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Post-Caremark Implications for Health Care Organization Boards of Directors

Kimberly D. Baker & Arissa M. Peterson¹

I. INTRODUCTION

In recent years, the government has devoted substantial resources to investigate and prosecute health care fraud and abuse. The increase in governmental prosecutorial activity in the health care industry can be traced to two significant trends: (1) concern over waste, fraud, and abuse as one of the Department of Justice's top priorities, and (2) increased awareness of the economic benefits of *qui tam* (whistleblower) suits. In the last several years, the Office of the Inspector General (OIG) and the Department of Health and Human Services (HHS) have encouraged the health care community to prevent and reduce fraud and abuse in federal health care programs by implementing an effective compliance program. In 1996, a Delaware Chancery Court held in *In re Caremark Int'l Inc., Derivative Litigation* that the failure of a corporate director to make a good faith attempt at instituting an effective compliance program may, in some situations, constitute a breach of a director's fiduciary obligations.² The decision in *Caremark* changed the landscape of individual liability for boards of directors by making it easier for members of boards of directors to be held liable.³ Because of this decision and increased scrutiny by the government, health care organizations should implement and carry out effective corporate-compliance programs. The risk of personal liability for directors who fail to oversee compliance has risen as fiduciary doctrines have been reinforced.

This article will focus on the *Caremark* decision and a director's duty to oversee compliance with federal and state laws and regulations. First, the article will examine a board of director's liability under the theory of

fiduciary duties. Next, the article will discuss *Caremark* and the impact of its holding, as well as the additional layer of scrutiny imposed by the Sarbanes-Oxley Act that went into effect in 2002. Finally, this article will provide guidelines for implementing a corporate-compliance program that will satisfy *Caremark*. Directors face personal liability during this time of enhanced awareness of corporate responsibility. Accordingly, it is essential that a health care organization be familiar with *Caremark* and its implications for compliance, otherwise organizations may face harsh civil and criminal penalties.⁴ The *Caremark* decision and its progeny, as well as the recent passage of the Sarbanes-Oxley Act governing corporate conduct, make the implementation and adherence to a corporate-compliance program critical to the success of health care organizations.

II. DISCUSSION

A. *Fiduciary Duty Overview*

Health care organizations are subject to substantial state and federal regulatory requirements. The board of directors of a health care organization is, in broad terms, responsible for the conduct of the organization's business. Typically, in a larger corporation, the day-to-day management responsibilities are delegated to the executives and other senior staff. However, this delegation does not release the directors from responsibility to oversee the actions of senior management. All corporate boards are accountable to certain groups. In publicly owned corporations, the directors are accountable to the individual shareholders. A director may be found personally liable for failing to carry out his or her fiduciary duties. The usual mechanism for establishing personal liability is through a derivative suit, brought by shareholders or members on behalf of the corporation against the directors and officers.⁵

The role of a director is primarily one of monitoring—to review financial information and to oversee the organization's compliance with state and

federal laws and regulations. In order to carry out their duties, the directors must have a sufficient understanding of the nature of the business, as well as the management and information structures in place to determine if each structure is adequate to perform its respective role. Directors of both for-profit and nonprofit health care organizations are subject to the duty of care in the oversight of the business, including business performance and compliance with applicable laws and regulations. According to the OIG, the duty of care requires that a director make decisions (1) in “good faith,” (2) with that level of care that an ordinarily prudent person would exercise in like circumstances, and (3) in a manner that he or she reasonably believes is in the best interest of the corporation.⁶ Board members are not generally held liable for an organizational decision if it is consistent with the duty of care.⁷

Directors may face potential liability for a breach of the duty of care for failing to exercise appropriate attention in two distinct contexts. First, liability may follow from a board decision that results in a loss because that board decision was ill advised or negligent.⁸ Second, liability to the corporation for a loss may arise from an unconsidered failure of the board to act in circumstances where due attention would have prevented the loss (i.e., the duty to monitor).⁹ Liability usually stems from the business judgment rule, which states that the decision must be the product of a process that was either deliberately considered in good faith or was otherwise rational.¹⁰ Directors may be exempt from liability under the business judgment rule if the decisions were made in good faith, the director was disinterested and reasonably informed under the circumstances, and the director rationally believed the decision was in the best interest of the corporation.¹¹

This article will focus on a board of director’s duty of care in monitoring corporate operations and ensuring compliance with state and federal laws and regulations. While a board’s decision will normally be subject to the business judgment rule, the changing landscape of corporate responsibility

and compliance has altered the meaning of “duty of care” to allow for the personal liability of directors who fail to monitor corporate activities to minimize and respond to legal liability.

B. Caremark and Its Progeny: Expanded Liability for Health Care Boards of Directors

In 1996, the Delaware Chancery Court expanded personal liability for members of a board of directors by recognizing that a director’s failure to implement and carry out an effective corporate-compliance program may, in some circumstances, render a director liable.¹² The *Caremark* decision arose from a proposed settlement of a consolidated derivative action on behalf of Caremark International, Inc. (Caremark) involving claims against Caremark’s board of directors for violations of federal and state laws.

