

THE HEALTH CARE DIRECTOR'S COMPLIANCE DUTIES: A Continued Focus of Attention and Enforcement

A Joint Publication from the Office of the Inspector General, U.S. Department of Health and Human Services and the American Health Lawyers Association



*"...to serve as a public resource on selected healthcare legal issues"
—From the Mission Statement of the American Health Lawyers Association*

About the Organizations

The Health Care Director's Compliance Duties: A Continued Focus of Attention and Enforcement is a compilation of three corporate compliance resources, originally issued in 2003, 2004, and 2007. Developed in collaboration between the American Health Lawyers Association (AHLA) and the Office of the Inspector General (OIG) of the United States Department of Health and Human Services (HHS), AHLA's Corporate Responsibility Series can assist directors of healthcare organizations carry out their oversight responsibilities.

The AHLA is the nation's largest, nonpartisan, 501(c)(3) educational organization devoted to legal issues in the healthcare field with more than 10,000 members. The OIG is the independent and objective oversight unit of HHS, with a mission of promoting economy, efficiency, and effectiveness in the department's programs through the elimination of waste, abuse, and fraud.

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— from a declaration of the American Bar Association

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Since the initial publication of the three corporate responsibility resource guides by the American Health Lawyers Association (AHLA) and the Office of the Inspector General (OIG), U.S. Department of Health and Human Services (HHS), interest in the fiduciary duty of health care boards of directors, as it relates to compliance and quality, has continued to increase. Quality, cost efficiency, waste, and fraud are issues that are even more meaningful in light of the current health care reform debate.

In a recent survey¹ of published articles on governing board functions and responsibilities, the findings showed a very large increase in such articles published this decade. In the early 2000s, however, only a small minority of these related to quality and safety. By the late 2000s, nearly half related to quality and safety.

We note just a few specific examples of recent interest in the role of health care boards and quality of care: The Joint Commission, in 2007, published *Getting the Board on Board: What Your Board Needs to Know about Quality and Patient Safety*; the Institute for Healthcare Improvement, in 2006, published a white paper entitled *Leadership Guide to Patient Safety*; and the National Quality Forum, in 2004, published *Hospital Governing Boards and Quality of Care: A Call to Responsibility*.

The three articles in this AHLA-OIG Corporate Responsibilities Series now being reissued by The Governance Institute progressed in a similar direction—from a focus on defining the board's duty of care in the post-Sarbanes-Oxley and health care regulatory compliance context through a careful look at the roles of the general counsel and the chief compliance officer, to a specific look at corporate responsibility and health care quality.

Meanwhile, developments in corporate governance, fiduciary liability, non-profit organization oversight, and related areas continue to influence fiduciary duty in the health care setting. Case law continues to address standards of director conduct.² The IRS has stepped up its activities in the non-profit arena,

both with the release of its more detailed Form 990 and further guidance on corporate governance. The economic crisis of 2008–2009 has brought renewed scrutiny of boards of directors' actions, including those of non-profit boards.³

State and federal enforcement agencies also are demonstrating a growing recognition of the role of health care boards in promoting quality of care and ensuring compliance with federal health care program rules. In a number of cases involving the provision of substandard care to Medicare and Medicaid patients, the responsible medical professional and the hospital have been held responsible for the failure to provide quality care. In a number of recent fraud settlements, the OIG has imposed corporate integrity agreements that require boards to provide heightened scrutiny of their institutions' compliance systems and to take responsibility for the effectiveness of internal controls. The New York State Office of Medicaid Inspector General also has a specific focus on compliance oversight obligations of governing boards and stated its intention to pursue enforcement actions in the appropriate cases.

The ongoing efforts to reform the nation's health care system also implicate the boards of health care institutions. As part of the movement to improve outcomes and reduce health care costs, Medicare and Medicaid are beginning to link hospital payments to the quality of care. In addition to financially rewarding hospitals that improve care, Medicare and some other public and private insurers also are starting to refuse payment for preventable errors. As the link between payment and quality of care grows, boards will need to be involved in the oversight of the care provided by their health care institutions.

In light of these developments, the three resource guides in this AHLA-OIG Corporate Responsibility Series are increasingly relevant for boards of health care organizations. We are grateful to The Governance Institute for its support and assistance in making this information available.

1 See William J. Oetgen, MD, MBA, *The Governing Board's Quality Agenda, An Overview*, Prescriptions for Excellence in Healthcare, Jefferson School of Population Health and Lilly USA, LLC, Issue 5, Summer 2009.

2 See *Lyondell Chemical Co. v. Ryan*, C.A. No. 401, 2008 (Del. March 25, 2009) and *In re Citigroup Inc. Shareholder Derivative Litigation*, 964 A.2d. 106 (Del. Ch. 2009).

3 See *Lehman Board Faulted for Excessive Pay, Poor Governance Practices in Face of Crisis*, BNA's Corporate Accountability Reporter, Vol. 6, No. 40, October 10, 2008, and Carrie Coolidge, *Blumenthal May Investigate Charities Ripped Off by Madoff*, Forbes.com, December 22, 2008.

The AHLA-OIG Corporate Responsibility Series (Series) consists of three corporate compliance guidance resources:

- *Corporate Responsibility and Corporate Compliance* (2003)
- *An Integrated Approach to Corporate Compliance* (2004)
- *Corporate Responsibility and Health Care Quality* (2007)

Individually and collectively, the components of this Series were intended as an educational resource to assist governing board members of health care organizations to more responsibly carry out their compliance plan oversight obligations under applicable law.

Given the increasing emphasis on corporate compliance from legislative, regulatory, and public policy perspectives, the need to provide board-level compliance guidance is greater than ever. For these reasons, the Series is being reissued, with the gracious assistance of The Governance Institute. The following is an “executive briefing” synopsis of each of the three components of the Series.

Corporate Responsibility and Corporate Compliance

☑ **Theme:** The expansion of health care regulatory enforcement and compliance activities and heightened attention being given to the responsibilities of health care directors are critically important to all health care organizations. It is thus appropriate to evaluate the health care board’s unique fiduciary duty of compliance plan oversight and how that duty may be satisfied.

☑ **Key Points:**

- The duty of compliance plan oversight arises from the director’s fundamental fiduciary duty of care.
- Specifically, “[A] director’s obligations include a duty to attempt in good faith to assure that a corporate information and reporting system, which the board concludes is adequate, exists, and that failure to do so under some circumstances, may, in theory at least, render a director liable for losses caused by non-compliance with applicable legal standards.” This is the so-called *Caremark* standard.⁴
- The circumstances of each organization differ and application of the duty of care and

consequent reasonable inquiry will need to be tailored to each specific set of facts and circumstances.

☑ **Practical Applications:** While the opinion in *Caremark* established a board’s duty to oversee a compliance program, it did not enumerate a specific methodology for doing so. This particular compliance resource is designed to assist health care directors in exercising that responsibility by offering a series of suggested questions for directors. Several “structural” questions explore the board’s understanding of the scope of the organization’s compliance program. The remaining questions are directed to the operations of the compliance program and may facilitate the board’s understanding of its compliance program.

☑ **Why Still Relevant:** Regulators and other third parties continue to evaluate the board’s exercise of its compliance plan oversight duties. For example, the New York State Medicaid Inspector General has made it clear by regulation that directors may be held accountable for ineffective oversight that contributes to compliance violations. Further, a series of decisions of the influential Delaware courts continue to apply the framework of the *Caremark* standard.

An Integrated Approach to Corporate Compliance

☑ **Theme:** The health care entity governing board plays an important role in reconciling differing views (e.g., legislative, OIG, American Bar Association) regarding the proper role of the general counsel in health care compliance. The governing board should monitor the roles of the general counsel and the chief compliance officer in supporting the board’s compliance oversight responsibilities.

☑ **Key Points:**

- 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.
- Consideration of the role of the general counsel in overseeing compliance programs has been ongoing.
- The OIG has historically perceived some risk where an otherwise independent compliance function is subordinate to the general counsel or financial officer.

⁴ *In re Caremark International Inc. Derivative Legislation*, 698 A.2d 959 (Del. Cn. 1996).

- The Code of Professional Responsibility in many states requires lawyers to report “up the ladder” violations of the law by officers, employees, or agents.
- The American Bar Association has taken the view that the general counsel should have primary responsibility for assuring the implementation of an effective legal compliance system under the board’s oversight.
- A board member overseeing the compliance function should understand how the organization is addressing the issue of the role of the general counsel and chief compliance officer in the implementation of the organization’s compliance plan.

☑ **Practical Applications:** This particular compliance resource includes a series of suggested questions/ areas of inquiry that directors should pursue to ensure that (a) the board understands the role of the general counsel and the chief compliance officer in supporting the organization’s corporate compliance program, and (b) 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 related commentary recognize that boards may consider a variety of approaches in addressing these issues.

☑ **Why Still Relevant:** The interplay between the general counsel and the chief compliance officer remains of critical importance, especially as it relates to the board’s ability to receive reports on compliance in a coordinated, comprehensive manner. Further, as recent Corporate Integrity Agreements have noted, the OIG continues to believe that compliance “checks and balances” are more effectively maintained when the compliance function is separated from management functions (*e.g.*, the general counsel).

Corporate Responsibility and Health Care Quality

☑ **Theme:** With a new era of focus on quality and patient safety rapidly emerging, oversight of quality is becoming more clearly recognized as a core fiduciary responsibility of health care organization directors. Boards have distinct compliance-related responsibilities in this area because quality of care

is perceived as an enforcement priority for health care regulators.

☑ **Key Points:**

- Director obligations to monitor organizational quality of care arise from three particular bases: 1) the basic duty of care and the director’s obligation to oversee day-to-day corporate operations; 2) the related duty to oversee the compliance program; and 3) the duty of obedience to corporate purpose/mission (*e.g.*, conduct of the institution as a hospital).
- These duties are in addition to traditional board obligations with respect to supervising medical staff credentialing decisions.
- Many new financial relationships address quality of care issues, *e.g.*, pay-for-performance programs, gainsharing, and outcomes management arrangements, among others.
- Government enforcement authorities are increasingly focusing on the quality of care provided to beneficiaries of federal and state health care programs and the organization’s related legal liability profile.

