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A smooth transition

an interview with **Gerry Zack**
Incoming CEO
SCCE & HCCA

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Board responsibility for compliance oversight and program effectiveness

» Board should ensure adequate reporting methods for duty of care, decision-making, and compliance oversight.
» Board must address compliance program resources, structure, and operation.
» Board oversight must focus on compliance program effectiveness.
» Board should have access to healthcare compliance expertise.
» Board should have active and ongoing dialog with compliance professionals and strive to promote an ethical culture in the organization.

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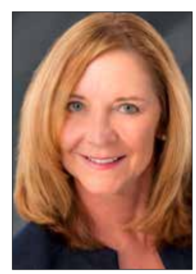
As the federal government continues to pursue healthcare organizations and dedicate resources to ferret out fraud and abuse, healthcare providers' members of governing bodies must be vigilant in implementing, maintaining, and updating their organization's compliance programs. Fueled by the private whistleblower movement, the potential for government identification of improper practices has resulted in an increased risk of liability for organizations and individuals alike. An expanded duty of care and duty of loyalty underlie what is required from a board of directors (board) to satisfy corporate oversight responsibility standards in a healthcare setting. Both must be satisfied, but the majority of a board's oversight responsibilities fall under the duty of care. Boards must ensure that their organizations have implemented and maintain an "effective" compliance program.

Imperato



Branan

The Federal Sentencing Guidelines for Organizations (FSGO) outline seven elements that are essential to an "effective" compliance program.[1] The second element—Compliance Program Administration—expressly addresses the role of the board and high-level personnel in compliance programs. The board must be "active" and knowledgeable about the organization's compliance program to satisfy the standard. Although the other elements may not expressly implicate the board's responsibilities, it is important to note the "oversight" role extends to other areas. These include the specific provisions surrounding communication, education, and training, as well as monitoring, auditing, and internal reporting systems. As a whole, knowledge regarding content and operations of the compliance program, coupled with oversight of the execution of the program to ensure effectiveness, form the foundation of the duties of the board.

The core of a director's responsibilities in oversight of a compliance program fall under two general prongs: (1) implementation of an effective program; and (2) monitoring of the system in place to ensure timely communication and resolution of potential threats to compliance.[2]

Instituting an effective compliance program

The first step is to institute a compliance program that adequately meets the unique needs of the healthcare organization. There is no one-size-fits-all formula, so a board starting from square one may benefit from professional consultation to navigate the many resources and standards that govern compliance programs.

Prioritizing compliance and communicating a clear message to the employees of the organization from the top down is essential to the success of any program. Creating a culture of ethical conduct and compliance from the beginning not only unifies the diverse membership of an organization in accordance with the compliance goals of the board, but it fosters open communication, which ultimately yields effective risk management. Necessary actions include creating a code of conduct, designating a compliance officer and compliance committee, and conducting a risk assessment to determine and prioritize potential problem areas.[3]

The Department of Justice (DOJ) has recently published questions for consideration when developing and assessing the effectiveness of a compliance program in its *Evaluation of Corporate Compliance Programs* (DOJ Evaluation).[4] The DOJ suggests first looking at the organization's history, to see how the company has previously designed and implemented new policies and procedures. This includes determining who were the key players involved at the design stage and whether any specific units or divisions were consulted to provide feedback prior to the implementation.

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The code of conduct

In its numerous publications, the Office of Inspector General for the Department of Health & Human Services (OIG) has provided general guidance as to what must be included in an organization's code of conduct (code). A code will typically begin with the board resolution that establishes the compliance program. This endorsement from the high-level personnel communicates the organization's clear commitment to the program and shows the active involvement of the board. The code must also clearly outline the standards for expected conduct, as well as the process for handling questions and reporting potential issues, with an emphasis on non-retaliation of those who report concerns. The key in evaluating the process is to look for whether it provides for timely reporting and resolution of compliance concerns. The chain of command for reporting compliance concerns must be described, including the key compliance personnel, not just the organization's compliance officer and compliance committee members. Further, the code should emphasize the organization's zero tolerance policy for fraud and abuse activity, commitment to submitting accurate and timely billing, and compliance with all laws and regulations.

Recently, the OIG (in conjunction with HCCA) published *Measuring Compliance*

Program Effectiveness: A Resource Guide, which provides sample topics and questions for boards to consider in evaluating a compliance program.[5] In the drafting stage, it is suggested that the code of conduct integrate the mission, vision, values, and ethical principles of the organization. Specific elements and statements from the organization's existing documents may be incorporated to increase cohesion and encourage smooth implementation. Once finalized, the OIG encourages a focus on the compliance program's distribution, awareness, and communication. This may be accomplished through a survey of the organization's employees to determine the extent to which they are familiar with the standards contained in the code and how they access it. New employees must be oriented with the policies during the onboarding process.

