information *(cont.)*

- D. Measures to Respond to Violations
1. What is process organization uses to evaluate and respond to suspected compliance violations?
 - How are reporting systems, such as the compliance hotline, monitored?
 2. Does organization have policies protecting "whistleblowers" and those accused of misconduct?

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Operational Information *(cont.)*

- What process is used to evaluate and respond to suspected compliance violations?
 - Preservation of relevant documents and information?
- What are the internal policies for reporting compliance violations to the Board?
- Are there policies that address reporting to government authorities of probable violations of law?

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CIA and Board Responsibilities

- Additional source for compliance guidance
- Additional source for suggested Board responsibilities and processes. For example, Tenet's CIA required Board to:
 1. Review/oversee compliance staff performance
 2. Annually review effectiveness
 3. Engage independent compliance consultant to assist Board in oversight ("Board expert")
 4. Submit resolution summarizing Board's review of compliance with CIA *and* Federal health care program requirements
- However, some CIAs do not include Board expert requirement where OIG has determined the Board already has sufficient **expertise and training**.

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Conclusion

- Stay abreast of rapidly evolving guidance from multiple federal agencies on how to implement and evaluate whether you have an effective compliance program
- Educate your Board
- Provide reports to Board and stakeholders to help them meet their oversight responsibilities
- Provide information needed by your Board to help it evaluate the effectiveness of your compliance program
- Ultimately, a health care organization with a Board engaged around compliance is a healthier organization for the long term

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Questions?

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Appendix – Resource List and Key Questions from Guidance



Resource List

- Justice Manual, Principles of Federal Prosecution of Business Organizations
- United States Sentencing Guidelines, Chapter 8, Sentencing of Organizations, Effective Compliance and Ethics Program
- AHIA/OIG, Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors (June 27, 2007)
- HEAT Provider Compliance Training Initiative (2011) (videos, podcasts, handouts, etc.)
- OIG/AHIA/AHIA/HCCA: Practical Guidance for Health Care Governing Boards on Compliance Oversight (April 2015)
- DOJ, Yates Memorandum (Sept. 2015); Rosenstein Update (Nov. 2018)
- DOJ Criminal Division, Fraud Section, "Evaluation of Corporate Compliance Programs" (Feb. 2017); Updated (April 2019)
- HCCA/OIG, Measuring Compliance Program Effectiveness: A Resource Guide (March 27, 2017) - <https://oig.hhs.gov/compliance/compliance-resource-portal/files/HCCA-OIG-Resource-Guide.pdf>
- DOJ, Benczkowski Memorandum (Oct. 2018)

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Risk Assessment

- Does the compliance program address the significant risks of the organization?
- How were those risks determined and how are new compliance risks identified and incorporated into the program?
- Ensure annually the documented risk assessment has been communicated to oversight committee
- Is there a risk based work plan that covers compliance plan elements with board approval and regular reporting on those projects to board?

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Written Standards

- Has the organization implemented policies and procedures that address compliance risk areas and established internal controls to counter those vulnerabilities?

Code of Conduct:

- How has it been incorporated into corporate policies across the organization?
- How do we know employees understood and it has been accepted across the organization?
- Has management taken affirmative steps to publicize the importance of the Code to all of its employees?

<https://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRsceGuide.pdf>

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Training

- What is the scope of compliance-related education and training across the organization?
- Does the organization provide risk area specific training to employees designated to be in high risk positions?
- Does the organization have an established compliance training plan? And the organization assures that training is completed according to the established plan?
- Has the effectiveness of such training been assessed?
- What policies/measures have been developed to enforce training requirements and to provide remedial training as warranted?
- How is the Board educated on risks and areas of concern?

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Audit and Monitoring

- Does the work plan have both audits and monitoring?
- Are proactive reviews completed of coding, contracts and quality of care?
- Is the audit and monitoring plan reviewed annually? Approved by Board?
- Does each audit developed with an audit program or focus that is documented and validated prior to completing?
- Are the audits assessed for systemic issues?
- Are corrective action plans presented and monitored by the Board?

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Compliance Officer/Role/Culture

- Is there open communication and feedback from employees to the compliance department?
- Is the compliance officer independent?
- Is compliance implemented within culture of the organization?
- Are employees held accountable for meeting these compliance-related objectives during performance reviews?
- Is the compliance officer a key stakeholder in the strategic initiatives of the organization?

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Enforcement and Response

- ❑ What processes are in place to ensure that appropriate remedial measures are taken in response to identified weaknesses?
- ❑ What is the process by which the organization evaluates and responds to suspected compliance violations?
- ❑ How are reporting systems, such as the compliance hotline, monitored to verify appropriate resolution of reported matters?
- ❑ Does the organization have policies that address the appropriate protection of “whistleblowers” and those accused of misconduct?

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Response to Violations

- ❑ What is the process by which the organization evaluates and responds to suspected compliance violations?
- ❑ What policies address the protection of employees and the preservation of relevant documents and information?
- ❑ What guidelines have been established for reporting compliance violations to the Board?
- ❑ What policies govern the reporting to government authorities of probably violations of law?

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