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Can My Outside Counsel Really Enhance My Organization's Compliance Program?

*Incorporating Legal Counsel Into Your Compliance Effort is Beneficial in
More Than One Way*

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In response to a variety of events and governmental initiatives, many health care organizations adopted corporate compliance programs in the 1990s. During this period, legal counsel served as a resource to organizations by helping them establish a work plan for the development of the compliance program. Moreover, outside law firms were engaged to perform various functions, including, but not limited to, recommending an infrastructure for the compliance department, developing codes of conduct or ethics, drafting policies and procedures, and developing training modules.

Today, many, if not most, health care organizations have an operating compliance program. Therefore, the question may arise whether outside counsel has a continuing role to play in assisting health care organizations with their compliance programs.

This article explores ways in which outside counsel can, and should, continue to be a resource to an organization's compliance efforts by: assisting an organization undergoing a government inquiry, conducting internal investigations when compliance issues arise, benchmarking an organization's success at implementing its compliance program, helping to keep the organization's compliance program up-to-date, fielding complicated questions and fact patterns, boosting a compliance department's credibility, and interacting with an organization's board of directors.

While this article is focused on the role of outside counsel, the author recognizes the important role of in-house counsel in corporate compliance and the need for coordination among a health care organization's internal counsel, corporate compliance professionals, and outside counsel. Indeed, the role of the internal corporate counsel in health care compliance has recently been the focus of public debate and reports by the American Bar Association (ABA). Moreover, the Office of Inspector General (OIG) has expressed its own view of the importance of separating the functions of an organization general counsel and chief compliance officer.

Although this article does not address this issue, a task force with representation from the OIG, the American Health Lawyers Association (AHLA), and the Health Care Compliance Association (HCCA) is working on an educational resource to supplement the joint 2003 OIG-AHLA publication *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors* and will address this pertinent and timely issue.

Government Inquiries

Health care providers and their employees can be subject to the harsh reality of investigations from a number of investigative agencies (e.g., the OIG, the Federal Bureau of Investigation, the Department of Justice) appearing either at their place of work or at home in order to ask questions or obtain documents.

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The improper handling of a government request to talk and/or provide documents can lead to a myriad of complications (e.g., charges of obstruction of justice), and thus it is important that health care providers receive guidance on how to respond to a government request for information. Consequently, participation of outside counsel with experience in advising clients in government investigations is important throughout the investigation process not only for their legal skills and knowledge of the process but also for their relationships with the relevant investigative bodies.

When a health care organization receives a "knock on the door" from a government agency, the organization should immediately involve outside counsel who can assist in various ways, including the following:

- Contacting the inquiring government agency in order to more accurately determine the nature and scope of the investigation
- Reviewing the document request or subpoena carefully in order to ensure that it is not overly broad
- Ensuring that all steps are taken to maintain the integrity of all documents (*i.e.*, no inadvertent destruction of documents)

Conducting Internal Investigations

After a potential compliance issue has been identified (either discovered internally or as part of a government inquiry), it will be necessary that an internal investigation occur. Although internal resources within an organization will be invaluable to this process, it is prudent to involve outside counsel for a number of reasons.

First, information gathered as part of the internal investigation should benefit from various protections and privileges afforded to attorneys—in particular, the attorney-client communication privilege and the attorney work product doctrine. Although many clients and attorneys alike automatically consider the need to protect communications under the attorney-client privilege, invariably when an internal investigation is being conducted, the more relevant doctrine to protect the underlying information is the attorney work product doctrine, which applies to materials prepared in anticipation of litigation.

In the end, the organization may choose to waive the privilege and present the information discovered through the internal investigation to the government (e.g., as part of a voluntary disclosure). Nevertheless, at the beginning of an internal investigation, it is important to have taken the steps to protect the information and then make the decision concerning waiver at a later date.

Second, even though individuals within an organization inevitably will be involved in the investigation, outside counsel can serve as an unbiased, objective third party. Many organizations fear that by bringing in out-

side counsel to perform an internal investigation, the cost will be high and less efficient than if conducted internally. A compliance investigation, however, may result in the identification of impropriety (either intentionally or unintentionally), and management of an organization can become "emotionally charged" in connection with such an assessment. Consequently, in order to ensure that decisions and actions are not made or taken on the basis of emotion, outside counsel can provide a level of objectivity to the review and the establishment of corrective actions or a game plan.

