

OIG Publishes New Guidance for Compliance Oversight by Health Care Boards

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Life Sciences | Health Care

On April 20, 2015, HHS's Office of Inspector General (OIG) published new compliance oversight guidance: *Practical Guidance for Health Care Governing Boards on Compliance Oversight*. Developed in collaboration with a group of industry associations,¹ the new guidance builds on previous guidance² by outlining practical suggestions for Boards to ask the right questions of management, get the right information to evaluate an organization's compliance program, hold accountable those who develop and execute the program, and make compliance the responsibility of all levels of an organization.

While it is not a comprehensive resource of Board oversight obligations, the new guidance is a useful and timely reminder for health care Boards and their counsel of the importance that OIG places on active and informed compliance oversight. As the guidance notes, a "Board may find that not every measure addressed [in the guidance] is appropriate for its organization, but every Board is responsible for ensuring that its organization complies with relevant Federal, State, and local laws."

Below are highlights of the direction from OIG on:

- General expectations for Board oversight of compliance program functions;
- Defining roles and relationships related to compliance oversight;
- Reporting of compliance-related information to the Board;
- Identifying and auditing potential risks; and
- Encouraging accountability and compliance throughout an organization.

¹ The Association of Healthcare Internal Auditors (AHIA), the American Health Lawyers Association (AHLA), and the Health Care Compliance Association (HCCA).

² OIG and AHLA previously issued a series of three corporate responsibility resource guides: *Corporate Responsibility and Corporate Compliance* (2003); *An Integrate Approach to Corporate Compliance* (2004); and *Corporate Responsibility and Health Care Quality* (2007). These guidance resources, together with a new executive briefing synopsis, were re-published as *The Health Care Director's Compliance Duties: A Continued Focus of Attention and Enforcement* (2011).

Expectations for Board Oversight of Compliance Program Functions

Make inquiries. In order to exercise its oversight responsibility, a Board should ask the right questions, ensure a reporting system is in place, and evaluate whether that system is adequate to assure the Board that it is receiving the information it needs relating to compliance with applicable laws.

Use benchmarking sources. Boards are encouraged to use three widely recognized sources as benchmarks: The Federal Sentencing Guidelines, OIG's voluntary compliance program guidance documents, and OIG Corporate Integrity Agreements (CIAs). In addition to using these sources as a measure, OIG observed that "[e]nsuring that management is aware of the Guidelines, compliance program guidance, and relevant CIAs is a good first step" in reviewing the adequacy of an individualized program.

Recognize that one size does not fit all. Boards should consider the scope and adequacy of an organization's compliance program in light of the size and complexity of the organization.

Formalize Board education. Boards should, in OIG's view, "develop a formal plan to stay abreast of the ever-changing regulatory landscape and operating environment." Keeping up-to-date will allow Boards to ask the right questions of management and make informed strategic decisions, including regarding resource allocation for compliance. Boards may consider outside educational programs or a formal education calendar to ensure that Board members are "periodically educated on the organization's highest risks."

Add resources with substantive expertise. The guidance suggests raising the level of substantive expertise of a Board "by adding to the Board, or periodically consulting with, an experienced regulatory, compliance, or legal professional." As noted in the guidance, Boards are generally entitled to rely on the advice of experts in fulfilling their duties, and experts can assist Boards in a variety of ways.

Roles and Relationships

Evaluate the role and relationships of key compliance-related functions. The guidance states that an organization should define the interrelationship of its audit, compliance, and legal functions in formal organization documents, and it illustrates how a charter describing the role of each function may "draw functional boundaries while also setting an expectation of cooperation and collaboration among those functions." Boards should then evaluate the adequacy, independence, and performance of those functions. The guidance also notes the need to balance attorney-client privilege with the goals of (1) providing access and (2) reporting and remediating violations.

Enact a process to ensure access. Boards should have a process to ensure appropriate access to information from key functions, which may be memorialized in a formal charter document.

Understand how management works together to address risk. Boards should consider the role of management functions in identifying compliance risks, investigating those risks, implementing appropriate corrective actions, and communicating between the functions. Boards

should also understand how management resolves conflicts or disagreements and decides on the appropriate course of action for compliance issues.

Reporting to the Board

Obtain separate, independent reports from a variety of functions. Boards should receive regular reports of the right information from a variety of key players, including audit, compliance, human resources, legal, quality, and information technology.

Get the right information. Boards should hold management accountable to clear expectations for informing the Board. The guidance lists a variety of information that the Board may wish to receive (e.g., objective scorecards, information on internal and external investigations, and serious issues raised in internal audits), and also notes the need to strike a balance between too much and too little information. The guidance notes further that some Boards use dashboards, risk-based reporting systems, or other mechanisms to ensure timely reporting to the Board, and they may also use these tools to track and identify trends.

Open a dialogue with key functions. To create “a continuous expectation of open dialogue” with leadership from compliance, legal, internal audit, and quality functions, Boards may also consider regular “executive sessions” without senior management.

Identifying and Auditing Potential Risk Areas

Engage a process for identifying risk areas. Boards should have strong processes for identifying risk areas with management, using both internal sources, such as hotlines and audits, and external sources. The guidance notes the importance of learning from publicized failures or problems in similar organizations. Boards should ask whether there are controls and processes to address similar misconduct or issues within their own organizations.

Ensure management is auditing risk and implementing corrective action. Boards should ensure first that management audits risk areas once identified, and then that the organization is developing, implementing, and monitoring corrective action plans.

Consider recent industry trends and newly available information. When designing risk assessment plans, compliance functions should consider recent industry trends, including the “increasing emphasis on quality, industry consolidation, and changes in insurance coverage and reimbursement.” The guidance notes, as an example, the emergence of new incentives and new compliance risks in connection with “new forms of reimbursement (e.g., value-based purchasing, bundling of services for a single payment, and global payments for maintaining and improving the health of individual patients and even entire populations).” The trend toward increasing transparency may also present opportunities, such as use of publicly available Sunshine Act payment data as a potential source of benchmarking.

Encouraging Accountability and Compliance

Assess employee performance in promoting and adhering to compliance. Boards may assess compliance-related performance at an individual, departmental, or facility level. Such assessments may be the basis for withholding incentives or providing bonuses, or they may be

used in connection with claw-back/recoupment provisions for employees and executives who do not meet compliance goals. As the guidance notes, these approaches “mirror Government trends” such as the management certifications required in CIAs, and they support a culture of compliance.

Encourage self-identification and voluntary disclosure of compliance failures. Consistent with prior guidance, this guidance observes that Boards “have multiple incentives to build compliance programs that encourage self-identification of compliance failures and to voluntarily disclose such failures to the Government.” Referencing OIG’s Self-Disclosure Protocol, the guidance also directs Boards to “ask management how it handles the identification of probable violations of law, including voluntary self-disclosure of such issues to the Government.”

Evaluate the effectiveness of communication within the organization. The guidance suggests that Boards may extend their oversight of reporting structures “by evaluating whether compliance systems and processes encourage effective communication” and “whether employees feel confident that raising compliance [issues] will result in meaningful inquiry without retaliation or retribution.” Boards should also evaluate the appropriateness of management responses to identified violations of policies or applicable laws.

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