

AN INTEGRATED APPROACH TO CORPORATE COMPLIANCE

A Resource For Health Care Organization Boards of Directors



United States Department of Health and Human Services
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I. Introduction

As a supplement to the publication last year of *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors*,¹ (“*Corporate Responsibility and Corporate Compliance*”), a joint educational effort of the Office of Inspector General of the U.S. Department of Health and Human Services (“OIG”) and the American Health Lawyers Association (“AHLA”), this document addresses the roles of the in-house corporate general counsel (“General Counsel”) and an organization’s Chief Compliance Officer in supporting the compliance oversight function of health care organization governing boards (“Boards of Directors” or “Boards”). This supplemental educational resource addresses issues raised by recent developments in the law with respect to corporate responsibility and lawyers’ professional ethics, the modifications to the Federal Sentencing Guidelines for Organizations (“Sentencing Guidelines”), and the recommendations of the American Bar Association Task Force on Corporate Responsibility (“ABA Task Force”).² It addresses these issues in the unique context of health care compliance and health care law, particularly in light of the expressed view of the OIG regarding the risk of structuring an organization’s compliance function as subordinate to the General Counsel function.

Recent developments in the corporate and securities world have refocused attention on effective corporate governance and the role of the General Counsel in promoting ethical conduct and compliance with the law. The health care field has certainly witnessed its share of high profile corporate misconduct cases. While corporate compliance programs are well established in most health care industry segments, they continue to evolve in response to emerging “best practices” and changes in the business environment. All of this suggests that there is value in examining the interplay in the roles of the General Counsel and the Chief Compliance Officer in supporting the Board’s compliance oversight responsibilities.

Consideration of the role of the General Counsel in overseeing compliance programs has been ongoing. In 1998, the OIG stated the following:

“The OIG believes that there is some risk to establishing an independent compliance function if that function is subordina[te] to the hospital’s [G]eneral [C]ounsel, or comptroller or similar hospital financial officer. Freestanding compliance functions help to ensure independent and objective legal reviews and financial analyses of the institution’s compliance efforts and activities. By separating the compliance function from the key management positions of [G]eneral [C]ounsel or chief hospital financial officer (where the size and structure of the hospital make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.”³

In a similar vein, in a September 5, 2003, letter to Tenet Healthcare Corporation, United States Senator Charles Grassley (R-IA) observed:

“Apparently, neither Tenet nor (its General Counsel) saw any conflict in her wearing two hats as Tenet’s General Counsel and Chief Compliance Officer It doesn’t take a pig farmer from Iowa to smell the stench of conflict in that arrangement.”⁴

On the other hand, when assessing the role of the General Counsel in an organization’s corporate governance program, the ABA Task Force recommends that:

“The [G]eneral [C]ounsel of a public corporation should have primary responsibility for assuring the implementation of an effective legal compliance system under the oversight of the board of directors.”⁵

1 OFFICE OF INSPECTOR GENERAL (OIG), U.S. DEPT. OF HEALTH & HUMAN SERVICES (HHS) AND THE AMERICAN HEALTH LAWYERS ASSOCIATION, *CORPORATE RESPONSIBILITY AND CORPORATE COMPLIANCE: A RESOURCE FOR HEALTH CARE BOARDS OF DIRECTORS* (2003), available at <http://oig.hhs.gov/fraud/docs/complianceguidance/040203corpresprceguide.pdf> (lasted visited June 4, 2004).

2 James H. Cheek, III et al., *Report of the American Bar Association, Task Force on Corporate Responsibility* (2003), available at http://w3.abanet.org/buslaw/corporateresponsibility/final_report.pdf (last visited June 4, 2004).

3 OIG, HHS, *COMPLIANCE PROGRAM GUIDANCE FOR HOSPITALS* (1998), available at <http://www.oig.hhs.gov/authorities/docs/cpghosp.pdf> (last visited June 4, 2004).

4 See, Grassley Investigates Tenet Healthcare’s Use of Federal Tax Dollars, available at <http://www.senate.gov/~grassley/releases/2003/p03r09-08.htm> (last visited June 4, 2004).

5 Cheek, *supra* note 2, at 32. The Task Force report affirms the application of its recommendations to non-public organizations as well. Id. at 31.

So how do we reconcile these views? What role should the General Counsel play in health care organization corporate compliance? To what extent should Boards seek out and rely upon the organization's Chief Compliance Officer? What should be the relationship between the General Counsel and the Chief Compliance Officer? What can a Board expect regarding interactions with company legal counsel (both in-house and outside) in the new environment of corporate responsibility?

In light of the OIG position regarding the separation of the compliance function from the General Counsel, some health care organizations and advisors reportedly have taken a stringent view of this concept of separation, treating it more in the nature of a "requirement." Some have even gone so far as to view an otherwise independent compliance officer with a law degree as potentially undercutting the effectiveness of the compliance program. On the other hand, in light of recent developments in the area of lawyer professional responsibility, some may now believe that persons in the position of General Counsel are mandated to assume responsibility in the compliance area.

In reality, a variety of structures for organizing the compliance function is in place in health care organizations. As reflected in the results of a survey conducted by the American Health Lawyers Association and the Health Care Compliance Association, attached as Appendix A, some organizations operate with the same person serving as General Counsel and Chief Compliance Officer, while others assign these functions to distinct individuals and/or departments. Nevertheless, a board member overseeing the compliance function should understand how the organization is addressing the issue of the roles of the General Counsel and Chief Compliance Officer in the implementation of the organization's compliance program. This supplemental educational resource is intended to provide the conscientious director with additional assistance in evaluating the organization's approach to this important question.

II. The Role of the General Counsel

As discussed at length in *Corporate Responsibility and Corporate Compliance*, directors are entitled to rely, in good faith, on officers, employees, and corporate advisors in fulfilling their duty to exercise active oversight and informed judgment on behalf of the corporation. Consequently, the General Counsel, as well as outside lawyers, plays a critical role in the organizational reporting systems that provide information on compliance issues to management and the Board. The contributions lawyers can make to corporate governance include the role of counselor to the Board as it exercises its critical oversight obligation. In this function, lawyers assist the Board in understanding relevant laws and regulations, and in analyzing the associated business risks.

As part of the effort to reinforce the role of lawyers in promoting corporate responsibility and compliance with the law, an ABA Task Force examined the professional conduct of lawyers in internal corporate governance. On March 31, 2003, the Task Force issued its report on corporate responsibility. The report called upon lawyers (specifically, the General Counsel) to "assist in the design and maintenance of the corporation's procedures for promoting legal compliance."⁶ The report also enumerated a series of recommended governance "best practices" consistent with this emphasis on the role of lawyers in promoting corporate responsibility and developing practices designed to enhance lawyer/client communication on compliance matters.⁷

These recommendations included assigning to the General Counsel the primary responsibility for assuring an effective legal compliance system. To provide the Board with information and analysis necessary to fulfill its oversight responsibilities, the ABA Task Force recommended that the General Counsel meet regularly and in executive session with a committee composed of independent directors to review and communicate concerns with respect to legal compliance matters faced by the corporation. Additionally, the report suggested the creation of direct lines of communication between outside counsel for the corporation and the General Counsel to inform the General Counsel of potential or ongoing violations of law by the corporation.

The ABA recommendations are provided in the midst of an increased focus on the professional obligations of lawyers to serve the interests of their organizational clients. Simultaneous with the adoption of the corporate governance "best practices" recommendations, the ABA also approved revisions to the Model Rules of

⁶ Id. at 21.

