

Compliance and Governance for Health Care Organizations

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¶22,110 Introduction

Directors of health care organizations have important responsibilities relating to corporate compliance requirements that are unique to the health care industry. The risks of non-compliance have grown dramatically over the last decade as the government has dedicated substantial resources to respond to health care fraud and abuse.² Private whistleblowers, in addition to government investigators and auditors, now also play a role in identifying improper practices, and the need for effective corporate compliance programs for health care organizations has therefore increased.

The Board of Directors (Board) plays a central role in the implementation and oversight of such compliance programs, and they have further become the focal point of the corporate governance system via an expansion of the directors' fiduciary duty and duty of care.³ In addition to the financial responsibility of the Board, there is an increased focus on patient safety and quality of care. This additional focus affects Boards of health care organizations because the oversight of these areas is increasingly recognized as a core fiduciary responsibility of the Boards of such organizations.⁴

This chapter of the Manual examines the role of corporate governance and compliance for health care organizations, the duties of the Board and how they are satisfied, as well as the consequences of failing to meet such duties.

Part I discusses the role of corporate governance and compliance for health care organizations.

Part II provides an overview of the Board of Directors' duties.

Part III examines when the Board of Directors' duties are satisfied.

Part IV discusses the consequences of the Board of Directors' failure to fulfill such duties.

Part I: The Role of Corporate Governance and Compliance for Health Care

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² AMERICAN HEALTH LAWYERS ASSOCIATION, THE HEALTH CARE DIRECTOR'S COMPLIANCE DUTIES: A CONTINUED FOCUS OF ATTENTION AND ENFORCEMENT 6 (2011).

³ Richard P. Kusserow et al., *Sarbanes-Oxley: Best Practices for Private and Nonprofit Health Care Entities* 5-6 (2003).

⁴ AMERICAN HEALTH LAWYERS ASSOCIATION, THE HEALTH CARE DIRECTOR'S COMPLIANCE DUTIES: A CONTINUED FOCUS OF ATTENTION AND ENFORCEMENT 2 (2011).

Organizations

In an effort to foster greater financial accuracy and curb corporate malfeasance in the wake of corporate scandal, the government enacted the Sarbanes-Oxley Act (SOX or the Act) in the summer of 2002. This was the first attempt by Congress to govern corporate conduct by imposing criminal liability directly on executives for investor fraud.⁵

¶22,115 Sarbanes-Oxley Act Objectives

A new era of corporate responsibility has emerged since the enactment of the Sarbanes-Oxley Act (SOX or the Act) in 2002 in response to several corporate scandals. One purpose of the corporate governance reform was to change the way audit firms conduct their businesses, while simultaneously assigning a greater level of accountability to corporate executives.⁶ After the passage of SOX, corporate managers had to personally attest to the accuracy of their company's financial figures.⁷ The intent of Congress was to restore investor confidence by allowing for criminal prosecution of managers when financial information was found to be fraudulent.⁸

There are four general objectives to SOX:

- First, the Act is intended to increase the accountability of corporate executives and board members for their actions by implementing a "checks and balances system" and increasing penalties. The Act strengthened the penalties for corporate misconduct and fraud. Under Title 18 of the United States Code §1519, any person who "knowingly alters, destroys, mutilates, conceals, covers up, falsifies, or makes a false entry in any record, document, or tangible object with the intent to impede, obstruct, or influence the investigation or proper administration of any matter within the jurisdiction of any department or agency of the United States...shall be fined... [or] imprisoned not more than 20 years, or both."⁹
- The second objective is to increase the truthfulness of financial information and encourage complete disclosure. To accomplish this objective the chief executive officer and chief financial officer are now required to certify that: (1) submitted financial statements do not contain untrue or misleading information, (2) the organization has internal controls to ensure that officers are cognizant of all relevant facts needed to complete reporting; (3) the financial information was evaluated and includes a clear explanation of how their financial assessments differ from the Generally Accepted Accounting Principles (GAAP); and (4) all fraudulent activity has been reported to the Audit Committee.¹⁰ Additionally, the Act requires public companies to certify the various internal audit controls used.¹¹

⁵ See generally Neil H. Aronson, Preventing Future Enrons, Implementing the Sarbanes-Oxley Act of 2002, *Stanford Journal of Law Business & Finance* 127 (2002).

⁶ Aronson, Preventing Future Enrons, Implementing the Sarbanes-Oxley Act of 2002, *Stanford Journal of Law Business & Finance* 127 (2002) at 132.

⁷ *Worthless Promises?*, *Economist*, Sept. 28, 2002, available at 2002 WL 7247603.

⁸ *Worthless Promises?*.

⁹ 18 U.S.C. § 1519 (2002).

¹⁰ Richard P. Kusserow et al., *Sarbanes-Oxley: Best Practices for Private and Nonprofit Health Care Entities* 9-10 (2003).

¹¹ *Sarbanes-Oxley Reforms: Implications for Nonprofit Health Care Industry*, Jones Day commentaries 1, (May 2003) available at <http://www.lawrenceassociates.com/Files/Sarbanes-OxleyJonesDay.pdf>.

- Third, the Act seeks to improve the disclosure of information by eliminating conflicts of interest both internally and externally. Congress realized that executive self-dealing provided a heavy incentive for upper level employees to "cook the books." The need for independent review within a corporation is the backbone to the elimination of self-dealing, the theory being that an executive under the watch of an independent third party is less likely to break the law. The Act keeps these third parties independent by: (1) prohibiting auditors from providing any services to an organization during the audit period, (2) punishing any party who attempts to interfere with or influence an auditor or accountant during the investigation or review, and (3) requiring organizations to rotate their external audit partners at least once every five years.¹² This rotation system seeks to avoid collusion between the two entities in an effort to deter relationships similar to that of Enron and Arthur Andersen.¹³
- The fourth objective of the Act is to foster a corporate climate in which employees at all levels are encouraged to report unethical or questionable behavior to management rather than suppress the information.¹⁴ This is typically satisfied by the creation of compliance programs that encourage internal investigations into employee complaints and allegations and the disclosure of any wrongdoing on the part of the corporation.

SOX does not require an organization to establish a compliance program, but in the context of the health care industry an effective compliance program helps health care organizations meet SOX's objectives.

¶22,120 Sarbanes-Oxley: The Impact on the Health Care Industry

The directors of health care organizations face unique challenges associated with doing business in the health care industry that may be unfamiliar to those employed in other industrial or service sectors. Providers and suppliers of health care goods and services are subject to complex statutory and regulatory schemes governing coverage and reimbursement for medical services. The rules that govern the industry are specific but not always so clear, and some of them may make certain actions illegal that in other industries may not be. The Sarbanes-Oxley Act (SOX or the Act) and health care fraud and abuse laws have strongly established the need for all health care organizations to be vigilant in their compliance efforts and operations. The HealthSouth example below illustrates one of the first decisions concerning fraud in the context of a health care organization after SOX was enacted.

The HealthSouth Example

On March 19, 2003, the Securities and Exchange Commission (SEC) filed a complaint against the HealthSouth Corporation, the nation's largest provider of out-patient surgery, diagnostic imaging,

¹² *Sarbanes-Oxley Reforms* at 11.

¹³ Enron, a Houston-based energy company that at the time was the nation's seventh-largest corporation, collapsed in a large-scale corporate scandal due to improper accounting practices that were audited, and approved by its accounting firm, Arthur Andersen, with whom Enron had a long-term relationship. See Enron's Collapse: An Overview, N.Y. TIMES (Jan. 16, 2002) available at <http://www.nytimes.com/2002/01/16/business/enron-s-collapse-overview-arthur-andersen-fires-executive-for-enron-orders.html>.

¹⁴ Kusserow, *supra* note 12, at 9.

and rehabilitative services.¹⁵ The Department of Justice filed an eighty-five count indictment alleging that HealthSouth and some of its top executives (1) perpetrated fraud upon the purchasers of its securities, (2) filed financial statements with the SEC that contained materially misstated revenues, assets and liabilities, (3) failed to make and keep books, records and accounts that accurately and fairly reflected transactions and dispositions of assets, and (4) failed to maintain an internal accounting system to ensure that transactions were executed in accordance with company policy, among other things.¹⁶

The problematic conduct began in early 1997 when HealthSouth executives recognized that the company's earnings were falling below Wall Street's expectations. In response, the chief executive officer influenced his subordinates to fraudulently inflate the company's financial statements to hide the company's true financial condition. Subsequently, the company falsified increases in earnings and assets and by the third quarter of 2002, HealthSouth had over-inflated its assets by more than \$800 million.

By the end of the first quarter of 2003, HealthSouth could no longer hide the over-inflation and announced a write-down of \$445 million. In the fallout that occurred after the announcement, the former chief financial officer pled guilty to conspiring to falsify financial statements and the company publicly admitted that its financial statements could no longer be relied upon. By the end of 2003, at least 15 executives pled guilty to crimes relating to the falsification of financial information resulting in over \$2 billion in fraudulent entries.¹⁷ The criminal charges levied against the executives were the first such charges brought under SOX.

