Three CIA Provisions that Will Enhance Your Compliance Program

April 7, 2019

Laura E. Ellis
Senior Counsel
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services
(202) 834-1665
Laura.Ellis@oig.hhs.gov

Michael B. Lampert
Partner
Ropes & Gray LLP
(617) 951-7095
Michael.Lampert@ropesgray.com

Introduction

WHY DO THESE PROVISIONS MATTER?
Introduction

WHY DO THESE PROVISIONS MATTER?

• Board accountability to shareholders
• Leadership accountability to the organization
• Increased buy-in of compliance mission by directors, leaders, and managers
• Increased awareness of compliance risks to be managed

Board Resolutions – Background

_In re Caremark International, Inc. Derivative Litigation_

“[L]iability to the corporation for a loss may be said to arise from an unconsidered failure of the board to act in circumstances in which due attention, would, arguably, have prevented the loss.” Directors must “attempt in good faith to assure that a corporate information and reporting system, which the board concludes is adequate, exists. . . .”

_U.S. Sentencing Commission Organizational Guidelines_

“The organization’s governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program.”

_HHS-OIG Compliance Program Guidance for Hospitals_

“The OIG believes that every effective compliance program must begin with a formal commitment by the hospital’s governing body to include all of the applicable elements listed below.”
Board Resolutions – CIAs

The Board shall, at a minimum, be responsible for the following . . .

  c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of [Company’s] compliance with Federal health care program 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 [Company’s] Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, [Company] has implemented an effective Compliance Program to meet Federal health care program 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 . . . .

Board Resolutions – Considerations

• Hold individuals accountable
  • Board members ask more questions
  • Directors hold leaders accountable
  • Compliance mission given more attention

• Require underlying processes
  • Need information and data to support resolution

• What if board cannot pass resolution?
  • Resolution details issues
  • Action plan to address
Board Resolutions – Preparation

- Board members should be preparing for year-round
- Resources
  - Budget
  - Staff
  - Support from other departments
- Executive sessions with Compliance Officer
- Information and Reports
  - Audits
  - Investigations
  - Disclosures
- Question others about compliance
  - Have leaders considered and prepared for compliance issues in their projects or proposals?
  - How do leaders talk about compliance to workforce?

Board Resolutions – Evaluation

*U.S. Department of Justice, Criminal Division, Fraud Section*
*Evaluation of Corporate Compliance Programs (2017)*

Oversight –

- What compliance expertise has been available on the board of directors?
- Have the board of directors and/or external auditors held executive or private sessions with the compliance and control functions?
- What types of information have the board of directors and senior management examined in their exercise of oversight in the area in which the misconduct occurred?
Board Resolutions – Evaluation


<table>
<thead>
<tr>
<th>Element 2: Compliance Program Administration</th>
<th>What to Measure</th>
<th>How to Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Board of Directors:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1 Active Board of Directors</td>
<td>• Review minutes of meetings where Compliance Officer reports in-person to the Audit and Compliance Committee of the Board of Directors on a quarterly basis.</td>
<td></td>
</tr>
<tr>
<td>2.2 Board understanding and oversight of their responsibilities</td>
<td>• Review of training and responsibilities as reflected in meeting minutes and other documents (training materials, newsletters, etc.). Do minutes reflect board’s understanding?</td>
<td>• Review/audit board education – how often is it conducted? Conduct interviews to assess board understanding.</td>
</tr>
<tr>
<td>2.3 Appropriate escalation to oversight body</td>
<td>• Review minutes/checklist in compliance officer files</td>
<td></td>
</tr>
<tr>
<td>2.4 Commitment from top</td>
<td>• Review compliance program resources (budget, staff).</td>
<td>• Review documentation to ensure staff, board and management are actively involved in the program.</td>
</tr>
<tr>
<td>2.5 Process for escalation and accountability</td>
<td>Process review (document review, interviews, etc.). Is there timely reporting and resolution of matters?</td>
<td></td>
</tr>
</tbody>
</table>

Management Certifications – Background

_U.S. Sentencing Commission Organizational Guidelines_

“High-level personnel of the organization shall ensure that the organization has an effective compliance and ethics program, as described in this guideline. Specific individual(s) within high-level personnel shall be assigned overall responsibility for the compliance and ethics program.”