Caremark is a Delaware corporation that was formed in 1992 with its headquarters in Illinois.¹³ The corporation was a spin-off of Baxter International, Inc., and became a publicly held company listed on the New York Stock Exchange.¹⁴ For the relevant time period relating to the lawsuit, Caremark provided both patient care and managed care services as its main health care business.¹⁵ During the relevant time period, Caremark had 7,000 employees and ninety branch operations.¹⁶ The majority of Caremark’s revenues were derived from the patient care services, which involved alternative site health care services, including infusion therapy, growth hormone therapy, HIV/AIDS-related treatments and hemophilia therapy.¹⁷ Caremark’s managed care services included prescription drug programs and multi-specialty group practices.¹⁸ Like many health care organizations, a substantial part of Caremark’s revenues were derived from third-party payments, insurers, and Medicare and Medicaid reimbursement programs.¹⁹

The *Caremark* lawsuit involved claims that the members of the Caremark Board of Directors (the Board) breached their duty of care to the corporation. The plaintiffs alleged that the board was negligent when it

failed to adequately address violations of federal and state laws and regulations that were allegedly committed by Caremark employees. The allegations included violations of the Anti-Referral Payments Law (ARPL) (unlawful “kickbacks”); unlawful billing practices, including excessive and medically unnecessary treatments for patients, potentially improper waivers of patient co-payment obligations; and, inadequate records maintained at Caremark pharmacies.²⁰ As a result of the alleged violations, Caremark was subject to an extensive four-year investigation by the United States Department of Health and Human Services and the Department of Justice, which resulted in an indictment for multiple felonies.²¹ Caremark entered into a number of agreements, including a plea agreement in which it pleaded guilty to a single felony of mail fraud and agreed to pay civil and criminal fines.²² Later, Caremark agreed to pay reimbursements to various public and private parties totaling approximately \$250 million.²³

In response to the governmental investigation, the Board took several steps consistent with an effort to assure compliance with company policies concerning the ARPL.²⁴ Throughout the period of governmental investigations, Caremark had an internal audit plan designed to assure compliance with business and ethics policies.²⁵ In addition, Caremark took additional steps aimed at increasing management supervision, including adopting new policies for local branch managers to certify compliance with the ethics program.²⁶

The *Caremark* court explained that to establish director liability for breaching the duty to exercise appropriate attention to potentially illegal corporate activities was “possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment.”²⁷ Without a conflict of interest or facts demonstrating suspect motivation, it is difficult to charge directors with responsibility for corporate losses for an alleged breach of care.²⁸ Director liability under this theory may arise from (1) a board decision that resulted in a loss because the decision was ill-advised,

or (2) “an unconsidered failure of the board to act in circumstances in which due attention would, arguably, have prevented the loss.”²⁹

Board member inattention can be a basis for director liability, even though most corporate decisions are not subject to director attention.³⁰ “[A] director’s obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the [b]oard 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.”³¹ Ordinary business decisions made by officers and employees deeper in the corporation can significantly injure the corporation and make it subject to criminal sanctions.³²

The level of detail needed for an information system is a matter of business judgment. The *Caremark* decision set a high standard that, in some circumstances, could result in liability for seemingly minor actions. Under the *Caremark* standard, directors may be held personally liable for losses caused by failing to maintain reasonable information and reporting systems, or failing to monitor and improve suspect practices that have been brought to the board’s attention.

[I]t 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 as a matter of ordinary operations, so that it may satisfy its responsibility.³³

While unconsidered inaction, in theory, can render a director liable, no *Caremark* directors were found personally liable. *Caremark* enhanced a director’s risk of liability by opening the door to increased scrutiny and reinforcement of the duty to monitor.

Subsequent cases opened the door to personal liability for directors even further. In 2001, the Sixth Circuit expanded *Caremark* by eliminating the need for directors to act intentionally to harm the corporation.³⁴ *McCall v.*

Scott involved a consolidated stockholder derivative action brought against current and former directors of Columbia/HCA Healthcare Corporation, the owner and operator of nearly half of all the for-profit hospitals in the United States.³⁵ The complaint alleged that the Columbia board knew of senior management efforts to devise schemes to improperly increase revenue and profits and perpetuate a management philosophy that provided strong incentives for employees to commit fraud.³⁶ The *McCall* court concluded that the decision in *Caremark* does not require a director to have intentionally acted to harm the corporation.³⁷ The court reviewed the factual allegations only for the purpose of examining the sufficiency of the pleadings with respect to demand futility.³⁸ The complaint cited significant factors indicating that the board must have been aware of the fraud, including (1) audit discrepancies between cost reports submitted to the government and secret reserve reports, (2) improper acquisition practices in which at least one of the directors personally was involved, (3) a *qui tam* action alleging a widespread strategy to engage in violations of federal law, and (4) an extensive criminal investigation that included raids on thirty-five Columbia facilities in six different states.³⁹ These particularized facts were sufficient to present a substantial likelihood of liability on the part of at least five of Columbia's directors.⁴⁰

A significant factor in the court's conclusion was the prior experience of a number of the defendant directors.⁴¹ Given the defendants' prior experience in business and/or as board members, the court in *McCall* was persuaded that the failure to react to the criminal investigation and other "red flags" created a strong inference of intentional or reckless disregard.⁴² Thus,

when director liability is predicated upon ignorance of liability-creating activities, "only a sustained or systematic failure of the board to exercise oversight—such as an utter failure to attempt to assure a reasonable information reporting system exists—will establish the lack of good faith that is a necessary condition to liability."⁴³

In 2002, the Seventh Circuit followed suit with *McCall* and again expanded personal liability for directors.⁴⁴ *In Re Abbott Laboratories Derivative Shareholders Litigation* involved a shareholder derivative suit against Abbott's board of directors. The plaintiffs alleged that the directors breached their fiduciary duties created in a consent decree, resulting in harm to the corporation. The harm included paying a \$100 million civil fine to the Food and Drug Administration (FDA), withdrawing 125 types of medical diagnostic test kits from the U.S. market, destroying certain inventory, and making a number of corrective changes in its manufacturing procedures after six years of federal violations.⁴⁵ Plaintiffs maintained that the directors were aware of the six-year history of noncompliance problems with the FDA and that they had a duty to take necessary action to correct these problems.⁴⁶ During a six-year period, the FDA conducted thirteen separate inspections of Abbott's facilities.⁴⁷ The FDA sent four formal certified warning letters to Abbott, cautioning that failure to correct certain deviations could result in severe regulatory action.⁴⁸ Because information concerning the violations had been made known to the general public early in the six-year period, the plaintiffs maintained that the directors had a duty under rules promulgated by the Securities and Exchange Commission (SEC) to comply with "comprehensive government regulations."⁴⁹