This early example of a post-SOX decision concerning corporate fraud illustrates the role of the Board in setting the tone in the organization with respect to compliance with the governing laws. It is crucial that the Board is involved in the creation and oversight of a compliance program to ensure that the program is effective and that the Board monitors the roles of general counsel and the chief compliance officer as part of its compliance oversight responsibilities, as discussed in Part II below.

Part II: A Director's Duty of Care – Common Law Formulations

The Sarbanes-Oxley Act (SOX or the Act) does not specifically require a Board to create a compliance program. However, such a requirement was formulated and refined in subsequent court decisions. The decision in the case *In Re Caremark Int'l, Inc. Derivative Litigation*¹⁸ (*Caremark*) established a Board's duty to oversee a compliance program in the context of a health care organization, but did not describe a specific methodology for doing so.¹⁹ Ten years later, in the case *Stone v. Ritter*,²⁰ the Delaware Supreme Court clarified the duties of corporate directors articulated in the *Caremark* decision.

¶22,125 The Implications of the *Caremark* Decision for Corporate Directors

¹⁵ *In re HealthSouth Corp. Shareholders Litig.*, 845 A.2d 1096, 1101 (Del. Ch. 2003).

¹⁶ *SEC v. HealthSouth Corp.*, 261 F.Supp. 2d 1298; 1302 (N.D. Ala. 2003).

¹⁷ *In re HealthSouth Corp. Shareholders Litig.*, 845 A.2d at 1101-1102.

¹⁸ *In Re Caremark Int'l, Inc. Derivative Litig.*, 698 A.2d 959 (Del. Chancery Ct. 1996).

¹⁹ AMERICAN HEALTH LAWYERS ASSOCIATION, THE HEALTH CARE DIRECTOR'S COMPLIANCE DUTIES: A CONTINUED FOCUS OF ATTENTION AND ENFORCEMENT 2 (2011).

²⁰ *Stone v. Ritter*, 911 A.2d 362 (Del. 2006).

In 1996, Delaware's Court of Chancery decided *Caremark*, a case that sent ripples across both the compliance and corporate law communities as a result of its implications for corporate directors.

In Re Caremark International, Inc. Derivative Litigation

In 1994, Caremark International Inc. (Caremark) was charged in a multiple felony indictment relating to various anti-kickback violations. The allegations centered on the contractual relationships between the corporation and individual hospitals and physicians. The indictment charged Caremark, two of its officers, a sales employee, and a physician with self-referral prohibition and anti-kickback violations. According to the indictment, the physician received more than \$1 million in research grants and consulting agreements to distribute a drug marketed by Caremark.

Management denied any wrongdoing and claimed that the contractual relationship was legal. Despite its contention that the relationships were legal, Caremark terminated all remaining financial relationships related to its drug and pharmaceutical lines and entered into settlement negotiations with the federal government.²¹ Caremark agreed to plead guilty to one count of mail fraud, pay civil and criminal fines, and cooperate with the Office of Inspector General (OIG) concerning any pending investigation. In exchange, the OIG would allow Caremark to continue to participate in federally funded health care programs. As part of the agreement, the government stipulated that "no senior executive of Caremark participated in, condoned, or was willfully ignorant of [the] wrongdoing." Additionally, Caremark agreed to enter into a "Corporate Integrity Agreement" designed to ensure compliance with the law. The Board of Directors agreed to the settlement provisions.²²

²¹ During the investigatory period, Caremark restructured the organization moving to a more centralized management structure. After the reorganization, Caremark eliminated management fees paid to physicians for Medicaid and Medicare services and the Board of Directors (the "Board") took additional steps to assure compliance with the Anti-Referral Payment Law ("ARLP") and implemented a new internal "Guide to Contractual Relations" (the "Guide") manual. The Guide mandated that all agreements had to comply with ARLP regulations or exclude Medicare and Medicaid patients altogether and each contractual relationship must be approved by the president of the local regional office. Over the next few years, Caremark took additional steps to ensure compliance with the ARPL including a new internal audit charter, sales force education, and increased management supervision. See generally *In Re Caremark Int'l, Inc. Derivative Litig.*, 698 A.2d 959 (Del. Ch. Ct. 1996).

²² The major terms of the settlement agreement included:

1. That Caremark, undertakes that it and its employees, and agents not pay any form of compensation to a third party in exchange for the referral of a patient to a Caremark facility or service or the prescription of drugs marketed or distributed by Caremark;
2. That Caremark, undertakes that it and its employees, and agents not split fees with physicians, joint ventures, and business combination in which Caremark maintains a direct financial interest;
3. That the Board shall discuss all relevant material changes in government health care regulations and their effect on relationships with health care providers on a semi-annual basis;
4. That Caremark's officers will remove all personnel from health care facilities or hospitals who have been placed in such facility for the purpose of providing remuneration in exchange for a patient referral for which reimbursement may be sought from Medicare or Medicaid;
5. That every patient will receive written disclosure of any financial relationship between Caremark and the health care professional or provider who made the referral;
6. That the Board will establish a Compliance and Ethics Committee...to meet at least four times a year to effectuate these policies and monitor business segment compliance with [federal and state legislation], and report to the board semi-annually concerning compliance by each business segment.

Caremark was later sued by several private insurance company payors under the theory that Caremark was liable to them for improper business practices. Fearing the excessive cost of litigation and the potential fallout of a suit, the Board settled with the private insurance companies in the amount of \$98.5 million. In total, Caremark was required to pay more than \$250 million in penalties, fines, and restitution.²³

Subsequently, several shareholders filed suit against members of the Board alleging a breach of the Board's fiduciary duty of care by failing to supervise management or implement compliance measures, thus exposing Caremark to liability. The shareholders sought to recover the losses from the individual Board members. The company and shareholders agreed to a fairness hearing to determine if the shareholders had been injured by the actions of the Board of Directors.

Reasonability of Settlement Agreement

The issue for the court to decide was whether the proposed settlement agreement was fair and reasonable, in light of all relevant factors, to both Caremark and its shareholders. The shareholders claimed the Board allowed the violations to develop and continue, exposing the corporation to liability in violation of the Board's duty to actively monitor corporate performance. Typically, liability stemming from directorial decisions takes one of two forms. Director liability may arise from a decision that results in a loss based on an ill advised or negligent decision. Alternatively, director liability may arise from an "unconsidered failure of the board to act," in situations in which action would have prevented the loss.²⁴

The Caremark shareholders brought suit under the "failure to monitor" theory of liability. The shareholders argued that the Board was the party ultimately responsible for the violation of the anti-kickback laws. To recover under a breach of duty of care theory, the shareholders had to prove that (1) the directors knew the violations occurred or should have known the violations were occurring, (2) the Board failed to remedy the violation, and (3) such failure resulted in the financial loss sought in the complaint.²⁵

In most organizations, decisions of the board of directors are limited to significant corporate acts or transactions such as mergers and acquisitions, changes to organizational structure, appointment of upper level management, and changes in capital structure. Yet as this case proves, ordinary business decisions made by officers and directors within the organization can have a profound effect on the company's strategic and corporate goals. In *Caremark*, lower level managers and directors were responsible for managing contractual relationships with physicians and other referral sources, rather than the Board. The court stated that, "absent cause to suspicion there is no duty upon directors to install and operate a corporate system of espionage to ferret out wrongdoing that they have no reason to suspect existed." Therefore, absent grounds to suspect deception or illegalities, a corporate board cannot be charged with wrongdoing for simply assuming the integrity of lower level employees acting on the company's behalf. The court concluded that the Board did not violate its

7. That corporate officers responsible for business segments shall serve as compliance officers who must report semi-annually to the Compliance and Ethics Committee.

In Re Caremark Int'l, Inc. Derivative Litig., 698 A.2d 959, 966 (Del. Ch. Ct. 1996).

²³ *Caremark*, 698 A.2d at 961.

²⁴ *Caremark*, 698 A.2d at 967-68.

²⁵ *Caremark*, 698 A.2d at 972.

duty of care and that the settlement was fair and reasonable.²⁶

Court's Focus on Corporate Governance

The importance of *Caremark* is not in the outcome of the case, but rather in the court's emphasis on corporate governance. The court acknowledged that a board has some responsibility with respect to monitoring an enterprise to assure that the corporation functions within the boundaries of the law. For proof, the court pointed to the United States Sentencing Guidelines for Organizations,²⁷ (discussed in further detail in Part III), which offer powerful incentives for corporations to have compliance programs in place to (1) detect and prevent violations of law, (2) promptly report violations to appropriate officials, and (3) take voluntary remedial efforts to correct them. The court will evaluate the effectiveness of any corporate self-governance effort via the requirements outlined in the sentencing guidelines.

Throughout its opinion, the court continued to stress the importance of internal and external factors of compliance. This decision recognized a compliance program's ability to shield company directors from personal liability arising from the wrongdoings of employees.