☑ **Practical Applications:** This particular compliance resource seeks to help the health entity board as it develops an understanding of relevant quality and patient safety issues, and focuses on performance goals that help the organization provide the best quality and most efficient care. Accordingly, this resource includes a series of suggested questions that may be helpful as the board examines the scope and operation of the organization’s quality and safety initiatives.

☑ **Why Still Relevant:** Health care quality and patient safety issues are at the forefront of multiple health care reform initiatives at both the federal and state level. Amendments to the False Claims Act increase the potential for substantial quality of care-based and similar enforcement actions related to quality of care concerns. Recent regulatory initiatives by the New York State Medicaid Inspector General demonstrate how quality of care oversight can be interpreted as a component part of an “effective” corporate compliance plan for a health care provider.

I. Introduction

As corporate responsibility issues fill the headlines, corporate directors are coming under greater scrutiny. The Sarbanes-Oxley Act, state legislation, agency pronouncements, court cases, and scholarly writings offer a myriad of rules, regulations, prohibitions, and interpretations in this area. While all Boards of Directors must address these issues, directors of health care organizations also have important responsibilities that need to be met relating to corporate compliance requirements unique to the health care industry. The expansion of health care regulatory enforcement and compliance activities and the heightened attention being given to the responsibilities of corporate directors are critically important to all health care organizations. In this context, enhanced oversight of corporate compliance programs is widely viewed as consistent with and essential to ongoing federal and state corporate responsibility initiatives.

Our complex health care system needs dedicated and knowledgeable directors at the helm of both for-profit and non-profit corporations. This educational resource, co-sponsored by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), and the American Health Lawyers Association (AHLA), the leading health law educational organization, seeks to assist directors of health care organizations in carrying out their important oversight responsibilities in the current challenging health care environment. Improving the knowledge base and effectiveness of those serving on health care organization boards will help to achieve the important goal of continuously improving the U.S. health care system.

A. Fiduciary Responsibilities

The fiduciary duties of directors reflect the expectation of corporate stakeholders regarding oversight of corporate affairs. The basic fiduciary duty of care principle, which requires a director to act in good faith with the care an ordinarily prudent person would exercise under similar circumstances, is being tested in the current corporate climate. Personal liability for directors, including removal, civil damages, and tax liability, as well as damage to reputation, appears not so far from reality as once widely believed. Accordingly, a basic understanding of the director's fiduciary obligations and how the duty of care may be exercised in overseeing the company's compliance systems has become essential.

Embedded within the duty of care is the concept of reasonable inquiry. In other words, directors should make inquiries to management to obtain information necessary to satisfy their duty of care. Although in the *Caremark* case, also discussed later in this educational resource, the court found that the *Caremark* board did not breach its fiduciary duty, the court's opinion also stated the following: "[A] director's obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the Board concludes is adequate, exists, and that failure to do so under some circumstances, may, in theory at least, render a director liable for losses caused by non-compliance with applicable legal standards." Clearly, the organization may be at risk and directors, under extreme circumstances, also may be at risk if they fail to reasonably oversee the organization's compliance program or act as mere passive recipients of information.

On the other hand, courts traditionally have been loath to second-guess Boards of Directors that have followed a careful and thoughtful process in their deliberations, even where ultimate outcomes for the corporation have been negative. Similarly, courts have consistently upheld the distinction between the duties of Boards of Directors and the duties of management. The responsibility of directors is to provide oversight, not manage day-to-day affairs. It is the process the Board follows in establishing that it had access to sufficient information and that it has asked appropriate questions that is most critical to meeting its duty of care.

B. Purpose of this Document

This educational resource is designed to help health care organization directors ask knowledgeable and appropriate questions related to health care corporate compliance. These questions are not intended to set forth any specific standard of care. Rather, this resource will help corporate directors to establish, and affirmatively demonstrate, that they have followed a reasonable compliance oversight process.

Of course, the circumstances of each organization differ and application of the duty of care and consequent reasonable inquiry will need to be tailored to each specific set of facts and circumstances. However, compliance with the fraud and abuse laws and other federal and state regulatory laws applicable to health care organizations is essential for the lawful behavior and corporate success of such organizations. While these laws can be complex, effective compliance is an asset for

both the organization and the health care delivery system. It is hoped that this educational resource is useful to health care organization directors in exercising their oversight responsibilities and supports their ongoing efforts to promote effective corporate compliance.

II. Duty of Care

Of the principal fiduciary obligations/duties owed by directors to their corporations, the one duty specifically implicated by corporate compliance programs is the *duty of care*.¹

As the name implies, the duty of care refers to the obligation of corporate directors to exercise the proper amount of care in their decision-making process. State statutes that create the duty of care and court cases that interpret it usually are identical for both for-profit and non-profit corporations.

In most states, duty of care involves determining whether the directors acted (1) in “good faith,” (2) with that level of care that an ordinarily prudent person would exercise in like circumstances, and (3) in a manner that they reasonably believe is in the best interest of the corporation. In analyzing whether directors have complied with this duty, it is necessary to address each of these elements separately.

The “good faith” analysis usually focuses upon whether the matter or transaction at hand involves any improper financial benefit to an individual, and/or whether any intent exists to take advantage of the corporation (a corollary to the duty of loyalty). The “reasonable inquiry” test asks whether the directors conducted the appropriate level of due diligence to allow them to make an informed decision. In other words, directors must be aware of what is going on about them in the corporate business and must, in appropriate circumstances, make such reasonable inquiry as would an ordinarily prudent person under similar circumstances. Finally, directors are obligated to act in a manner that they reasonably believe to be in the best interests of the corporation. This normally relates to the directors’ state of mind with respect to the issues at hand.

In considering directors’ fiduciary obligations, it is important to recognize that the appropriate stan-

dard of care is not “perfection.” Directors are not required to know everything about a topic they are asked to consider. They may, where justified, rely on the advice of management and outside advisors.

Furthermore, many courts apply the “business judgment rule” to determine whether a director’s duty of care has been met with respect to corporate decisions. The rule provides, in essence, that a director will not be held liable for a decision made in good faith, where the director is disinterested, reasonably informed under the circumstances, and rationally believes the decision to be in the best interest of the corporation.

Director obligations with respect to the duty of care arise in two distinct contexts:

- The *Decision-Making Function*: The application of duty of care principles to a specific decision or a particular board action, and
- The *Oversight Function*: The application of duty of care principles with respect to the general activity of the board in overseeing the day-to-day business operations of the corporation, *i.e.*, the exercise of reasonable care to assure that corporate executives carry out their management responsibilities and comply with the law.

Directors’ obligations with respect to corporate compliance programs arise within the context of that oversight function. The leading case in this area, viewed as applicable to all health care organizations, provides that a director has two principal obligations with respect to the oversight function. A director has a duty to attempt in good faith to assure that (1) a corporate information and reporting system exists, and (2) this reporting system is adequate to assure the board that appropriate information as to compliance with applicable laws will come to its attention in a timely manner as a matter of ordinary operations.² In *Caremark*, the court addressed the circumstances in which corporate directors may be held liable for breach of the duty of care by failing to adequately supervise corporate employees whose misconduct caused the corporation to violate the law.

In its opinion, the *Caremark* court observed that the level of detail that is appropriate for such an information system is a matter of business judgment. The court also acknowledged that no

1 The other two core fiduciary duty principals are the duty of loyalty and the duty of obedience to purpose.

2 *In re Caremark International Inc. Derivative Litigation*, 698 A.2d 959 (Del. Ch. 1996). A shareholder sued the Board of Directors of Caremark for breach of the fiduciary duty of care. The lawsuit followed a multi-million dollar civil settlement and criminal plea relating to the payment of kickbacks to physicians and improper billing to federal health care programs.

rationally designed information and reporting system will remove the possibility that the corporation will violate applicable laws or otherwise fail to identify corporate acts potentially inconsistent with relevant law.

Under these circumstances, a director's failure to reasonably oversee the implementation of a compliance program may put the organization at risk and, under extraordinary circumstances, expose individual directors to personal liability for losses caused by the corporate non-compliance.³ Of course, crucial to the oversight function is the fundamental principle that a director is entitled to rely, in good faith, on officers and employees as well as corporate professional experts/advisors in whom the director believes such confidence is merited. A director, however, may be viewed as not acting in good faith if she is aware of facts suggesting that such reliance is unwarranted.

In addition, the duty of care test involving reasonable inquiry has not been interpreted to require the director to exercise "proactive vigilance" or to "ferret out" corporate wrongdoing absent a particular warning or a "red flag." Rather, the duty to make reasonable inquiry increases when "suspicions are aroused or *should be aroused*"—that is, when the director is presented with extraordinary facts or circumstances of a material nature (*e.g.*, indications of financial improprieties, self-dealing, or fraud), or a major governmental investigation. Absent the presence of suspicious conduct or events, directors are entitled to rely on the senior leadership team in the performance of its duties. Directors are not otherwise obligated to anticipate future problems of the corporation.

Thus, in exercising her duty of care, the director is obligated to exercise general supervision and control with respect to corporate officers. However, once presented (through the compliance program or otherwise) with information that causes (or should cause) concerns to be aroused, the director is then obligated to make further inquiry until such time as her concerns are satisfactorily addressed and favorably resolved. Thus, while the corporate director is not expected to serve as a compliance officer, she is expected to oversee senior management's operation of the compliance program.

III. The Unique Challenges of Health Care Organization Directors

The health care industry operates in a heavily regulated environment with a variety of identifiable risk areas. An effective compliance program helps mitigate those risks. In addition to the challenges associated with patient care, health care providers are subject to voluminous and sometimes complex sets of rules governing the coverage and reimbursement of medical services. Because federal and state-sponsored health care programs play such a significant role in paying for health care, material non-compliance with these rules can present substantial risks to the health care provider. In addition to recoupment of improper payments, the Medicare, Medicaid and other government health care programs can impose a range of sanctions against health care businesses that engage in fraudulent practices.