⁷ The report suggests that if a corporation has no internal general counsel, it should identify and designate a lawyer or law firm to act as general counsel. Id. at 63.

Professional Conduct, designed in large part to address the proper role of lawyers in disclosing to internal and external third parties information concerning clients' criminal or fraudulent conduct.⁸

Specifically, Model Rules 1.13, Organization as Client, and 1.6, Confidentiality of Information, attempt to deal more effectively with the extraordinary scenario in which a corporation may be threatened with the potential for substantial injury due to actual or potential action by a corporate employee. Revisions to Model Rule 1.13 are designed to clarify a lawyer's obligation to communicate with, and report wrongdoing to, a higher organizational authority. Revisions to Model Rule 1.6 are designed to permit disclosure of confidential client information to prevent substantial injury to the corporation. While controversial, these revised Model Rules reflect growing awareness of the role of lawyers in enhancing organizational commitment to corporate responsibility.

III. An Integrated Response to Corporate Compliance

Given its focus on the General Counsel, the ABA Task Force Report did not address specifically the role of the Chief Compliance Officer in promoting the compliance oversight function of the Board. In some respects, the position of a Chief Compliance Officer is unique within a corporate organization. No other person has primary functional responsibility for the day-to-day operations of the compliance and ethics program. The breadth of the responsibilities and roles of a Chief Compliance Officer will vary, but may include:

1) developing and implementing policies, procedures, and practices; 2) overseeing and monitoring the implementation of the program; 3) updating and revising the program, as appropriate; 4) developing, coordinating, and participating in a multi-faceted training and education program; 5) coordinating internal audits; 6) reviewing, responding to, and investigating reports of non-compliance; 7) serving as a resource across the organization on substantive compliance questions and issues; and 8) reporting directly to the Board of Directors, CEO, and president on compliance matters. In that process, the Chief Compliance Officer is expected to have a broad knowledge of the organization and operational matters and an awareness of applicable laws and regulations. Similarly, few individuals in the organization have the breadth of interaction with individuals at all levels of the organization: board, management, employees, and third parties, including federal and state government representatives.

The Chief Compliance Officer of a health care organization may also bring a depth of experience to the position. Even before the recent corporate scandals, the health care industry experienced a decade of scrutiny by regulators and law enforcement agencies. Health care providers operate in a heavily-regulated environment with rules that may carry significant penalties for non-compliance. The government has committed substantial resources to identifying and sanctioning the individuals and entities that defraud and abuse federal and state health care programs. The net result is that the health care industry has advanced further than many other business sectors in establishing compliance and ethics programs and "best practice" standards. This in turn suggests that the roles of the General Counsel and the Chief Compliance Officer in supporting the Board's compliance oversight function may be more complex in the health care industry than in other industry sectors.

Consider, for example, the significant degree to which health care providers, ranging from highly complex health care systems to small physician practices, have implemented systems that promote compliance with federal and state health care program requirements. These systems require a detailed knowledge of particularized health care reimbursement schemes, including Medicare and Medicaid regulations and interpretations and third-party payer rules and policies. In this environment, a multi-disciplinary compliance team is essential in assisting an organization's General Counsel and Chief Compliance Officer in gathering and interpreting pertinent information.

The health care industry may also be distinguished by obligations to disclose the adverse findings of an internal audit or employee misconduct. When a compliance review identifies program violations that result in overpayments or a breach of a legal duty, the organization may be compelled to take steps to ensure that the matter is reported appropriately. While a corporation generally may not have a specific legal duty to disclose

⁸ Cheek, *supra* note 2, at 77-89. The ABA Model Rules of Professional Conduct emphasize the lawyer's responsibility "[a]s advisor [to] provide a client with an informed understanding of the client's legal rights and obligations and explain their practical implications." *Id.* at 21.

a violation of the law, participants in the Medicare and Medicaid programs submit an increasing number of reports, certifying to compliance with program requirements. A provider that certifies compliance with program requirements, having knowledge of an undisclosed infraction, may commit a new offense of making a false statement. Furthermore, there may be specific statutes or regulations that compel a health care provider to report known violations of law as a requirement of state licensure or as a condition of program participation. Finally, a provider that is operating under a Corporate Integrity Agreement, as part of the settlement of a fraud case, agrees to disclose to the OIG substantial overpayments and probable violations of criminal, civil, or administrative laws applicable to any federal health care program for which penalties or exclusion may be authorized.

The failure to appropriately monitor compliance with the complex health care regulatory requirements can, in certain circumstances, lead to the submission of a false claim to a third-party payer or the government. In addition, a health care provider's violation of the prohibitions against certain financial relationships with referral sources may trigger criminal, civil, and administrative liability. The consequences of these and other types of violations range from the requirement to repay any improperly received reimbursement amount with interest to the imposition of severe financial penalties, criminal prosecution, and exclusion from participation in any federal health care program. In light of the severe potential consequences that may result from a lack of adherence to applicable legal requirements, it is essential for a health care organization to have an independent compliance team that has a broad base in terms of training, background, and expertise.

As part of the evolution of compliance programs, compliance officers have established themselves as an essential part of a health care provider's management team. These professionals often have demonstrated an expertise in technical health care reimbursement matters, internal controls, troubleshooting, and remedial measures, and may be the point person for employee concerns about the organization. While these attributes may make compliance officers highly effective, they may also create confusion with the respective roles to be played by the organization's General Counsel and its Chief Compliance Officer. Ironically, the relative maturity of compliance programs within the health care industry may mean that role of the General Counsel in overseeing compliance matters is subject to challenge within the organization.

In this regard, the recent changes to the Federal Sentencing Guidelines for Organizations provide guidance on the roles and reporting relationships of particular categories of personnel with respect to compliance program responsibilities.⁹ The Sentencing Guidelines reaffirm the key principle in *Corporate Responsibility and Corporate Compliance* — to have an effective compliance program, the organization's governing authority must be knowledgeable about the content and operations of the compliance program and exercise reasonable oversight over it.¹⁰

The new Sentencing Guidelines also provide more specific and exacting requirements for the staffing and operation of compliance and ethics programs. To be considered effective, a program must be the responsibility of high-level personnel who have substantial control over the organization or who have a substantial policy-making role within the organization. While other individuals may be assigned day-to-day operational responsibilities for the program, accountability for the compliance program must rest with upper management.¹¹ Recognizing the value of an independent voice, free of any potential filtering by senior organization managers, the Sentencing Guidelines direct that, where operational responsibility for the compliance program is delegated, those individuals with day-to-day responsibility must have direct access to the Board of Directors or an appropriate Board committee. Further, reports from the individuals responsible for the day-to-day operations of the compliance program must be provided to the Board at least annually.¹² This admonition to protect the independence of the compliance function makes clear that whether responsibility for the compliance program is assigned to the General Counsel or to a distinct Chief Compliance Officer, individuals with day-to-day responsibilities must have appropriate authority and direct access to the Board of Directors.

9 On April 13, 2004, the United States Sentencing Commission voted to amend the Sentencing Guidelines. The Commission made the standards for a compliance and ethics program more rigorous and put greater responsibility on boards of directors and executives for the oversight and management of the compliance program. The amendments have been submitted to Congress and will take effect November 1, 2004, unless Congress disapproves them. The proposed amendments relating to compliance programs can be found at <http://www.ussc.gov/2004guid/2004cong.pdf> (last visited June 4, 2004).