[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.²⁸

While the court noted the importance and the need for an information and reporting system, the court stopped short of outlining the requirements for such a system. The level of detail that each system is required to have is a question of business judgment. "It is important that the board exercise a good faith judgment that the corporation's information and reporting system is in concept and design adequate to assure the board that appropriate information will come to its attention in a timely manner ... so that it may satisfy its responsibility."²⁹

The lesson learned in *Caremark* is that "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 operation."³⁰

¶22,130 The *Stone v. Ritter* Decision

In 2006, the Delaware court in the *Stone v. Ritter*³¹ decision clarified the duties of corporate directors.

²⁶ The court indicated that the settlement agreement provided very modest benefits to the corporation and, thus, in turn, the shareholders. The court noted that post-settlement *Caremark* would have a more centralized management structure and the establishment of a Compliance and Ethics Committee should ensure future compliance at low level management position.

²⁷ See Part III ¶22,145.

²⁸ *In Re Caremark Int'l, Inc. Derivative Litig.*, 698 A.2d 959, 970 (Del. Ch. 1996).

²⁹ *Caremark*, 698 A.2d at 970.

³⁰ Richard P. Kusserow et al., *Sarbanes-Oxley: Best Practices for Private and Nonprofit Health Care Entities 1* (2003), at 5-6.

³¹ *Stone v. Ritter*, 911 A.2d 362 (Del. 2006).

Stone v. Ritter

Stone v. Ritter involved a derivative action by shareholders of AmSouth Bancorporation (AmSouth) after the disclosure that AmSouth had paid \$50 million in fines and civil penalties arising from violations of the federal Bank Secrecy Act. The lawsuit alleged that the directors of AmSouth had breached their duty to act in good faith because, though AmSouth maintained a program to monitor Bank Secrecy Act compliance, the program was not adequate to prevent the violations giving rise to the fines and civil penalties. The Chancery Court dismissed the complaint on the basis that, under *Caremark*,³² directors can only be liable in situations involving a sustained or systematic failure of the board to exercise oversight, and the Court found that the complaint did not establish the requisite lack of good faith on which to base liability.

In *Stone*, the Supreme Court of Delaware established two important principles. First, the court determined that the *Caremark* standard is the appropriate standard for director duties with respect to corporate compliance issues. Second, the court concluded that there is no duty of "good faith" that forms a basis, independent of the duties of care and loyalty, for director liability.

Consistent with the standard articulated in *Caremark*, the standard in *Stone* for director liability is whether there is a "sustained or systematic failure of the board to exercise oversight – such as an utter failure to attempt to assure a reasonable information and reporting system exists..." The *Stone* decision reinforces the proposition that directors are not responsible for ensuring the legality of every act of the corporation's personnel, even if the illegal conduct disclosed a failure of the corporate compliance program.³³

The court concluded that, in a case such as *Stone*, where information failed to reach the board because of ineffective internal controls, but information systems had been established and the directors neither knew nor should have known of the violations of law, there has been no violation of the duty of good faith. The court also reiterated what the *Caremark* court had stated ten years earlier: that the plaintiffs' theory of liability in *Stone* – attempting to hold directors liable for the misconduct of employees in the organization – is possibly "the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment."³⁴

¶22,135 The Duty of Care in the Health Care Industry

In the wake of the *Caremark*³⁵ and *Stone*³⁶ decisions, it is clear that the directors of health care organizations owe a fiduciary duty to shareholders concerning compliance with the law. The one fiduciary duty specifically implicated by corporate compliance programs is the *duty of care*.³⁷

The courts in *Caremark* and *Stone* clearly stated that there is a duty to assure that a corporate information system exists and that failure to do so may render a director liable. Thus, it is necessary for directors to establish information and reporting systems to fulfill their duty of care. Typically,

³² *Caremark*, 698 A.2d 959 (Del. Ch. 1996).

³³ *Stone v. Ritter*, 911 A.2d 362 (Del. 2006).

³⁴ *Stone v. Ritter*, 911 A.2d 362 (Del. 2006).

³⁵ *In Re Caremark Int'l, Inc. Derivative Litig.*, 698 A.2d 959 (Del. Ch. 1996).

³⁶ *Stone v. Ritter*, 911 A.2d 362 (Del. 2006).

³⁷ AMERICAN HEALTH LAWYERS ASSOCIATION, THE HEALTH CARE DIRECTOR'S COMPLIANCE DUTIES: A CONTINUED FOCUS OF ATTENTION AND ENFORCEMENT 5 (2011).

the duty of care requires that a director act (1) in good faith, (2) with the level of care that an ordinarily prudent person would exercise under the same circumstances, and (3) in a manner they reasonably believe to be in the best interest of the corporation.³⁸

In the health care context, the duty of care arises in either the decision-making function or the oversight function. The decision-making function applies to a particular situation or a specific action. The duty of care principle in the oversight function pertains to the general activity of overseeing the day-to-day functions of the business.³⁹ The *Caremark* and *Stone* decisions are perfect examples of the application of the duty of care to director oversight. The duty with respect to oversight is satisfied if the director assures that a compliance program exists and is adequate to provide the board with information relevant to make its decisions. A board's failure to implement a compliance program will not only put the organization at risk, but also may create personal liability for directors. However, the mere existence of a compliance program is insufficient to shield a director from liability and to protect the organization, if the program is inadequate to assure that information will be provided to the Board in a timely matter as a matter of ordinary operations.

The responsibilities imposed on directors may seem great, but the duty of care inquiry has not been extended to require that directors engage in "proactive vigilance."⁴⁰ Simply put, the courts have refused to mandate that a director should act as an internal investigator. Rather, the duty of care arises when a red flag is raised or suspicions are or should be aroused. "Absent the presence of suspicious conduct or events, directors are entitled to rely on the senior leadership team in the performance of it duties."⁴¹ Therefore, a director will only have violated his duty of care if he fails to act after he has information that causes some concern.

The best way to find these red flags and ferret out the suspicious conduct or transaction is by using an effective compliance program as contemplated in the United States Sentencing Guidelines for Organizations. The *Caremark* decision, in effect, brought the Sentencing Guidelines for Organizations directly into the corporate boardroom.

Part III: Satisfying the Duties of the Board of Directors

The Board's duty of care concerning compliance may be satisfied with the implementation and maintenance of an effective compliance program. In order to craft an effective compliance program it is helpful to look to the specific factors the Department of Justice (DOJ) considers when deciding whether to charge an organization, as well as to the criteria the courts apply when determining how to sentence an organization.

In 1999 the DOJ issued the Principles of Federal Prosecution of Business Organizations that articulates and standardizes the factors federal prosecutors consider when deciding which organizations to prosecute. The principles have been amended in a series of memoranda. These memoranda and their impact on the fate of corporations are discussed in further detail below.

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Id.

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Richard P. Kusserow et al., *Sarbanes-Oxley: Best Practices for Private and Nonprofit Health Care Entities 1* (2003), at appendix A; *Corporate Responsibility and Corporate Compliance: A resource for Health Care Board of Directors*, The Office of Inspector General of the U.S. Department of Health and Human Services and The American Health Lawyer at 2.

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Kusserow, at 3.

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Kusserow, at 3.

The United States Federal Sentencing Guidelines for Organizations (Guidelines), mentioned above in the *Caremark* decision in Part II, guide courts in sentencing decisions after liability for wrongdoing has been established. The Guidelines provide a good starting point for creating an effective compliance program because they set forth detailed criteria for the court to assess the nature and extent of an organization's wrongdoing.

Additionally, the Board can look to the Compliance Program Guidances issued by the Office of the Inspector General (OIG) when crafting a compliance program. These Guidances provide a blueprint for compliance policies and procedures by health care industry segment.

The following discusses the aforementioned three resources in greater detail.

¶22,140 The Department of Justice Principles of Federal Prosecution of Business Organizations and Amendments in Subsequent Memoranda.

The Department of Justice (DOJ) issued the Principles of Federal Prosecution of Business Organizations in 1999. Some of the significant amendments to the principles are discussed below.

The Thompson Memorandum

The 2003 amendment referred to as the Thompson Memorandum came on the heels of several major corporate scandals and reinforced general prosecutorial objectives involving the charging of a corporation. In this memorandum, the focus of the DOJ was to increase emphasis on the thoroughness of a corporation's cooperation as well as to scrutinize the authenticity of the cooperation.

An important objective of the Thompson Memorandum was to stress the need for the DOJ to vigorously prosecute entities and officers responsible for corporate malfeasance. The Thompson Memorandum also emphasized the need for prosecutors to consider corporations, in addition to individuals, as potential criminal targets in all cases involving organizational wrongdoing.⁴² This prosecutorial approach was meant to "provide a unique opportunity for deterrence on a massive scale" because of the possibility of personal liability. Another objective was to reinforce the principles of the United States Sentencing Guidelines for Organizations (discussed at ¶22,145) by recognizing the importance of effective corporate compliance programs in the investigatory stage of the pre-indictment inquiries.

The Thompson Memorandum changed the DOJ's approach to corporate prosecution in several ways. First, it established a more consistent and unified approach for law enforcement officials to respond to corporate fraud. Second, it stressed the need for faster prosecutions. Third, it mandated a more proactive approach to detecting corporate crime. Finally, it called for a change in case disposition by stressing the need to be uniform in its approach to prosecutions.

