Changing Expectations for Board Oversight of Healthcare Quality: The Emerging Paradigm

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Changing Expectations for Board Oversight of Healthcare Quality: The Emerging Paradigm

Tracy E. Miller and Valerie L. Gutmann

ABSTRACT: Within healthcare institutions, leadership is an essential driver of expectations, performance, and culture. Yet boards of directors traditionally played a limited role in overseeing healthcare quality, providing final approval of credentialing decisions but deferring to the medical staff to set standards for the institution. Case law and standards provide little guidance for board performance in overseeing quality of care. Recent developments—the availability of comparative quality data, public reporting, and financial incentives for higher quality—have transformed expectations for board oversight. Enforcement of fraud and abuse laws based on poor quality of care, as well as federal standards for board oversight of healthcare quality and compliance, have set higher standards for board conduct. This article examines the emerging paradigm for board oversight of healthcare quality, and recommends how boards should proceed to meet their responsibilities in an era of comparative quality measures and transparency.

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BOARD OVERSIGHT OF HEALTHCARE QUALITY

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Introduction

Healthcare quality depends on leadership as an essential driver of expectations, performance, and culture. Yet the broad concepts of fiduciary duty convey little guidance about how boards should undertake this responsibility. Traditionally, board oversight of quality focused on approval of credentialing decisions—often a pro forma approval of judgments made by the medical staff.

Recent developments in quality improvement and measurement, as well as changes in regulatory oversight, have established strong financial incentives for boards to carry out their responsibilities on quality effectively. Rapid changes in the quality arena—the availability of comparative quality data, public reporting on quality measures, and pay-for-performance—all bring heightened attention and financial pressure to improve quality. The development of “never events” as markers of patient safety creates a well-delineated floor for board oversight. The stakes for increased transparency and public measures of substandard performance also have been raised by mounting compliance enforcement linking poor quality to false claims, generating the possibility of substantial financial penalties.

This article examines emerging trends in healthcare quality and the implications of these changes for board oversight. For an explicit road-
map, boards can now look to guidelines from the federal government for board actions on quality and compliance; state oversight of healthcare delivery; and corporate integrity and deferred prosecution agreements in the healthcare arena. The article assesses the expectations for board oversight of quality that have emerged in the wake of the transformation in healthcare measurement and improvement. It compares the quality oversight responsibilities of boards of healthcare providers with those of parent boards of health systems and examines the available empiric data on board activities to oversee quality. The article concludes by recommending steps boards should take to fulfill their responsibilities in an era of comparative quality measures and transparency.

The Transformation of Quality Measurement and Improvement

Traditionally, the performance of individual physicians was the primary basis for understanding and evaluating quality. Until the 1990s, responsibility for overseeing the quality of care in hospitals rested primarily with the medical staff, which functioned through a committee structure largely independent of the board of directors and management. Through credentialing, peer review of serious errors, and a medical staff committee structure, physicians engaged in a largely self-regulated process to oversee quality of care. Consistent with this focus on individual practitioners as the locus of healthcare quality, boards of directors had the authority to grant final approval of credentialing decisions; however, in practice, substantive evaluation of physicians occurred for the most part at the medical staff level. By and large, the processes to improve care were retrospective and episodic, focusing on post-hoc analysis of serious events to understand errors made in individual cases. The roles of the board, medical staff, and executive management often were coordinated poorly to serve quality goals, with the medical staff dominating quality oversight by virtue of both its professional knowledge and perspective that quality standards were solely the provenance of medical expertise.1

1 Legal commentators have criticized the weakness of what has been called the “three-legged stool” of oversight for quality, with responsibility and accountability divided between the medical staff, executive management, and the board. See John D. Blum, Feng Shui and the Restructuring of the Hospital Corporation: A Call for Change in the Face of the Medical Error Epidemic, 14 HEALTH MATRIX: J. L.-MED. 5 (2004); Thomas Greaney, New Governance Norms and Quality of Care in Nonprofit Hospitals, 14 ANNUALS HEALTH L. 421, 422 (2005); Richard Johnson, Revisiting “the Wobbly Three Legged Stool,” 4 HEALTH CARE MGMT. REV. 15 (1979); Brian M. Peters & Jonathan Z. Cohen, Board Quality Oversight: A “Real World” Systemic Compliance Model, 14TH ANNUAL HEALTH LAW INST. (Mar. 2008); John P. Marren et al., The Hospital Board at Risk and the Need to Restructure the Relationship with the Medical Staff: Bylaws, Peer Review and Related Solutions, 12 ANNUALS HEALTH L. 179 (2003).
Historically, the Joint Commission on Accreditation of Health Care Organizations (JCAHO, now the Joint Commission) was the primary external arbiter of hospital quality, apart from malpractice actions. Both the federal and state governments rely on accreditation by the Joint Commission to evaluate the quality of hospital care. Only a handful of states, such as New York, have conducted their own surveys. Criticized in the past for emphasizing administrative procedures more than clinical processes and outcomes, the Joint Commission changed its survey process in 2004 to include additional measures of clinical quality. Although accreditation decisions became publicly available in 1996, survey scores are not publicly released.

