

Health care boards of directors' legal responsibilities for quality

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This is the third in a series of articles by Foley & Lardner LLP published in Compliance Today designed to address the compliance risks associated with quality of care in the hospital setting. This article explores and explains the legal responsibilities of health care boards of directors and how compliance officers can educate and assist boards in fulfilling their legal responsibilities.

The Institute of Medicine's landmark report,¹ which documented that medical errors were one of the leading causes of death in the United States,

served as a wake-up call for the health care industry. In response to growing concerns about health care quality and patient safety, federal and state governments, purchasers, and health plans began launching new initiatives to increase quality and accountability in the health care system. This emerging quality movement has shifted the focus on accountability for health care quality and patient safety from individual practitioners to the health care system itself. Consistent with this shift in perspective, the government has charged governing boards of health care organizations with the overall responsibility for the quality of care delivered at their organizations. As this article will show, health care boards of directors are increasingly being held accountable for quality failures. It would not be a surprise if, eventually, this accountability translated into legal liability for board members in enforcement actions for quality failures.

The Centers for Medicare and Medicaid Services (CMS) clarified its intent to hold hospital leadership responsible and accountable for quality in the 2003 revisions of the hospital Conditions of Participation (CoP), which included the Quality Assessment and Performance Improvement Program (QAPI).² The revised QAPI CoP sets forth a standard, titled "Executive Responsibilities," which emphasizes the role of the hospital's governing body, medical staff, and administrative officials in establishing a culture of safety and quality and defining the importance of QAPI

activities throughout the institution.³

Under the pre-existing QAPI standards, the hospital leadership was responsible for ensuring that QAPI addressed priorities for improved quality of care and patient safety and that all improvement actions were evaluated. The revisions strengthened the standard by additionally requiring the hospital's governing body to set expectations for safety and to allocate adequate resources for measuring, assessing, improving, and sustaining the hospital's performance and for reducing risks to patients.⁴ These defined responsibilities are just one aspect of the hospital governing board's general oversight duty to ensure that the hospital's QAPI reflects the complexity of the hospital's organization and services, involves all hospital departments and services, focuses on indicators related to improvement of health outcomes, and the prevention and reduction of medical errors.⁵

Fiduciary responsibilities of the board

The emergence of the quality movement (accompanied by a myriad of new regulatory and payment provisions that impact health organizations) prompted the National Quality Forum to issue its groundbreaking "Call to Responsibility" to health care organizations. This Call urged health care boards to make serious efforts to ensure quality of care and outlined principles that boards should follow in ensuring health care quality.⁶ To inform and educate board members about their new roles and responsibilities, the Department of Health and Human Services' Office of Inspector General (OIG) and the American Health Lawyers Association (AHLA) issued three joint reports on corporate responsibility, compliance, and health care quality.⁷ According to the most recent OIG/AHLA white paper, oversight of quality has become a core fiduciary responsibility of health care

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organization boards.⁸

Duty of care. The board of directors' legal obligations with respect to the duty of care arise in two distinct contexts: (1) the decision-making function, and (2) the oversight function. In fulfilling its duty of care, the board is obligated to conduct due inquiry, make responsible decisions, and provide appropriate oversight to the health care organization. Generally, the duty of care is satisfied when directors act:

- in "good faith,"
- with the care an ordinarily prudent person would exercise in like circumstances, and
- in a manner that they reasonably believe to be in the best interests of the corporation.⁹

In recent years, the "reasonable inquiry standard" has been interpreted to require directors to actively inquire into aspects of corporate operations where appropriate.¹⁰

With regard to health care quality, boards exercise their decision-making function when they review and approve or disapprove medical staff credentialing recommendations. Boards exercise their oversight function when they assess emerging issues of quality of care and patient safety, review quality data reporting by their organization, and evaluate the effectiveness of the corporate compliance program. Although directors are not expected to serve as compliance officers, they are responsible for oversight of management's operation of the compliance program. In carrying out their duty of care, boards are also obligated to exercise general supervision and control with respect to corporate officers. If information is presented—either through the compliance program, through complaints, or otherwise—that causes or should cause concerns to be aroused, the director is obligated to make further inquiry until such time as the concerns are satisfactorily addressed and

favorably resolved. Given the recent government interest in quality of care, the OIG/AHLA white paper instructs boards to take a more active role in overseeing quality issues within their organizations in order to satisfy the duty of care.¹¹

The seminal Caremark case established the legal liability of the board members for breach of fiduciary duty. In the Caremark case, the court found that the board did not breach its fiduciary duty, but the court's opinion also stated that:

"[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."¹²

In accordance with this decision, health care boards might be susceptible to legal risk, in extreme circumstances, if they fail to reasonably oversee the organization's compliance program or act as mere passive recipients of information.