While the Thompson Memorandum was viewed as a positive tool for providing a uniform method to be used by prosecutors when determining whether to prosecute a corporation, the Memorandum

⁴² Thompson Memorandum, Jan. 20, 2003.

had its negative side effects. The most controversial issues resulting from the Thompson Memorandum were related to waiver of the attorney-client and work-product privileges. The issue of waiver of the attorney-client and work-product privileges came up frequently in federal law enforcement efforts, especially when investigations focused on schemes to defraud that were increasingly sophisticated and complex, and could often span an entire industry. The comment section of the Thompson Memorandum stated that waiver of a corporation's attorney-client privilege was not an absolute requirement, but may sometimes be necessary. The directive promised leniency to business organizations that quickly and voluntarily complied with disclosure and cooperation.

The provisions of the Thompson Memorandum and the application of its principles by DOJ attorneys encouraging corporations to waive the protections of the attorney-client and work-product privileges came under attack from many directions, including from the courts. In a series of rulings, Judge Lewis Kaplan of the Southern District of New York found that certain aspects of the Memorandum, as applied in the case before him, were unconstitutional. In June 2006, the court in *United States v. Stein*, found that the government could not, by relying on the principles of the Thompson Memorandum, interfere with the right of an individual criminal defendant to a fair trial and effective assistance of counsel.⁴³ In July 2006, the same Court ruled that economic coercion used to secure a waiver of privilege against self-incrimination was a violation of the Fifth Amendment.⁴⁴

The McNulty Memorandum

The District Court's decisions in *United States v. Stein* case, as well as the other actions taken in opposition to the Thompson Memorandum, set the stage for change. In December 2006, Deputy Attorney General Paul J. McNulty issued a revised version of the Thompson Memorandum. The revised "*Principles for Federal Prosecution of Business Organizations*" (referred to as the McNulty Memorandum) clarifies how prosecutors will evaluate a company's cooperation when making charging decisions.⁴⁵ The McNulty Memorandum upholds many of the basic provisions of the Thompson Memorandum; however, it includes strict limitations and procedures for prosecutors seeking privileged information.

Factors Considered

The McNulty Memorandum affirms the provisions of the Thompson Memorandum outlining the basic factors that prosecutors must consider in making decisions regarding what actions to take against a corporate target. In general, prosecutors must weigh factors such as the sufficiency of the evidence, the likelihood of success at trial, consequences of conviction, and the adequacy of noncriminal approaches. Due to the unique nature of the corporate "person," additional factors must be considered when determining what action to take against a corporation. Those factors include:

1. the nature and seriousness of the offense;

⁴³ *United States v. Stein* ("Stein I"), 435 F. Supp. 2d 330, 382 (S.D.N.Y. June 26, 2006).

⁴⁴ *United States v. Stein* ("Stein II"), 440 F. Supp. 2d 315, 326 (S.D.N.Y. July 25, 2006).

⁴⁵ Memorandum from Deputy Attorney General Paul J. McNulty, to the Heads of Department Components United States Attorneys (Dec. 2006) available at http://www.justice.gov/dag/speeches/2006/mcnulty_memo.pdf [hereinafter McNulty Memorandum].

2. the pervasiveness of the wrongdoing within the corporation;
3. the corporation's history of similar conduct;
4. the corporation's timely and voluntary disclosure of wrongdoing *and its willingness to cooperate in the investigation of its agents*;
5. the existence and adequacy of the corporation's pre-existing compliance program;
6. the corporation's remedial actions, *including any efforts to cooperate with the relevant government agencies*;
7. collateral consequences;
8. the adequacy of the prosecution of individuals responsible for the corporation's malfeasance; and
9. the adequacy of remedies such as civil or regulatory enforcement actions.⁴⁶

Cooperation

In determining whether a corporation will be viewed as having cooperated, the McNulty Memorandum makes specific provisions regarding the waiver of the attorney-client and work product privileges. Prosecutors may request waiver of privilege only in rare circumstances, and before waiver can be requested, the request must be approved by the local United States Attorney or the Deputy Attorney General. To gain approval, prosecutors must show a legitimate need for the information they are seeking. To meet this test, prosecutors must show: (1) the likelihood and degree to which the privileged information will benefit the government's investigation; (2) whether the information sought can be obtained in a timely and complete fashion by using alternative means that do not require waiver; (3) the completeness of the voluntary disclosure already provided; and (4) the collateral consequences to the corporation in requesting the waiver.⁴⁷ If these elements are not shown, the request for waiver will not be authorized.

The McNulty Memorandum further mandates that even when a legitimate need for information is found to exist, federal prosecutors are required to seek the least intrusive waiver necessary to conduct the investigation. The McNulty Memorandum divides privileged information into two categories, requests for which are handled differently. The first category is referred to as "factual" information related to the underlying misconduct. Factual information may include copies of key documents, witness statements, or purely factual interview memoranda. Requests should first be made for privileged "factual" information. When a prosecutor is seeking waiver for information of this kind, the prosecutor must obtain approval of the request for waiver from the local United States Attorney, who must consult with the Deputy Attorney General.⁴⁸

The second category of privileged information is attorney-client communications or nonfactual attorney work product. This includes legal information given to the corporation before, during, or

⁴⁶ McNulty Memorandum (Dec. 12, 2006) (emphasis added).

⁴⁷ McNulty Memorandum (Dec. 12, 2006).

⁴⁸ McNulty Memorandum (Dec. 12, 2006).

after the underlying misconduct occurred (i.e., attorney notes, legal determinations, or legal advice). Waiver for this type of information can only be requested when factual information does not allow for a thorough investigation. A request for waiver of this type of information must be authorized in writing by the Deputy Attorney General.⁴⁹ The McNulty Memorandum stresses that this type of information should only be requested in rare circumstances.

Even if a federal prosecutor shows a legitimate need for privileged information and subsequently gets approval to request waiver, a corporation may choose not to waive privilege and turn over the requested information. Corporations should note that their response to a government request for waiver of privilege for factual information can be considered in determining whether a corporation has cooperated in the government's investigation. If, however, a corporation declines to waive privilege for attorney-client communications or nonfactual attorney work product, the declination cannot be held against the corporation by prosecutors when making a charging decision.

In *U.S. v. Stein*, the Court found that the Thompson Memorandum, as applied, violated the defendants' Right to Counsel (see further ¶22,140).⁵⁰ In the light of that case, the McNulty Memorandum makes it clear that "prosecutors generally should not take into account whether a corporation is advancing attorneys' fees to employees or agents under investigation and indictment." Because many state indemnification statutes grant corporations the power to advance such fees for officers under investigation prior to a determination of guilt and many corporations have contractual obligations to advance legal fees in certain situations, the McNulty Memorandum does not consider a corporation's compliance with governing state law and contractual obligations a failure to cooperate. Prosecutors, however, are permitted to inquire about an attorney's representation of a corporation or its employees.

There is an exception to this general rule. In "extremely rare" cases, the advancement of attorneys' fees may be taken into account when the totality of the circumstances shows that it was intended to impede a criminal investigation. In such situations, prosecutors may consider fee advancement to make a determination that the corporation is acting improperly to shield itself and its culpable employees from government scrutiny. When a prosecutor determines that these circumstances exist, the prosecutor must receive approval from the Deputy Attorney General before considering payment of legal fees when making a charging decision.

Compliance Programs

Among the factors that prosecutors will consider in deciding whether to prosecute a corporation is "the existence and adequacy of the corporation's pre-existing compliance program."⁵¹ Therefore, the existence of an operating and effective compliance program within a corporation may help the corporation avoid prosecution altogether. In the alternative, if the corporation is prosecuted and convicted, a compliance program will be an advantage when the corporation is sentenced under the United States Sentencing Guidelines (discussed in ¶22,145).

The McNulty Memorandum expressly supports the existence of corporate compliance programs but

⁴⁹ McNulty Memorandum (Dec. 12, 2006).

⁵⁰ In *Stein*, prosecutors, under the auspices of the Thompson Memorandum, informed the corporation that advancement of attorney's fees to employees facing indictment would work against the corporation when determining if the corporation had "cooperated" in the investigation.

⁵¹ McNulty Memorandum (Dec. 12, 2006).

warns corporations that having a compliance program is not sufficient, in and of itself, to justify not charging a corporation for criminal conduct undertaken by its officers, directors, employees, or agents.⁵² On the contrary, such criminal conduct performed in the face of a compliance program may suggest that the corporation is not adequately enforcing its program. When evaluating a compliance program, prosecutors will determine whether the program is adequately designed for maximum effectiveness in preventing and detecting wrongdoing by employees and whether corporate management is enforcing the program.

The Department of Justice has no formal guidelines for corporate compliance programs; however, the existence of a mere "paper program" will not be of any advantage to the corporation when prosecutors make a charging decision. Some factors that will be considered by prosecutors in determining if a compliance program is adequate include: (1) the comprehensiveness of the compliance program; (2) the extent and pervasiveness of the compliance program; (3) the seriousness, duration, and frequency of the misconduct; (4) the number and level of the corporate employees involved; (5) any remedial actions taken by the corporation; and (6) the promptness of any disclosure of wrongdoing to the government.⁵³

The McNulty Memorandum also notes that compliance programs should be designed to detect the particular types of misconduct most likely to occur in a particular corporation's line of business. Because many corporations operate in an environment unfamiliar to many criminal prosecutors, prosecutors are encouraged to consult with relevant federal and state agencies with the expertise to evaluate the adequacy of the program's design and implementation.