The court found that the directors' actions fell outside the protection of the business judgment rule by examining the magnitude and duration of the alleged wrongful conduct.⁵⁰ The court concluded that unlike the board members in *Caremark*, the board members in *Abbott* were aware of the problems.⁵¹ The court noted that "[t]he facts in *Abbott* do not support the conclusion that the directors were 'blamelessly unaware of the conduct leading to the corporate liability.'"⁵² Accordingly, the court held that the plaintiffs sufficiently pleaded allegations of a breach of the duty of good faith that, if true, led one to reasonably conclude that the directors' actions fell outside the protection of the business judgment rule.⁵³

The *Caremark* holding did not make any monumental changes to corporate law. Yet, the *Caremark* court specifically addressed the issue of corporate directors' individual liability for failing to adequately monitor a corporation's activities. While the *Caremark* directors were not found to have breached the duty of care by failing to monitor the organization's activities, the *Caremark* decision has set a demanding standard that can be imposed on boards of directors of health care organizations. The *McCall* and *Abbott* decisions demonstrate that something less than intentional conduct may result in personal liability. First and foremost, "the magnitude and duration of the alleged wrongdoing is relevant in determining whether the failure of the directors to act constitutes a lack of good faith."⁵⁴ Specific factors gleaned from *Caremark*, *McCall*, and *Abbott* may include experience on the board and prior board experience, knowledge of ongoing government or SEC investigations, and the public's general knowledge of wrongdoing or non-compliance, all of which may be indicative of a board's "unconsidered inaction" under the *Caremark* standard.⁵⁵

C. The Sarbanes-Oxley Act

In addition to *Caremark* and decisions following, an additional layer of scrutiny has been added in light of the Sarbanes-Oxley Act (SOA), which was signed into law on July 30, 2002.⁵⁶ The SOA was intended to promote disclosure of corporate wrongdoing. Publicly held companies and those companies required to file reports under the Securities and Exchange Act section 15(d) must be attentive to the prohibitions under section 806 of the SOA and the civil remedial measures afforded to whistleblowers who report a reasonable belief of misconduct.⁵⁷ The act provides for expansive civil sanctions and establishes timelines and burdens of proof that are markedly different from whistleblower claims in most other employment settings.

Given its breadth of making individuals potentially liable and its harsh fines and/or imprisonment for criminal misconduct, the SOA surpasses all other similar acts. Section 806 of the SOA, the civil provisions, affords

federal protection for whistleblowers who work for a company with a class of securities registered under section 12 of the Security Exchange Act of 1934 (SEA) (15 U.S.C. § 781) or those who work for a company that is required to file reports under section 15(d) of the SEA (15 U.S.C. § 780(d)).⁵⁸ Section 806 amends 18 U.S.C. by adding section 1514A, which prohibits retaliatory conduct toward anyone who participates in the lawful reporting of violations concerning financially fraudulent company activities.⁵⁹ In order to receive protection under this statute, the whistleblower must reasonably believe that the activities constitute a violation of (1) federal securities law, (2) SEC rules or regulations, or (3) other federal law provisions that relate to shareholder fraud.⁶⁰

The three key elements necessary to receive protection under the act are reporting, individual liability, and criminal liability. To warrant protection under the SOA, the alleged violations must be reported to a law enforcement officer or to someone with supervisory authority or authority to investigate, discover, or correct the violations.⁶¹ Section 806 provides protection for employees who report a reasonable belief of the occurrence of a civil violation of sections 1341, 1343, 1344, and 1348 of Title 18 of the U.S. Code.⁶² Section 1107 provides criminal penalties for any individual who knowingly, and with the intent to retaliate, takes harmful action against an employee who provides law enforcement with truthful information about a commission or potential commission of any federal offense.⁶³ The criminal penalties of section 1107 are not exclusive to those sections of Title 18 of the U.S. Code to which section 806 pertains. Under section 1107, criminal liability attaches to both private and public companies and nonprofit organizations.⁶⁴

Health care organizations need to be aware of the SOA and the penalty scheme imposed for violations. This act provides for whistleblower and retaliation protection as well as individual liability for violations. In implementing corporate-compliance programs, organizations need to

understand the SOA and its applicability to the organization, as well as create compliance programs and policies tailored to meet its requirements.

D. Suggestions for Implementing Effective Compliance Programs

In evaluating the fiduciary duties of the board of directors, board members need to be especially diligent about acting in good faith to assure that adequate corporate information and reporting systems exist. Implementing an effective compliance program is critical for insulating health care organizations from harsh criminal and civil sanctions and exclusion from federal programs. An effective compliance program extends through many layers of the organization. *Caremark* is particularly instructive in reinforcing the need for a tailored compliance program specific to the health care organization. While *Caremark* and other cases have established the directors' duty to oversee compliance programs, none provide a specific methodology to structure such a program.

On April 2, 2003, the OIG in collaboration with the American Health Lawyers Association (AHLA) published *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors* (hereinafter referred to as the "OIG Guidance").⁶⁵ While this guidance is a good starting point for board members, it is not a "one size fits all" exacting standard.⁶⁶ The purpose of the guidance is to help directors of both profit and nonprofit health care organizations perform organizational oversight and ask probing questions about compliance.⁶⁷ In the wake of several accounting scandals such as Enron and the passage of the Sarbanes-Oxley Act, the guidance serves as a reminder of the obligations of corporate directors and of the increased attention by government regulators on health care organizations' corporate compliance.

As a preliminary matter, each health care organization is unique and should carefully examine its legal compliance requirements. A compliance program should address the myriad of federal and state statutes and regulations that apply to the organization, including, but not limited to (1)

health care fraud and abuse laws (for example, anti-kickback, physician self-referral and false claims laws), (2) conflicts of interest and business ethics laws, (3) privacy laws and regulations (including Health Insurance Portability and Accountability Act (HIPAA) and other state privacy laws), and (4) the Sarbanes-Oxley Act.⁶⁸ For instance, compliance with SOA and other federal statutes requires an understanding of complex civil and criminal penalty schemes.