Benchmarking the Compliance Program's Efforts

One of the keys to any corporate compliance program is that it must be "effective." Accordingly, a health care organization's corporate compliance program should be an evolving program that is modified, supplemented, and potentially "retooled" over time in order to ensure its "effectiveness." Therefore, instead of merely reacting to "suspected wrongdoing," outside counsel can serve to review an organization's compliance program efforts to determine whether it is achieving its objectives. Moreover, by conducting these reviews on a periodic basis, these reviews can serve as a benchmark on the degree to which the organization is improving its compliance program over time.

As part of this review, outside counsel would perform the following:

- Review the organization's compliance program manual.
- Interview both the members of the organization's compliance committee and a random sample of employees who work at different locations and who are in different departments (reimbursement and billing, marketing, finance, human resources, nursing services, pharmacy services). The goal of these interviews is to assess the individuals' awareness of the compliance program in general, the compliance training they have received, the compliance program manual, the hot line, and other specific components of the compliance program.
- Review any and all documents related to the compliance program (documentation that employees received training, paperwork associated with compliance issues identified).
- Provide an assessment of the organization's compliance program as well as recommendations for the future.

Keeping the Compliance Program "Up-To-Date"

Because state and federal laws that affect health care organizations are constantly being adopted and modified, compliance programs must adapt to this change.

Therefore, when a new health care statute or set of regulations is implemented, outside counsel can assist an organization by drafting (or reviewing) new policies and procedures that address these issues.

For example, with the implementation of the various sets of regulations developed as a result of the Health Insurance Portability and Accountability Act of 1996 concerning privacy, security, and electronic transaction sets, outside counsel was used by many organizations in order to develop policies and procedures. By engaging one's outside law firm, organizations were able to benefit from same efficiencies as such firms were developing substantially the same policies and procedures for various clients in the health care industry.

Moreover, outside counsel can assist an organization develop new and update existing educational training modules. For example, when the Centers for Medicare and Medicaid Services (CMS) has provided additional guidance or even modified regulations related to the Emergency Medical Treatment and Active Labor Act, outside counsel has been effective in making presentations to hospitals' administrative and professional staff on the impact of these changes on day-to-day hospital operations.

Fielding Complicated Questions and Fact Patterns

The types of issues that compliance officers often face are complicated. Moreover, many legal questions arising in health care cannot be analyzed under a set of "black and white" criteria but instead require an analysis as to the "shade of gray" the particular set of facts raises. Although an organization may have in-house counsel that is familiar with these types of issues, outside counsel who specializes in the multifaceted regulations and interpretations of, for example, the anti-kickback and Stark laws, can be an important supplemental resource.

Boosting a Compliance Department's Credibility

Compliance officers all too often are confronted by members of the management team who say, "What do you mean I can't do that? Where are you getting that from? We have always done that, and I know that other health care providers do it, too! You must be making that up!" For example, the regulations under the federal physician self-referral law (commonly referred to as the Stark Law) create an exception for gifts and items being given to physicians as long as the value of the gifts and items is not greater than \$300 annually.

Therefore, as compliance departments have been tasked with the job of monitoring and tracking the value of all such items and gifts, many compliance officers are faced with questions on whether certain items and gifts even fall within the ambit of the statute. Even an organization that has a management team that strongly embraces compliance can be "aghast" at the notion of how this law has been interpreted. Therefore, when heated debates arise on this type of issue, outside counsel can provide the organization's compliance department with additional "credibility."

Interaction with the Board of Directors

As a matter of fiduciary duty, ultimate oversight of an organization's compliance program rests with its board of directors. A key to success in compliance is assuring that the board has access to all appropriate information to increase its oversight. A lawyer representing an organization is obligated to serve the interests of the organization, itself, and not the interests of any individual director, shareholder, officer, or employee.

Consequently, an organization's board of directors should be entitled to rely on corporate advisors to furnish information on a variety of issues, including health regulatory compliance. In response, in part to some recent developments in the corporate world, the ABA adopted amendments in 2003 to the Model Rules of Professional Conduct. Specifically, Rule 1.13 was modified so as to refine the circumstances in which a lawyer has a duty to take action within the organization relating to identified violations of law. Similar concepts are contained in Section 307 of the Sarbanes-Oxley Act, applicable to publicly traded companies.

Outside counsel can, and is ethically obligated to, serve as a resource both in counseling the board in its exercise of oversight over an organization's corporate compliance program and in increasing awareness of potential compliance violations.

Conclusion

Health care compliance is a complex endeavor. It typically involves a team of professionals in the compliance office who coordinate their activities with counsel's office in ultimate service to their organization and its board of directors. While the specific role outside counsel might play varies based on the size and scope of in-house resources, the answer to the question of whether outside counsel can actually enhance an organization's compliance program efforts usually is a resounding "YES." **JHCC**

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