Particularly given the current "corporate responsibility" environment, health care organization directors should be concerned with the manner in which they carry out their duty to oversee corporate compliance programs. Depending upon the nature of the corporation, there are a variety of parties that might in extreme circumstances seek to hold corporate directors personally liable for allegedly breaching the duty of oversight with respect to corporate compliance. With respect to for-profit corporations, the most likely individuals to bring a case against the directors are corporate shareholders in a derivative suit, or to a limited degree, a regulatory agency such as the Securities and Exchange Commission. With respect to non-profit corporations, the most likely person to initiate such action is the state attorney general, who may seek equitable relief against the director (*e.g.*, removal) or damages. It is also possible (depending upon state law) that a dissenting director, or the corporate member, could assert a derivative-type action against the directors allegedly responsible for the "inattention," seeking removal or damages.

Over the last decade, the risks associated with non-compliance have grown dramatically. The government has dedicated substantial resources, including the addition of criminal investigators and prosecutors, to respond to health care fraud and abuse. In

³ Law is not static, and different states will have different legal developments and standards. Standards may also vary depending on whether an entity is for profit or non-profit. Boards of public health care entities may have additional statutory obligations and should be aware of state and federal statutory requirements applicable to them.

addition to government investigators and auditors, private whistleblowers play an important role in identifying allegedly fraudulent billing schemes and other abusive practices. Health care providers can be found liable for submitting claims for reimbursement in reckless disregard or deliberate ignorance of the truth, as well as for intentional fraud. Because the False Claims Act authorizes the imposition of damages of up to three times the amount of the fraud and civil monetary penalties of \$11,000 per false claim, record level fines and penalties have been imposed against individuals and health care organizations that have violated the law.

In addition to criminal and civil monetary penalties, health care providers that are found to have defrauded the federal health care programs may be excluded from participation in these programs. The effect of an exclusion can be profound because those excluded will not receive payment under Medicare, Medicaid or other federal health care programs for items or services provided to program beneficiaries. The authorities of the OIG provide for mandatory exclusion for a minimum of five years for a conviction with respect to the delivery of a health care item or service. The presence of aggravating circumstances in a case can lead to a lengthier period of exclusion. Of perhaps equal concern to board members, the OIG also has the discretion to exclude providers for certain conduct even absent a criminal conviction. Such conduct includes participation in a fraud scheme, the payment or receipt of kickbacks, and failing to provide services of a quality that meets professionally recognized standards. In lieu of imposing exclusion in these instances, the OIG may require an organization to implement a comprehensive compliance program, requiring independent audits, OIG oversight and annual reporting requirements, commonly referred to as a Corporate Integrity Agreement.

IV. The Development of Compliance Programs

In light of the substantial adverse consequences that may befall an organization that has been found to have committed health care fraud, the health care industry has embraced efforts to improve compliance with federal and state health care program requirements. As a result, many health care providers have developed active compliance programs tailored to their particular circumstances. A recent survey by the Health Care Compliance Association, for example, has found that in just three years, health care organizations with active compliance programs have grown from

55 percent in 1999 to 87 percent in 2002. In support of these efforts, the OIG has developed a series of provider-specific compliance guidances. These voluntary guidelines identify risk areas and offer concrete suggestions to improve and enhance an organization's internal controls so that its billing practices and other business arrangements are in compliance with Medicare's rules and regulations.

As compliance programs have matured and new challenges have been identified, health care organization boards of directors have sought ways to help their organization's compliance program accomplish its objectives. Although health care organization directors may come from diverse backgrounds and business experiences, an individual director can make a valuable contribution toward the compliance objective by asking practical questions of management and contributing her experiences from other industries. While the opinion in *Caremark* established a Board's duty to oversee a compliance program, it did not enumerate a specific methodology for doing so. It is therefore important that directors participate in the development of this process. This educational resource is designed to assist health care organization directors in exercising that responsibility.

V. Suggested Questions for Directors

Periodic consideration of the following questions and commentary may be helpful to a health care organization's Board of Directors. The structural questions explore the Board's understanding of the scope of the organization's compliance program. The remaining questions, addressing operational issues, are directed to the operations of the compliance program and may facilitate the Board's understanding of the vitality of its compliance program.

A. Structural Questions

- 1. How is the compliance program structured and who are the key employees responsible for its implementation and operation? How is the Board structured to oversee compliance issues?**

The success of a compliance program relies upon assigning high-level personnel to oversee its implementation and operations. The Board may wish as well to establish a committee or other subset of the Board to monitor compliance program operations and regularly report to the Board.

2. **How does the organization's compliance reporting system work? How frequently does the Board receive reports about compliance issues?**

Although the frequency of reports on the status of the compliance program will depend on many circumstances, health care organization Boards should receive reports on a regular basis. Issues that are frequently addressed include (1) what the organization has done in the past with respect to the program and (2) what steps are planned for the future and why those steps are being taken.

3. **What are the goals of the organization's compliance program? What are the inherent limitations in the compliance program? How does the organization address these limitations?**

The adoption of a corporate compliance program by an organization creates standards and processes that it should be able to rely upon and against which it may be held accountable. A solid understanding of the rationale and objectives of the compliance program, as well as its goals and inherent limitations, is essential if the Board is to evaluate the reasonableness of its design and the effectiveness of its operation. If the Board has unrealistic expectations of its compliance program, it may place undue reliance on its ability to detect vulnerabilities. Furthermore, compliance programs will not prevent all wrongful conduct and the Board should be satisfied that there are mechanisms to ensure timely reporting of suspected violations and to evaluate and implement remedial measures.

4. **Does the compliance program address the significant risks of the organization? How were those risks determined and how are new compliance risks identified and incorporated into the program?**

Health care organizations operate in a highly regulated industry and must address various standards, government program conditions of participation and reimbursement, and other standards applicable to corporate citizens irrespective of industry. A comprehensive ongoing process of compliance risk assessment is important to the Board's awareness of new challenges to the organization and its evaluation of management's priorities and program resource allocation.

5. **What will be the level of resources necessary to implement the compliance program as envisioned by the Board? How has management determined the adequacy of the resources dedicated to implementing and sustaining the compliance program?**

From the outset, it is important to have a realistic understanding of the resources necessary to implement and sustain the compliance program as adopted by the Board. The initial investment in establishing a compliance infrastructure and training the organization's employees can be significant. With the adoption of a compliance program, the organization is making a long term commitment of resources because effective compliance systems are not static programs but instead embrace continuous improvement. Quantifying the organization's investment in compliance efforts gives the Board the ability to consider the feasibility of implementation plans against compliance program goals. Such investment may include annual budgetary commitments as well as direct and indirect human resources dedicated to compliance. To help ensure that the organization is realizing a return on its compliance investment, the Board also should consider how management intends to measure the effectiveness of its compliance program. One measure of effectiveness may be the Board's heightened sensitivity to compliance risk areas.

B. Operational Questions

The following questions are suggested to assist the Board in its periodic evaluation of the effectiveness of the organization's compliance program and the sufficiency of its reporting systems.

1. **Code of Conduct—How has the Code of Conduct or its equivalent been incorporated into corporate policies across the organization? How do we know that the Code is understood and accepted across the organization? Has management taken affirmative steps to publicize the importance of the Code to all of its employees?**

Regardless of its title, a Code of Conduct is fundamental to a successful compliance program because it articulates the organization's commitment to ethical behavior. The Code should function in the same way as a constitution, *i.e.*, as a document that details the fundamental principles, values, and

framework for action within the organization. The Code of Conduct helps define the organization's culture—all relevant operating policies are derivative of its principles. As such, codes are of real benefit only if meaningfully communicated and accepted throughout the organization.

2. Policies and Procedures—Has the organization implemented policies and procedures that address compliance risk areas and established internal controls to counter those vulnerabilities?

If the Code of Conduct reflects the organization's ethical philosophy, then its policies and procedures represent the organization's response to the day-to-day risks that it confronts while operating in the current health care system. These policies and procedures help reduce the prospect of erroneous claims, as well as fraudulent activity by identifying and responding to risk areas. Because compliance risk areas evolve with the changing reimbursement rules and enforcement climate, the organization's policies and procedures also need periodic review and, where appropriate, revision.⁴ Regular consultation with counsel, including reports to the Board, can assist the Board in its oversight responsibilities in this changing environment.

3. Compliance Infrastructure

a. Does the Compliance Officer have sufficient authority to implement the compliance program? Has management provided the Compliance Officer with the autonomy and sufficient resources necessary to perform assessments and respond appropriately to misconduct?

Designating and delegating appropriate authority to a compliance officer is essential to the success of the organization's compliance program. For example, the Compliance Officer must have the authority to review all documents and other information that are relevant to compliance activities. Boards should ensure that lines of reporting within management and to the Board, and from the Compliance Officer and consultants, are sufficient to ensure timely and candid reports for those responsible for the compli-

ance program. In addition, the Compliance Officer must have sufficient personnel and financial resources to implement fully all aspects of the compliance program.

b. Have compliance-related responsibilities been assigned across the appropriate levels of the organization? Are employees held accountable for meeting these compliance-related objectives during performance reviews?

The successful implementation of a compliance program requires the distribution throughout the organization of compliance-related responsibilities. The Board should satisfy itself that management has developed a system that establishes accountability for proper implementation of the compliance program. The experience of many organizations is that program implementation lags where there is poor distribution of responsibility, authority and accountability beyond the Compliance Officer.

4. Measures to Prevent Violations

a. What is the scope of compliance-related education and training across the organization? Has the effectiveness of such training been assessed? What policies/measures have been developed to enforce training requirements and to provide remedial training as warranted?

A critical element of an effective compliance program is a system of effective organization-wide training on compliance standards and procedures. In addition, there should be specific training on identified risk areas, such as claims development and submission and marketing practices. Because it can represent a significant commitment of resources, the Board should understand the scope and effectiveness of the educational program to assess the return on that investment.

b. How is the Board kept apprised of significant regulatory and industry developments affecting the organization's risk? How is the compliance program structured to address such risks?

⁴ There are a variety of materials available to assist health care organizations in this regard. For example, both sponsoring organizations of this educational resource offer various materials and guidance, accessible through their web sites, www.healthlawyers.org and www.oig.hhs.gov.

The Board's oversight of its compliance program occurs in the context of significant regulatory and industry developments that impact the organization not only as a health care organization but more broadly as a corporate entity. Without such information, it cannot reasonably assess the steps being taken by management to mitigate such risks and reasonably rely on management's judgment.