10 U.S. SENTENCING COMM'N, ORGANIZATIONAL SENTENCING GUIDELINES § 8B2.1, available at <http://www.ussc.gov/2004guid/2004cong.pdf> (last visited June 4, 2004).

11 *Id.* § 8B2.1(b)(2), cmt. n. 3 (2004).

12 *Id.*

IV. Considerations for Health Care Boards

Corporate Responsibility and Corporate Compliance suggested areas of inquiry that directors should pursue with management to ensure that the Board understands the scope of its compliance program and challenges inherent in achieving program goals. The following questions are suggested to ensure: 1) that the Board understands the roles of the General Counsel and the Chief Compliance Officer in supporting the Board's oversight function and the organization's corporate compliance program; and 2) that appropriate processes are in place to assure the Board that it receives appropriate information and candid assessments arising out of the compliance program in a timely manner. These suggested questions and commentary recognize that Boards may consider a variety of approaches in addressing these issues.

1. To what extent is the General Counsel utilized by the Board to provide relevant advice regarding compliance matters?

Ultimately, the structure of operational responsibilities for the compliance program and the Board's relationship with the General Counsel must assure the Board that it receives appropriate and timely information on organizational compliance with applicable laws. The changes to the Sentencing Guidelines give greater clarity to the responsibilities of corporate boards in this regard. Specifically, the Board must not only be knowledgeable about the corporate compliance program, but also be able to evaluate and recommend modifications to the program in light of ongoing organizational risk assessments. Thus, the Board needs to be knowledgeable of any major risks of unlawful conduct facing the organization to evaluate the adequacy of its compliance program in mitigating those risks. As recognized by the ABA Task Force, the General Counsel is an essential resource to the Board for understanding the organization's legal risks and the adequacy of the compliance program in addressing those risks.

2. Where and how is the General Counsel involved in each of the fundamental elements of the compliance program?

Given the ABA Task Force's recommended role for the General Counsel in compliance and the OIG's expressed concerns regarding compliance officer independence, the Board needs to be sure it understands and agrees with the role of its principal legal advisor in the compliance program's design and operation.

The ABA Task Force suggests that a prudent corporate governance program should utilize the General Counsel to assist in the design and maintenance of the corporation's procedures for promoting legal compliance. In many health care organizations, the Chief Compliance Officer has primary responsibility for the development, coordination, and monitoring of the compliance and ethics program. However, given the diversity of Chief Compliance Officer professional backgrounds, the General Counsel can serve as a critically important program resource. For example, the General Counsel can provide essential insights into government regulations and their policy implications to the organization, and the potential legal consequences of proposed courses of action. The Board's oversight function is enhanced if it understands the complementary roles of the General Counsel and the Chief Compliance Officer in their support of the Board's oversight responsibilities.

3. How does the General Counsel receive notice of, and provide input on, the organization's response to identified or suspected compliance failures?

One of the key features of a compliance program is the appropriate organizational response to suspected violations of law. The nature of the response can have a significant impact on the organization internally, as well as on its relationship with federal and state health care programs and third-party payers. The roles of Chief Compliance Officer and General Counsel are no more acutely interwoven and in potential tension than in this context.

Among the typical Chief Compliance Officer's primary responsibilities are the investigation and coordination of an organization's response to such suspected compliance failures. However, the General Counsel also must play a pivotal role in directing the organization's response to suspected compliance failures, particularly when they may trigger administrative, civil, or criminal liability. The Board needs to understand the distinction in the roles and perspectives of the General Counsel and the Chief Compliance Officer, especially when the Chief Compliance Officer is not a lawyer. Assuring the timely involvement of

the General Counsel in assessing the significance of potential violations of law, participating appropriately in the investigation, and evaluating options for resolution will help the Board respond appropriately to these challenges to the integrity of the organization.

4. What are the roles of the organization's Chief Compliance Officer and General Counsel in operating the corporate compliance program? Who has responsibility for reporting to the Board on compliance matters?

The Chief Compliance Officer and the General Counsel may have different, and yet ultimately complementary, responsibilities in the operation of the organization's compliance program. The responsibilities of the Chief Compliance Officer are detailed in the OIG's Compliance Program Guidances.¹³ Although the Chief Compliance Officer may have a legal background, typically he or she is not acting in the capacity as counsel for the organization.

The amendments to the Sentencing Guidelines make clear that, as part of an effective compliance program, the Chief Compliance Officer must periodically report to the Board on the status of the compliance program, the resources required to maintain its vitality, and the organization's response to identified compliance deficiencies. A direct reporting relationship helps avoid any potential filtering or censoring influence of senior organization managers. As previously discussed, the OIG has expressed concern about the wisdom of the Chief Compliance Officer being subordinate to the General Counsel or Chief Financial Officer. The OIG believes that the independence and objectivity of legal and financial analyses of the corporation's activities are enhanced through a system of checks and balances, which includes separating the compliance function from key management positions, including the General Counsel.

As noted earlier, however, the ABA Task Force suggests that the active involvement of the General Counsel in the compliance program is essential to provide the Board with the information and analysis needed for the directors to discharge their oversight responsibilities. The Task Force also suggests that "counsel . . . should have primary responsibility for assuring the implementation of an effective legal compliance system under the oversight of the [B]oard."¹⁴

The General Counsel's primary responsibility is to represent the legal interests of the organization by acting as a legal counselor to the organization (through its board of directors, officers, and managers) on a wide variety of topics, including compliance with relevant legal obligations. In the context of the compliance program, the General Counsel serves as an important resource to the compliance staff, as well as to the Board in its exercise of oversight over the organization's compliance systems.

It is the Board's responsibility to reconcile these potentially conflicting views into a complementary set of responsibilities and reporting relationships. Ultimately, the interaction between the General Counsel and the Chief Compliance Officer must support the Board in its oversight responsibilities by ensuring that the Board receives accurate information and candid advice.

5. How is the Board notified when there are disagreements among management, the Chief Compliance Officer and/or the General Counsel relating to the organizational response to specific compliance matters?

Significant disagreements among management, the General Counsel, and the Chief Compliance Officer may arise as the organization considers how to respond to internal compliance evaluations that have potential significant financial and legal consequences for the organization. For example, there may be divergence of opinion regarding whether to report to the government the adverse finding of an internal audit. While such disagreements should not necessarily be resolved at the board level, it is important for the Board to understand how management approaches such issues and receives a consensus on a course of action. Consideration should be given to establishing policies that standardize reporting to the Board on such investigations.

The OIG and the U.S. Sentencing Commission recommend that compliance officers have direct access to the Board of Directors and Chief Executive Officer. The expressed concern is that a reporting line through

¹³ OIG FRAUD PREVENTION & DETENTION COMPLIANCE GUIDANCE, available at <http://www.oig.hhs.gov/fraud/complianceguidance.html> (last visited June 4, 2004).

¹⁴ Cheek, *supra* note 2, at 32.

the General Counsel, Chief Financial Officer, or other senior manager may interject other operational concerns into compliance reviews and financial analyses performed by the Chief Compliance Officer. In many organizations, however, a number of practical and operational reasons may support a Chief Compliance Officer reporting directly to a high-level manager or the General Counsel. If this is the case, it may be in the best interests of the program that the General Counsel or other senior manager not be the sole recipient of compliance reports.