_HHS-OIG Compliance Program Guidance for Hospitals_

“It is incumbent upon a hospital’s corporate officers and managers to provide ethical leadership to the organization and to assure that adequate systems are in place to facilitate ethical and legal conduct.”

“We recognize that full implementation of all [compliance program] elements may not be immediately feasible for all hospitals. However, as a first step, a good faith and meaningful commitment on the part of the hospital administration, especially the governing body and the CEO, will substantially contribute to a program’s successful implementation.”
Management Certifications – CIAs

[Designated Company] employees . . . are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable . . . department is in compliance with applicable Federal health care program requirements and the obligations of this CIA[, as follows] . . .

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

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Management Certifications – Considerations

- **Education**
  - Understanding purpose and importance of certification
    - Organization is relying on them
    - Consequences if certification proves incorrect
      - Corrective action up to termination
      - Eligibility for bonuses, profit sharing, etc.
  - Awareness all year-long that leader will be signing certification
- **Preparation**
  - Reports
  - Interviews with direct reports
  - Interview with Compliance Officer (?)
  - Sub-certifications?
- **Frequency**
Management Certifications – Evaluation

U.S. Department of Justice, Criminal Division, Fraud Section, Evaluation of Corporate Compliance Programs (2017)

“What specific actions have senior leaders and other stakeholders (e.g., business and operational managers, Finance, Procurement, Legal, Human Resources) taken to demonstrate their commitment to compliance, including their remediation efforts?”


<table>
<thead>
<tr>
<th>Element 2: Compliance Program Administration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>What to Measure</td>
<td>How to Measure</td>
</tr>
<tr>
<td>2.13 Cascade administration of compliance program throughout the organization</td>
<td>Different operational areas give some certification/disclosure to the compliance office</td>
</tr>
</tbody>
</table>

Internal Review & Assessment – Background

U.S. Sentencing Commission Organizational Guidelines

“In implementing [standards and procedures to deter criminal conduct], the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify [standards and procedures] to reduce the risk of criminal conduct identified through this process.”

HHS-OIG Compliance Program Guidance for Hospitals

“[R]isk areas should be assessed . . . and incorporated into the written policies and procedures and training elements developed as part of their compliance programs.”
Internal Review & Assessment – CIAs

Within 120 days after the Effective Date, [Company] shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with [Company]'s participation in the Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries.

Internal Review & Assessment – CIAs (cont’d)

The risk assessment and internal review process shall require compliance, legal, and department leaders, at least annually, to:
(1) identify and prioritize risks,
(2) develop internal audit work plans related to the identified risk areas,
(3) implement the internal audit work plans,
(4) develop corrective action plans in response to the results of any internal audits performed, and
(5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans.

[Company] shall maintain the risk assessment and internal review process for the term of the CIA.
Internal Review & Assessment – Types of Risks

- Compliance Risks
- Business Risks

Internal Review & Assessment – Considerations

- Compliance, Legal, and Department Heads
  - Involvement of Operations and Other Support Functions (HR, IT) Critical
  - Strengthens involvement with Compliance function.
- Identify and Prioritize Risks
  - Not all risks are equal
  - What criteria will be used to evaluate?
Internal Review & Assessment – Evaluation

*U.S. Department of Justice, Criminal Division, Fraud Section, Evaluation of Corporate Compliance Programs (2017)*

“Risk Management Process – What methodology has the company used to identify, analyze, and address the particular risks it faced?”

“Manifested Risks – How has the company’s risk assessment process accounted for manifested risks?”

---

Internal Review & Assessment – Evaluation


<table>
<thead>
<tr>
<th>Element 5: Monitoring, Auditing, and Internal Reporting Systems</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What to Measure</strong></td>
<td><strong>How to Measure</strong></td>
</tr>
<tr>
<td>Risk Assessments:</td>
<td></td>
</tr>
</tbody>
</table>
| 5.28 Risk Assessment Process | Process map of risk assessment process.  
- Who participates?  
- How are topics prioritized?  
- What is the process?  
- How are mitigation steps determined?  
- Is education provided?  
- How are the results reported? |
| 5.29 Risk based work/audit plan | Document review. Is the compliance work/audit plan based on a documented risk assessment and is it risk based? |