- c. How are “at risk” operations assessed from a compliance perspective? Is conformance with the organization’s compliance program periodically evaluated? Does the organization periodically evaluate the effectiveness of the compliance program?**

Compliance risk is further mitigated through internal review processes. Monitoring and auditing provide early identification of program or operational weaknesses and may substantially reduce exposure to government or whistleblower claims. Although many assessment techniques are available, one effective tool is the performance of regular, periodic compliance audits by internal or external auditors. In addition to evaluating the organization's conformance with reimbursement or other regulatory rules, or the legality of its business arrangements, an effective compliance program periodically reviews whether the compliance program's elements have been satisfied.

- d. What processes are in place to ensure that appropriate remedial measures are taken in response to identified weaknesses?**

Responding appropriately to deficiencies or suspected non-compliance is essential. Failure to comply with the organization's compliance program, or violation of applicable laws and other types of misconduct, can threaten the organization's status as a reliable and trustworthy provider of health care. Moreover, failure to respond to a known deficiency may be considered an aggravating circumstance in evaluating the organization's potential liability for the underlying problem.

5. Measures to Respond to Violations

- a. What is the process by which the organization evaluates and responds to suspected compliance violations? How are reporting systems, such as the compliance hotline, monitored to verify appropriate resolution of reported matters?**

Compliance issues may range from simple overpayments to be returned to the payor to possible criminal violations. The Board's duty of care requires that it explore whether procedures are in place to respond to credible allegations of misconduct and whether management promptly initiates corrective measures. Many organizations take disciplinary actions when a responsible employee's conduct violates the organization's Code of Conduct and policies. Disciplinary measures should be enforced consistently.

- b. Does the organization have policies that address the appropriate protection of “whistleblowers” and those accused of misconduct?**

For a compliance program to work, employees must be able to ask questions and report problems. In its fulfillment of its duty of care, the Board should determine that the organization has a process in place to encourage such constructive communication.

- c. What is the process by which the organization evaluates and responds to suspected compliance violations? What policies address the protection of employees and the preservation of relevant documents and information?**

Legal risk may exist based not only on the conduct under scrutiny, but also on the actions taken by the organization in response to the investigation. In addition to a potential obstruction of a government investigation, the organization may face charges by employees that it has unlawfully retaliated or otherwise violated employee rights. It is important, therefore, that organizations respond appropriately to a suspected compliance violation and, more critically, to a government investigation without damaging the corporation or the individuals involved. The Board should confirm that processes and policies

for such responses have been developed in consultation with legal counsel and are well communicated and understood across the organization.

d. What guidelines have been established for reporting compliance violations to the Board?

As discussed, the Board should fully understand management's process for evaluating and responding to identified violations of the organization's policies, as well as applicable federal and state laws. In addition, the Board should receive sufficient information to evaluate the appropriateness of the organization's response.

e. What policies govern the reporting to government authorities of probable violations of law?

Different organizations will have various policies for investigating probable violations of law. Federal law encourages organizations to self-disclose wrongdoing to the federal government. Health care organizations and their counsel have taken varied approaches to making such disclosures. Boards may want to inquire as to whether the organization has developed a policy on when to consider such disclosures.

VI. Conclusion

The corporate director, whether voluntary or compensated, is a bedrock of the health care delivery system. The oversight activities provided by the director help form the corporate vision, and at the same time promote an environment of corporate responsibility that protects the mission of the corporation and the health care consumers it serves.

Even in this "corporate responsibility" environment, the health care corporate director who is mindful of her fundamental duties and obligations, and sensitive to the premises of corporate responsibility, should be confident in the knowledge that she can pursue governance service without needless concern about personal liability for breach of fiduciary duty and without creating an adversarial relationship with management.

The perspectives shared in this educational resource are intended to assist the health care director in performing the important and necessary service of oversight of the corporate compliance program. In so doing, it is hoped that fiduciary service will appear less daunting and provide a greater opportunity to "make a difference" in the delivery of health care.

I. Introduction

As a supplement to the publication, *Corporate Responsibility and Corporate Compliance*,¹ (*Corporate Compliance*), a joint educational effort of the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) 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 U.S. Sentencing Commission's 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

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?

1 *Corporate Responsibility and Corporate Compliance*, Office of Inspector General, U.S. Dept. of Health & Human Services and the American Health Lawyers Association, (2003), available at www.healthlawyers.org/CorporateCompliance.

2 James H. Cheek, III et al., *Report of the American Bar Association, Task Force on Corporate Responsibility* (March 31, 2003), available at http://meetings.abanet.org/webupload/commupload/CL116000/otherlinks_files/ABA_CCMR-RecommendationsforReorganizingtheUSRegulatoryStructure.pdf (last visited Aug. 29, 2011).

3 OIG COMPLIANCE PROGRAM GUIDANCE FOR HOSPITALS, 63 Fed. Reg. 8987 (Feb. 23, 1998), available at <http://www.oig.hhs.gov/authorities/docs/cpghosp.pdf> (last visited Aug. 29, 2011).

4 See, Grassley Investigates Tenet Healthcare's Use of Federal Tax Dollars, Sept. 8, 2003, available at <http://grassley.senate.gov/releases/2003/p03r09-08.htm> (last visited Aug. 29, 2011).

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

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 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 extraordi-

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 generalcounsel. *Id.* at 63.

⁸ See, *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.

nary 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 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 Sentencing Guidelines 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.

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 that 1) 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) appropriate processes are in place

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 took effect November 1, 2004. The proposed amendments relating to compliance programs can be found at http://www.uscc.gov/Legal/Amendments/Official_Text/20040501_Amendments.pdf, at 75-90 (last visited Aug. 29, 2011). See also http://www.uscc.gov/Legislative_and_Public_Affairs/Newsroom/Press_Releases/20040413_Press_Release.htm (last visited Aug. 29, 2011).

10 U.S. SENTENCING COMMISSION, ORGANIZATIONAL SENTENCING GUIDELINES § 8B2.1, available at http://www.uscc.gov/Legal/Amendments/Official_Text/20040501_Amendments.pdf, at 75-90 (last visited Aug. 29, 2011).

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

12 *Id.*

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.

A. 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.

B. 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 back-

grounds, 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.

C. 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.

D. 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 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.

E. 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 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

¹³ See *supra* note 3.

¹⁴ See, *supra* note 2, at 32.

may also promote the integrity of the compliance program, while respecting the operational preferences of management.

F. 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.

G. 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 require-

ment 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. 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.

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

1. Consider the adoption of a recusal process by which the General Counsel may recuse 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 AHLA-HCCA survey reported utilizing such processes.
2. Consider periodic Board initiated third-party audits or assessments of the compliance program, as suggested in the OIG Compliance Program Guidances.
3. Consider authorizing the Board Audit or Compliance Committee to retain outside counsel or consultants with respect to selected matters under Board-approved criteria.

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.

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

1. 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.
2. 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.
3. 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

1. 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.
2. Consider routine General Counsel reviews of matters being reported to the Board by the Chief Compliance Officer.
3. 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 organiza-

tions 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 educational resource has discussed, there are a variety of effective approaches to such coordination, many of which are a matter of current practice. This 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 document to be of assistance to health care Boards in exercising this important responsibility.

APPENDIX A

The American Health Lawyers Association (AHLA) and the Health Care Compliance Association (HCCA) sent out a survey designed to explore the relationship between general counsel and compliance officer in different health care organizations. AHLA sent the survey to 1,964 in-house counsel. HCCA sent the survey to 2,490 members, many of whom work as compliance officers in health care organizations. 429 recipients responded to the survey, a response rate of 9.6%.

The survey included nine questions for all respondents to answer. It then asked respondents to answer several questions applicable to their particular organizational and reporting structure. The

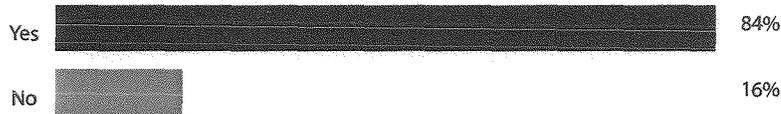
survey included questions for respondents at organizations where the general counsel serves as the compliance officer; where the compliance officer reports to the general counsel; and where the compliance officer does not report to the general counsel.

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.

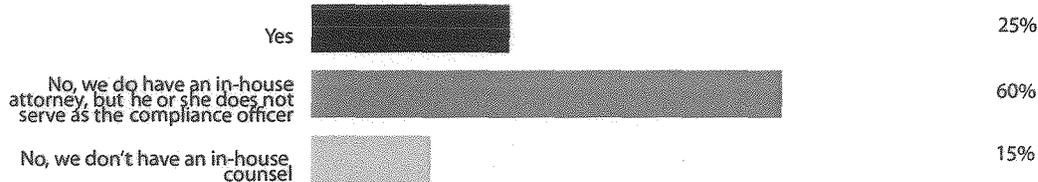
Survey Results

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?



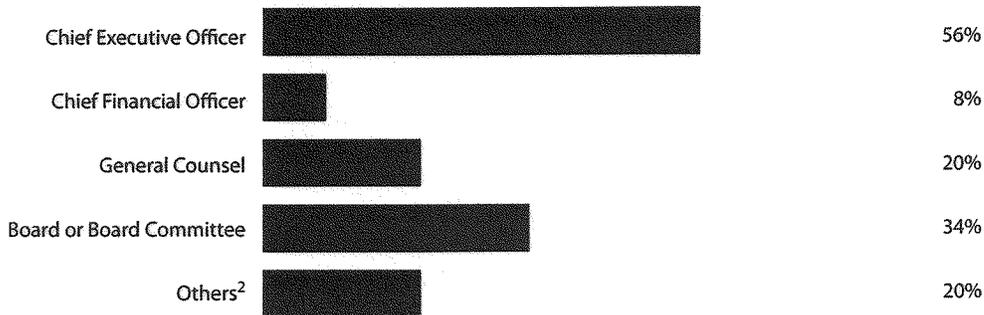
3. Does your organization employ an individual whose principal duty is to act as the corporate compliance officer for the organization?