In remarks made to the "Lawyers for Civil Justice," coinciding with the release of the McNulty Memorandum, Deputy Attorney General Paul McNulty noted that "the best corporate prosecution is the one that never occurs. Through successful corporate compliance efforts, investor harm can be avoided. Corporate officials must be encouraged to seek legal advice if they are in doubt about the requirements of the law."⁵⁴ Further, the Deputy Attorney General recognized that attorneys need full and frank communication with employees to prevent or remedy any criminal wrongdoing. It is clear from these comments that the McNulty Memorandum was intended to eliminate or reduce some of the pitfalls of the Thompson Memorandum.

The Filip Memorandum

In 2008, the principles were updated by then Deputy Attorney General Mark Filip in the "Filip Memorandum."⁵⁵ In the most recent version, cooperation refers to the timely and voluntary disclosure of wrongdoing and does not require waiver of any privileges.⁵⁶ The operative question when considering cooperation is therefore whether the corporation disclosed relevant facts about misconduct in a timely and voluntary fashion, not whether the corporation waived its attorney-client

⁵² McNulty Memorandum (Dec. 12, 2006).

⁵³ McNulty Memorandum (Dec. 12, 2006).

⁵⁴ Deputy Attorney General Paul J. McNulty remarks delivered to the Lawyers for Civil Justice Membership Conference, New York, Dec. 12, 2006.

⁵⁵ Principles of Federal Prosecution of Business Organizations, Department of Justice (2008) *available at* <http://www.justice.gov/opa/documents/corp-charging-guidelines.pdf>

⁵⁶ *Id.* §§ 9-28.700, 9-28.710

or work-product privileges when it made the disclosures.⁵⁷

¶22,145 Application of the Federal Sentencing Guidelines to Organizations

While the Federal Sentencing Guidelines (Guidelines) were implemented in the early 1990's, it was the *Caremark* decision that ultimately brought the duty of oversight of compliance programs into the corporate boardroom.

The Guidelines and the 2004 and 2010 amendments to the Guidelines provide a statutory basis for the duty of the directors to ensure that management adopts an effective compliance program to detect and prevent the violations of law previously articulated in the *Caremark* decision (see discussion in ¶22,125).

Generally, organizations cannot be imprisoned for wrongful and illegal conduct, and accordingly, sentencing schemes traditionally imposed on individuals, cannot operate in a meaningful way to determine criminal sanctions against corporations.⁵⁸ Organizations can act only through agents and, under federal criminal law, are generally vicariously liable for offenses committed by their agents. At the same time, individual agents are responsible for their own criminal conduct and are sentenced individually under a separate set of federal sentencing guidelines. Chapter 8 of the Guidelines sets out the sentencing scheme for organizations and operates differently from the sentencing scheme for individuals.

The Guidelines define the roles and reporting relationships of particular categories of personnel with respect to an organization's compliance and ethics program. Additionally, they explicitly encourage business organizations to partner with the federal government in a program of crime control and provide strong incentives for organizations to self-police, self-report, and to cooperate in investigations of its own wrongdoing.

The Guidelines work in two parts subsequent to an adjudication of guilt. First, the court is charged with determining the correct amount of restitution and determines whether the corporation should be forced to take any remedial measures. Next, "the court must determine the appropriate fine by first calculating a base offense level, and then adding and subtracting points to that level based on a detailed set of criteria to arrive at a 'culpability score' to reflect the nature and extent of the organization's wrongdoing."⁵⁹ An organization's culpability score can be reduced when the corporation has an effective compliance and ethics program and when the organization fully cooperates in the investigation.⁶⁰

The Guidelines were amended in 2004 and 2010 to further emphasize the importance of an effective compliance and ethics program. The amendments stress the importance of developing a corporate culture that promotes ethical conduct and compliance with all laws and focus on the increased accountability of the Board.⁶¹ The current Guidelines require the organization to exercise due diligence in preventing and detecting criminal conduct. They also require the organization's

⁵⁷ See *id.*

⁵⁸ Kathryn Keneally, *White Collar Crime*, 28 *Champion* 42 (June 2004).

⁵⁹ Mary Beth Buchanan, *Effective Cooperation by Business Organizations and the Impact of Privilege Waivers*, 39 *Wake Forest Law Review* 587, 595 (Fall 2004), at 594 (citing U.S. Sentencing Guideline Manual §8A1.2).

⁶⁰ U.S. Sentencing Guideline (USSG) Manual, § 8C2.5.

⁶¹ U.S. Sentencing Guideline (USSG) Manual, § 8B2.1(a).

governing authority to be knowledgeable about the content and operation of the compliance and ethics program and to exercise reasonable oversight with respect to the implementation and effectiveness of the program.⁶² The organization must also provide compliance program training to the Board and employees as well as agents, as appropriate.⁶³

Effect of an Effective Compliance and Ethics Program on Sentencing

Governing bodies of health care organizations need to be aware of the mitigating impact an effective compliance program can have on criminal penalties against companies, if their employees are found to have engaged in criminal conduct.

The ability of a business organization to implement and sustain an effective corporate compliance program can literally mean the difference between its survival and its demise under the Guidelines. The fulfillment of the expectations of the Guidelines for compliance has the potential to reduce an organization's culpability score, in terms of dollars, from astronomical amounts to virtually zero. Furthermore, compliance with the Guidelines is attractive to courts as a requirement for probationary sentences for a business organization.

To allow businesses to effectively detect and prevent misconduct, the United States Sentencing Commission (the Commission) proposed amendments in 2004 regarding effective compliance and ethics programs.⁶⁴ Among other recommendations, the amendments provided for periodic review and modification of the compliance programs by the corporations themselves.⁶⁵ This requires corporations to continually evaluate the risks of impropriety and update their compliance programs accordingly.

The Guidelines offer substantial incentives to organizations to reduce and ultimately eliminate criminal conduct by providing a structural foundation from which an organization may self-police its own conduct through an effective compliance and ethics program. For purposes of the Guidelines, a "compliance and ethics program" means a program designed to prevent and detect criminal conduct. The existence of a compliance program, however, is not a guarantee that the corporation will go unpunished. The Guidelines prohibit the reduction of an organization's culpability score if any high-level personnel or a person involved with the compliance program participates in or contributes to the corporate malfeasance.⁶⁶ Additionally, a corporation may be ineligible for a reduction in score if the reporting is untimely, and in some circumstances an organization may receive an upward departure if the program in existence fails to respond to a court or administrative order.⁶⁷

⁶² U.S. Sentencing Guideline (USSG) Manual, § 8B2.1(b)(2).

⁶³ U.S. Sentencing Guideline (USSG) Manual, § 8B2.1(b)(4).

⁶⁴ USSG Manual, § 8B2.1.

⁶⁵ USSG Manual, § 8B2.1(b)(7).

⁶⁶ USSG Manual § 8C2.5(f). "High-level personnel of the organization" means an individual who has substantial control over the organization or who have a substantial role in the making of policy within the organization. The term includes: a director; an executive officer; an individual in charge of a major business or functional unit of the organization, such as sales, administration, or finance; and an individual with a substantial ownership interest." USSG Manual § 8C2.5(f) Participation of an individual within substantial authority personnel in an offense results in a rebuttable presumption that the organization did not have an effective program to prevent and detect violations of law. USSG Manual § 8C2.5(f).

⁶⁷ See USSG Manual at §§ 8C2.5(f), 8C4.10.

Under the Guidelines, an effective compliance and ethics program will not only prevent and detect criminal conduct within an organization, but also should facilitate compliance with all applicable laws (civil, administrative, and regulatory). The organization's governing authority must "be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program." It is the organizational leadership, defined as "high-level personnel," who must ensure that the organization's program is effective. While another individual or individuals may be assigned operational responsibility for the compliance program, high-level personnel must assume ultimate responsibility for the program's effectiveness. Individuals who have day-to-day responsibility for the compliance and ethics program must report on the compliance program to organizational leadership and, at least annually, to the governing authority on the organization's compliance program activities. Personnel with day-to-day compliance responsibility must have direct access to the governing authority or appropriate subgroup of the governing authority.