In fact, transparency in quality of care did not exist until recently—it ran counter to the ethos of a profession accustomed to self-regulation and peer review confidentiality. Boards of directors could receive internal reports of patient deaths or serious events, but lacked systematic data to evaluate quality. Although malpractice cases escalated in the 1970s and 80s, they provided limited insight into quality of care.


3 The Centers for Medicare and Medicaid Services (CMS) approved the Joint Commission survey as the mechanism to grant hospitals certification to participate in and receive funds under the Medicare Program. 42 U.S.C. § 1395bb(a), (b), and § 1395x(e); 42 C.F.R. § 488.5. In 2009, the Joint Commission's categories for accreditation were changed; they are now provisional accreditation, conditional accreditation, preliminary denial of accreditation, denial of accreditation, and preliminary accreditation. Joint Commission, Joint Commission Fact Sheets: Accreditation Process Overview, available at www.jointcommission.org/AboutUs/Fact_Sheets/overview_qa.htm;


5 Molly Coye, No Toyotas in Health Care: Why Medical Care Has Not Evolved to Meet Patients’ Needs, 20 HEALTH AFF. 44, 47 (2001) [hereinafter Coye, No Toyotas in Health Care].


7 Communication with Joint Commission Communications Office, 3/5/09. The most current accreditation decision for an organization is available on Quality Check, the Joint Commission's website, and accreditation histories can be obtained by writing or calling the Joint Commission. Facts about the Public Information Policy, available at www.jointcommission.org/AboutUs/Fact_Sheets/08_pip.htm.
By the early 1990s, studies had begun to show that malpractice actions were closer to a lottery than a fair, equitable way to reimburse patients for medical harm; the number of actions brought grossly under-represented the rate of medical injury, and patients who did sue often lacked a valid claim. Data on the exceptionally high rate of medical errors leading to patient death or serious injury began to emerge in the 1990s, and confirmed that malpractice actions covered only a small fraction of instances of patient harm from malpractice. The number of disciplinary actions by state governments, like malpractice cases, encompassed a small subset of physician malpractice.

The science of quality measurement and improvement first emerged in the 1970s as an organized field, prompted by government and private payor concerns about the cost of care and studies showing wide regional variation in utilization of healthcare procedures unrelated to population needs. Seeking to reduce the high rate of medical errors, researchers sought to apply the model of continuous quality improvement developed by industry to the processes of healthcare delivery.

In this evolving understanding of quality, systems of care—not individual practitioner error—were both the cause of many serious adverse events and the potential solution for prevention. Quality experts and researchers developed measures of processes and outcomes of care designed to evaluate the treatment provided to individual patients, as well as the systems of care within hospitals, health plans, and other providers.

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8 R. Localio et al., Relation Between Malpractice Claims and Adverse Events Due to Negligence: Results of the Harvard Medical Practice Study, 325 NEW ENG. J. MED. 245 (1991) (explaining that malpractice claims are only a rough measure of identifying andremedying specific problems, and malpractice claims are not very useful as an indicator of the quality of care). One study showed that 98 percent of all adverse events due to negligence did not result in malpractice claims, and thus, the fraction of medical negligence that leads to claims is probably under 2 percent.

9 The Institute of Medicine report, To Err is Human: Building a Safer Health System, was a watershed in public recognition of the extraordinarily high rate of preventable medical errors, and the toll of those errors on morbidity and mortality of patients across the economic and healthcare spectrum. INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Linda T. Kohn, et al, eds. 2000) [hereinafter TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM].

10 Id. A study in the 1990s by the Public Citizen Research Group found that there were only approximately three thousand disciplinary actions each year (among 584,900 medical doctors), and fewer than 10 percent of those were for negligent or poor-quality care.

11 Prominent healthcare quality researchers noted that healthcare quality problems could be classified into three categories: underuse, overuse, and misuse, with widespread errors in all three categories. Mark Chassin & Robert Gavin, The Urgent Need to Improve Health Care Quality, 280 JAMA 1000, 1002 (1998) [hereinafter Chassin & Gavin, The Urgent Need to Improve Health Care Quality].