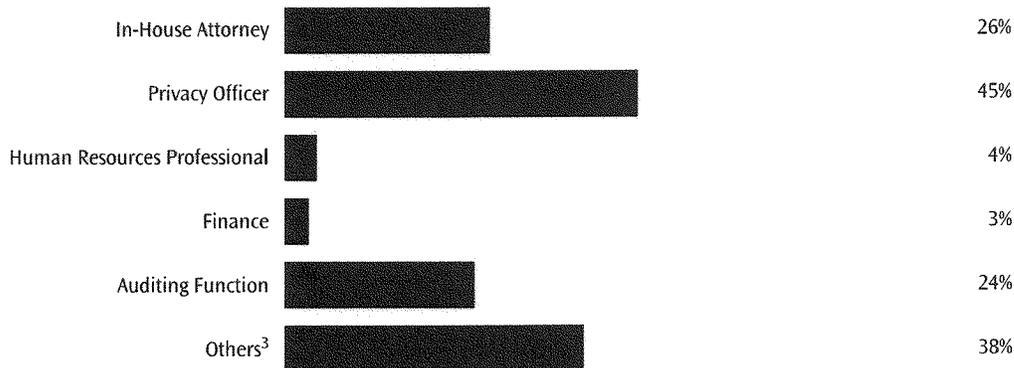
4. Is the corporate compliance officer for your organization also an attorney?



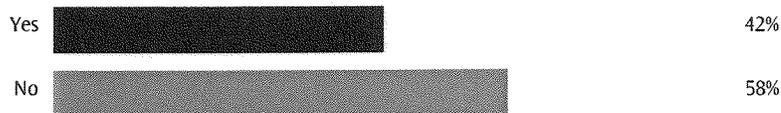
5. To whom does the compliance officer report?¹



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.

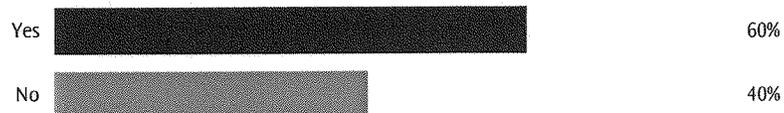
² Other positions named included VP Government Affairs; Chief Administrative Officer; Audit Committee; Chief Medical Officer; Chief Information Officer; Chief Technology Officer; Vice President Academic Affairs; Dean, College of Medicine; Chief Operating Officer; VP for Quality; Chief Financial Officer; 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 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?

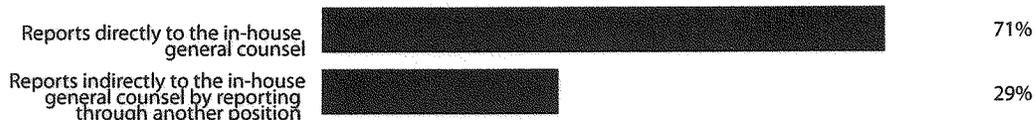


13. Does the in-house general counsel/attorney report to the Board on compliance issues on a regular basis?



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?



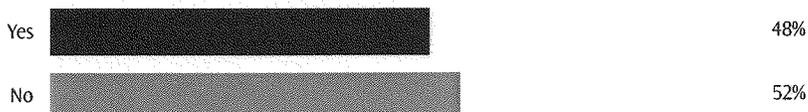
16. Has the organization established an alternative mechanism to provide the compliance officer direct reporting to members of senior management if the compliance officer feels such is necessary?



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?

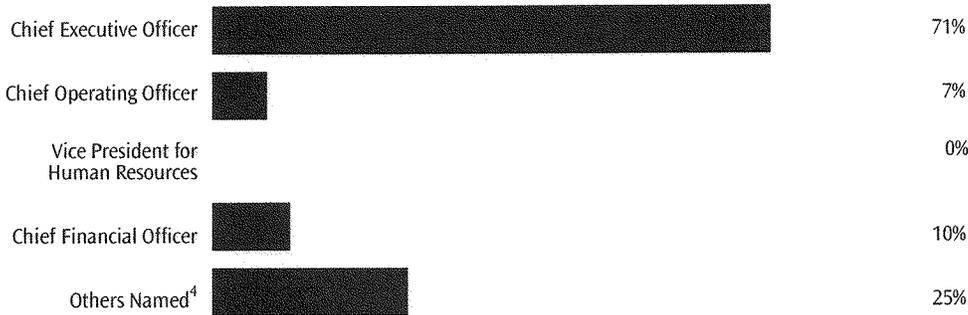


20. Does the compliance officer have independent authority to retain counsel or other consultants, if he or she believes it necessary?



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)?



25. Does the compliance officer copy the general counsel/attorney on significant correspondence?



26. Does the compliance officer generally seek advice from the general counsel/attorney when asserting privilege?



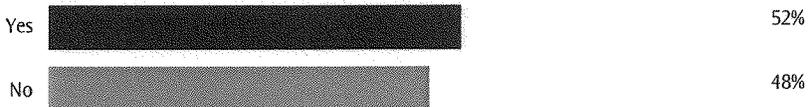
27. Does the compliance officer routinely report directly to the Board on compliance matters?



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



29. Does the compliance officer have independent authority to retain counsel or other consultants?



I. Introduction

This educational resource is the third in a Corporate Responsibilities Series (Series) of co-sponsored documents by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) and the American Health Lawyers Association (AHLA), the leading health law educational organization.¹ It seeks to assist directors of health care organizations in carrying out their important oversight responsibilities in the current challenging health care environment. Improving the knowledge base and effectiveness of those serving on health care organization boards will help to achieve the important goal of continuously improving the U.S. health care system.

The prior publications in this Series addressed the unique fiduciary responsibilities of directors of health care organizations in the corporate compliance context. With a new era of focus on quality and patient safety rapidly emerging, oversight of quality also is becoming more clearly recognized as a core fiduciary responsibility of health care organization directors. Health care organization boards have distinct responsibilities in this area because promoting quality of care and preserving patient safety are at the core of the health care industry and the reputation of each health care organization. The heightened attention being given to health care quality measurement and reporting obligations also increasingly impacts the responsibilities of corporate directors. Indeed, quality is also emerging as an enforcement priority for health care regulators.

The fiduciary duties of directors reflect the expectations of corporate stakeholders regarding oversight of corporate affairs. The basic fiduciary duty of care principle, which requires a director to act in good faith with the care an ordinarily prudent person would exercise under similar circumstances, is being tested in the current corporate climate. Embedded within the duty of care is the concept of reasonable inquiry. In other words, directors are expected to make inquiries to management to obtain the information necessary to satisfy their duty of care.

This educational resource is designed to help health care organization directors ask knowledgeable and appropriate questions related to health care quality requirements, measurement tools, and

reporting requirements. The questions raised in this document are not intended to set forth any specific standard of care, nor to foreclose arguments for a change in judicial interpretation of the law or resolution of any conflicts in interpretation among various courts. Rather, this resource will help corporate directors establish, and affirmatively demonstrate, that they have followed a reasonable quality oversight process.

Of course, the circumstances of each organization differ and application of the duty of care and consequent reasonable inquiry by boards will need to be tailored to each specific set of facts and circumstances. However, compliance with standards and regulations applicable to the quality of services delivered by health care organizations is essential for the lawful behavior and corporate success of such organizations. While these evolving requirements can be complex, effective compliance in the quality arena is an asset for both the organization and the health care delivery system. It is hoped that this educational resource is useful to health care organization directors in exercising their oversight responsibilities and supports their ongoing efforts to promote effective corporate compliance as it relates to health care quality.

II. Board Fiduciary Duty and Quality in the Health Care Setting

Governing boards of health care organizations increasingly are called to respond to important new developments—clinical, operational and regulatory—associated with quality of care. Important new policy issues are arising with respect to how quality of care affects matters of reimbursement and payment, efficiency, cost controls, collaboration between organizational providers and individual and group practitioners. These new issues are so critical to the operation of health care organizations that they require attention and oversight, as a matter of fiduciary obligation, by the governing board.

This oversight obligation is based upon the application of the fiduciary duty of care board members owe the organization and, for non-profit organizations, the duty of obedience to charitable mission. It is additive to the traditional duty of board

¹ The other two co-sponsored documents in the series are *Corporate Responsibility and Corporate Compliance*, The Office of Inspector General of the U.S. Department of Health and Human Services and The American Health Lawyers Association, 2003; and *An Integrated Approach to Corporate Compliance*, The Office of Inspector General of the U.S. Department of Health and Human Services and The American Health Lawyers Association, 2004, both of which precede this chapter in this guidebook.

members in the hospital setting to be responsible for granting, restricting and revoking privileges of membership in the organized medical staff.

A. Duty of Care

The traditional and well-recognized duty of care refers to the obligation of corporate directors to exercise the proper amount of care in their decision-making process. State corporation laws, as well as the common law, typically interpret the duty of care in an almost identical manner, whether the organization is non-profit or for-profit.

In most jurisdictions, the duty of care requires directors to act (1) in “good faith,” (2) with the care an ordinarily prudent person would exercise in like circumstances, and (3) in a manner that they reasonably believe to be in the best interests of the corporation.² In analyzing compliance with the duty of care, courts typically address each of these elements individually. In addition, in recent years, the duty of care has taken on a richer meaning, requiring directors to actively inquire into aspects of corporate operations where appropriate – the “reasonable inquiry” standard.

Thus, the “good faith” analysis normally focuses upon whether the matter or transaction at hand involves any improper financial benefit to an individual and/or whether any intent exists to take advantage of the corporation. The “prudent person” analysis focuses upon whether directors conducted the appropriate level of due diligence to allow them to render an informed decision. In other words, directors are expected to be aware of what is going on around them in the corporate business and must in appropriate circumstances make such reasonable inquiry as would an ordinarily prudent person under similar circumstances. The final criterion focuses on whether directors act in a manner that they reasonably believe to be in the best interests of the corporation. In this regard, courts typically evaluate the board member’s state of mind with respect to the issues at hand.

When evaluating the fiduciary obligations of board members, it is important to recognize that “perfection” is not the required standard of care. Directors are not required to know everything about a topic they are asked to consider. They may, where justi-

fied, rely on the advice of executive leadership and outside advisors.