According to the OIG Guidance, there are seven essential elements to an effective compliance program for any health care organization and these seven elements are modeled on the seven steps of the Federal Sentencing Guidelines.⁶⁹ At a minimum, all compliance programs aimed at reducing health care fraud and abuse should include the following seven elements:

1. The development and distribution of written standards of conduct, as well as written policies and procedures that promote the hospital's commitment to compliance (e.g., by including adherence to compliance as an element in evaluating managers and employees) that address specific areas of potential fraud, such as claims development and submission processes, code naming, and financial relationships with physicians and other health care professionals;
2. The designation of a chief compliance officer and other appropriate bodies, for example, a corporate-compliance committee charged with the responsibility of operating and monitoring the compliance program, who report directly to the CEO and the governing body;
3. The development and implementation of regular, effective education and training programs for all affected employees;
4. The maintenance of a process, such as a hotline, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;

5. The development of a system to respond to the allegations of improper/illegal activities and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations or federal health care program requirements;
6. The use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas; and
7. The investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.⁷⁰

The OIG Guidance expanded the seven elements into a more detailed overview of corporate responsibility and guidance on structuring a compliance program. In addition to an overview of a board's duty to implement and oversee compliance, the OIG Guidance provides directors with a list of eighteen questions that they can ask their organization's management team to better educate themselves regarding their organization's compliance efforts and help protect themselves from unnecessary exposure to liability.⁷¹

1. Structural Implementation

A board of directors should determine the key employees responsible for the implementation of the compliance program because the success of the program relies upon assigning high-level personnel to oversee the implementation and operations.⁷² When management is decentralized, as was the case in *Caremark*, it is important to assign key employees across levels of management to oversee compliance. For example, adopting policies and procedures for local branch managers to certify compliance is a good way to avoid problems associated with decentralized management. A board may want to establish a committee to monitor compliance program operations and regularly report to the board.⁷³ An organization must have a

compliance reporting system whereby the board receives reports on a regular basis.⁷⁴

A solid understanding of the rationale and objectives of the compliance program, as well as its goals and inherent limitations is essential if the board is to evaluate the reasonableness of its design and effectiveness of its operations.⁷⁵ The board needs to be realistic about its goals and limitations.⁷⁶ Compliance programs will not prevent all wrongful conduct; however, the board can be satisfied that mechanisms are in place to ensure the timely reporting of suspected violations and to evaluate and implement remedial measures.⁷⁷ For instance, the *Caremark* board took several steps to assure compliance with company policies concerning alleged violations of federal and state statutes.⁷⁸

The compliance program should address the significant risks of the organization.⁷⁹ A comprehensive and ongoing process of compliance risk assessment is important to the board's awareness of new challenges to the organization. Compliance risk assessment is also important for the board's evaluation of management priorities and program resource allocation.⁸⁰ From the beginning, the board must address the resources necessary to implement and to carry out the compliance program.⁸¹ The investment can be significant and requires a long-term commitment of resources for continuous oversight and improvement of the program.⁸² The investment may include annual budgetary commitments and human resources dedicated to compliance.⁸³

2. Operational Compliance

A code of conduct is fundamental to a successful compliance program because it articulates the organization's commitment to ethical behavior.⁸⁴ The code should detail the fundamental principles, values, and framework for action within the organization.⁸⁵ The code helps define the organization's culture and its commitment to unearthing potential illegal conduct within the organization.⁸⁶ Codes are beneficial only if they are

meaningfully communicated throughout the organization and enforced.⁸⁷ The organization should have zero tolerance for non-compliance with the code of conduct. In addition, the organization should implement policies and procedures to address compliance risk areas and establish internal controls to counter vulnerabilities.⁸⁸ Because health care laws and regulations often change, an organization's policies and procedures need periodic review and revision if appropriate.⁸⁹ Regular communication with counsel can assist the board in its oversight responsibilities in the changing regulatory environment.⁹⁰

The organization must assign a compliance officer who has the autonomy and sufficient resources to perform assessments and respond appropriately to misconduct.⁹¹ The compliance officer should be sufficiently neutral from the board and upper management to make independent decisions concerning the oversight of the compliance program. The compliance officer must have the authority to review all documents and other information that is relevant to compliance activities.⁹² Boards should maintain open lines of communication and reporting within management and between the board, compliance officers, and consultants in order to ensure timely and candid reports for those responsible for the compliance program.⁹³ For example, in *McCall*, the complaint alleged that the board was knowledgeable of senior management's efforts to devise schemes to improperly increase revenues and profits and to perpetuate a management philosophy that provided strong incentives for employees to commit fraud.⁹⁴ A neutral and autonomous compliance officer could have responded to the misconduct and addressed the situation in a candid manner.

The compliance officer must have adequate financial resources and personnel to implement all aspects of the compliance program. Compliance-related responsibilities should be assigned across all appropriate levels of the organization, and employees need to be held accountable for meeting compliance-related objectives during performance reviews.⁹⁵ This will ensure that there is accountability for proper

implementation or oversight of the compliance program. Where there is poor distribution of responsibility and authority for accountability beyond the compliance officer, implementation may lag.⁹⁶ All employees need to be held accountable for compliance, and this can be enhanced by creating incentives—both positive and negative—for complying with the organization's policies and procedures.