Duty of obedience. A health care entity/board also is subject to the duty of obedience to corporate purpose and mission.¹³ For nonprofits, the board has a particular duty to ensure that the organization is acting in the furtherance of the defined purpose and mission of the organization as set forth in the corporate charter and bylaws.

As the OIG/AHLA white paper indicates, "perfection" is not required in order to discharge the duty of care or duty of obedience to corporate purpose and mission obligations.¹⁴ Instead, it is recommended that

boards exercise general oversight of patient safety and quality of care issues by:

- Understanding the emergence of quality-of-care issues, challenges, and opportunities;
- Overseeing the development of specific quality-of-care measurement and reporting requirements (including asking the executive staff for periodic education); and
- Requesting periodic updates from the executive staff on organizational quality-of-care initiatives and how the organization intends to address legal issues associated with those initiatives.¹⁵

If these efforts uncover quality-of-care issues, then additional inquiry may be required in order for boards to satisfy their duties to their organizations.

Government regulation and enforcement

Governing boards must be conversant in the clinical, operational, and policy issues associated with quality of care to respond to the increasingly expansive and complex federal and state regulatory scheme governing health care quality. New policies that affect reimbursement and payment, efficiency, and collaboration among organizational providers and individual and group practitioners require the governing board to closely monitor the activities of their organization as part of their oversight responsibility. Clearly, Medicare CoP require hospital boards to monitor quality through credentialing of medical staff and to maintain effective quality assessment and performance improvement programs; that is just one strand in the web of quality regulations. New financial incentives, such as Pay for Performance, gain-sharing, and other financial arrangements are regulated under state and federal law. Federal quality reporting initiatives and state adverse-event reporting regulations also apply

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to health care providers and expose them to legal risk for non-compliance.

The government is developing a variety of means to identify quality-of-care issues that run afoul of the complex regulatory requirements. State certification surveys are the traditional mechanism of identifying quality deficiencies; however, federal government agencies have developed new data mining methodologies to apply to health care claims, hospital adverse-event reports, and data submitted for annual payment updates and physician quality reports to identify quality problems. Because the data submitted to government agencies and third-party payers is being used for determining reimbursement, inaccurate submission of such data could result in the misrepresentation of the status of patients and residents, the submission of false claims, and potential enforcement action under the False Claims Act (FCA).¹⁶ Quality issues also can be brought to the government's attention through whistleblower lawsuits or qui tam actions.¹⁷

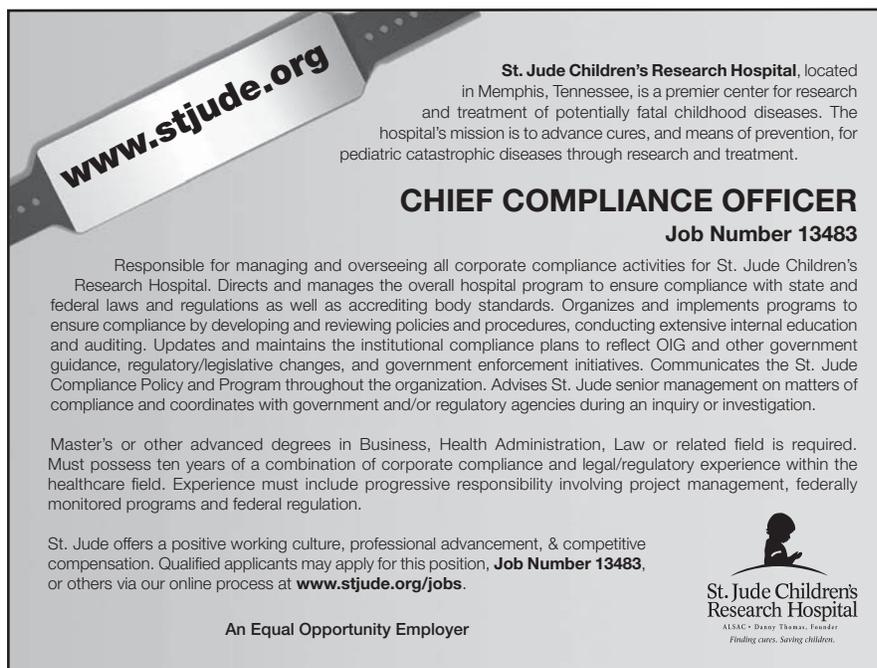
When quality problems are identified, the regulatory scheme includes a range of

progressive administrative sanctions and monetary penalties that may be imposed against providers that fail to comply with the legal requirements. In addition to the administrative penalties, OIG, Department of Justice, state Attorney Generals, and state fraud control units are working together to enforce quality for beneficiaries of federal health care programs. The consequences of quality violations range from a requirement to repay any improperly received reimbursement amount with interest, to the imposition of severe financial penalties, criminal prosecution, and exclusion from participation in any federal health care program for the corporation or organization.