In addition, many courts apply the “business judgment rule” to determine whether a director’s duty of care has been met with respect to corporate decisions. The rule provides, in essence, that a director will not be held liable for a decision made in good faith, where the director is disinterested, reasonably informed under the circumstances, and rationally believes the decision to be in the best interests of the corporation. In other words, courts will not “second guess” the board member’s decision when these criteria are met.

Director obligations with respect to quality of care may arise in two distinct contexts:

- The *Decision-Making Function*: The application of duty of care principles as to a specific decision or a particular board action, and
- The *Oversight Function*: The application of duty of care principles with respect to the general activity of the board in overseeing the operations of the corporation (*i.e.*, acting in good faith to assure that a reasonable information and reporting system exists).³

Board members’ obligations with respect to supervising medical staff credentialing decisions arise within the context of the decision-making function. These are discrete decisions periodically made by the board and relate to specific recommendations and a particular process.

The emerging quality of care issues discussed in this resource arise in the context of the oversight function—the obligation of the director to “keep a finger on the pulse” of the activities of the organization.

The basic governance obligation to guide and support executive leadership in the maintenance of quality of care and patient safety is an ongoing task. Board members are increasingly expected to assess organizational performance on emerging quality of care concepts and arrangements as they implicate issues of patient safety, appropriate levels of care, cost reduction, reimbursement, and collaboration among providers and practitioners. These are all components of the oversight function.

² American Bar Association, Section of Business Law, Revised Model Nonprofit Corporation Act, Section 8.30 (1987).

³ *In re Caremark International Inc. Derivative Litigation*, 698 A.2d 959 (Del. Ch. 1996).

This duty of care with respect to quality of care also is implicated by the related duty to oversee the compliance program.⁴ Many new financial relationships address quality of care issues, including pay-for-performance programs, gainsharing, and outcomes management arrangements, among others. State and federal law closely regulate many of these arrangements. Given that directors have an obligation to assure that the organization has an “effective” compliance program in place to detect and deter legal violations, they may fairly be regarded as having a concomitant duty to make reasonable inquiry regarding the emerging legal and compliance issues associated with quality of care initiatives, and to direct executive leadership to address those issues. The board may direct executive staff to provide periodic briefings to the board with respect to quality of care developments so that the directors may establish a proper “tone at the top” in terms of related legal compliance. In other words, it is the role of the executive staff to brief the board concerning new developments in the law and related legal implications, and it should be the ongoing obligation of the board to reasonably inquire whether the organization’s compliance program and other legal control mechanisms are in place to monitor the associated legal risks.

B. Duty of Obedience to Corporate Purpose and Mission

Oversight obligations with respect to quality of care initiatives also arise, for non-profit boards, in the context of what is generally referred to as the fiduciary duty of obedience to the corporate purpose and mission⁵ of health care organizations. Non-profit corporations are formed to achieve a specific goal or objective (e.g., the promotion of health), as recognized under state non-profit corporation laws. This is in contrast to the typical business corporation, which often is formed to pursue a general corporate purpose. It is often said of non-profits that “the means and the mission are inseparable.”⁶

The fundamental nature of the duty of obedience to corporate purpose is that the non-profit director is charged with the obligation to further the purposes of the organization as set forth in its articles of incorporation or bylaws.⁷ For example, the articles of

incorporation of a non-profit health care provider might describe its principal purpose as “the promotion of health through the provision of inpatient and outpatient hospital and health care services to residents in the community.” Given that the board is responsible for reasonably inquiring whether there are practices in place to address the quality of patient care, it is fair to state that the concept of quality of care is inseparable from, and is essentially subsumed by, the mission of the organization.

In the hospital setting, various provisions of the law dealing with the relationship to the medical staff also provide a link to the duty of obedience to corporate purpose. These include, for example, traditional provisions that confirm the responsibility of the board for (a) the conduct of the hospital as an institution, (b) ensuring that the medical staff is accountable to the governing board for the quality of care provided to patients, and (c) the maintenance of standards of professional care within the facility and requiring that the medical staff function competently. The “duty of obedience” concept with respect to assuring compliance with law also might be considered to incorporate a duty to assure compliance with those state laws (and perhaps accreditation principles as well) that require the governing board to assume ultimate responsibility for organizational performance, which includes the quality of the provider’s medical care.

C. Summary

In exercising her duty of care and, as appropriate, duty of obedience to corporate purpose and mission, the governing board member may be expected to exercise general supervision and oversight of quality of care and patient safety issues. This is likely to include (a) being sensitive to the emergence of quality of care issues, challenges and opportunities, (b) being attentive to the development of specific quality of care measurement and reporting requirements (including asking the executive staff for periodic education), and (c) requesting periodic updates from the executive staff on organizational quality of care initiatives and how the organization intends to address legal issues associated with those initiatives. Board members are expected to make reasonable further inquiry

⁴ *Id.*

⁵ In some states, this duty is subsumed within the definition of the broader duty of loyalty.

⁶ Daniel L. Kurtz, *Board Liability: Guide for Nonprofit Directors* 84 (Moyer Bell Limited, New York, 1988), citing *Commonwealth of Pennsylvania v. The Barnes Foundation*, 398 Pa. 458, 159 A.2d 500, 505 (1960); *In re Manhattan Eye, Ear & Throat Hosp.*, 715 N.Y.S.2d 575 (1999).

⁷ Kurtz, *supra*.

when concerns are aroused or should be aroused. These expectations increasingly are becoming more significant with the increased attention to quality of care issues from policy makers, providers and practitioners, payors and regulators. Board members must be, and must be perceived as, responsive to this changing environment.

III. Defining Quality of Care and the Critical Need to Implement Quality Initiatives

“The American health care delivery system is in need of fundamental change. Many patients, doctors, nurses and health care leaders are concerned that the care delivered is not, essentially, the care we should receive ... Quality problems are everywhere affecting many patients. Between the healthcare we have and the care we could have lies not just a gap, but a chasm.”⁸

In *Crossing the Quality Chasm*, the Institute of Medicine (IOM) provided a six-part definition of health care quality that some view as the emerging standard. According to the IOM, health care should be: *safe* – avoiding injuries to patients from the care that is intended to help them; *effective* – providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively); *patient-centered* – providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions; *timely* – reducing waits and sometimes harmful delays for both those who receive and those who give care; *efficient* – avoiding waste, including waste of equipment, supplies, ideas, and energy; and *equitable* – providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socio-economic status.⁹ Because this definition of quality increasingly is being adopted by payors, providers and regulators, health care organizations and their boards will need to be mindful of its implications.

The U.S. health care system is at a challenging point in its history. It is, for many important historical

reasons, a mixed public-private system, and there is no foreseeable dynamic on the horizon suggesting a major change to this reality. The health care system also arguably is driving the U.S. economy. A recent federal forecast predicts that over the next decade, U.S. health care spending will double from today’s level to \$4.1 trillion and will represent 20% of the gross domestic product.¹⁰ We have a health care system that is extraordinarily advanced, yet is inefficient, uneven, and too often unsafe. A consensus is forming that improvement in the system will require better collaboration and cooperation among independent providers, payors and purchasers, more integrated care, and better aligned incentives. Such collaboration and cooperation inevitably will raise legal compliance issues that health care organization boards of directors will need to understand in exercising their oversight function.

A scorecard on the U.S. health care system developed by the Commonwealth Fund in 2006 showed the following results, among others:¹¹

- For 37 key indicators for five health care system dimensions (quality, access, equity, outcomes and efficiencies), the overall U.S. score was 66 out of a possible 100.
- Efficiency was the single worst score among the five dimensions. For example, in 2000/2001, the U.S. ranked 16th out of 20 countries in use of electronic health records.
- The U.S. is the worldwide leader in costs.
- The U.S. scored 15th out of 19 countries in mortality attributable to health care services.
- Basic tools (i.e., Health IT) are missing to track patients through their lives.
- We do poorly at transition stages —hospital readmission rates from nursing homes are high; our reimbursement system encourages “churning.”
- Improving performance in key areas would save 100,000 to 150,000 lives and \$50 billion to \$100 billion annually.

The report makes several key recommendations. The U.S. should expand health insurance coverage; implement major quality and safety improvements; work toward a more organized delivery system that emphasizes primary and preventive care that is patient-centered; increase transparency and reporting on quality and costs; reward performance for quality and efficiency; expand the use of inter-

⁸ *Crossing the Quality Chasm*, Institute of Medicine, 2001, p.1

⁹ *Id.* at 6.

¹⁰ “Health Care Spending Projected to Pass \$4 Trillion Mark by 2016,” *Health Affairs*, February 21, 2007.

¹¹ The Commonwealth Fund Commission on a High Performance Health System, “Why Not the Best? Results from a National Scorecard on U.S. Health System Performance,” The Commonwealth Fund, September 2006.

operable information technology; and encourage collaboration among stakeholders.

In a similar vein, the IOM recently stated in one of several follow-up reports to *Crossing the Quality Chasm* that the Medicare payment system does not reward efficiency and provides few disincentives for overuse, underuse or misuse of care.¹² Furthermore, the IOM proposed that incentives should encourage delivery of high-quality care efficiently, require providers to assume shared accountability for transitions between care settings and require coordination of care for patients with chronic disease.