13 Id. at 115.
Comparative measures as a precursor to transparency

As early as the 1990s, private payors, including large employers such as General Electric, regional business coalitions, and government purchasers, sought to drive payment based on quality, or “pay-for-performance.” However, public and private payors lacked sufficient market share and access to comparative measures across hospitals, health plans, and other providers necessary to effect change. As noted by commentators, the business case for quality was weak; hospitals and other providers were not rewarded for higher performance or investment in quality, outside of capitated systems that could capture some of the savings. Moreover, providers were not penalized for poor performance.

In 2000, the National Quality Forum (NQF) was created as part of a concerted strategy by public and private payors to coordinate purchasing power to generate publicly available, reliable measures as a basis to improve quality, create public transparency, and enable market choice by purchasers and consumers. Over the past eight years, this coordinated effort, combined with advances in quality measurement and improvement, has generated comparative measures across three interrelated dimensions of healthcare quality: patient safety, quality improvement, and patient satisfaction.

Patient safety

By the mid 1990s, empirical studies showing the frequency of patient deaths and serious harm caused by medical error had generated public alarm about the safety of medical practice. The landmark 1999 report by the Institute of Medicine, To Err is Human, attributed approximately 44,000 to 98,000 deaths each year to medical errors. Medication errors...
alone accounted for 7,000 deaths a year.19 Studies issued before and after the report reinforced the notion of a healthcare system fraught with risk for patients. Studies showed widespread errors, high rates of inappropriate treatment that posed risks to patients, and undertreatment that led to patient harm.20 Studies of medical errors spurred development of patient safety protocols by specialty societies, hospitals, and quality improvement experts, but did not generate data showing widespread improvement.21 By 2002, the NQF had developed a list of “never” events that should not occur, such as operation on the wrong patient, operation on the wrong site or limb, and death or serious disability associated with a medication error. The list was updated in 2006.22 On April 30, 2008, The Centers for Medicare and Medicaid Services (CMS) announced that Medicare would not pay for certain conditions acquired during the hospital stay, effective October 1, 2008.23
wake of the CMS policy decision not to pay for hospital-acquired conditions, private plans embraced the same approach.\textsuperscript{24}

**Quality improvement measures**

The decision by CMS not to pay for hospital-acquired conditions followed its initial pay-for-performance initiative based on quality of care measures for five conditions:

1. heart attack,
2. heart failure,
3. pneumonia,
4. coronary artery bypass graft, and
5. hip and knee replacements.\textsuperscript{25}

In 2000, CMS reported in the \textit{Journal of the American Medical Association} on national measures of hospital quality of care for these conditions by region, informing hospitals confidentially of their own scores compared to regional and national rates of performance.\textsuperscript{26} CMS reported that care for Medicare fee-for-service plan beneficiaries “improved substantially” between 1998-1999 and 2000-2001, but the agency still called for further improvement.

**Patient satisfaction**

The third dimension of quality measurement and reporting advanced by researchers, private organizations, and the federal government relates to patient satisfaction.\textsuperscript{27} Patient satisfaction measures assess the patient’s experience of care, seeking to capture broad considerations of whether patients and their families are treated with dignity and respect and whether care is patient-centered, i.e., engineered to meet patients’

\textsuperscript{24} For example, Cigna HealthCare announced on April 17, 2008 that it would no longer reimburse for these avoidable events when permitted under its hospital contracts. Mike Mitka, \textit{Public, Private Insurers Refusing to Pay Hospitals for Costs of Avoidable Errors}, 299 JAMA 2495, 2495 (2008).

\textsuperscript{25} Press Release, CMS, Medicare Pay-For-Performance Demonstration Shows Significant Quality of Care Improvement at Participating Hospitals (May 3, 2005), available at www.cms.hhs.gov/apps/media/press/release.asp?Counter=1441&IntNumPerPage=10 &checkDate=&checkKey=2&srchType=2&numDays=0&srchOpt=0&srchData=part+d&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=1&pYear=0&year=0&desc=false&cbOrder=date.

\textsuperscript{26} Stephen F. Jencks et al., \textit{Quality of Medical Care Delivered to Medicare Beneficiaries: A Profile at State and National Levels}, 284 JAMA 1670 (2000). See also Stephen F. Jencks et al., \textit{Change in the Quality of Care Delivered to Medicare Beneficiaries, 1998-1999 to 2000-2001, 289 JAMA 305 (2003).

\textsuperscript{27} CMS, \textit{Hospital Quality Initiatives: HCAHPS: Patients’ Perspectives of Care Survey}, available at www.hcahpsonline.org/home.aspx. See also Picker Inst., \textit{About Picker Institute}, available at www.pickerinstitute.org/about/about.html.