Assembling a compliance team

The next key role of the board involves the appointment of a compliance officer to oversee the program. The scope of the position will depend on the size and configuration of the organization, although the individual selected should have some background in healthcare, at minimum. The board may develop a job description for the compliance officer or invite the officer to craft their own description to be submitted for approval. Regardless of the drafting method selected, important considerations for the compliance officer's role include ensuring effective prevention and detection of compliance violations, regular review of the program to ensure it is current with government standards, recommending adjustments to the program as needed, reporting to the board, and coordinating resources to ensure the ongoing effectiveness of the program.[6]

A larger organization may require a compliance committee, which would function to assist the compliance officer. Although compliance officers are responsible for the program, they may require additional support in the Compliance department. This support includes education and training, as well as monitoring and auditing personnel. The organization's compliance team works together to ensure that regular risk assessments are conducted, to receive complaints or reports from employees, and to address areas of concern effectively.

As to additional compliance personnel, the board's responsibilities are first implicated at the hiring stage. Independent of subject matter expertise, those selected as compliance personnel must be approachable and have strong interpersonal skills. This encourages open discourse from ground-level employees who will report potential risk areas to the compliance staff. In addition, those who are selected for technical roles, including monitoring and auditing, must have the proper certifications and subject matter expertise (e.g., Certified Professional Coder or Registered Health Information Management Administrator). The OIG encourages that a board prioritize diverse expertise in the members of a compliance committee. Representatives from various departments within the organization, including Operations, Finance, Auditing, Human Resources, Utilization Review, Social Work, Discharge Planning, Medicine, Coding, and Legal, as well as employees and managers of key operating units are needed on the compliance committee.[7] The integration of physicians onto a compliance committee is also an effective way to encourage buy-in from the medical staff. A diverse compliance team yields a strong network to encourage organization-wide accountability and creates a strong culture of compliance from the initiation of the program.

Also critical to assembling an effective compliance team is to maintain the independence of the Compliance department. The compliance officer may use the resources of the general counsel but should maintain independence in function.

Risk assessment for compliance program design

During the development stage of the compliance program, the board should arrange for a risk assessment to be completed. The target of the assessment is to identify potential problem areas in the current practices and procedures of the organization. This assessment should focus on pinpointing risk factors, identification of potential regulatory and compliance issues, and confirmation of the effectiveness of the compliance controls that are already integrated into the organization's practices.[8] Although there is no single way to complete a risk assessment, the OIG provides various resources that identify potential areas for risk consideration. These include cultural issues; necessity of education and policy revision; billing, documentation, and coding issues; and Stark Law/Anti-Kickback Statute violations, as well as the annual OIG Work Plan and the organization's history of compliance problems.[9,10]

The actual exercise of the risk assessment will likely be delegated by the board to qualified compliance personnel, but the DOJ Evaluation expressly highlights the necessity of participation of business leadership in risk resolution.[11] It is important for directors to receive regular risk reports and for inclusion of risks to be communicated to the compliance committee. Finally, the directors may be responsible for assessment of effective follow-up, if risk resolution falls "off-track."

Funding adequacy

Financial support is crucial to the success of any compliance program. Following the risk assessment, the board is aptly positioned to approve the necessary compliance program budget. The *OIG Resource Guide* provides that a budget must be based on the organization's assessment of risk, with built-in considerations for future program improvement and effectiveness evaluations.[12] The budget must be sufficient to provide the resources for adequate staffing and efficient channels for risk identification and resolution. After the initial budget approval, the OIG suggests that the charter of the board be reviewed with regularity to verify that the approval of the compliance budget is properly documented and accurate.

Determining a budget is not limited to staffing and actual operational costs. The OIG has identified the necessity for boards to establish a plan to keep abreast of the ever-changing regulatory landscape.[13] First, this may be accomplished through education. An investment in the education of the board, key compliance personnel, and all employees and contractors may be a substantial factor in the overall budget calculation. A board may address its subject matter expertise on regulatory compliance by adding to the board or consulting with an experienced legal professional. As a peripheral benefit, the addition of a regulatory, compliance, or legal professional on a board may serve to reinforce the organization's commitment to compliance. The board's ability to properly identify risk factors and ask pertinent questions specific to an organization's industry requires a baseline understanding of the relevant regulatory framework. Thus, an investment by the company in education of the board and key compliance executives is expected.