In pursuit of its oversight responsibilities for the compliance program, the Board should reasonably assure itself that the compliance function is appropriately free of undue constraints and that the Chief Compliance Officer is able to provide the Board with objective information, analyses, and recommendations. The concept of “checks and balances” in the compliance reporting process is prudent, regardless of who has formal responsibility for the compliance program. Direct reporting to the Board and alternative reporting processes may also promote the integrity of the compliance program, while respecting the operational preferences of management.

6. Does the Board understand how the organization utilizes the attorney/client and work product privileges when responding to third party requests for information?

Investigations into suspected violations of law can have profound implications for an organization. In this sensitive area, it is important that the Board receive timely and objective information and sound legal advice on proposed courses of action. Judicially-recognized privileges exist to promote candid and confidential communications between the client and its counsel, including the attorney/client and attorney work product privileges.¹⁵ While certain aspects of an attorney’s investigation into allegations of misconduct may be protected from disclosure to third parties, the organization’s responses to identified material violations of law may involve reporting the misconduct to the appropriate government agency. The cooperation expected from organizations by the government in resolving such matters can give rise to a tension between the sufficiency of such disclosures and the appropriate assertion of these privileges.

From the government’s perspective, blanket or routine assertions of the work product or attorney-client privilege in routine auditing and compliance monitoring activities may undermine the vitality of the asserted privilege and diminish the credibility of the compliance program and the organization. It is important, therefore, that the Board receive sound advice on the nature, utility, and limitations of these privilege doctrines and the policies and practices of management and General Counsel in their application.

7. Are processes in place to enable the General Counsel to bring issues of legal compliance to the appropriate authorities within the organization?

The extent of inside and outside counsels’ responsibility to report potential violations of law, a breach of duty to the corporation, and other substantial legal concerns is an issue of continuing debate. With the enactment of Sarbanes-Oxley, the SEC has established minimum standards of professional conduct for attorneys appearing and practicing before the Commission, including a requirement to report evidence of material violations of law under certain circumstances “up the ladder” within an organization. Similar obligations are contemplated by the revisions to ABA Model Rules 1.13 and 1.6, which address the circumstances under which an attorney may be ethically obligated to withdraw from the representation of a client.

Although the circumstances giving rise to such “up the ladder” reporting should be extraordinary, it is important that the Board: 1) understand these particular responsibilities of counsel to exercise informed professional judgment in determining what steps are reasonably necessary in the best interests of the organization; and 2) ensure that lines of communication are established to enable the General Counsel to report any concerns about significant compliance issues up to the highest levels of authority within the organization.¹⁶ The Board may wish to consider various mechanisms, including periodic executive sessions between the General Counsel and the Board, to ensure that critical compliance issues are brought to its attention.

¹⁵ It is beyond the scope of this educational resource to address these privileges in any detail. Additional information on the privileges and their restrictions should be obtained from counsel.

¹⁶ DC:242809v3

V. Summary Considerations

Recognizing the important responsibilities of both the General Counsel and the Chief Compliance Officer to every health care organization, the following are certain summary considerations that might enhance a system of checks and balances to help meet the organization's compliance program objectives and program oversight.

A. Where the General Counsel Serves as the Chief Compliance Officer

- Consider the adoption of a recusal process by which the General Counsel may recuse himself or herself from a compliance investigation, as well as alternative reporting processes, if the matter may implicate the General Counsel. A substantial majority of respondents to the AHHA-HCCA survey reported utilizing such processes.
- Consider periodic Board initiated third-party audits or assessments of the compliance program, as suggested in the OIG Compliance Program Guidances.
- Consider authorizing the Board Audit or Compliance Committee to retain outside counsel or consultants with respect to selected matters under Board-approved criteria.

B. Where the Chief Compliance Officer is Separate from the General Counsel, but Reports to the General Counsel

- Consider formally establishing alternative reporting mechanisms to provide the Chief Compliance Officer direct reporting to another member of senior management if the Chief Compliance Officer deems such reporting to be necessary. Such a mechanism provides protections for the Board and the organization against any real or perceived obstruction.
- Consider procedures to have someone other than the General Counsel authorize the Chief Compliance Officer to pursue compliance investigations, including the right to hire outside counsel. Here, the authority to independently initiate investigations should be balanced by required notice and consultation with the General Counsel.
- Consider periodic direct reports from the Chief Compliance Officer to the Board, balanced by the General Counsel's prior review and consultation so that both may report to and advise the Board consistent with their responsibilities.

C. Where the Compliance Officer is Separate from and Does Not Report to the General Counsel

Consider the benefit of having the General Counsel involved in: 1) periodic risk assessments; 2) review of proposed policies and reports on compliance processes; 3) conducting investigations; and 4) devising remedial measures to address violations of law.

- Consider routine General Counsel reviews of matters being reported to the Board by the Chief Compliance Officer.
- Consider requiring notice to, and consultation with, the General Counsel where there is independent authority for the Chief Compliance Officer to retain outside counsel and consultants.

VI. Conclusion

The recent developments in corporate accountability, stemming from a series of high profile corporate misconduct cases, including such issues as "up the ladder" reporting, have prompted organizations to refocus on how matters of potential or alleged corporate misconduct are brought to the attention of Boards of Directors. In the heavily-regulated field of health care, however, the roles of the General Counsel and the

Chief Compliance Officer in corporate compliance have been a focus of attention for many years. Perhaps, in the end, the current attention being given to these roles by Congress, federal agencies, and the industry is simply an appropriate refocus on the basic principle of the ultimate duty of an attorney or a senior manager to serve the client, which in the corporate context is the corporate organization under the leadership of its Board of Directors.

For health care organizations, the unique operational environment and regulatory requirements mandate coordination between the legal function and the compliance function. As the AHLA-HCCA survey indicates, and as this supplemental educational resource has discussed, there are a variety of effective approaches to such coordination, many of which are a matter of current practice. This supplemental educational resource has attempted to assist members of health care organization Boards think through the issues related to: 1) the critical role of the General Counsel in support of the Board's oversight responsibility for corporate compliance, by informing the Board about potential problem areas, and advising the Board about applicable legal requirements; 2) the essential part played by Chief Compliance Officers, whose breadth of responsibility, expertise, and experience typically places them in a unique position to assist the Board in determining the effectiveness of the organization's compliance program; and 3) the relationship between the General Counsel and the Chief Compliance Officer, and the development of a system of checks and balances that enhances the ability of these two individuals to contribute their knowledge and skills in a way that furthers the interests of the organization.

Ultimately, it is important that a Board receives a sufficient flow of information to effectively conduct its compliance oversight. Establishing and coordinating the roles and responsibilities of the General Counsel and the Chief Compliance Officer within health care organizations to best serve the organization and best assist the Board in its compliance oversight function is essential. It is the goal of this supplemental educational resource to be of assistance to health care Boards in exercising this important responsibility.

APPENDIX A

The American Health Lawyers Association (Health Lawyers) sent out a survey designed to explore the relationship between general counsel and compliance officer in different health care organizations. Health Lawyers sent the survey to 1964 in-house counsel and 2490 healthcare personnel, many of whom work as compliance officers. 429 recipients responded to the survey.

The survey included 9 questions for all respondents to answer. It then asked respondents to answer several questions applicable to their particular organizational and reporting structure. The survey included questions for respondents at organizations where the general counsel serves as the compliance officer; where the compliance officer reports to the general counsel; and where the compliance officer does not report to the general counsel.

The responses to the survey provide Board members, CEOs, counsel, compliance officers, and others interested in health care management with insights into the different structures that health care organizations use to manage their compliance activities. The diversity of compliance management structures and reporting relationships reinforce the conclusion that effective Boards will receive regular information and analysis on how their health care organizations manage their compliance activities.