3. Preventing and Responding to Violations

One of the most important elements of an effective compliance program is organization-wide training on compliance standards and procedures, including remedial training as needed.⁹⁷ Specifically, there should be training on identified risk areas particular to the organization, as well as an educational program to assess those risks.⁹⁸

The oversight of the compliance program occurs in the context of significant regulatory and industry developments that impact the organization not only as a health care organization but also more broadly as a corporate entity.⁹⁹ Therefore, the board must be kept apprised of significant regulatory and industry developments and must structure the compliance program to address those changing risks.¹⁰⁰

The compliance program should be monitored and audited periodically to evaluate its effectiveness.¹⁰¹ Monitoring may provide early identification of program or operational weaknesses and could substantially reduce exposure to government or whistleblower claims.¹⁰² One effective method for monitoring is the performance of regular, periodic compliance audits by internal or external auditors.¹⁰³ Under the SOA, for instance, employers are required to establish audit committees and to adopt procedures for the confidential and anonymous reporting of questionable accounting or auditing practices.¹⁰⁴ In addition to evaluating the organization's conformity with specific regulatory rules or the legality of business arrangements, an effective compliance program periodically reviews whether program elements have been satisfied.

The organization must respond appropriately to deficiencies or suspected non-compliance.¹⁰⁵ Failure to abide by the compliance program, violation of laws, and other types of misconduct can threaten the organization's status as a reliable and trustworthy provider of health care.¹⁰⁶ In addition, failure to respond to a known deficiency or suspected violation may be considered an aggravating factor in evaluating the organization's potential liability for the underlying problem.¹⁰⁷ In *McCall*, several "red flags" such as audit discrepancies, a whistleblower action, and an extensive criminal investigation indicated that the board was, or should have been, aware of the fraud.¹⁰⁸ Similarly in *Abbott*, the board of directors knew about a six-year history of non-compliance and took no corrective action.¹⁰⁹

The board's duty of care requires that it explore whether procedures are in place to respond to allegations of misconduct and whether management promptly initiated corrective measures.¹¹⁰ Many organizations will take disciplinary action when employee conduct violates the organization's code of conduct and policies.¹¹¹ Any disciplinary measures should be enforced uniformly.¹¹² The organization also must have policies in place that address the appropriate protection of whistleblowers and those accused of misconduct.¹¹³ In order for a compliance program to work, employees must be able to ask questions and to report problems.¹¹⁴ In fulfilling its duty of care, the board should have a process in place to encourage such constructive communication.¹¹⁵

Legal risk may exist not only based on conduct under scrutiny, but also on actions taken by the organization in response to an investigation. In addition to potential obstruction of a government investigation, the organization may face charges by employees for unlawful retaliation or violation of employee rights. For such responses, the board should confirm that processes and policies have been developed in consultation with legal counsel and are well communicated and understood across all levels of the organization.

The board should fully understand management's process for evaluating and responding to identified violations of the organization's policies, as well as violations of federal or state laws.¹¹⁶ In addition, the board should receive sufficient information to evaluate the appropriateness of the organization's response.¹¹⁷ Boards should have policies governing when to report probable violations to government authorities.¹¹⁸ Federal law encourages organizations to self disclose wrongdoing, but boards should work with legal counsel to develop a policy on when and whether to make those disclosures.¹¹⁹

4. Compliance and Reporting Tailored to the Sarbanes-Oxley Act

To avoid prosecution under the SOA, an employer should adopt a protocol by which employees may report workplace violations of accounting and securities laws. As a preliminary matter, employers should train all employees, particularly managers and supervisors, about the SOA's provisions. Employers should communicate to employees that the company has a "zero tolerance" policy regarding violations of securities and other laws. The zero tolerance policy must be embraced not only by the upper management, but also by supervisory and non-supervisory employees. Employers should also consider adopting and implementing policies that encourage reporting and that discourage retaliation in response to employee reporting. To be effective, such policies should include the following information:

- What constitutes material violations, adapting language from 18 U.S.C. sections 1341, 1343, 1344, and 1348;
- How to report and to whom to report (with several alternatives);
- How the report will be investigated; and,
- How violations will be addressed.

It is imperative that an employer's reporting policy contain provisions for confidential or anonymous reporting. The policy should state the employer's intention to keep reports of violations confidential (subject to such disclosure as may be required to investigate the complaint), remedy any violative behavior, and/or to respond to governmental agency inquiries.

Employers should take efforts to distribute a copy of the policy to all employees on a periodic basis. The policy should also be posted in prominent locations around the office and should be given to the independent auditing committee. The prohibition against retaliation should be included in bolder print. After distributing the policy, the employer should have all of its employees sign a receipt or acknowledgment form. This form should be maintained in their personnel file, along with employment manuals and non-competition agreements.

It is also important that numerous persons, not only employee supervisors, receive reports of violations. Employers are advised to treat complaints seriously, investigate the allegations thoroughly with trained investigators, and then take appropriate actions designed to end any violations. Those responsible for investigating reported violations should commence investigation promptly and aggressively.

Employers should establish a procedure for documenting investigations. Information that should be documented includes the identities of interviewed witnesses and witnesses who were not interviewed or who refused to be interviewed. The investigator should write a summary of each witness's testimony and should keep a log of reviewed documents. In addition, the investigator should prepare a succinct written conclusion of the investigation and record any remedial steps taken. Finally, employers should hold supervisors and employees accountable for any inappropriate behavior that actually or potentially constitutes harassment or retaliation.

5. Additional Considerations Regarding Corporate Compliance

Enhanced corporate governance and compliance do more than mitigate risk and reduce fraud and abuse. Compliance programs foster a sense of trust in investors and in the public. An effective compliance program outlines policies and procedures for recognizing and reducing risk of health care fraud and abuse, which in turn, increases trust and confidence on all levels of the organization among employees, staff, and directors. A compliance program also reduces the likelihood of a *qui tam* lawsuit because employees are more likely to report violations within the organization when they know policies exist to protect them against retaliation.

The OIG Guidance is a good starting place for developing organizational compliance, but it does not go far enough in pointing out the real risks of non-compliance examined in *Caremark* and its progeny. The OIG Guidance does not detail the real and personal financial risk that directors face for compliance violations. For example, the OIG Guidance suggests that directors face liability only in “extraordinary circumstances”; however, case law, such as that found in *McCall* and *Abbott*, suggests that something less than extreme circumstances may expose directors to personal liability. While the government may not pursue directors except under extraordinary circumstances, shareholder derivative suits and whistleblower suits expose directors to increased scrutiny in monitoring the affairs of the corporation.