Effect of Cooperation under the Guidelines

An organization's culpability score also can be reduced for "Self-Reporting, Cooperation, and Acceptance of Responsibility."⁶⁸ A corporation is eligible for the reduction only if it has "fully" cooperated with an investigation of its own wrongdoing. First, the cooperation must be timely. Timeliness mandates that the organization begin to cooperate as soon as it is notified of a criminal investigation. Second, the cooperation must be thorough. To be thorough, the corporation must disclose all pertinent information known by the organization. "A prime test of whether the organization has disclosed all pertinent information is whether the information is sufficient for law enforcement personnel to identify the nature and extent of the offense and the individual(s) responsible for the criminal conduct."⁶⁹

What constitutes "cooperation" under the United States Sentencing Guidelines (Guidelines) was the source of much debate between the business and legal communities and the United States Department of Justice. Much of the debate centered on the need to disclose materials typically protected under the attorney-client privilege and the work-product privilege. The original language of the Guidelines provided that the waiver of the attorney-client and work-product privileges was not a prerequisite to a reduction in the culpability score, but, in some circumstances, "may be required to satisfy the requirements of cooperation." Following extensive criticism of the original language, the language was "softened" and provided that waiver of the attorney-client and work-product privileges was not a prerequisite to a reduction in the culpability score, unless waiver was necessary to provide timely and thorough disclosure of all pertinent information known to the organization.

In March 2006, in response to widespread criticism by the American Bar Association, the U.S. Chamber of Commerce, and others, the United States Sentencing Commission abandoned the policy that encouraged prosecutors to seek waivers of attorney-client and work-product privileges from corporations hoping to obtain a reduction in culpability score. All language supporting that policy was removed from the Guidelines. After receiving and evaluating public comment and testimony, the Commission acknowledged that the Guidelines, as previously worded, "could be misinterpreted:

⁶⁸ See generally U.S. Sentencing Guideline (USSG) Manual at §8C2.5(g).

⁶⁹ USSG Manual at § 8C2.5, application note 12.

to encourage waivers."⁷⁰

¶22,150 Office of Inspector General – Compliance Program Guidances

Beginning in 1998, the Office of Inspector General (OIG) developed a series of guidance documents aimed at assisting various segments of the health care industry in developing voluntary compliance programs.⁷¹ This was part of the OIG's ongoing initiative to prevent the submission of erroneous claims and to reduce fraud and abuse in the federal health care programs through voluntary compliance efforts.⁷² The OIG issued several Compliance Program Guidances (CPG) that provide blueprints for compliance policies and procedures for various health care industry segments. CPGs were published for industry segments such as: Nursing Facilities, Hospitals, Pharmaceutical Manufacturers, Individual and Small Group Physician Practices, and Hospices.

Compliance officers and health care boards can look to the CPG that is appropriate for their individual segment for discussions of risk areas, enforcement priorities and compliance "lessons learned" in their segment.⁷³ The CPGs are not intended to be "one-size-fits-all" and individual compliance programs should be tailored to the provider's or entity's needs. While different health care industry segments present their own unique set of circumstances and challenges some areas of risk are common to most health care industry segments and are briefly addressed below but are set forth more fully in the individual CPGs as well as in other parts of this manual.

Common Risk Areas Identified in OIG's Compliance Program Guidances

The CPGs do not establish any new legal obligations and the recommendations and suggestions are not mandatory. However, they provide a good benchmark for developing and evaluating a compliance program because the CPGs alert each health care industry segment to specific risk areas that compliance officers and health care boards should focus on. Some of the specific risk areas are:

False Claims Act – Submission of Accurate Claims and Information

It is imperative that claims and requests for reimbursement from federal health care programs be complete, accurate, and reflect reasonable and necessary services.⁷⁴ Submitting a false claim (or causing a false claim to be submitted) to a federal health care program can subject an individual, or entity, or both, to civil as well as criminal penalties under the False Claims Act.⁷⁵ A false claim includes, inaccurate and incorrect coding, upcoding, unbundling of services, billing for medically unnecessary services, or services not covered by the relevant health care program, billing for services not provided, duplicate billing, insufficient documentation, and false or fraudulent cost reports.⁷⁶ In addition to civil and criminal

⁷⁰ Notice of Submission to Congress of Amendments to the Sentencing Guidelines Effective November 1, 2006, 71 FR 28063, May 15, 2006.

⁷¹ Compliance Guidance, OFFICE OF THE INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, <https://oig.hhs.gov/compliance/compliance-guidance/index.asp> (last visited Jan. 24, 2014).

⁷² *Id.*

⁷³ *Id.*

⁷⁴ OIG Supplemental Compliance Program for Hospitals, at 4859.

⁷⁵ 31 U.S.C. § 3729.

⁷⁶ OIG Supplemental Compliance Program for Hospitals, at 4860.

penalties an entity or provider can also be excluded from participation in federal health care programs, as a result of submitting a false claim.

Stark Law – The “Physician Self-Referral Law”

Section 1877 of the Social Security Act,⁷⁷ is also known as the “Physician Self-Referral Law” and is commonly referred to as the “Stark Law.” It prohibits a physician from making referrals for certain Designated Health Services (DHS)⁷⁸ payable by Medicare or Medicaid to an entity that the physician, or an immediate family member of the physician, has a financial relationship with, unless an exception applies.⁷⁹

The OIG presents a three-part inquiry to analyze financial relationships under the Stark Law. To review a financial relationship under the Stark Law start by asking: 1) is there a *referral* from a physician for a DHS? – if yes – then ask: 2) does the physician or an immediate family member of the physician, have a *financial relationship* with the entity furnishing the DHS? – if yes – the third and last inquiry is: 3) Does the financial relationship fit in an *exception*? If not, the statute has been violated.⁸⁰ If the answer to either inquiry is “no,” then the Stark Law is not implicated; however, keep in mind that other laws may be implicated instead, such as the False Claims Act.

The Federal Anti-Kickback Statute

Section 1128B(b) of the Social Security Act, the “Anti-Kickback Statute,”⁸¹ prohibits some practices in the health care industry that are common in other business sectors. A practice such as offering gifts to reward past referrals or to induce new referrals that are related to items or services reimbursable by *any* federal health care program is prohibited by the Anti-Kickback Statute.⁸² The statute and promulgating regulations set up a number of “safe harbors” for common business arrangements, such as: equipment rental safe harbor, sale of practice safe harbor, discount safe harbor etc.⁸³ It is important to review a provider’s or entity’s arrangements or practices to ensure that they do not violate the statute or that all conditions are met if the arrangement or practice fits in a safe harbor exception. The OIG identifies health care industry business practices that merit careful scrutiny in light of the federal Anti-Kickback Statute. Among those are joint ventures, compensation arrangements with physicians, recruitment arrangements, discounts, and malpractice insurance subsidies.⁸⁴

Gainsharing Arrangements

⁷⁷ 42 U.S.C. 1395nn

⁷⁸ There are currently twelve Designated Health Services including i.e.: Physical therapy services, home health services, outpatient prescription drugs, radiation therapy services and supplies, inpatient and outpatient hospital services etc. For a complete list see 42 U.S.C. 1395nn(h)6.

⁷⁹ 42 U.S.C. 1395nn, see also <http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html?redirect=/physicianselfreferral/>.

⁸⁰ OIG Supplemental Compliance Program for Hospitals, at 4863.

⁸¹ 42 U.S.C. 1320a-7b. OIG provides an illustrative comparison chart of the Anti-Kickback statute and the Stark Law available at <https://oig.hhs.gov/compliance/provider-compliance/training/files/StarkandAKSChartHandout508.pdf> (last visited Jan. 24, 2014).

⁸² OIG Supplemental Compliance Program for Hospitals, at 4863.

⁸³ 42 C.F.R. § 1001.952 (Exceptions).

⁸⁴ OIG Supplemental Compliance Program for Hospitals, at 4865-4869.

A gainsharing arrangement typically refers to an arrangement between a hospital and a physician, where the hospital gives the physician a share of any reduction in the hospital's cost for patient care attributable in part to the physician's efforts.⁸⁵

Section 1128A(b) of the Social Security Act⁸⁶ prohibits tying the physician's compensation for services to the reduction or limitation in items or services provided to the patient. Gainsharing agreements that include payments to reduce or limit services are therefore prohibited. Such arrangements, in addition to exposing entities to civil money penalties, may implicate the Stark law and the Anti-Kickback law. The OIG recommends that entities considering entering into a cost-saving arrangement should structure it to fit into the personal services safe harbor provision in order to except it from this prohibition.⁸⁷

HIPAA Privacy and Security Rules

The Health Insurance Portability and Accountability Act's (HIPAA) Privacy rule protects individually identifiable personal health information (PHI) held by covered entities and their business associates.⁸⁸ The term "Covered Entity" includes i.e. doctors, clinics, and HMOs, and the term "Business Associate" includes third parties that provide i.e. billing, accounting, or legal services to Covered Entities and, by virtue of the services they provide, have access to PHI.⁸⁹

HIPAA's Security rule provides safeguards for PHI that is stored electronically.

Although both the Privacy rule and the Security rule allows a Covered Entity and its Business Associates some flexibility in creating their own privacy procedures they should ensure that such procedures comply with all applicable provisions of the rules. For the Privacy rule such provisions include standards for when to disclose PHI with or without the patient's authorization and provisions distinguishing between required and permitted disclosures.⁹⁰ For the Security rule, important considerations include how to identify and protect against reasonably anticipated threats to the security or integrity of the electronically stored PHI, as well as protecting against reasonably anticipated, impermissible uses or disclosures of such PHI.

The HITECH Act and the Breach Notification Requirement.

The Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted in 2009, requires HIPAA Covered Entities and their Business Associates to provide notification following a breach of unsecured PHI.⁹¹

⁸⁵ OIG Supplemental Compliance Program for Hospitals, at 4870.