Survey Results

ALL RESPONDENTS ANSWERED THE QUESTIONS IN THIS SECTION.

1. Does your organization employ an in-house general counsel or attorney?



2. Does your in-house general counsel or one of your in-house attorneys also serve as the corporate compliance officer?



3. Does your organization employ an individual whose principal duty is to act as the corporate compliance officer for the organization?



4. Is the corporate compliance officer for your organization also an attorney?



5. To whom does the compliance officer report?¹



6. If your compliance officer has other official responsibilities within the organization, what are they?



7. If your organization has a compliance officer and not an in-house counsel or in-house attorney, does your organization designate an outside lawyer as the organization's general counsel?



¹ Some responses to the survey have a greater than 100% response rate because individual respondents included more than one response for particular questions.

² Other positions named included VP Government Affairs; Chief Administrative Officer; Audit Committee; Chief Medical Officer; Chief Information Officer; Chief Technology Officer; Vice President Academic Affairs; Dean, College of Medicine; Chief Operating Officer; 'VP for Quality;' Chief Financial Officer; 'Risk Manager;' and Compliance Advisory Committee.

³ Other responsibilities included risk management; operations officer; public policy; mission effectiveness; security officer; information systems; patient and community relations; quality assurance; business practices; physician relations and contracting; outpatient services; conflict of interest oversight; regulatory affairs; privacy officer; safety officer; limited English proficiency coordinator; research administration; research integrity officer; human protections administrator; social services director; administration; FOIA officer; HIPAA Officer; labor relations; IRB; Clinical Services; and charge description master.

8. Does your organization's Board require that it be informed of any governmental investigation related to an alleged violation of federal or state law?



9. Are internal investigations routinely carried out under the protection of the attorney-client privilege as a matter of policy or practice?



IF THE ORGANIZATION HAS ITS IN-HOUSE GENERAL COUNSEL OR ATTORNEY SERVE AS THE COMPLIANCE OFFICER:

10. Does the organization have a formal policy to allow the in-house general counsel or attorney responsible for compliance independent access to the Board of Directors on a compliance issue if the attorney believes it necessary?



11. Does the organization have a mechanism for the referral of an investigation to an alternative individual if the in-house general counsel or attorney wants to recuse him or herself from a compliance investigation?



12. Does the organization have a mechanism for allowing an individual with a compliance issue or complaint to bypass the in-house general counsel/attorney if the complaint may implicate the general counsel/attorney.

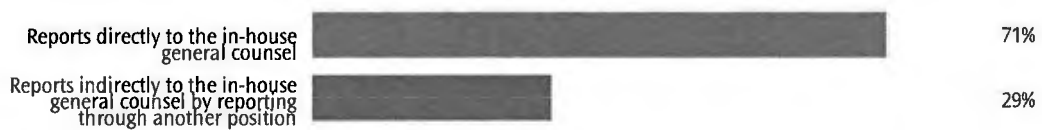


13. Does the in-house general counsel/attorney report to the Board on compliance issues on a regular basis?



IF THE ORGANIZATION HAS A SEPARATE COMPLIANCE OFFICER WHO REPORTS THROUGH THE IN-HOUSE GENERAL COUNSEL:

14. How does the individual responsible for corporate compliance report through the in-house general counsel?



15. Is the compliance officer authorized to pursue compliance investigations without notice to or prior consultation with the general counsel?



16. Has the organization established an alternative mechanism to provide the compliance officer direct reporting to members of senior management if the compliance officer feels such is necessary?



17. Is there a policy/protocol providing for counsel to review/give input on compliance or internal audit matters to be reported to the Board?



18. Does the organization have a policy or practice of requiring an in-house or outside counsel to conduct/or consult on any compliance investigation?



19. Does the compliance officer routinely report directly to the Board at Board meetings on compliance matters?



20. Does the compliance officer have independent authority to retain counsel or other consultants, if he or she believes it necessary?



IF THE ORGANIZATION DOES NOT HAVE ITS COMPLIANCE OFFICER REPORT THROUGH AN IN-HOUSE GENERAL COUNSEL OR ATTORNEY:

21. If the compliance officer does not report to the in-house general counsel or an in-house attorney, to whom does the corporate compliance officer directly report?















22. Does the organization require consultation/review/input between the compliance officer and an in-house general counsel or attorney or an outside counsel prior to a compliance investigation?



23. Does the organization require consultation/review/input between the compliance officer and an in-house or outside attorney if there is a particular red flag during an investigation?



⁴ Answers similar to those provided in footnote 1.


- 24. Do the compliance officer and the general counsel/attorney meet formally or informally on a frequent basis (meaning once a week or more)?**
- | | | |
|-----|--|-----|
| Yes |  | 55% |
| No |  | 45% |
- 25. Does the compliance officer copy the general counsel/attorney on significant correspondence?**
- | | | |
|-----|--|-----|
| Yes |  | 77% |
| No |  | 23% |
- 26. Does the compliance officer generally seek advice from the general counsel/attorney when asserting privilege?**
- | | | |
|-----|--|-----|
| Yes |  | 85% |
| No |  | 15% |
- 27. Does the compliance officer routinely report directly to the Board on compliance matters?**
- | | | |
|-----|--|-----|
| Yes |  | 79% |
| No |  | 21% |
- 28. Is there a policy/protocol providing for counsel review/input on compliance or internal audit matters to be reported to the Board?**
- | | | |
|-----|--|-----|
| Yes |  | 43% |
| No |  | 57% |
- 29. Does the compliance officer have independent authority to retain counsel or other consultants?**
- | | | |
|-----|--|-----|
| Yes |  | 52% |
| No |  | 48% |

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Practical Guidance for Health Care Governing Boards on Compliance Oversight

Office of Inspector General,
U.S. Department of Health and Human Services
Association of Healthcare Internal Auditors
American Health Lawyers Association
Health Care Compliance Association



About the Organizations

This educational resource was developed in collaboration between the Association of Healthcare Internal Auditors (AHIA), the American Health Lawyers Association (AHLA), the Health Care Compliance Association (HCCA), and the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS).

AHIA is an international organization dedicated to the advancement of the health care internal auditing profession. The AHLA is the Nation's largest nonpartisan, educational organization devoted to legal issues in the health care field. HCCA is a member-based, nonprofit organization serving compliance professionals throughout the health care field. OIG's mission is to protect the integrity of more than 100 HHS programs, including Medicare and Medicaid, as well as the health and welfare of program beneficiaries.

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This document is intended to assist governing boards of health care organizations (Boards) to responsibly carry out their compliance plan oversight obligations under applicable laws. This document is intended as guidance and should not be interpreted as setting any particular standards of conduct. The authors recognize that each health care entity can, and should, take the necessary steps to ensure compliance with applicable Federal, State, and local law. At the same time, the authors also recognize that there is no uniform approach to compliance. No part of this document should be taken as the opinion of, or as legal or professional advice from, any of the authors or their respective agencies or organizations.