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personal needs and values. While hundreds of patient satisfaction measures had been available from private vendors and companies, in 1995 CMS launched the Consumer Assessment of Healthcare Providers and Systems Program (CAHPS) initiative to develop a standard set of publicly reported, valid measures that would permit comparison across institutions. Available now on the CMS website, the measures evaluate eighteen key aspects of the hospital experience, including:

- communication with nurses and doctors;
- responsiveness of hospital staff;
- cleanliness and quietness of the hospital environment;
- pain management;
- communication about medicines;
- discharge information;
- overall rating; and
- recommendation of the hospital.\(^{28}\)

**Moving to transparency and pay-for-performance**

The transparency of quality data has become instrumental in the evolution of pay-for-performance programs and quality improvement generally, with clear implications for board duties and accountability to public authorities.\(^ {29}\) Beginning in 2003, CMS offered hospitals a financial incentive to report quality and safety data.\(^ {30}\) In 2005, CMS established the Hospital Compare website, providing quality data to spur hospital improvement and promote consumer choice based on quality.\(^ {31}\) The Hospital Compare website provides comparative data

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28 CMS, HCAHPS Fact Sheet (CAHPS® Hospital Survey) (Mar. 2008), available at www.cms.hhs.gov/HospitalQualityInits/Downloads/HospitalHCAHPSFactSheet200807.pdf [hereinafter HCAHPS Fact Sheet]. Similar patient satisfaction measures also have been developed for nursing home care.

29 Studies have confirmed that publicly reported measures have led to quality improvement. See Peter K. Lindenauer et al., Public Reporting and Pay for Performance in Hospital Quality Improvement, 356 NEW ENGL. J. MED. 486 (2007); Constance Fung et al., Systemic Review: The Evidence that Publishing Patient Care Performance Data Improves Quality of Care, 148 ANN. INTERN. MED. 111 (2008); Judith Hibbard et al., Does Publicizing Hospital Performance Stimulate Quality Improvement Efforts? 22 HEALTH AFF. 94 (2003) (making quality information public results in increased quality improvement efforts). See also Mark Chassin, Achieving and Sustaining Improved Quality: Lessons from New York State and Cardiac Surgery, 21 HEALTH AFF. 40 (2002); But see Mark Chassin et al., Benefits and Hazards of Reporting Medical Outcomes Publicly, 334 NEW ENGL. J. MED. 394 (1996) for a description of the potential pitfalls with the release of quality data. The data are more equivocal about the impact of transparency on consumer choice. See note 45.

30 Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU), 42 U.S.C. § 1395ww(b)(3)(B). See also CMS, Hospital Quality Initiatives: Reporting Hospital Quality Data for Annual Payment Update, available at www.cms.hhs.gov/HospitalQualityInits/08_HospitalRHQDAPU.asp.

31 The Hospital Compare website is available at www.hospitalcompare.hhs.gov.

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from the Hospital Quality Initiative\textsuperscript{32} and voluntarily submitted data on patient satisfaction from the Hospital CAHPS initiative.\textsuperscript{33} Starting in July 2007, hospitals that collected and submitted CAHPS data to CMS were rewarded, and those that failed to do so were penalized.\textsuperscript{34}

Pay-for-performance became operational for a defined set of hospital quality measures in 2005, with hospitals incentivized and reimbursed based on their performance.\textsuperscript{35} Among the demonstration projects implemented by CMS, the Premier Hospital Quality Incentive Demonstration, started in 2003, is one of the most significant.\textsuperscript{36} Hospitals scoring in the top 10\% for a given set of quality measures received a 2\% bonus payment on top of the standard DRG payment for the relevant discharges.\textsuperscript{37} Those scoring in the next highest 10\% received a 1\% bonus. In the third year of the program, CMS reduced payments to hospitals that did not meet a threshold score on quality measures.

In November 2002, CMS implemented public reporting on comparative quality measures for nursing homes with the Nursing Home Quality Initiative (NHQI).\textsuperscript{38} The NHQI measures assess nursing home quality of care, examining specific services such as the percent of residents given vaccinations (such as pneumococcal and influenza), and the percent of residents who have pressure sores or urinary tract infections, who lose too much weight, or who have moderate to severe

\textsuperscript{32} Numerous other websites also report comparative data on hospital performance on these and other measures. Among these are the Leapfrog Group, the National Committee on Quality Assurance (NCQA), and the Health Plan Employer Data and Information Set (HEDIS). States often have their own public reporting sites, such as the one operated by California's Hospital Assessment and Reporting Taskforce (CHART) program, which publishes its data at CalHospitalCompare.org.

\textsuperscript{33} Voluntary collection of Hospital CAHPS (HCAHPS) data for public reporting began in October 2006, and the first public reporting of HCAHPS results occurred in March 2008. HCAHPS Fact Sheet.

\textsuperscript{34} CMS, Hospital Quality Initiatives: Reporting Hospital Quality Data for Annual Payment Update, available at www.cms.hhs.gov/HospitalQualityInits/08_HospitalRHQDAPU.asp.