Increased government scrutiny and enhanced enforcement create new risks for corporate compliance, but they may also increase risk for individual board members, owners, and high-ranking executives, who may, in certain circumstances, be held liable for quality-of-care failures. Hospitals have been held liable for failure to investigate and act on medically unnecessary care provided by its medical staff. Administrators and chief executive officers (CEOs) also have been subject to

civil and criminal liability where the facility has provided substandard or inadequate care or where the executives have restricted the budget to such an extent that adequate care could not have been provided. The following examples of quality-of-care investigations that have resulted in significant settlements and convictions illustrate the government's focus:

- A Michigan hospital and individual members of the Medical Executive Committee were indicted in federal court on charges of criminal conspiracy, mail fraud, and wire fraud by billing for medically unnecessary pain procedures. The government's case centered on the hospital's allegedly deficient peer review procedures, which failed to properly investigate and curtail the unnecessary pain procedures. The hospital pled guilty to wire fraud, and the case resulted in a settlement agreement of \$1 million, \$750,000 in restitution, and an agreement by the individuals to plead guilty to state charges.¹⁸
- In another case focusing on deficient peer review procedures, a northern California hospital and its parent corporation paid \$59.5 million to settle civil FCA allegations that the hospital inadequately performed credentialing and peer review of cardiologists on its staff who performed medically unnecessary invasive cardiac procedures.¹⁹
- The former owner and CEO of a Chicago teaching hospital was found liable for approximately \$64 million damages for conspiracy and violation of the FCA, where the hospital compensated physicians excessively for their services and billed for services that were not performed. The hospital's administrator and several physicians received prison sentences and were required to make restitution payments.²⁰
- A long-term care facility management company, its CEO, and three nursing homes were found guilty of conspiracy and



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health care fraud based on their imposition of budgetary constraints that prevented the facilities from providing adequate care to residents. In 2007, the CEO was sentenced to pay \$29,000 in criminal fines and to serve an 18-month sentence. The management company and nursing homes were each sentenced to pay \$182,250 in criminal fines. In a related civil case, the corporate defendants paid \$1.25 million to resolve FCA allegations, and agreed to be excluded from federal health care programs.²¹

- On June 10, 2008, the owner of a personal care home in Philadelphia agreed to pay the United States \$700,000, close the facility, and also agreed to lifetime exclusion from the Medicare and Medicaid programs for providing grossly inadequate housing and care for residents. The owners agreed never again own or operate a patient, personal, or residential care facility or a program or facility that participates in any federally funded health care program.²²

Implications for boards of directors

The new emphasis on quality raises the stakes for health care organizations, both financially and legally. In light of the severe consequences that might result from a lack of adherence to applicable legal requirements, it is essential for the board of directors to be cognizant of its evolving responsibilities. Health care organizations are required to be mindful of the Anti-kickback Statute, the physician self-referral (Stark) law, civil money penalty statutes, the Health Insurance Portability and Accountability Act, federal tax exemption standards, antitrust law, fraud laws, and other legal compliance standards.²³ Boards must excise oversight of the organization's compliance programs and must reasonably inquire whether appropriate control mechanisms are in place to monitor the associated legal risks.

To fulfill their responsibilities and avoid legal risk, board members must take action. An action plan for the board of directors should involve the following steps:

- **Fiduciary duty.** Boards of directors must recognize quality of care as a core fiduciary duty. Health care quality must be established as a key component of corporate mission and elevated to the same level of fiduciary obligation as financial viability and corporate compliance.

- **Education.** Boards of directors must be educated on quality of care policies, laws, and issues as they relate to their oversight responsibilities. Recognizing the importance of an informed and educated board, the American Hospital Association's Center for Healthcare Governance has developed a Quality Curriculum for Trustees,²⁴ which was developed to increase hospital board member knowledge of the quality imperative. This curriculum was created and piloted with the Massachusetts Hospital Association. Blue Cross Blue Shield of Massachusetts has supported the initiative and is offering incentives to hospitals after their trustees complete the six-hour quality improvement course.²⁵

- **Risk assessment.** Health care boards must assess organizational risk. The board needs to review the quality of care provided by the organization and identify any quality of care failures. To help identify issues that could signal legal liability, the board should begin with an inquiry into the following issues:

- Has there been a systemic failure by management and the board to address quality issues?
- Has the organization made false reports about quality, or failed to make mandated reports?
- Has the organization profited from ignoring poor quality, or ignoring

providers of poor quality?

- Have patients been harmed by poor quality, or given false information?
- Have there been complaints on quality from existing staff? Complaints of this nature can lead to potential whistleblower suits.
- What are the results of the quality of care/legal risks audit and/or risk assessment?