We are entering a new era of thinking about health care quality and collaboration among health care providers. Numerous new measures of health care quality are becoming public every day. Purchasers, payors, state governments, the Joint Commission and others are requiring reporting, particularly by hospitals, of outcomes pursuant to such measures. Pay-for-performance programs are becoming common among both public and private payors. A new generation of “gainsharing” proposals and demonstrations are emerging.¹³ In late February 2007, HHS Secretary Mike Leavitt unveiled a new quality-improvement plan, called “Value Exchanges,” that would establish local quality-improvement collaborations with an eye toward a national link-up in a few years.¹⁴ All of this puts increasing focus and scrutiny on health care organizations, and their boards of directors, in connection with the quality issue. Indeed, the National Quality Forum, perhaps the most well known source of nationally approved quality measures, has issued a paper entitled *Hospital Governing Boards and Quality of Care: A Call to Responsibility*.¹⁵

Perhaps one of the most critical and often misunderstood components of health care quality is the relationship between overall quality and cost efficiency. Increasingly, it is becoming more widely understood that quality and efficiency are complementary, not contradictory, elements of an effective health care system. Efficiency, by definition, means avoidance of unnecessary, and often harmful, care. As Don Berwick, a recognized national quality expert, stated in *Health Affairs* in 2005, “Right from the start it has been one of the great illusions in

the reign of quality that quality and cost go in opposite directions. There remains very little evidence of that.”¹⁶

Because it is coming from the federal government, state government, and private purchasers and payors, the emphasis on collaborative arrangements and cooperation in care giving across independent providers, aggregate payment pools and aligned incentives will require providers to look for legal ways to collaborate and, indeed, align incentives through new financial relationships. In particular, innovative hospital-physician financial relationships, including a variety of formal and informal partnering arrangements, are critical to the achievement of all six of the aims set forth in *Crossing the Quality Chasm*. Examples include pay-for-performance demonstrations, gainsharing initiatives, electronic health record implementation efforts, outpatient care centers, service line joint ventures, and management and leasing arrangements. Evidence-based medicine reasonably can define proper use and increasingly is relied upon to do so. It is expected that the public sector will continue to seek to balance its role as both purchaser and regulator in the search for quality improvement in health care. The private sector at times may have to initiate change before the payment system and regulations catch up, but the rewards are potentially very high—in terms of organizational success as well as social benefit. At the same time, however, legal compliance issues likely will arise in connection with efforts to implement these changes. Health care organizations with oversight by their boards of directors will be required in this regard to be mindful of the anti-kickback statute, the physician self-referral (Stark) law, civil money penalty statutes, the Health Insurance Portability and Accountability Act (HIPAA), federal tax-exemption standards and antitrust law, among other legal areas.

There is an opportunity for the best performers in the industry to create profound change, and then open up these best practices through transparency of data and the promotion of collaboration to spread change. Health care boards of directors have the unique opportunity to take leadership in implementing quality systems that will advance their organizations’ respective missions and the

12 *Rewarding Provider Performance: Aligning Incentives in Medicine*, Institute of Medicine, 2007.

13 OIG reviews gainsharing and pay-for-performance programs on a case-by-case basis, and CMS’ position on applicability of the Stark Law to such programs is still evolving.

14 Press Release, U.S. Department of Health & Human Services, HHS Secretary Leavitt Unveils Plan for “Value Exchanges” to Report on Health Care Quality and Cost at Local Level (February 28, 2007).

15 “Hospital Governing Boards and Quality of Care: A Call to Responsibility,” The National Quality Forum, December 2, 2004.

16 Robert Galvin, “‘A Deficiency of Will and Ambition’: A Conversation with Donald Berwick,” *Health Affairs Web Exclusive*, January 12, 2005.

nation's health. They also have the responsibility to do so in a legally compliant manner.

IV. The Government's Role in Enforcing Health Care Quality

An extensive federal and state regulatory scheme governs the care delivered by health care providers. Designed to promote quality of care, these standards provide a baseline for assessing the level of care provided to the patient and, as discussed previously, increasingly determine the health care provider's reimbursement. For example, Medicare and Medicaid conditions of participation require hospitals to monitor quality through credentialing of medical staff and maintaining effective quality assessment and performance improvement programs. These conditions of participation specify that the medical staff is accountable to a hospital's governing body for the quality of care provided to patients. Long term care providers must meet specific quality of care standards, undergo state surveys, and pass state certifications to participate in government programs. The regulatory framework includes a range of progressive administrative sanctions, including heightened oversight and monetary penalties that may be imposed against providers that fail to comply with the regulatory requirements.

In addition to these administrative remedies, the government enforcement authorities are increasingly focusing on the quality of care provided to beneficiaries of the federal health care programs. The OIG, the U.S. Department of Justice, and state Attorneys General are working collaboratively with the health care regulatory agencies to address the provision of substandard care by individuals and institutions. Sanctions may range from monetary penalties to exclusion from federal and state health care programs and even incarceration for the most serious offenses. For example, a health care provider can be subject to exclusion from the federal health care programs if it provides medically unnecessary services or services that fail to meet professionally recognized standards of care. Even individuals who are not direct care providers, such as hospital administrators and nursing home owners, may be subject to exclusion if they cause others to provide substandard care. Consequently, all levels of a health care organization, from the direct caregiver to the governing body of an institutional provider, could face liability for failing to meet the quality of care obligations applicable to government program providers.

As part of these enforcement efforts, authorities are closely evaluating quality-reporting data. For example, government authorities are increasingly scrutinizing quality data submitted by health care providers to identify inconsistencies and evidence of ongoing quality problems that providers fail to address. Sources of quality-reporting data include, for example, the hospital quality data for the annual payment updates, physician quality-reporting data reported to CMS, medical error and "sentinel event" data reported to the Joint Commission, and quality reporting required under state law. The accuracy of the data submitted to government agencies and third party payors is vital. In addition to relying on such information for monitoring quality and patient safety issues, the federal health care programs increasingly use this data for determining reimbursement, as in the case of the Minimum Data Set in the nursing home setting. Consequently, inaccurate reporting of quality data could result in the misrepresentation of the status of patients and residents, the submission of false claims, and potential enforcement action. As authorities continue to scrutinize quality-reporting data, boards will benefit from ensuring that structures and processes exist within their institution to carefully review this data for accuracy and address potential quality of care issues. To evaluate the potential risk to the organization, it is important that board members understand the theories of liability relied upon by the government. The predominant criminal and civil fraud theories—medically unnecessary services and "failure of care"—rely on the submission of a claim for reimbursement to the government to establish jurisdiction over the provider. Medicare and Medicaid only cover costs that are reasonable and necessary for the diagnosis or treatment of illness or injury. When medically unnecessary services are provided, the patient is unnecessarily exposed to risks of a medical procedure and the federal health care programs incur needless costs. Hospitals have been subject to prosecution under this theory. For example, a grand jury indicted a Michigan hospital based on its failure to properly investigate medically unnecessary pain management procedures performed by a physician on its medical staff. In another case, a California hospital recently paid \$59.5 million to settle civil False Claims Act allegations that the hospital inadequately performed credentialing and peer review of cardiologists on its staff who performed medically unnecessary invasive cardiac procedures. The second theory of liability involves the provision of care that is so deficient that it amounts to no care at all. This theory derives from the concept commonly applied in the financial fraud context, which subjects providers to liability for billing

government programs for services that were not actually rendered. These cases frequently involve providers, such as nursing homes, that receive “per diem” payments for providing all necessary treatment to patients. For example, a Colorado rehabilitation center entered into a \$1.9 million civil False Claims Act settlement to resolve allegations that it provided worthless services to patients, resulting from systemic understaffing at the facility, where deficient services and abuse caused six patient deaths. Federal prosecutors in Missouri charged a long term care facility management company, its CEO, and three nursing homes with conspiracy and health care fraud based on the contention that the defendants imposed budgetary constraints that they knew or should have known would prevent facilities from providing adequate care to residents. The CEO was sentenced to pay \$29,000 in criminal fines and to serve an 18-month period of incarceration. The management company and nursing homes were each sentenced to pay \$182,250 in criminal fines. In a related civil case, the defendants paid \$1.25 million to resolve False Claims Act allegations, and agreed to be excluded from federal health care programs.

This fraud theory also is applied in cases involving violations of regulatory requirements related to quality of care. For example, a Pennsylvania hospital entered into a \$200,000 civil False Claims Act settlement to resolve substandard care allegations related to the improper use of restraints.

In addition to substantial civil penalties and criminal fines, health care providers that systematically fail to provide care of an acceptable quality can be excluded from federal health care programs, meaning Medicare and Medicaid will not pay for items or services furnished by the provider. The provision of care that fails to meet accepted standards of care is an enforcement priority for OIG, which is actively pursuing these cases under administrative sanction authorities that explicitly address quality of care. OIG can impose exclusion from the federal health care programs against anyone who furnishes or causes to be furnished medically unnecessary services or services that fail to meet professionally recognized standards of health care.¹⁷ Additionally, OIG is required by law to exclude anyone convicted of patient neglect or abuse.¹⁸

As part of global settlements of civil health care fraud matters, OIG may negotiate a waiver of the

permissive exclusion in exchange for a provider's agreement to enter into a corporate integrity agreement (CIA). In cases involving substandard care, these agreements can involve comprehensive monitoring provisions designed to assess the provider's internal quality improvement infrastructure. A list of the health care providers currently subject to CIAs (including nursing homes, psychiatric facilities, and regional and national chains) is found at the OIG's website, <http://oig.hhs.gov/fraud/cias.asp>.

A CIA also might entail board-level obligations to help ensure that the organization embraces a commitment to the delivery of quality care. For example, the Tenet Healthcare Corporation board of directors has specific obligations under the organization's current CIA. OIG has required the board to (1) review and oversee the performance of the compliance staff, (2) annually review the effectiveness of the compliance program, (3) engage an independent compliance consultant to assist the board in its review and oversight of Tenet's compliance activities, and (4) submit to OIG a resolution summarizing its review of Tenet's compliance with the CIA and federal health care program requirements. These obligations reflect a growing recognition of the critical role that boards of directors play in ensuring that their organizations promote quality, ensure patient safety, and are in compliance with the obligations of government health care programs.

V. Health Care Board Fiduciary Duty and Quality

Health care is unique in representing both a social good and an economic commodity. Boards of directors of many health care organizations have been called upon to see that their organization's approach those realities in concert, not in competition, with each other. These boards understand that the quality of the products and services their organizations provide can have life or death implications. Health care organizations generally view themselves as mission-driven and health care quality is a key component of that mission. Yet, the Institute of Medicine's recognition in 1999 that medical errors lead to as many as 100,000 deaths per year served as a wake-up call. Evolving evidence and research into best practices and outcomes measures have provided the impetus to today's rapidly growing “quality movement,” which is triggering a whole variety of mandatory and voluntary activities by health care organizations to improve quality and reduce costs.

¹⁷ 42 U.S.C. § 1320a-7(b)(6)(B).

¹⁸ 42 U.S.C. § 1320a-7(a)(2).