⁸⁶ 42 U.S.C. § 1320a-7a(b)

⁸⁷ OIG Supplemental Compliance Program for Hospitals, at 4869-4870.

⁸⁸ Health Information Privacy, U.S. Department of Health and Human Services, *available at* <http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html>

⁸⁹ For further information concerning what constitutes a "covered entity" and a "business associate" *see* <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveridentities/index.html>.

⁹⁰ OIG Supplemental Compliance Program for Nursing Facilities, at 56847.

⁹¹ For further information on the HITECH Act's Breach Notification Requirement *see* <http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/index.html>.

The U.S. Department of Health and Human Services (HHS) issued a new rule in January, 2013, expanding the notification requirements to Business Associates of Covered Entities that receive PHI because some of the largest breaches reported to the HHS involved Business Associates. The new rule also strengthens the HITECH Breach Notification requirement by clarifying when breaches of unsecured PHI must be reported to HHS.⁹²

The foregoing is an illustrative list of some of the important risk areas associated with the health care industry. The list highlights the need for compliance officers and health care boards to educate themselves in these areas in order to craft effective compliance programs and to competently meet the duty of care required by their positions within the organization.

Part IV: The Board of Directors' Role in Compliance Programs

The mere existence of a compliance program is insufficient to protect an organization from prosecution the program must be effective.⁹³ While an adequately designed reporting and information system cannot eliminate the possibility that a corporation may violate the law, its benefits far outweigh its burdens. Corporate compliance at its heart devolves corporate ethics and encourages a culture of ethical conduct; the Board should recognize its central role in fostering an environment that promotes such values.⁹⁴ The following discusses the value of corporate compliance and addresses the consequences of non-compliance to the organization and its board.

¶22,155 The Value of Corporate Compliance Programs

The goal of any self-governance program is to promote ethical behavior and to comply with applicable laws and regulations. Self-governance teaches employees that ethical behavior is not only in the corporation's best interest but, in their best interests as well.

The value of a compliance program lies in the early detection of corporate misconduct. Early detection maximizes an organization's ability to not only respond to the wrongdoing, but also diminish its negative impact.⁹⁵ Early detection also results in significant financial benefits to corporations by not only reducing business loss in the form of civil and criminal penalties, but reducing the loss associated with suspension or debarment from government programs.⁹⁶ This may be more relevant for health care entities as participants in the Medicare and Medicaid programs, than many other types of entities. In evaluating the possibility of the debarment of a corporation from a governmental contract or program, the debarring official must evaluate "[w]hether the contractor had effective standards of conduct and internal control systems in place at the time of the activity that constitutes cause for debarment or had adopted such procedures prior to any government investigation of the activity cited as a cause for debarment."⁹⁷ Even if a compliance

⁹² HHS News Release <http://www.hhs.gov/news/press/2013pres/01/20130117b.html>.

⁹³ Principles of Federal Prosecution of Business Organizations, Department of Justice § 9-28.800 (2008) available at <http://www.justice.gov/opa/documents/corp-charging-guidelines.pdf>

⁹⁴ Jean K. Fitzsimon and Scott W. MacKay, The framework for Corporate Self-Governance: An effective Ethics and Compliance Program, ABA Business Section Spring Meeting 10, at 2.

⁹⁵ Fitzsimon, at 2 (citing "Programs for Employees Keep companies on Track Ethically," BNA corporate Counsel Weekly, Dec. 9, 1998 at 5.)

⁹⁶ Fitzsimon, at 2 (citing "Programs for Employees Keep companies on Track Ethically," BNA corporate Counsel Weekly, Dec. 9, 1998 at 5.)

⁹⁷ FAR subpart 9.406-1(a)(1), available at <http://www.arnet.gov/far>.

program fails to prevent prosecution, it may reduce the severity of punishment.

While the benefits of a compliance program are great, an organization must recognize the need to devote time, energy, and resources to make it effective. The *Caremark* court was quick to point out that a hollow program is no program at all. The worst mistake an organization can make in implementing a compliance program is to ignore the internal review function and turn a blind eye with the fear that the program may reveal damaging evidence that could lead to the company's prosecution. This type of "paper" compliance program may ultimately end up hurting, rather than helping an organization. For example, "a prosecutor...may try to use a corporation's ethics and compliance program as the standard by which employee conduct should be judged in a civil or criminal trial, arguing that any failure to meet the program's requirements is indicative of fraudulent intent, a knowing act, or negligence."⁹⁸

Detractors of internal compliance programs fear the possibility of employees taking advantage of reportable information and using it to their advantage. This is extremely prevalent in the health care industry where corporate internal investigations may unearth wrongdoings that can fuel employee *qui tam*⁹⁹ lawsuits (also commonly referred to as "whistleblower actions") under the False Claims Act.¹⁰⁰ Not only can this information be used by the *qui tam* relator or whistleblower to initiate the suit, it can provide the framework for investigators to evaluate the effectiveness of the program "by providing insight into the corporation's assessment of relative culpability among sanctioned employees."¹⁰¹

Regardless of concerns about revealing damaging evidence and risking *qui tam* suits, the relevant legislation, the Federal Sentencing Guidelines, and case law send a clear message that operating in the health care industry without a compliance program could easily amount to corporate suicide.

While the Sarbanes-Oxley Act (SOX or the Act) does not require a company to have a compliance program, there is a presumption in favor of ethical programs. The certification requirements of the Act (§§302 and 906) encourage corporate executives to make internal disclosures an essential part of any compliance program.¹⁰² These provisions speak to the chief executive officer (CEO) and chief financial officer certification process. The parties must certify that:

- (1) the company's financial information accurately reflects the company's financial condition and contains no material misstatements or omissions;

⁹⁸ Fitzsimon, at 7-8 (citing Pitt & Groskaufmanis, "Minimizing Corporate Civil and Criminal Liability: A Second Look at Corporate Codes of Conduct," 78 Geo. L. J. 1559, 1605-14 (1990)).

⁹⁹ *Qui tam* is an abbreviation for the Latin term "*qui tam pro domino rege quam pro se ipso in hac parte sequitur*," meaning, "who pursues this action on our Lord the King's behalf as well as his own." *United States ex rel. S. Praver & Co. v. Fleet Bank*, 24 F.3d 320, 324 n. 7 (1st Cir. 1994). *Qui tam* provisions allowed for individuals to bring suit on behalf of the monarch or sovereign. The individual or third party litigating on behalf of the crown became known as the "Relator." *What is the False Claims Act?*, The *Qui Tam* Online Network, at <http://www.quitamonline.com/whatis.html> (last visited Aug. 5, 2008). Today's *qui tam* provision can be traced back centuries and is deeply rooted in Anglo-Saxon jurisprudence. The *qui tam* provision allows a private plaintiff, with evidence of fraud against federal programs or contracts, to sue the responsible party on behalf of the government.

¹⁰⁰ Fitzsimon, *supra* note 92, at 8.

¹⁰¹ Fitzsimon, at 8.

¹⁰² Fitzsimon, at 12.

- (2) they were responsible for establishing, maintaining, and evaluating the disclosure controls and procedures, and
- (3) they have identified significant deficiencies or weakness of the internal control procedures and report any fraudulent activity to an outside audit committee, and
- (4) they have included their evaluation of the internal controls in its annual filings with the Securities Exchange Commission (SEC).¹⁰³

These disclosure controls and procedures are designed to ensure that all relevant information is "recorded, processed, summarized and reported in an accurate and timely manner" to management and is properly disclosed to the SEC. These factors are very similar to the requirements of an effective compliance program outlined by the *Caremark* court.¹⁰⁴ The disclosure controls and the *Caremark* "information and reporting system" both aim to assure that the upper level management is well informed as a matter of ordinary operation.

Section 406 of the Act requires companies to disclose the existence of a code of ethics for company executives. Specifically, that code applies to the corporation's principal executive officer, principal financial officer, principal accounting officer or controller, or a person acting in a similar capacity.¹⁰⁵ The SEC defined "code of ethics" to mean "written standards that are reasonably designed to deter wrongdoing and to promote:

[h]onest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; [f]ull, fair, accurate, timely, and understandable disclosure in reports and documents that a registrant files with, or submits to, the Commission and in other public communications made by the registrant; [c]ompliance with applicable governmental laws, rules and regulations; [t]he prompt internal reporting to an appropriate person or persons identified in the code of violations of the code, and [a]ccountability for adherence to the code.¹⁰⁶

If the company chooses not to adopt a code of ethics, it is required to provide a reason for not having one.¹⁰⁷ Additionally, the Act requires that any modification of waiver of an ethics code be disclosed in an 8-K Form no later than five days after the modification or waiver.

U.S. v. Caputo

The repercussions of ineffective compliance programs were illustrated in *U.S. v. Caputo* in 2006.¹⁰⁸ In this case, CEO and chief compliance officer ("CCO") were criminally charged with counts of mail and wire fraud and conspiracy and the introduction of an altered or misbranded device into interstate commerce.¹⁰⁹ They were found to have aggressively marketed an "off-label" use for a sterilizer of hospital re-usable medical supplies, which had not been approved by the Food and Drug

¹⁰³ Fitzsimon, at 13.