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Introduction

Previous guidance¹ has consistently emphasized the need for Boards to be fully engaged in their oversight responsibility. A critical element of effective oversight is the process of asking the right questions of management to determine the adequacy and effectiveness of the organization's compliance program, as well as the performance of those who develop and execute that program, and to make compliance a responsibility for all levels of management. Given heightened industry and professional interest in governance and transparency issues, this document seeks to provide practical tips for Boards as they work to effectuate their oversight role of their organizations' compliance with State and Federal laws that regulate the health care industry. Specifically, this document addresses issues relating to a Board's oversight and review of compliance program functions, including the: (1) roles of, and relationships between, the organization's audit, compliance, and legal departments; (2) mechanism and process for issue-reporting within an organization; (3) approach to identifying regulatory risk; and (4) methods of encouraging enterprise-wide accountability for achievement of compliance goals and objectives.

A critical element of effective oversight is the process of asking the right questions....

¹ OIG and AHHA, *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors* (2003); OIG and AHHA, *An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors* (2004); and OIG and AHHA, *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors* (2007).

Expectations for Board Oversight of Compliance Program Functions

A Board must act in good faith in the exercise of its oversight responsibility for its organization, including making inquiries to ensure: (1) a corporate information and reporting system exists and (2) 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.² The existence of a corporate reporting system is a key compliance program element, which not only keeps the Board informed of the activities of the organization, but also enables an organization to evaluate and respond to issues of potentially illegal or otherwise inappropriate activity.

Boards are encouraged to use widely recognized public compliance resources as benchmarks for their organizations. The Federal Sentencing Guidelines (Guidelines),³ OIG's voluntary compliance program guidance documents,⁴ and OIG Corporate Integrity Agreements (CIAs) can be used as baseline assessment tools for Boards and management in determining what specific functions may be necessary to meet the requirements of an effective compliance program. The Guidelines "offer incentives to organizations to reduce and ultimately eliminate criminal conduct by providing a structural foundation from which an organization may self-police its own conduct through an effective compliance and ethics program."⁵ The compliance program guidance documents were developed by OIG to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. CIAs impose specific structural and reporting requirements to

2 *In re Caremark Int'l, Inc. Derivative Litig.*, 698 A.2d 959 (Del. Ch. 1996).

3 U.S. Sentencing Commission, *Guidelines Manual* (Nov. 2013) (USSG), http://www.ussc.gov/sites/default/files/pdf/guidelines-manual/2013/manual-pdf/2013_Guidelines_Manual_Full.pdf.

4 OIG, *Compliance Guidance*, <http://oig.hhs.gov/compliance/compliance-guidance/index.asp>.

5 USSG Ch. 8, Intro. Comment.

promote compliance with Federal health care program standards at entities that have resolved fraud allegations.

Basic CIA elements mirror those in the Guidelines, but a CIA also includes obligations tailored to the organization and its compliance risks. Existing CIAs may be helpful resources for Boards seeking to evaluate their organizations' compliance programs. OIG has required some settling entities, such as health systems and hospitals, to agree to Board-level requirements, including annual resolutions. These resolutions are signed by each member of the Board, or the designated Board committee, and detail the activities that have been undertaken to review and oversee the organization's compliance with Federal health care program and CIA requirements. OIG has not required this level of Board involvement in every case, but these provisions demonstrate the importance placed on Board oversight in cases OIG believes reflect serious compliance failures.

Although compliance program design is not a “one size fits all” issue, Boards are expected to put forth a meaningful effort....

Although compliance program design is not a “one size fits all” issue, Boards are expected to put forth a meaningful effort to review the adequacy of existing compliance systems and functions. Ensuring that management is aware of the Guidelines, compliance program guidance, and relevant CIAs is a good first step.

One area of inquiry for Board members of health care organizations should be the scope and adequacy of the compliance program in light of the size and complexity of their organizations. The Guidelines allow for variation according to “the size of the organization.”⁶ In accordance with the Guidelines,

6 USSG § 8B2.1, comment. (n. 2).

OIG recognizes that the design of a compliance program will depend on the size and resources of the organization.⁷ Additionally, the complexity of the organization will likely dictate the nature and magnitude of regulatory impact and thereby the nature and skill set of resources needed to manage and monitor compliance.

While smaller or less complex organizations must demonstrate the same degree of commitment to ethical conduct and compliance as larger organizations, the Government recognizes that they may meet the Guidelines requirements with less formality and fewer resources than would be expected of larger and more complex organizations.⁸ Smaller organizations may meet their compliance responsibility by “using available personnel, rather than employing separate staff, to carry out the compliance and ethics program.” Board members of such organizations may wish to evaluate whether the organization is “modeling its own compliance and ethics programs on existing, well-regarded compliance and ethics programs and best practices of other similar organizations.”⁹ The Guidelines also foresee that Boards of smaller organizations may need to become more involved in the organizations’ compliance and ethics efforts than their larger counterparts.¹⁰

Boards should develop a formal plan to stay abreast of the ever-changing regulatory landscape and operating environment. The plan may involve periodic updates from informed staff or review of regulatory resources made available to them by staff. With an understanding of the dynamic regulatory environment, Boards will be in a position to ask more pertinent questions of management

7 Compliance Program for Individual and Small Group Physician Practices, 65 Fed. Reg. 59434, 59436 (Oct. 5, 2000) (“The extent of implementation [of the seven components of a voluntary compliance program] will depend on the size and resources of the practice. Smaller physician practices may incorporate each of the components in a manner that best suits the practice. By contrast, larger physician practices often have the means to incorporate the components in a more systematic manner.”); Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14,289 (Mar. 16, 2000) (recognizing that smaller providers may not be able to outsource their screening process or afford to maintain a telephone hotline).

8 USSG § 8B2.1, comment. (n. 2).

9 *Id.*

10 *Id.*

and make informed strategic decisions regarding the organizations' compliance programs, including matters that relate to funding and resource allocation. For instance, new standards and reporting requirements, as required by law, may, but do not necessarily, result in increased compliance costs for an organization. Board members may also wish to take advantage of outside educational programs that provide them with opportunities to develop a better understanding of industry risks, regulatory requirements, and how effective compliance and ethics programs operate. In addition, Boards may want management to create a formal education calendar that ensures that Board members are periodically educated on the organizations' highest risks.

Finally, a Board can raise its level of substantive expertise with respect to regulatory and compliance matters by adding to the Board, or periodically consulting with, an experienced regulatory, compliance, or legal professional. The presence of a professional with health care compliance expertise on the Board sends a strong message about the organization's commitment to compliance, provides a valuable resource to other Board members, and helps the Board better fulfill its oversight obligations. Board members are generally entitled to rely on the advice of experts in fulfilling their duties.¹¹ OIG sometimes requires entities under a CIA to retain an expert in compliance or governance issues to assist the Board in fulfilling its responsibilities under the CIA.¹² Experts can assist Boards and management in a variety of ways, including the identification of risk areas, provision of insight into best practices in governance, or consultation on other substantive or investigative matters.

11 See Del Code Ann. tit. 8, § 141(e) (2010); ABA Revised Model Business Corporation Act, §§ 8.30(e), (f)(2) Standards of Conduct for Directors.

12 See Corporate Integrity Agreements between OIG and Halifax Hospital Medical Center and Halifax Staffing, Inc. (2014, compliance and governance); Johnson & Johnson (2013); Dallas County Hospital District d/b/a Parkland Health and Hospital System (2013, compliance and governance); Forest Laboratories, Inc. (2010); Novartis Pharmaceuticals Corporation (2010); Ortho-McNeil-Janssen Pharmaceuticals, Inc. (2010); Synthes, Inc. (2010, compliance expert retained by Audit Committee); The University of Medicine and Dentistry of New Jersey (2009, compliance expert retained by Audit Committee); Quest Diagnostics Incorporated (2009); Amerigroup Corporation (2008); Bayer HealthCare LLC (2008); and Tenet Healthcare Corporation (2006; retained by the Quality, Compliance, and Ethics Committee of the Board).