These new programs and requirements raise the stakes for health care organizations, both financially and legally. Poor quality and value, or the failure to demonstrate good quality and value, increasingly may affect the viability of health care providers, products manufacturers and others. Law enforcement agencies are increasing their scrutiny of providers that deliver substandard care to federal health care beneficiaries. On the other hand, demonstrated quality and value likely will have a positive mission as well as financial effect. Accurate measurement and reporting—indeed, effective compliance with an evolving set of obligations—will be required.

Directors will need to understand this evolving reality and, if they have not already done so, elevate quality as newly defined to the same level of focus that financial viability and regulatory compliance currently command. The next section of this resource provides directors with certain questions that may assist them in exercising their oversight responsibilities in this increasingly important area.

VI. Suggested Questions for Directors

Boards of Directors can play a critical role in advancing the clinical improvement initiatives in their organizations. To realize its full potential, a board needs to develop an understanding of the relevant quality and patient safety issues and then focus on performance goals that drive the organization to provide the best quality and most efficient care. The following series of suggested questions may be helpful as the board examines the scope and operation of the organization's quality and safety initiatives.

A. What are the goals of the organization's quality improvement program? What metrics and benchmarks are used to measure progress towards each of these performance goals? How is each goal specifically linked to management accountability?

There are a growing number of national public and private initiatives directed at promoting quality of care, patient safety, and the corresponding reduction in medical errors. These initiatives rely on clinical care benchmarks to facilitate oversight and promote improved quality outcomes. Such benchmarks, used in conjunction with industry-wide reported data, can

provide a context for creating quality of care goals, aligning organizational incentives, and providing a framework for management's reports to the board. Once these parameters are defined, the board can more readily hold management accountable for meeting the organization's quality performance goals.

B. How does the organization measure and improve the quality of patient/resident care? Who are the key management and clinical leaders responsible for these quality and safety programs?

As a threshold matter, the board may wish to confirm its understanding of the structures and processes the organization relies upon to oversee and improve clinical quality and patient safety. Only after it has a complete understanding of how the organization's quality assurance functions operate can the board evaluate the breadth and effectiveness of a quality improvement program. The organizational assessment also can provide a common basis from which management and the board can evaluate these processes against current and emerging regulatory requirements.

C. How are the organization's quality assessment and improvement processes integrated into overall corporate policies and operations? Are clinical quality standards supported by operational policies? How does management implement and enforce these policies? What internal controls exist to monitor and report on quality metrics?

Consistent with the fundamental fiduciary responsibility of oversight, the board has responsibility for institutional policies and procedures relative to quality of care. Increasingly, common law recognizes among a board's non-delegable duties the duty to formulate, adopt, and enforce adequate rules and policies to ensure quality care for all of the organization's patients and residents. Although boards appropriately may utilize the expertise of the medical staff and other professionals to address professional competency and quality issues, these professionals should work actively with the board to advance the institution's quality agenda, to identify systemic deficiencies and to make appropriate recommendations for action. Periodic reviews with management of the quality of care provided to patients and evaluations of the adequacy of these policies in light of evolving standards, clinical practices, and claims experience or trends are consistent with board responsibilities.

D. Does the board have a formal orientation and continuing education process that helps members appreciate external quality and patient safety requirements? Does the board include members with expertise in patient safety and quality improvement issues?

In an era of increasing governance accountability, the boards of health care organizations are expected to understand and be involved in the assessment of performance on quality and patient safety initiatives of their organizations. An understanding of clinical quality measurements, the ability to read quality scorecards and spot red flags, and an appreciation of quality of care as a corporate governance issue may be critical to an effective board. Equally important, board members need a general understanding of national trends in health care quality. Collectively, these skills will enable the board to appreciate the interrelationship of patient safety, health care quality and performance measurement, as well as the business case for quality. For the same reasons a board has financial experts on its audit committee, health care organizations that provide or arrange for goods or services need members with competencies in quality and patient safety issues. With such resources, the board is better positioned to call for and evaluate meaningful quality information using recognized performance metrics from which to evaluate the organization's clinical quality performance.

E. What information is essential to the board's ability to understand and evaluate the organization's quality assessment and performance improvement programs? Once these performance metrics and benchmarks are established, how frequently does the board receive reports about the quality improvement efforts?

The board should consider the nature and level of information it needs to oversee the quality of care in the organization. If there are too many quality indicators, the data may become overwhelming and the critical measures of success may be overlooked. The board may want to work with management and the organization's medical leadership to identify a focused number of vital indicators that are probative of quality or indicative of changes in quality of patient care. In determining which performance measures to include in its "dashboard," the board may want to consider the quality data reviewed by

government agencies, the information subject to mandatory reporting requirements, and relevant industry benchmarks.

As part of its oversight of the quality of care delivered by subsidiaries, parent or system boards may have different information needs. While a grounding in quality and patient safety initiatives remains important, the parent board appropriately may rely on local boards to oversee clinical quality of the local facilities under its purview. In large health care systems, the parent board may exercise its governance responsibilities by focusing on the effectiveness of the local boards.

F. How are the organization's quality assessment and improvement processes coordinated with its corporate compliance program? How are quality of care and patient safety issues addressed in the organization's risk assessment and corrective action plans?

As discussed in *Corporate Responsibility and Corporate Compliance*,¹⁹ an effective corporate compliance program can be instrumental in the board's exercise of its fiduciary duty of care. Increasingly, monitoring quality and patient safety issues is recognized as integral to promoting corporate compliance, as well as to risk management and organizational reputation. Use of regulatory compliance processes to continually assess the organization's quality performance can assist in exposing deficiency patterns, which if not recognized and addressed in a timely and effective manner, may expose the organization to enforcement action. Accordingly, as quality improvement takes on increased significance in the organization's compliance program, the board may want to assure itself that the compliance officer is collaborating with the organization's clinical leadership.

G. What processes are in place to promote the reporting of quality concerns and medical errors and to protect those who ask questions and report problems? What guidelines exist for reporting quality and patient safety concerns to the board?

A lack of transparency in the organization's response to concerns about quality and patient safety can contribute to a culture where problems are not addressed and are therefore likely to reoccur. Improving the effectiveness and safety of

¹⁹ See *supra* note 1.

services and quality of care requires participation by clinical staff at all levels. In fulfilling its duty of care, the board should consider verifying that the organization has a mechanism to encourage constructive criticism and reporting of errors. Effective compliance programs are structured to address “whistleblower” reporting and protections, and the organization should consider incorporating the reporting of quality and patient safety concerns into both existing compliance procedures and general operating practices.

H. Are human and other resources adequate to support patient safety and clinical quality? How are proposed changes in resource allocation evaluated from the perspective of clinical quality and patient care? Are systems in place to provide adequate resources to account for differences in patient acuity and care needs?

Participation in the federal health care programs requires that the health care organization deliver care of a quality that meets professionally recognized standards of care. When investigating allegations of substandard quality of care, the government will scrutinize whether the health care provider devoted sufficient resources to ensure that the care provided to patients or residents met basic quality requirements. Inadequate levels of professional and support staff, for example, may result in a pattern of substandard care. As part of its annual review of the organization’s operating plans and budget, the board should consider the impact of these resource allocation decisions on the quality of care and patient safety. For the same reason, the board should ensure that management has assessed the impact of staff reductions or other budget constraints on quality of care.

A companion area for oversight relates to approvals of new services and significant technology acquisitions. Inquiry regarding the scientific bases supporting the efficacy and safety of new services and the identification of supportive processes to ensure quality and safety of new technology and services may serve to protect financial resources as well as patient safety.

I. Do the organization’s competency assessment and training, credentialing, and peer review processes adequately recognize the necessary focus on clinical quality and patient safety issues?

Boards rely heavily on the expertise of their medical staff and the integrity and comprehensiveness of its competency assessment and training, credentialing, and peer review processes to ensure the competency of clinical staff. Alignment of professional staff credentialing standards with quality data can advance a quality-driven model for the professional staff and allows the organization to take appropriate action when significant quality deficiencies are identified.

J. How are “adverse patient events” and other medical errors identified, analyzed, reported, and incorporated into the organization’s performance improvement activities? How do management and the board address quality deficiencies without unnecessarily increasing the organization’s liability exposure?

Providers operate under significant federal and state requirements relating to quality reporting and improvement. Hospitals, for example, are required to maintain an effective, data-driven quality assessment and improvement program as a condition of participation in the Medicare program. These programs must track quality indicators, including adverse patient events, and set performance improvement priorities that focus on high-risk or problem-prone areas. A growing number of states have mandatory reporting systems for at least some forms of adverse events occurring in acute care hospitals. For example, some states are mandating the reporting of “never events,” those errors in medical care that are clearly identifiable, preventable and serious in their consequences for patients. Examples of “never events” include surgery on the wrong body part, a mismatched blood transfusion, and severe “pressure ulcers” acquired in the hospital. In addition, there are other reporting requirements, including the peer review reporting provisions of the Health Care Quality Improvement Act, state peer review statutes, and the privilege and confidentiality provisions of the Patient Safety and

Quality Improvement Act of 2005. Although the application of these statutes to medical staff credentialing, peer review, and broader quality reporting and improvement activities may be challenging, greater organizational risks may lie in the failure to address known or foreseeable quality deficiencies.

Obviously, corporate boards and managers need to evaluate and address quality and patient safety issues but without unnecessarily increasing organizational exposure to liability resulting from the provision of deficient care. It is therefore important for the board to understand the scope of federal and state statutory protections given certain quality-related activities and to make reasonable inquiry to assure that management and the medical staff effectively manage this issue. A discussion with legal counsel on this topic may be helpful.

VII. Conclusion

Contemporary health care quality, patient safety, and cost efficiency initiatives provide an opportunity for health care organizations to make a positive difference to society while promoting their missions and enhancing their financial success. However, health care boards of directors will need to exercise their oversight responsibilities in this area diligently and assure that their organizations are pursuing these opportunities in compliance with evolving legal requirements. The comments and perspectives shared in this educational resource will, it is hoped, assist health care organization boards in exercising their duty of care as it relates to health care quality effectively, efficiently, and in a manner that will help improve the nation's health care system.



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