New considerations may arise post-implementation, when a board evaluates the effectiveness of its compliance program. Assessing the allocation of funding and resources should include how the decisions have been made regarding the allocation of personnel and resources for the compliance and relevant control functions in the past.[14]

The key is to determine whether the allocation comports with the risk profile of the company, as determined through regular audits and compliance reviews. Another suggested area for consideration asks whether there have been times that resources have been denied for the compliance and relevant control functions. If so, boards must consider who was charged with the final decision and what factors were considered in making the determination to withhold resources.

Permissible reliance

Expanding on oversight responsibilities, the OIG has clarified the test as to a board's duty of care. The standard for directors has not been interpreted to require an exercise of "proactive vigilance" or to "ferret out corporate wrongdoing."[15] Rather, the duty of care arises when a red flag is raised or suspicions are, or reasonably should be, aroused. Where the director should have known of the improper activity, failure to act or to become properly informed is what establishes a breach of the duty of care and oversight requirements.

This interpretation paves the way for directors to rely on officers and advisors in conducting their oversight functions. Essentially, where a board is active in reviewing the reports of key compliance personnel, heeding recommendations to maintain and update an effective compliance program, and fostering a culture of compliance within the organization, the oversight role under duty of care will generally be found to be satisfied.

An important caveat to the permissibility of reliance on other personnel is the requirement that directors act in good faith. In the exercise of this duty, the focus must be twofold: (1) whether there is an improper personal financial benefit that will result from a particular matter or transaction; and (2) whether the director spots any intent to take advantage of the corporation.

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If misconduct comes to light, the DOJ Evaluation provides a sampling of questions for directors to consider when analyzing and remediating situation. Directors should analyze the root cause of the misconduct to first identify it, and secondly determine whether it is systemic in nature. The next step may include looking to whether there were any prior indications that would have provided an opportunity to detect the misconduct. Directors should scan audit reports for allegations or identified control failures, complaints, or investigations that involved similar issues. The final stage should address why the organization missed the opportunities to remedy the issue prior to the occurrence of the misconduct.

Reporting to the board

The individual assigned the overall responsibility for the compliance and ethics program (i.e., the compliance officer) must periodically report directly to the board on the compliance program activities. The organization's governing authority is required to be knowledgeable about both the content and operation of the compliance and ethics programs in place. With knowledge about the compliance program, the board will be equipped to make inquiries into its structure, operation, and effectiveness. Receiving reports from the compliance officer is essential for the board's exercise of oversight regarding the implementation and effectiveness of the programs in place. To document the "active" nature of the organization's governing authority, the OIG recommends that the board documents such reports in meeting minutes where the compliance officer reports in-person to the board or to the board's audit and compliance committee on a quarterly basis.[16]

Conclusion

The duty of care compels an organization's board to be active in the process of ensuring compliance. This begins with the institution of a program that effectively addresses the unique concerns of an organization's specialty that is adequately funded and equipped with the necessary resources. The key to satisfaction is to maintain a system that adequately provides the board with information relevant to make decisions. This will not only ensure that the organization meets the federal regulatory compliance standards, but also shields individual directors from personal liability.

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1. Federal Sentencing Guidelines for Organizations § 2(a)–(c).
2. U.S. Department of Health & Human Services Office of Inspector General: Practical Guidance for Health Care Governing Boards on Compliance Oversight. 2015. Available at http://bit.ly/2BdHEpw
3. Debbie Troklus and Sheryl Vacca: Compliance 101, 4th edition. pp 50–53.
4. U.S. Department of Justice, Criminal Division, Fraud Section: "Evaluation of Corporate Compliance Programs" February 2017. Available at http://bit.ly/2lEphmk
5. Health Care Compliance Association & Office of Inspector General: *Measuring Compliance Program Effectiveness: A Resource Guide.* March 27, 2017. Available at http://bit.ly/2nFBFCZ
6. Ibid, Ref #3, p 106.
7. Ibid, Ref #3, p 55.
8. Ibid, Ref #2, p 12.
9. Ibid, Ref #3, p 56.
10. OIG website: Compliance Resource Material. Available at http://bit.ly/2E7wOE2
11. Ibid, Ref #5, p 33.
12. Ibid, Ref #5, p 9.
13. Ibid, Ref #2 at 4.
14. Ibid, Ref #2, p 3.
15. OIG & The American Health Lawyers Association: *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors. 2017.* Available at http://bit.ly/2C0MhzZ
16. Ibid, Ref #5, p 9.