¹⁰⁴ Fitzsimon.

¹⁰⁵ SEC Release 34-47137 available at <http://www.sec.gov/rules/proposed/34-47137.htm> (last visited August 5, 2008).

¹⁰⁶ SEC Release 34-47137.

¹⁰⁷ Fitzsimon, *supra* note 92, at 10.

¹⁰⁸ *U.S. v. Caputo*, 456 F.Supp. 2d 970 (N.D. Ill. 2006) (vacated in part on other grounds).

¹⁰⁹ *Caputo*, at 972.

Administration ("FDA"). A smaller version of the sterilizer had been approved by the FDA, but the larger sterilizer that was marketed and distributed was not. The Court found that the CEO and the CCO effectively carried out a bait-and-switch scheme on the FDA and their hospital customers by obtaining clearance on the smaller sterilizer, but using the clearance to sell the larger, unapproved sterilizer to unsuspecting customers.¹¹⁰

The marketing strategy that was implemented depended entirely on inducing hospital customers to purchase the large sterilizer for "off-label" uses beyond the clearance that the FDA had previously approved for the smaller sterilization unit.¹¹¹ The CEO and CCO sold the larger sterilizer to unsuspecting hospital customers who were under the misimpression that they were buying a device that the FDA had previously approved. Representatives of numerous hospitals testified at trial that the defendant's misrepresentations concerning FDA approval of the larger sterilizer were material facts, which, if known, would have precluded the hospitals from purchasing the unit.¹¹² This was the underlying basis for the convictions on the mail and wire fraud charges and conspiracy charges.

The evidence at trial identified multiple marketing misrepresentations and even concealment of information to hospital customers and the FDA. There were numerous instances of patient health and safety problems associated with the use of the larger sterilizer. The CCO received numerous complaints of serious eye injuries caused by a blue-green residue that developed on certain instruments sterilized in the device.¹¹³ The CCO failed to conduct an investigation into this issue and even "whitewashed" a report about the eye injuries to other hospitals.¹¹⁴

The Court discussed at length the total failure of corporate compliance in this medical device company and specifically pointed out that the CEO selected the CCO for improper reasons, including that (1) the CCO could be dominated and manipulated by the CEO; (2) the CCO did not have any real training as a compliance officer; and (3) before beginning work in the health care industry, the only training the CCO had was in marketing.¹¹⁵

The Court further pointed out that the compliance officers are the corporate "fire personnel" and are an organization's "first responder" and must focus on both proactive and reactive efforts to be effective.¹¹⁶ The Court discussed that the proactive efforts necessary for effective compliance must emphasize the goals of crime detection and prevention and organizational ethical behavior. The Court highlighted the need for both general and specific deterrence in the area of corporate crime and the need to support regulatory efforts in the health care industry.¹¹⁷

The underlying message of this case was clear—compliance problems that are not proactively and reactively addressed may result in both individual and organizational liability.

¶22,160 Responsible Corporate Officer doctrine

¹¹⁰ *Caputo*, at 978.

¹¹¹ *Caputo*, at 974.

¹¹² *Caputo*, at 974.

¹¹³ *Caputo*, at 976.

¹¹⁴ *Caputo*, at 978.

¹¹⁵ *Caputo*, at 984.

¹¹⁶ *Caputo*, at 970.

¹¹⁷ *Caputo*, at 985.

The Responsible Corporate Officer (RCO) doctrine has its roots in the two Supreme Court cases *United States v. Dotterweich* and *United States v. Park*.¹¹⁸ Both cases provide that a corporate officer who stands in a “responsible relation” to misdemeanor misconduct may be held criminally liable even without having played a direct role in the misconduct. The courts reasoned that, because of the officers’ role within the organizations, they had the responsibility and authority either “to prevent in the first instance, or promptly to correct, the violation complained of, and . . . failed to do so.”¹¹⁹ The government must show that the corporate agent had the authority to prevent or correct the violation and failed to do so; it is insufficient to show that the person simply held a particular position within the organization.

Executives in the health care industry should also consider the collateral consequences of wrongdoing, such as the possibility of exclusion from participation in federal health care programs. Misdemeanor misconduct where an executive pleads guilty to RCO charges, even without an admission of wrongdoing, can lead to lengthy exclusions from federal programs. In 2007 in *United States v. Purdue Frederick Co.*,¹²⁰ three executives plead guilty to RCO charges but did not admit to wrongdoing. Several months later, the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) determined that the executives should be excluded from participation in federal health care programs pursuant to 42 U.S.C. § 1320a-(7)(b)(1) and (3).¹²¹ Although the executives challenged the exclusion, the D.C. Circuit Court of Appeals in 2012 upheld the decision that the HHS had the authority to exclude executives on this basis.¹²²

At the time, the HHS had not often exercised its permissive authority to exclude owners, officers, and managing employees of an entity that had been convicted of certain offenses. However, the OIG issued the Guidance for Implementing Permissive Exclusion Authority at the same time as the case was winding its way through the court system.¹²³ The issuance of the new guidance was seen as an indication of the commitment to holding individuals accountable for corporate wrongdoing.

¶22,165 Tips and Resources for Boards of Directors Monitoring Compliance Program

The following list of suggestions is helpful in establishing and maintaining an effective compliance and ethics program and the resources listed provide additional information to aid in the process.

- **Promote and enforce the compliance program** – The Board should foster an environment and organizational culture that promotes ethical conduct and compliance through appropriate incentives and disciplinary measures. The Board should be conscious of the “tone at the top,” and make sure the

¹¹⁸ *U.S. v. Dotterweich*, 320 U.S. 277 (1943) and *U.S. v. Park*, 421 U.S. 658 (1975).

¹¹⁹ *Park*, 421 U.S. at 674.

¹²⁰ *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569 (W.D. Va. 2007).

¹²¹ *Friedman v. Sebelius*, 686 F.3d 813, 816 (D.C. Cir. 2012).

¹²² *Friedman*, 686 F.3d at 821.

¹²³ Guidance for Implementing Permissive Exclusion Authority, Office of the Inspector General, Department of Health and Human Services available at http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf.

compliance program is an integral, living part of the organization, and not just a “paper program.”

- **Educate the Board and employees** – The Board should ensure that compliance and ethics program training is provided to Board members as well as employees.
- **Avoid conflicts of interest** – Compliance committees that include i.e. physicians may be faced with an issue that requires the physician to “self-report.” Committees should be composed in such a way that conflicts of interests are avoided or minimized. Conflicts of interest policies should be implemented and enforced and should require disclosure of board members’ and employees’ conflicts of interest.
- **Review and update the compliance program periodically** – The compliance program should be revised periodically in order to comply with recent laws, regulations, and court decisions. The Board should oversee this process and review the program at least yearly to take changes in laws and government enforcement initiatives and the company compliance history into consideration. The program should also be reviewed at least annually to assess whether the program is effective in preventing, detecting and correcting violations of the law and ethical problems.
- **Provide direct access to the Board** – Individuals with day-to-day responsibility for compliance activities, such as the Compliance Officer, should have direct access to the Board or to the Board’s compliance and/or audit committee.
- **Tailor the compliance program to the organization** – Different organizations may have different risk areas. To assess the risk areas specific to the organization, the Board can look to the organization’s prior history, which may indicate types of criminal conduct that the compliance program should be designed to prevent.
- **Utilize the resources provided by the government** – There are a number of helpful resources available on government websites such as those of the Office of the Inspector General¹²⁴ and the Department of Health and Human Resources;¹²⁵ some of these resources are cited throughout this chapter and provide information, advisory opinions, fraud alerts, bulletins, educational podcasts, charts, and guidelines that are useful to Boards.

¶22,170 Conclusion

The Board’s oversight activities help promote an environment of greater corporate responsibility

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Office of Inspector General, U.S. Department of Health and Human Services *available at* <http://oig.hhs.gov/>.

¹²⁵

U.S. Department of Health and Human Services *available at* <http://www.hhs.gov/>.

and at the same time help protect the organization and its directors from liability. The resources and perspectives shared in this chapter assist a health care organization's directors in meeting their duties concerning such oversight activities and in understanding the potential consequences of the failure to do so.

The Sarbanes-Oxley Act, along with the U.S. Federal Sentencing Guidelines, the Department of Justice prosecution guidelines, and the government enforcement of the Federal Anti-kickback Statute and Stark Laws put enormous strain on directors of health care firms to devise new internal controls. The real threat of whistleblower actions brought pursuant to the False Claims Act increase pressure on the Boards to ensure that their organizations have effective compliance and ethics programs in place. The lesson that should be learned from such legislation and recent enforcement efforts is that companies, large or small, both public and private, must take efforts to ferret out wrongful conduct. In today's climate, a corporation simply cannot run the risk of failing to implement an effective governance and compliance program. Boards will need to be more diligent about oversight of high-ranking company executives and ensure that they have compliance programs in effect that can detect corporate fraud. The benefits of these compliance programs are simply too great to ignore.