\textsuperscript{35} CMS, Medicare “Pay-for-Performance (P4P)” Initiatives, available at www.cms.hhs.gov/apps/media/press/release.asp?counter=1343 [hereinafter Medicare “Pay-for-Performance (P4P)” Initiatives]. CMS’s Value-Based Purchasing (VBP) initiatives are intended to continue the transition from Medicare’s fee-for-service payment systems to a system focused on quality of care. See Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) § 131(d); US DHHS, DEVELOPMENT OF A PLAN TO TRANSITION TO A MEDICARE VALUE-BASED PURCHASING PROGRAM FOR PHYSICIAN AND OTHER PROFESSIONAL SERVICES: ISSUES PAPER (Dec. 9, 2008), available at www.cms.hhs.gov/PhysicianFeeSched/downloads/PhysicianVBP-Plan-Issues-Paper.pdf.

\textsuperscript{36} In another effort to provide standardized mechanisms to compare healthcare quality, most HMOs report quality performance data to the National Committee for Quality Assurance (NCQA) as a basis for quality “report cards.” For a discussion of the limitations of health plan reports cards for consumers, see Coye, No Toyotas in Health Care.

\textsuperscript{37} Medicare “Pay-for-Performance (P4P)” Initiatives.


Not surprisingly, the impact of financial incentives offered by the federal government has been magnified by the adoption of pay-for-performance by health plans. HMOs were the earliest and broadest adopters of quality measures. A 2006 study found that more than half of commercial HMOs use pay-for-performance in their provider contracts. Health plans also have extended pay-for-performance to physicians, provoking controversy about whether publicly released measures actually assess quality of care or cost savings. In one highly publicized enforcement action, the New York State Attorney General sought changes in health plan quality measures to assure that they reflected quality of care, rather than efficiency or cost savings.

Taken together, advances in quality measurement and public reporting over the past two decades create powerful new incentives for boards of healthcare institutions to focus on quality—direct financial incentives, potential harm or gain to reputation, and the impact on market share and consumer choice. For the first time, boards of

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42 Coye, No Toyotas in Health Care.
45 Generally, consumers have not used quality data but relied more on word of mouth. Judith H. Hibbard & Jacquelyn J. Jewett, Will Quality Report Cards Help Consumers?, 16 HEALTH AFF. 218 (1997). But a more recent study by Hibbard et al. found that consumers will use quality information if the reports are salient and actionable. Judith H. Hibbard et al., It Isn’t Just about Choice: The Potential of a Public Performance Report to Affect the Public Image of Hospitals, 62 M.D. CARE RES. & REV. 358 (2005). In a major study, company executives reported that they examine health plan quality data when choosing employee health plans, but few use the data to influence employee choice of plan.
directors have the data and tools to fulfill their fiduciary duty to oversee quality in a meaningful way, ranging from patient safety to quality improvement and patient satisfaction. These changes have significant implications for existing legal standards and government oversight of healthcare board fiduciary duties.

Board Fiduciary Duties: Standards from Statutes and Case Law

Boards of directors for nonprofit and for-profit organizations must meet two basic fiduciary duties: the duties of care and loyalty.46 Boards of directors for nonprofit entities are held to a third duty: the duty of obedience to mission.47 These duties are set forth both in case law and state statutes governing nonprofit corporations.48

The duty of care requires directors to carry out their obligations in good faith with the degree of care, attention, and skill that a person in a like position would reasonably believe appropriate under the circumstances.49 Judicial decisions interpret this duty to require board members to make an informed decision and to act in a manner that is

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48 In addition, nonprofit corporations are governed by the mandates set forth by the Internal Revenue Service (IRS) regarding their tax exemption. See I.R.C. § 501 (c)–(d) (2004). The IRS rules focus primarily on mission, or in the context of healthcare, the requirements of the community benefit standard, and the duty of loyalty. In 2007, the IRS set forth standards that cover board governance.
49 MODEL NONPROFIT CORPORATION ACT, THIRD EDITION § 8.30(b). The newest iteration of the Model Act has been revised from the 1987 version: the Revised Model Nonprofit Corp. Act § 8.30(a)(2) called for “care of an ordinary prudent person in a like position under similar circumstances;” while the Third Edition § 8.30(b) requires the “care that a person in a like position would reasonably believe appropriate under the circumstances.” For a detailed discussion of the duty of loyalty, see Fishman, Improving Charitable Accountability, at 233–37.

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not reckless. Notably, courts have not held that board members have a duty to investigate to uncover a problem; board members may rely on others to provide them with notice or information about a problem. The duty of care is shaped by the business judgment rule, which as a practical matter affords board members broad protection. Specifically, the business judgment rule establishes that board members cannot be held liable for a decision they make, even if the decision later proves wrong and harmful to the corporation, if the directors acted in good faith and with the required degree of care.