Roles and Relationships

Organizations should define the interrelationship of the audit, compliance, and legal functions in charters or other organizational documents. The structure, reporting relationships, and interaction of these and other functions (e.g., quality, risk management, and human resources) should be included as departmental roles and responsibilities are defined. One approach is for the charters to draw functional boundaries while also setting an expectation of cooperation and collaboration among those functions. One illustration is the following, recognizing that not all entities may possess sufficient resources to support this structure:



The compliance function promotes the prevention, detection, and resolution of actions that do not conform to legal, policy, or business standards. This responsibility includes the obligation to develop policies and procedures that provide employees guidance, the creation of incentives to promote employee compliance, the development of plans to improve or sustain compliance, the development of metrics to measure execution (particularly by management) of the program and implementation of corrective actions, and the development of reports and dashboards that help management and the Board evaluate the effectiveness of the program.

The legal function advises the organization on the legal and regulatory risks of its business strategies, providing advice and counsel to management and the Board about relevant laws and regulations that govern, relate to, or impact the organization. The function also defends the organization in legal proceedings and initiates legal proceedings against other parties if such action is warranted.

The internal audit function provides an objective evaluation of the existing risk and internal control systems and framework within an organization. Internal audits ensure monitoring functions are working as intended and identify where management monitoring and/or additional

Board oversight may be required. Internal audit helps management (and the compliance function) develop actions to enhance internal controls, reduce risk to the organization, and promote more effective and efficient use of resources. Internal audit can fulfill the auditing requirements of the Guidelines.

The human resources function manages the recruiting, screening, and hiring of employees; coordinates employee benefits; and provides employee training and development opportunities.

The quality improvement function promotes consistent, safe, and high quality practices within health care organizations. This function improves efficiency and health outcomes by measuring and reporting on quality outcomes and recommends necessary changes to clinical processes to management and the Board. Quality improvement is critical to maintaining patient-centered care and helping the organization minimize risk of patient harm.

Boards should be aware of, and evaluate, the adequacy, independence,¹³ and performance of different functions within an organization on a periodic basis. OIG believes an organization's Compliance Officer should neither be counsel for the provider, nor be subordinate in function or position to counsel or the legal department, in any manner.¹⁴ While independent, an organization's counsel and compliance officer should collaborate to further the interests of the organization. OIG's position on separate compliance and legal functions reflects the independent roles and professional obligations of each function;¹⁵

13 Evaluation of independence typically includes assessing whether the function has uninhibited access to the relevant Board committees, is free from organizational bias through an appropriate administrative reporting relationship, and receives fair compensation adjustments based on input from any relevant Board committee.

14 See OIG and AHHA, *An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors*, 3 (2004) (citing Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8,987, 8,997 (Feb. 23, 1998)).

15 See, generally, *id.*

the same is true for internal audit.¹⁶ To operate effectively, the compliance, legal, and internal audit functions should have access to appropriate and relevant corporate information and resources. As part of this effort, organizations will need to balance any existing attorney-client privilege with the goal of providing such access to key individuals who are charged with the responsibility for ensuring compliance, as well as properly reporting and remediating any violations of civil, criminal, or administrative law.

The Board should have a process to ensure appropriate access to information; this process may be set forth in a formal charter document approved by the Audit Committee of the Board or in other appropriate documents. Organizations that do not separate these functions (and some organizations may not have the resources to make this complete separation) should recognize the potential risks of such an arrangement. To partially mitigate these potential risks, organizations should provide individuals serving in multiple roles the capability to execute each function in an independent manner when necessary, including through reporting opportunities with the Board and executive management.

Boards should also evaluate and discuss how management works together to address risk, including the role of each in:

1. identifying compliance risks,
2. investigating compliance risks and avoiding duplication of effort,
3. identifying and implementing appropriate corrective actions and decision-making, and
4. communicating between the various functions throughout the process.



¹⁶ Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8,987, 8,997 (Feb. 23, 1998) (auditing and monitoring function should “[b]e independent of physicians and line management”); Compliance Program Guidance for Home Health Agencies, 63 Fed. Reg. 42,410, 42,424 (Aug. 7, 1998) (auditing and monitoring function should “[b]e objective and independent of line management to the extent reasonably possible”); Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14,289, 14,302 (Mar. 16, 2000).

Boards should understand how management approaches conflicts or disagreements with respect to the resolution of compliance issues and how it decides on the appropriate course of action. The audit, compliance, and legal functions should speak a common language, at least to the Board and management, with respect to governance concepts, such as accountability, risk, compliance, auditing, and monitoring. Agreeing on the adoption of certain frameworks and definitions can help to develop such a common language.

Reporting to the Board

The Board should set and enforce expectations for receiving particular types of compliance-related information from various members of management. The Board should receive regular reports regarding the organization's risk mitigation and compliance efforts—separately and independently—from a variety of key players, including those responsible for audit, compliance, human resources, legal, quality, and information technology. By engaging the leadership team and others deeper in the organization, the Board can identify who can provide relevant information about operations and operational risks. It may be helpful and productive for the Board to establish clear expectations for members of the management team and to hold them accountable for performing and informing the Board in accordance with those expectations. The Board may request the development of objective scorecards that measure how well management is executing the compliance program, mitigating risks, and implementing corrective action plans. Expectations could also include reporting information on internal and external investigations, serious issues raised in internal and external audits, hotline call activity, all allegations of material fraud or senior management misconduct, and all management exceptions to the organization's

The Board should receive regular reports regarding the organization's risk mitigation and compliance efforts....

code of conduct and/or expense reimbursement policy. In addition, the Board should expect that management will address significant regulatory changes and enforcement events relevant to the organization's business.

Boards of health care organizations should receive compliance and risk-related information in a format sufficient to satisfy the interests or concerns of their members and to fit their capacity to review that information. Some Boards use tools such as dashboards—containing key financial, operational and compliance indicators to assess risk, performance against budgets, strategic plans, policies and procedures, or other goals and objectives—in order to strike a balance between too much and too little information. For instance, Board quality committees can work with management to create the content of the dashboards with a goal of identifying and responding to risks and improving quality of care. Boards should also consider establishing a risk-based reporting system, in which those responsible for the compliance function provide reports to the Board when certain risk-based criteria are met. The Board should be assured that there are mechanisms in place to ensure timely reporting of suspected violations and to evaluate and implement remedial measures. These tools may also be used to track and identify trends in organizational performance against corrective action plans developed in response to compliance concerns. Regular internal reviews that provide a Board with a snapshot of where the organization is, and where it may be going, in terms of compliance and quality improvement, should produce better compliance results and higher quality services.

As part of its oversight responsibilities, the Board may want to consider conducting regular “executive sessions” (i.e., excluding senior management) with leadership from the compliance, legal, internal audit, and quality functions to encourage more open communication. Scheduling regular executive sessions creates a continuous expectation of open dialogue, rather than calling such a session only when a problem arises, and is helpful to avoid suspicion among management about why a special executive session is being called.

Identifying and Auditing Potential Risk Areas

Some regulatory risk areas are common to all health care providers. Compliance in health care requires monitoring of activities that are highly vulnerable to fraud or other violations. Areas of particular interest include 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.