Compliance violations have numerous consequences. The government has devoted substantial resources to ferreting out health care fraud and abuse. Penalties for failure to oversee a proper compliance program include, but are not limited to, treble damages, civil monetary penalties of \$11,000 per false claim, exclusion from federal and state health care programs, and personal liability for directors. Private whistleblowers play an active role in identifying fraudulent practices within a health care organization and are also eligible for a potentially large pay-off. An

organization may receive significantly reduced sanctions upon conviction of criminal wrongdoing if it has adopted an effective compliance program.

Consequences of non-compliance extend beyond the individual health care organization and board of directors. Taxpayers bear the burden of funding the increased budget needed for government prosecutorial action. Penalizing an organization by excluding them from federal and state health care programs such as Medicare and Medicaid hurts both the organization and Medicare and Medicaid recipients. Exclusion from programs like Medicare and Medicaid is a harsh penalty for health care organizations that derive a significant amount of reimbursement from these programs. Exclusion also affects Medicare and Medicaid patients by limiting access to health care at these organizations. Non-compliance also encourages whistleblower actions because they come with a potentially large payoff for the individual who reports misconduct to the government. Encouraging health care organizations to identify and prevent fraud and abuse benefits the organization, itself, as well as members of society.

III. CONCLUSION

The health care industry operates in a heavily regulated environment with multiple high-risk areas. Health care organizations and boards of directors face unique challenges, especially in light of the government's increased oversight and focus on health care fraud, waste, and abuse. *Caremark* and its progeny, as well as the recent passage of the Sarbanes-Oxley Act, increase the level of detail directors must pay to corporate compliance and oversight in carrying out their duties. Failure to comply with federal and state statutes and regulations can be devastating for a health care organization facing the resulting penalties. In addition to criminal and civil monetary penalties, health care providers that have defrauded federal health care programs may be excluded from participation in federal and state-sponsored health care programs. Exclusion from health care programs is damaging to organizations because of vital role such programs play in

funding health care. The crippling effects of financial penalties and exclusion from federal programs have been the death knell for health care organizations. The focus on “corporate responsibility” via federal and state statutes and judicial law places additional pressure on health care organizations to implement and carry out effective corporate-compliance programs. The “good old days” of sitting around the boardroom smoking cigars and talking politics are gone. Instead of being filled with cigar smoke, today’s boardroom is filled with the ever present need for board diligence regarding the organization’s operations—with thoughtful consideration about significant decisions affecting the organization—and with enhanced candor encouraging all board members to engage in open discussion and to bring prospective issues to light in a timely manner.

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

³ *See id.*

⁴ *See* Press Release, Dept. of Justice, Justice Dept. Civil Fraud Recoveries Total \$2.1 Billion for FY 2003 False Claims Act Recoveries Exceed \$12 Billion Since 1986 (Nov. 10, 2003), http://www.usdoj.gov/opa/pr/2003/November/03_civ_613.htm. The following sample of the DOJ’s largest recoveries during 2003 for fraud and abuse in health care is an example of some of the penalties that health care organizations have recently faced:

1. \$641 million from HCA Inc. (formerly known as Columbia/HCA and HCA - The Healthcare Company) for cost report fraud, the payment of kickbacks to physicians, and overbilling Medicare for HCA’s wound care centers. This settlement concluded litigation in numerous *qui tam* lawsuits as well as separate investigations initiated by the government. Along with an earlier civil settlement and criminal guilty plea reached in 2000, as well as a related administrative settlement with HHS, HCA has paid the United States \$1.7 billion with whistleblowers receiving a combined share of \$154 million—by far setting record recoveries both by the United States and whistleblowers.
2. \$382 million from Abbott Laboratories and its Ross Products Division. [Abbott’s conduct resulted in] the first combined civil settlement and criminal conviction arising from “Operation Headwaters,” an undercover investigation by the Federal Bureau of Investigation, the U.S. Postal Inspection Service, and the Office of the Inspector General for HHS, in which federal agents created a fictitious medical supplier known as Southern Medical Distributors. During its

operation, various manufacturers, including Ross, offered kickbacks to undercover agents to purchase the manufacturers' products and then advised them how to fraudulently bill the government for those items. In addition to federal Medicare and Medicaid recoveries, the states recovered \$18 million in state Medicaid funds in connection with the federal government's claims and an additional \$14.5 million on claims the states pursued alone. Abbott subsidiary C G Nutritionals also paid \$200 million in criminal fines.

3. \$280 million from AstraZeneca Pharmaceuticals, LP, to resolve allegations that AstraZeneca conspired with health care providers to charge Medicare, Medicaid, and other federally funded insurance programs for free samples of its prostate cancer drug, Zoladex, and for otherwise inflating the price of the drug in violation of the Prescription Drug Marketing Act. The whistleblower's share of this settlement was \$47.7 million.
4. \$143 million from Bayer Corporation to resolve a whistleblower's allegations that Bayer defrauded the Medicaid and Public Health Service programs by re-labeling products sold to a health maintenance organization at deeply discounted rates and then concealing the discounts to avoid paying rebates in violation of the Medicaid Rebate program. In addition, Bayer paid \$108 million to reimburse state Medicaid programs for the same conduct.
5. \$47 million from SmithKline Beecham Corporation, doing business as GlaxoSmithKline, to settle claims similar to those against Bayer. GlaxoSmithKline paid an additional \$40 million to reimburse state Medicaid programs and Public Health Service entities.
6. \$51 million from Tenet Healthcare Corporation and Tenet Health Systems Hospitals, Inc. to settle government allegations that Tenet's Redding, California facility performed unnecessary cardiac procedures that were then billed to Medicare, Medicaid and TRICARE. In addition, Tenet paid nearly \$3 million to reimburse California's Medicaid funds.
7. \$49 million from Endovascular Technologies, Inc., a subsidiary of Guidant Corp., to settle the government's allegations that Endovascular Technologies failed to report to the Food and Drug Administration thousands of adverse incidents involving its "Ancure" cardiac device. The failure resulted in the submission of tens of millions of dollars of false claims for Medicare, Medicaid and VA benefits for procedures involving the device. In several instances, the device was linked to patient injuries and deaths. Endovascular Technologies also paid \$43.4 million in criminal fines and forfeitures.