The duty of loyalty obligates board members to act solely in the interests of the corporation, and to place the corporation’s interest above their personal gain. Board members cannot enrich themselves at the expense of the corporation. While transactions between an interested director and the corporation are not barred, state statutes and case law require that any such transaction be fair to the corporation, fully disclosed, and entered into without undue influence by the interested director. The Internal Revenue Code imposes other highly detailed requirements that bar directors from excess benefit in any transaction with the corporation. Directors who breach the duty of loyalty may

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50 Thus, courts are likely to find liability only when the board’s conduct rises to the level of gross negligence. See Michael W. Peregrine and James R. Schwartz, Revisiting the Duty of Care of the Nonprofit Director, 36 J. HEALTH L. 183, 190 (2003).

51 Graham v. Allis-Chalmers, 188 A.2d 125 (Del, 1963); Model nonprofit corporation act, third edition § 8.30(b).


53 See Fishman, Improving Charitable Accountability, at 233 for an in-depth discussion of the business judgment rule.

54 See Model Nonprofit Corporation Act, Third Edition § 8.30(a)(2). Stone ex rel. AmSouth Bancorporation v. Ritter, 911 A.2d 362, 370 (Del. 2006), clarified the duty of good faith, explaining that the duty is breached where a fiduciary acts with a purpose other than that of advancing the best interests of the corporation, with the intent to violate the law, or where the fiduciary fails to act in the face of a known duty to act. The duty to act in good faith is not an independent fiduciary duty, but often is considered a necessary element of the duties of loyalty and care, discussed below. See id. at 369–70.

55 Fishman, Improving Charitable Accountability, at 234–37. In some states, certain transactions, such as a loan to directors, are prohibited. In 2004, 28 states prohibited loans to directors. Marion R. Fremont-Smith, Governing nonprofit organizations 226 (2004). See, e.g., not-for-profit corp. act § 716 “Loans to Directors and Officers.” However, a majority of states limit the personal liability of nonprofit directors, unless the actions are clearly self-interested, in bad faith, or grossly negligent. See also McVeigh & Borenstein, The Changing Accountability Climate, at 123.

be held personally liable and may be denied indemnification for legal fees and cost of the breach.57

The third core fiduciary duty for nonprofit directors is the duty of obedience: the obligation to act in a manner that preserves the mission of the corporation.58 The duty of obedience prohibits transactions or diversion of resources for purposes outside the scope of the corporation’s mission as set forth in the articles or certificate of incorporation.59 In recent years, this duty has come to the fore, as state attorneys general have weighed the conversion of nonprofit healthcare plans to for-profit status and the closure of institutions.60

While fiduciary duties establish expectations for board conduct, application of these duties and the broad sweep of the business judgment rule reflect courts’ reluctance to hold nonprofit board members, most of whom serve as volunteers, to an exacting standard.61 In fact, legal commentators have noted the shortcomings of fiduciary duty standards for both for-profit and nonprofit boards as a vehicle to hold boards accountable and provide needed oversight.62 In the nonprofit

57 Board members may face removal by state attorneys general and criminal liability for actions that violate federal and state laws. See, e.g., Butterworth v. Anclote Manor Hosp., 566 So. 2d 296 (Fla. Dist. Ct. App. 1990). However, the “bar for director liability is quite high and the range of potential defenses and protection from liability is broad. Indeed, directors can go about their jobs even in a grossly negligent manner and have no liability, with one caveat: directors must act in good faith ...” Gary Brown, Unclean Hands: As Dangerous in the Boardroom as the Operating Room? HEALTH LAW. NEWS 19, 20 (Sept. 2008) [hereinafter Brown, Unclean Hands]. Some states have granted immunity and mandated corporate indemnification and interim advancement of litigation expenses for directors from suits arising from affairs of the nonprofit corporation where there is good faith. Id.

58 See note 47.

59 For examples of cases where the board was held accountable for diverting resources for reasons outside the corporation’s mission, see Brown v. Mem'l Nat’l Home Found., 329 P.2d 118 (Cal. Dis. Ct. App. 1958) (corporation’s attempt to dedicate funds to unauthorized purpose led to removal of trustee); Queen of Angels Hosp. v. Younger, 136 Cal. Rptr. 36 (Cal. Ct. App. 1977) (articles of incorporation called for operation of hospital, not establishment of neighborhood clinics).