The Board should ensure that management and the Board have strong processes for identifying risk areas. Risk areas may be identified from internal or external information sources. For instance, Boards and management may identify regulatory risks from internal sources, such as employee reports to an internal compliance hotline or internal audits. External sources that may be used to identify regulatory risks might include professional organization publications, OIG-issued guidance, consultants, competitors, or news media. When failures or problems in similar organizations are publicized, Board members should ask their own management teams whether there are controls and processes in place to reduce the risk of, and to identify, similar misconduct or issues within their organizations.

The Board should ensure that management consistently reviews and audits risk areas, as well as develops, implements, and monitors corrective action plans. One of the reasonable steps an organization is expected to take



under the Guidelines is “monitoring and auditing to detect criminal conduct.”¹⁷ Audits can pinpoint potential risk factors, identify regulatory or compliance problems, or confirm the effectiveness of compliance controls. Audit results that reflect compliance issues or control deficiencies should be accompanied by corrective action plans.¹⁸

Recent industry trends should also be considered when designing risk assessment plans. Compliance functions tasked with monitoring new areas of risk should take into account the increasing emphasis on quality, industry consolidation, and changes in insurance coverage and reimbursement. 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) lead to new incentives and compliance risks. Payment policies that align payment with quality care have placed increasing pressure to conform to recommended quality guidelines and improve quality outcomes. New payment models have also incentivized consolidation among health care providers and more employment and contractual relationships (e.g., between hospitals and physicians). In light of the fact that statutes applicable to provider-physician relationships are very broad, Boards of entities that have financial relationships with referral sources or recipients should ask how their organizations are reviewing these arrangements for compliance with the physician self-referral (Stark) and anti-kickback laws. There should also be a clear understanding between the Board and management as to how the entity will approach and implement those relationships and what level of risk is acceptable in such arrangements.

Emerging trends in the health care industry to increase transparency can present health care organizations with opportunities and risks. For example, the Government is collecting and publishing data on health outcomes and quality measures (e.g., Centers for Medicare & Medicaid Services (CMS) Quality Compare Measures), Medicare payment data are now publicly available (e.g.,

17 See USSG § 8B2.1(b)(5).

18 See USSG § 8B2.1(c).

CMS physician payment data), and the Sunshine Rule¹⁹ offers public access to data on payments from the pharmaceutical and device industries to physicians. Boards should consider all beneficial use of this newly available information. For example, Boards may choose to compare accessible data against organizational peers and incorporate national benchmarks when assessing organizational risk and compliance. Also, Boards of organizations that employ physicians should be cognizant of the relationships that exist between their employees and other health care entities and whether those relationships could have an impact on such matters as clinical and research decision-making. Because so much more information is becoming public, Boards may be asked significant compliance-oriented questions by various stakeholders, including patients, employees, government officials, donors, the media, and whistleblowers.

Encouraging Accountability and Compliance

Compliance is an enterprise-wide responsibility. While audit, compliance, and legal functions serve as advisors, evaluators, identifiers, and monitors of risk and compliance, it is the responsibility of the entire organization to execute the compliance program.

In an effort to support the concept that compliance is “a way of life,” a Board may assess employee performance in promoting and adhering to compliance.²⁰ An organization may assess individual, department, or facility-level performance or consistency in executing the compliance program. These assessments can then be used to either withhold incentives or to provide bonuses

**Compliance is an
enterprise-wide
responsibility.**

¹⁹ See Sunshine Rule, 42 C.F.R. § 403.904, and CMS *Open Payments*, <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>.

²⁰ Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14,289, 14,298-14,299 (Mar. 16, 2000).

based on compliance and quality outcomes. Some companies have made participation in annual incentive programs contingent on satisfactorily meeting annual compliance goals. Others have instituted employee and executive compensation claw-back/recoupment provisions if compliance metrics are not met. Such approaches mirror Government trends. For example, OIG is increasingly requiring certifications of compliance from managers outside the compliance department. Through a system of defined compliance goals and objectives against which performance may be measured and incentivized, organizations can effectively communicate the message that everyone is ultimately responsible for compliance.

Governing Boards have multiple incentives to build compliance programs that encourage self-identification of compliance failures and to voluntarily disclose such failures to the Government. For instance, providers enrolled in Medicare or Medicaid are required by statute to report and refund any overpayments under what is called the 60 Day Rule.²¹ The 60-Day Rule requires all Medicare and Medicaid participating providers and suppliers to report and refund known overpayments within 60 days from the date the overpayment is "identified" or within 60 days of the date when any corresponding cost report is due. Failure to follow the 60-Day Rule can result in False Claims Act or civil monetary penalty liability. The final regulations, when released, should provide additional guidance and clarity as to what it means to "identify" an overpayment.²² However, as an example, a Board would be well served by asking management about its efforts to develop policies for identifying and returning overpayments. Such an inquiry would inform the Board about how proactive the organization's compliance program may be in correcting and remediating compliance issues.

²¹ 42 U.S.C. § 1320a-7k.

²² Medicare Program; Reporting and Returning of Overpayments, 77 Fed. Reg. 9179, 9182 (Feb. 16, 2012) (Under the proposed regulations interpreting this statutory requirement, an overpayment is "identified" when a person "has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.") disregard or deliberate ignorance of the overpayment."); Medicare Program; Reporting and Returning of Overpayments; Extensions of Timeline for Publication of the Final Rule, 80 Fed. Reg. 8247 (Feb. 17, 2015).

Organizations that discover a violation of law often engage in an internal analysis of the benefits and costs of disclosing—and risks of failing to disclose—such violation to OIG and/or another governmental agency. Organizations that are proactive in self-disclosing issues under OIG’s Self-Disclosure Protocol realize certain benefits, such as (1) faster resolution of the case—the average OIG self-disclosure is resolved in less than one year; (2) lower payment—OIG settles most self-disclosure cases for 1.5 times damages rather than for double or treble damages and penalties available under the False Claims Act; and (3) exclusion release as part of settlement with no CIA or other compliance obligations.²³ OIG believes that providers have legal and ethical obligations to disclose known violations of law occurring within their organizations.²⁴ Boards should ask management how it handles the identification of probable violations of law, including voluntary self-disclosure of such issues to the Government.

As an extension of their oversight of reporting mechanisms and structures, Boards would also be well served by evaluating whether compliance systems and processes encourage effective communication across the organizations and whether employees feel confident that raising compliance concerns, questions, or complaints will result in meaningful inquiry without retaliation or retribution. Further, the Board should request and receive sufficient information to evaluate the appropriateness of management’s responses to identified violations of the organization’s policies or Federal or State laws.

Conclusion

A health care governing Board should make efforts to increase its knowledge of relevant and emerging regulatory risks, the role and functioning of the organization’s compliance program in the face of those risks, and the flow and elevation of reporting of potential issues and problems to

²³ See OIG, *Self-Disclosure Information*, <http://oig.hhs.gov/compliance/self-disclosure-info>.

²⁴ See *id.*, at 2 (“we believe that using the [Self-Disclosure Protocol] may mitigate potential exposure under section 1128J(d) of the Act, 42 U.S.C. 1320a-7k(d).”)

senior management. A Board should also encourage a level of compliance accountability across the organization. A Board may find that not every measure addressed in this document is appropriate for its organization, but every Board is responsible for ensuring that its organization complies with relevant Federal, State, and local laws. The recommendations presented in this document are intended to assist Boards with the performance of those activities that are key to their compliance program oversight responsibilities. Ultimately, compliance efforts are necessary to protect patients and public funds, but the form and manner of such efforts will always be dependent on the organization's individual situation.

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