Id.

⁵ See Revised Model Business Corp. Act §§ 7.40–7.47 (2002); Mary E. O'Byrne, *Directors' Duty of Care to Monitor Information Systems in HMOs: Some Lessons from the Oxford Health Plan*, 14 J.L. & HEALTH 45, 48–50 (1999/2000) (see also accompanying footnotes).

⁶ The Office of Inspector General of the U.S. Department of Health and Human Services and the American Health Lawyers Association, *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Board of Directors*, at 2 (Apr. 2, 2003),

<http://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRscceGuide.pdf> (last visited Nov. 8, 2004) [hereinafter *Corporate Responsibility*]. The duty of care is governed by state law and is usually the same for nonprofit and for-profit entities. *Id.*

⁷ *See id.* at 3.

⁸ *In re Caremark*, 698 A.2d at 967.

⁹ *Id.*

¹⁰ *Id.*

¹¹ *See id.* at 967–68.

¹² *See id.* at 969.

¹³ *Id.* at 961.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.* at 962.

¹⁷ *Id.* at 961.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *See id.* at 964–65. The Anti-Referral Payments Law (ARPL) prohibits health care providers from paying any form of remuneration to induce the referral of Medicare or Medicaid patients. *Id.* at 961–62. This form of remuneration where a payment is made in exchange for or to induce patient referrals is referred to as a “kickback.” Caremark had a practice of entering into contracts for services with physicians, some of whom prescribed or recommended services or products that Caremark provided to Medicare and Medicaid recipients and other patients. *Id.* at 962. While such contracts are not prohibited by ARPL, they raise a possibility of unlawful kickbacks. *Id.*

²¹ *Id.* at 960.

²² *Id.*

²³ *Id.* at 960–61.

²⁴ *Id.* at 963.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.* at 967.

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.* at 968.

³¹ *Id.* at 970.

³² *See id.* at 969.

³³ *Id.* at 970.

³⁴ *McCall v. Scott*, 239 F.3d 808 (6th Cir. 2001).

³⁵ *Id.* at 813–14.

³⁶ *Id.* at 814.

³⁷ *Id.* at 818.

³⁸ *See id.* at 816.

³⁹ *See id.* at 819–24.

⁴⁰ *Id.* at 819.

⁴¹ *Id.*

⁴² See *id.*

⁴³ *Id.* at 817 (quoting *In re Caremark*, 698 A.2d at 971).

⁴⁴ *In re Abbot Lab., Derivative S'holder Litig.*, 293 F.3d 378 (7th Cir. 2002), *vacated by* 299 F.3d 898 (7th Cir. 2002), *and superseded by* 325 F.3d 795 (7th Cir. 2003).

⁴⁵ *In re Abbot Lab.*, 325 F.3d at 798.

⁴⁶ *Id.* at 802.

⁴⁷ *Id.* at 799.

⁴⁸ *Id.*

⁴⁹ *Id.* at 802.

⁵⁰ *Id.* at 809.

⁵¹ *Id.* at 806. The Abbott Chairman of the Board received the warning letters, a voluntary compliance plan was initiated in 1995, and Abbot was closed down in 1998 for continued violations. Directors who were members of the Audit Committee were aware of the violations, and as early as 1995 the problems were public knowledge. *Id.* The court concluded that all these facts imply knowledge of long-term violations that have not been corrected. *Id.* “Where there is a corporate governance structure in place, we must then assume the corporate governance procedures were followed and that the board knew of the problems and decided no action was required.” *Id.*

⁵² *Id.* (citing *In re Caremark*, 698 A.2d at 969 (quoting *Graham v. Allis-Chalmers Mfg. Co.*, 188 A.2d 125 (Del. 1963))).

⁵³ *Id.* at 809.

⁵⁴ *McCall*, 239 F.3d at 823.

⁵⁵ *Id.* at 817.

⁵⁶ Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, 116 Stat. 745 (codified in scattered sections of 15, 18, 28, and 29 U.S.C.A.).

⁵⁷ Sarbanes-Oxley Act of 2002, Title VII, § 806, *available at* <http://news.findlaw.com/hdocs/docs/gwbush/sarbanesoxley072302.pdf> (last visited Nov. 8, 2004):
 PROTECTION FOR EMPLOYEES OF PUBLICLY TRADED COMPANIES WHO PROVIDE EVIDENCE OF FRAUD.
 (a) In General.—Chapter 73 of title 18, United States Code, is amended by inserting after Section 1514 the following:
 Sec. 1514A. Civil action to protect against retaliation in fraud cases
 (a) Whistleblower Protection For Employees Of Publicly Traded Companies.
 —No company with a class of securities registered under Section 12 of the Securities Exchange Act of 1934 (15 U.S.C. 781), or that is required to file reports under Section 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 780(d)), or any officer, employee, contractor, subcontractor, or agent of such company, may discharge, demote, suspend, threaten, harass, or in any other manner discriminate against an employee in the terms and conditions of employment because of any lawful act done by the employee—
 (1) to provide information, cause information to be provided, or otherwise assist in an investigation regarding any conduct which the employee reasonably believes constitutes a violation of Sections 1341, 1343, 1344, or 1348, any rule or regulation of the Securities

and Exchange Commission, or any provision of Federal law relating to fraud against shareholders, when the information or assistance is provided to or the investigation is conducted by—

(A) a Federal regulatory or law enforcement agency;

(B) any Member of Congress or any committee of Congress; or

(C) a person with supervisory authority over the employee (or such other person working for the employer who has the authority to investigate, discover, or terminate misconduct); or

(2) to file, cause to be filed, testify, participate in, or otherwise assist in a proceeding filed or about to be filed (with any knowledge of the employer) relating to an alleged violation of Sections 1341, 1343, 1344, or 1348, any rule or regulation of the Securities and Exchange Commission, or any provision of Federal law relating to fraud against shareholders.

