What's a Board to Do? Practical Guidance for Boards of Directors on Addressing Compliance Program Effectiveness

The Office of Inspector General ("OIG"), U.S. Department of Health and Human Services, in collaboration with the Association of Healthcare Internal Auditors, the American Health Lawyers Association, and the Health Care Compliance Association, recently released the publication "Practical Guidance for Health Care Governing Boards on Compliance Oversight" ("Compliance Oversight Guidance").

Board oversight of compliance programs has become an increasingly important governance control in the healthcare and life sciences industry, and one that the government has required in more recent years. Corporate Integrity and Settlement Agreements (collectively "CIA") have included requirements that the Board of Directors meet on a regular basis to review the compliance program and annually pass a resolution to the effectiveness of the compliance program. In addition, starting in 2006 with the Tenet CIA and with increasing frequency in CIAs thereafter, the OIG required Boards to engage external compliance experts to serve as compliance advisors and to evaluate the effectiveness of their organization's compliance program. Today, with the release of the Compliance Oversight Guidance, the OIG and key industry collaborators have codified the principles of oversight that in the past had been gleaned from individual CIAs into a compilation of practical guidelines. The Compliance Oversight Guidance provides the following direction:

ASK THE RIGHT QUESTIONS

Foundational to the Board's responsibilities is knowing the right questions to ask (including, but not limited to):

- Is the scope and adequacy of the compliance program aligned to the size and complexity of the organization?
- Does the scope and adequacy of the compliance program align with well recognized programs at similar companies (benchmarking)?
- What has changed in the regulatory landscape that could affect the scope and adequacy of our compliance program?
- Is our compliance program appropriately resourced to achieve a level of scope and adequacy we expect?
- Do we need a compliance expert to advise the Board?

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FOUR KEY AREAS OF THE GUIDANCE

The four key areas addressed by this new educational guidance are:

1. Define the roles of, and inter-relationships between, the organization's audit, compliance, and legal departments;
2. Evaluate the mechanisms and processes for information gathering and issue-reporting within an organization;
3. Understand management's approach to identifying and resolving regulatory risk; and
4. Devise methods of encouraging enterprise-wide accountability for achievement of compliance goals and objectives.

To this end, we consider the practical action steps around these four key areas to be...

1. **Roles and Relationships**

   Define, through the use of a charter or other governing documents, the various functional responsibilities and boundaries for each department within the healthcare organization that retains an oversight role, including:

   - Compliance
   - Legal
   - Internal Audit
   - Human Resources
   - Quality Improvement

   The Board should have an awareness of and evaluate the adequacy, independence, and performance of these different functions. The Compliance Oversight Guidance states the OIG's belief that the Compliance Officer should not be Counsel for the healthcare organization, or subordinate to Counsel.

   Each function should be clear in its role in identifying and addressing compliance risks, identifying and implementing appropriate corrective actions, and communicating and coordinating between the functions throughout this process.

2. **Reporting to the Board**

   Expectations of management oversight of the various functions should be set and enforced by requiring each -separately and independently- to report to the Board its risk mitigation and compliance efforts – separately and independently.

   Consider objective scorecards that reflect management's performance in:

   - Executing/implementing the compliance program;
   - Identifying and mitigating risks; and
   - Implementing appropriate corrective actions.

   In addition, the following metrics should be reported (including, but not limited to):

   - Internal and external investigations
   - Serious issues raised in internal and external audits
   - Hotline call activity
   - All allegations of material fraud or senior management misconduct
   - Code of conduct and/or expense reimbursement policy exceptions
   - Significant regulatory changes
   - Enforcement events relevant to the organization's business

   The OIG also recommends that the Board consider conducting regular "executive sessions" (i.e. excluding senior management) with leadership from the compliance, legal, internal audit, and quality functions to foster more open communication, and conduct these sessions on a routine basis – not only when issues arise.

3. **Identifying and Auditing Potential Risk Areas**

   The OIG speaks to known areas of vulnerability in healthcare organizations, including referral relationships and arrangements, billing problems (e.g., upcoding, submitting claims for services not rendered and/or medically unnecessary services), privacy breaches, and quality-related events.

   More generally, Boards are recommended to have a clearly defined and robust process for identifying risk areas. The Board should ensure that management

consistently identify and assess areas of risk, audit these risk areas, develop and implement appropriate corrective action plans and periodically monitor effectiveness.

Audits and monitoring can help identify potential risk factors and compliance concerns. Audits that identify compliance risks should be followed with corrective action plans.

4. **Encouraging Accountability and Compliance**

   The OIG reinforces that "compliance is an enterprise-wide responsibility." Performance assessments are an important tool to reinforce this accountability and can be used to withhold incentives or provide bonuses based on compliance and quality outcomes.

   Organizations that are proactive in their disclosure of violations of the law to the OIG under the OIG's Self Disclosure Protocol are recipients of the following benefits:

   - Faster resolution of the case
   - Lower payment (1.5 vs double or triple damages)
   - Exclusion release as part of settlement with no CIA or other compliance obligations

HOW DOES THIS GUIDANCE IMPACT YOUR COMPANY?

The Compliance Oversight Guidance highlights some key Board responsibilities and considerations:

- Asking the right questions is a critical part of effective Board oversight
- OIG expects Boards to put forth a meaningful effort when reviewing existing compliance programs
- As a part of effective compliance program oversight, Boards need to receive regular reports around the company's risk mitigation and compliance efforts
- Compliance is the responsibility of the entire enterprise

In addition, the following components of the compliance program should be part of Board responsibilities and reviewed at the Board-level:

- Clarity in the roles and purpose of the various assurance functions across the organization
- Independence of the compliance function and inter-department and Board reporting relationships
- Existence of a risk management program that is designed for consistent risk evaluation, mitigation, auditing and monitoring and corrective action
- Reinforcement of the OIG's Self Disclosure Protocol
- Engagement of an independent compliance expert when needed