60 See, e.g., Manhattan Eye, Ear & Throat Hosp. v. Spitzer, 715 N.Y.S.2d 575 (Sup. Ct. 1999) (New York State Attorney General successfully blocked sale and close of Manhattan Eye, Ear & Throat Hospital (MEETH) based on failure to honor obedience to mission, but also in part on the board’s failure to fulfill its duty of care in seeking alternatives to closure and the deal terms negotiated by a conflicted agent).


62 Greaney & Boozang, Mission, Margin, and Trust in the Nonprofit Health Care Enterprise, at 7; Evelyn Brody, Agents Without Principles: The Economic Convergence of the Nonprofit and For-Profit Organizational Forms, 40 N.Y. L. SCH. L. REV., 457, 499–500 (1996); Thomas Boyd, A Call to Reform the Duties of Directors Under State Not-for-Profit Corporation Statutes, 72 IOWA L. REV. 725, 745 (1987). Just as failures of governance evidenced by cases such as Enron and Worldcom called into question the effectiveness of board standards and public accountability for for-profit companies, the most recent financial institution failures will no doubt spark renewed debate about the public accountability of boards of for-profit corporations, especially in light of the extraordinary price paid by taxpayers. For in-depth analysis of past corporate failures,
area, the paucity of legal precedents on board duties is compounded by the lack of transparency, the absence of third parties (such as shareholders) with an interest in overseeing the corporation’s actions, and the limited resources of state attorneys general. While the duty of mission could serve as an important litmus test for board duties with respect to overseeing healthcare quality, it has been applied unevenly by attorneys general and the courts, and has not served as meaningful ballast. Although much of the case law delineating board duties of care and loyalty focuses on financial mismanagement and self-dealing, several landmark cases have established expectations for the duty of care that have direct application to board oversight of quality, particularly in terms of the duties to investigate and require adequate reporting systems.

One of the first notable cases to address board fiduciary duties to prevent corporate misconduct, *Graham v. Allis-Chalmers*, set forth dicta broadly protecting board members from liability for corporate or employee wrongdoing absent explicit knowledge of the wrongdoing or facts that should have put board members on notice of the conduct. In the 1963 case, stockholders brought an action against the directors for breach of the duty of care in failing to prevent violation of federal antitrust laws. Specifically, the complaint asserted that the board members had actual knowledge of the wrongful conduct or facts that could have put them on notice, or in the alternative, were liable for failure to take action to learn of and prevent antitrust violations. The court soundly rejected the notion that the board should have put a system in place to bring misconduct to its attention, stating in what would become oft-repeated dicta, “there is no duty upon directors to install and operate a corporate system of espionage to ferret out wrongdoing which they have no reason to suspect exists.” The court recognized, however, that board members could be held accountable for ignoring signs of wrongdoing through willful conduct or inattention to obvious signs of misconduct.

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63 Legal scholars have described the limited accountability of directors and the weaknesses in a regulatory framework dependent on state attorneys general with scarce resources to oversee a vast set of institutions. See Greaney & Boozang, *Mission, Margin, and Trust in the Nonprofit Health Care Enterprise*, at 19, 44–46.

64 Lamenting the weakness of the doctrine as it has been applied to date, Greaney and Boozang advocate “mission primacy” as one means to invigorate and inform board oversight. *Id.* at 82–84.


66 *Id.* at 130.
Eleven years later, the 1974 case of *Stern v. Lucy Webb Hayes National Training School* set a somewhat higher standard for conduct of non-profit boards.67 A class action brought by patients of Sibley Memorial Hospital, the suit asserted that board members had breached their fiduciary duties of care and loyalty in the management of Sibley’s funds. Specifically, the plaintiffs maintained that the board was negligent in managing hospital funds; the Finance Committee did not meet between 1960 and 1972, during which time the funds were in accounts that earned little or no interest at five financial institutions. Five of the hospital trustees held positions of responsibility at the five financial institutions, leading to the claim of breach of loyalty.

Stating that corporate directors are liable for their negligent mismanagement of corporate funds, the court went on to note that while trustees often are held to a negligence standard, a director “must often have committed gross negligence.”68 The court made clear that a director who fails to acquire the information necessary to carry out his or her supervisory role has breached the duty of care. The court also noted that a board member “whose failure to supervise permits negligent mismanagement by others to go unchecked has committed an independent wrong against the corporation.”69

*In re Caremark International Inc. Derivative Litigation* addressed the duties of a board of directors to oversee legal compliance—or as the court framed the issue, “corporate performance.”70 The suit was brought by shareholders of the for-profit corporation. They charged that the board’s failure to oversee compliance with federal anti-kickback laws resulted in significant financial losses to the corporation. Holding that the board members had not breached their duty of care, the court pointed to the fact that the board had taken numerous steps to oversee and promote compliance, including adoption of a policy to curtail certain payments to physicians, appointment of the chief financial officer to serve as compliance officer, and issuance of compliance guidance for employees.