(b) Enforcement Action.—

(1) In General.—A person who alleges discharge or other discrimination by any person in violation of subsection (a) may seek relief under subsection (c), by—

(A) filing a complaint with the Secretary of Labor; or

(B) if the Secretary has not issued a final decision within 180 days of the filing of the complaint and there is no showing that such delay is due to the bad faith of the claimant, bringing an action at law or equity for de novo review in the appropriate district court of the United States, which shall have jurisdiction over such an action without regard to the amount in controversy.

(2) Procedure.—

(A) In General.—An action under paragraph (1)(A) shall be governed under the rules and procedures set forth in Section 42121(b) of title 49, United States Code.

(B) Exception.—Notification made under Section 42121(b)(1) of title 49, United States Code, shall be made to the person named in the complaint and to the employer.

(C) Burdens of Proof.—An action brought under paragraph (1)(B) shall be governed by the legal burdens of proof set forth in Section 42121(b) of title 49, United States Code.

(D) Statute of Limitations.—An action under paragraph (1) shall be commenced not later than 90 days after the date on which the violation occurs.

(c) Remedies.—

(1) In General.—An employee prevailing in any action under

subsection (b)(1) shall be entitled to all relief necessary to make the employee whole.

(2) Compensatory Damages.—Relief for any action under paragraph (1) shall include—

- (A) reinstatement with the same seniority status that the employee would have had, but for the discrimination;
- (B) the amount of back pay, with interest; and
- (C) compensation for any special damages sustained as a result of the discrimination, including litigation costs, expert witness fees, and reasonable attorney fees.

(d) Rights Retained By Employee.—Nothing in this section shall be deemed to diminish the rights, privileges, or remedies of any employee under any Federal or State law, or under any collective bargaining agreement.

⁵⁸ *Id.* at § 806(a).

⁵⁹ *See id.*

⁶⁰ *See id.*

⁶¹ *See id.*

⁶² *Id.*

⁶³ Sarbanes–Oxley Act of 2002, Title XI, § 1107(e).

⁶⁴ *See* BroadSource & Independent Sector, *The Sarbanes-Oxley Act and Implications for Nonprofit Organizations*, Nov. 12, 2003, at 10, at <http://www.independentsector.org/PDFs/sarbanesoxley.pdf> (last visited Nov. 8, 2004).

⁶⁵ *Corporate Responsibility*, *supra* note 6.

⁶⁶ For more information and guidance tailored to hospitals specifically, see *OIG Draft Supplemental Compliance Program Guidance for Hospitals*, 69 Fed. Reg. 32012–02 (Jun. 8, 2004).

⁶⁷ *See Corporate Responsibility*, *supra* note 6, at 1.

⁶⁸ The *OIG* has identified the following non-exhaustive list of risk areas that hospitals should be specifically aware of in considering written policies and procedures concerning regulatory exposure. These areas of concern include the following:

- Billing for items or services not actually rendered;
- Providing medically unnecessary services;
- Upcoding—The practice of using a billing code that provides a higher payment rate than the billing code that actually reflects the service furnished to the patient;
- “DRG creep”—Like upcoding, “DRG creep” is the practice of billing using a Diagnosis Related Group (DRG) code that provides a higher payment rate than the DRG code that accurately reflects the services furnished to the patient;
- Outpatient services rendered in connection with inpatient stays;
- Teaching physician and resident requirements for teaching hospitals;
- Duplicate billing;
- False costs reports;
- Unbundling—The practice of submitting bills piecemeal or in fragmented fashion to maximize the reimbursement for various tests or procedures that are required to be billed together and therefore at a reduced cost;

- Billing for discharge in lieu of transfer;
- Patient's freedom of choice;
- Credit balances—failure to refund;
- Hospital incentives that violate the anti-kickback statute or other similar federal or state statute or regulation;
- Joint ventures;
- Financial arrangements between hospitals and hospital-based physicians;
- Stark physician self-referral law;
- Knowing failure to provide covered services or necessary care to members of a health maintenance organization; and,
- Patient dumping.

See Publication of the OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987, 8990 (Feb. 23, 1998).

⁶⁹ *Id.* at 8989 (citing U.S. SENTENCING GUIDELINES MANUAL 8A1.2 comment (n.3(K))).

⁷⁰ *Id.*

⁷¹ See *Corporate Responsibility*, *supra* note 5, at 4–7.

⁷² *Id.* at 4.

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ See *id.* at 4–5.

⁷⁷ *Id.*

⁷⁸ See *infra* Part II.B. and accompanying notes.

⁷⁹ See *Corporate Responsibility*, *supra* note 6, at 5.

⁸⁰ *Id.*

⁸¹ See *id.*

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ See *id.*

⁸⁶ See *id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.* at 6.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ 239 F.3d 808, 814 (6th Cir. 2001).

⁹⁵ See *Corporate Responsibility*, *supra* note 6, at 6.

⁹⁶ *Id.*

⁹⁷ See *id.*

⁹⁸ See *id.*

⁹⁹ *Id.*

¹⁰⁰ See *id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ See 15 U.S.C.A. § 78(f) (2000).

¹⁰⁵ See *Corporate Responsibility*, *supra* note 6, at 6.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ See 239 F.3d 808, 816 (6th Cir. 2001); see *supra* notes 34–43.

¹⁰⁹ See *supra* notes 44–53.

¹¹⁰ See *Corporate Responsibility*, *supra* note 6, at 7.

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ See *id.*