Although the federal and state regulations governing quality continue to grow, directors do not have to address these issues on their own. Enlisting the aid of outside attorneys or consultants to evaluate quality-of-care risk areas within their organizations can help boards to fulfill their fiduciary duties for quality of care.

- **Integrated analysis.** Boards must encourage the development of an integrated quality improvement and assessment system, which moves beyond case-by-case evaluation of past problems (e.g., a "bad apples" approach) to integrated analysis and use of retrospective data to identify high-risk patterns. As part of this analysis, boards should assess any medical necessity issues. In so doing, boards must be careful not to violate any state laws, including but not limited to all appropriate peer review protections. Therefore, it is imperative that an organization involve its counsel in this assessment process. To fulfill their leadership responsibilities, boards should frame and agenda for quality of care and communicate it throughout the organization by working collaboratively with senior management and health care practitioners. Quality improvement is likely to involve significant restructuring of key departments and processes to integrate quality compliance throughout organization.

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Therefore, joint planning with board members and medical staff leadership can help facilitate development and implementation of a new agenda for quality.

- **Oversight.** The board must improve its oversight of quality. The board must support executive leadership in quality and patient safety initiatives, regularly review reports to the board on quality, patient safety, utilization review, reimbursement, risk management, quality data reporting, peer review, and corporate compliance. Effective oversight of the compliance program will require an evaluation of compliance with regulations that govern hospital acquired conditions, the Reporting Hospital Quality Data for Annual Program Update, state adverse event reporting requirements, gainsharing, physician incentives, and outcomes management initiatives.

Conclusion

Boards of directors must act swiftly to address their responsibilities for quality of care in light of the onslaught of government initiatives, coupled with increased government efforts to uncover quality failures through data mining and to enforce quality through the FCA, highlight the necessity of leadership on the part of health care boards of directors in ensuring quality of care. ■

- 1 Institute of Medicine, *To Err is Human: Building a Safe Health System* (2000).
- 2 68 Fed. Reg. 3435 (Jan. 24, 2003).
- 3 Id. see also 42 C.F.R. § 482.21(e).
- 4 Id.
- 5 42 C.F.R. § 482.21.
- 6 National Quality Forum, *Hospital Governing Boards and Quality of Care: A Call to Responsibility* (2004).
- 7 The OIG/AHLA, *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors* (2007); OIG/AHLA, *An Integrated Resource for Corporate Compliance: A Resource for Health Care Boards of Directors* (2004); OIG/AHLA, *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors* (2003).
- 8 OIG/AHLA, *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors* (2007).
- 9 Id.
- 10 Id.
- 11 Id.
- 12 *In re Caremark International*, 698 a. 2d. 959 (Del. Chan. Ct. 1996).
- 13 OIG/AHLA, *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors* (2007).
- 14 Id.
- 15 Id.
- 16 Id.
- 17 In a qui tam action, a private individual, or "whistleblower", with knowledge of past or present fraud committed against the U.S. federal government brings a lawsuit on behalf of the United States.
- 18 Testimony of Gregory E. Demske, Assistant Inspector General for Legal Affairs, U.S. Department of Health and Human Services before the U.S. Senate Special Committee on Aging on the Role of OIG in Identifying and Preventing the Abuse of the Elderly (July 18, 2007); U. S. v. United Memorial Hospital, U.S. District Court for the Western District of Michigan, Southern Division, No. 1:01-CR-238, Jan. 8, 2003.
- 19 Testimony of Gregory E. Demske, Assistant Inspector General for Legal Affairs, U.S. Department of Health and Human Services before the U.S. Senate Special Committee on Aging on the Role of OIG in Identifying and Preventing the Abuse of the Elderly (July 18, 2007);
- 20 *United States v. Rogan*, No. 02-C3310, 2006 WL 2860972 (N.D. Ill. Sept. 29, 2006).
- 21 Testimony of Lewis Morris before the Subcommittee on Oversight and Investigations Committee on Energy and Commerce U.S. House of Representatives, *In the Hands of Strangers: Are Nursing Home Safeguards Working?* (May 15, 2008).
- 22 Settlement Agreement, United States Eastern District of Pennsylvania and Brookwood Personal Home Care, Inc., Conlyn House, Inc., Thoroughgood, Inc., Health Horizons Unlimited, Inc., and Ivy Ridge Personal Care Center, Inc., <http://www.usdoj.gov/usao/pae/News/Pr/2008/jun>.
- 23 OIG/AHLA: *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors* (2007).
- 24 American Hospital Association, Center for HealthCare Governance, *Quality Curriculum for Trustees*. Available at <http://www.americangovernance.com/americangovernance/education/qualitycurriculum.html>.
- 25 Training Program for Hospital Trustees Adopted, *White Coat News* (March 21, 2008).