The *Caremark* court noted the difficulty of holding board members of a nonprofit accountable for breach of duty in the absence of a conflict of interest or self-dealing, but went on to recognize two grounds for such accountability: (1) a board decision that is ill-advised or negligent, and (2) “an unconsidered failure of the board to act in

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67 *Stern v. Lucy Webb Hayes National Training School*, 381 F. Supp. 1003 (D. D.C. 1974). It is useful to note that *Stern* is unique in that the patients were given standing. In most jurisdictions, only the Attorney General has standing to pursue board misconduct.
68 *Id.* at 1013.
69 *Id.* at 1014.
circumstances in which due attention would, arguably, have prevented the loss.71 Expressly narrowing the broad sweep of the dicta in *Graham v. Allis-Chalmers*, the court stated that while boards have no affirmative duty to conduct investigations to identify wrongdoing, they can and should be held responsible for assuring that an effective information gathering and reporting system exists as a predicate for the board to fulfill its duty of care.72

In 2001, shareholders successfully pursued board personal liability for failure to act in the face of persistent board inattention to violations of federal quality standards.73 In *In re Abbott Laboratories Derivative Shareholders Litigation*, the Food and Drug Administration (FDA) had issued post-inspection and warning letters beginning in 1993 that informed the corporation of its failure to comply with quality standards designed to protect consumers from undue risk. The corporation’s safety failures were reported in the *Wall Street Journal* in 1995, and again in the press in 1999, after Abbott violated its obligations under an earlier voluntary compliance agreement with the FDA. In ruling for the plaintiffs, the court pointed to the “sustained and systematic failure of the board to exercise oversight” over a period of more than six years.74 Given the egregious nature of the board failure, the case does not establish a high bar for board conduct; however, the ruling set significant precedent by holding the board members personally liable for breach of the duty of care in the absence of a conflict of interest or self-dealing. The *Abbott* court stated that the board’s failure was tantamount to a lack of good faith, suggesting that in even in the face of the board’s long-term, serious failure, the court framed its decision in terms of willful conduct and lack of good faith, rather than relying solely on a finding of negligence.75 Subsequent cases followed suit, making it clear that directors who commit gross negligence by failing to take action will be presumed to have violated their obligation to act in good faith, and will fall outside the protection of the business judgment rule.76

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71 Id. at 967.
72 Id. at 970. However, the court qualified this statement in the context of personal liability, asserting “that failure to do so under some circumstances may, in theory at least, render a director liable . . . .”
73 In re Abbott Labs. Derivative Shareholders Litig., 325 F.3d 795 (7th Cir. 2003).
74 Id. at 809.
75 Id. at 809.
76 In a decision handed down the same year as *Abbott*, two outside directors were held personally liable for approving a transaction despite having no personal interest in the transaction. *In re Emerging Commc’n’s, Inc. S’holder Litig.*, C.A. No. 16415 (Del. Ch. May 3, 2004). See also *In re Walt Disney Co. Derivative Litig.*, 825 A.2d 275, 289 (Del. Ch. 2003) (finding the board’s failure to inquire about conditions and terms of executive compensation or to review any written agreements constituted lack of good faith to advance the best interest of the company); Stone *ex rel. AmSouth Bancorporation v. Ritter*, 911 A.2d 362 (Del. 2006). While board members have protection from the business judgment rule if they decide to take no action after an informed process, the
Despite Caremark’s recognition of the board’s duty to assure that an effective reporting system exists, the case law consistently reinforces the basic demarcation between the duties of the board and executive management; the board oversees the actions of executives, but is not itself responsible for managing day-to-day operations or conducting investigations without notice of the need to do so. The obligation to manage operations and senior staff in every realm, including quality measurement and improvement, is a management function. For example, the board is not responsible for developing a system of quality measurement and reporting, but must assure that an effective system exists and review the data it generates to evaluate the institution’s performance.

**Bringing Quality Within the Purview of Hospital and Board Duties**

As case law evolved to recognize minimum standards for board fiduciary duties, legal doctrines developed to establish hospital liability for quality, bringing the quality of care within the ambit of hospital board responsibilities. Until 1965, hospital boards of directors essentially had no obligations to oversee healthcare quality, except for the duty to use reasonable care in selecting physicians. The hospital was regarded as a venue in which physicians provided treatment, rather than as a direct provider of healthcare services. The 1965 decision in Darling v. Charleston Community Memorial Hospital upset that assumption as a matter of prevailing law. The plaintiff in Darling was an 18-year-old who broke his leg playing football. Due to negligent treatment provided by the physician on call in the emergency room on the day of admission, and thereafter by the physician and nurses, the plaintiff developed gangrene, resulting in the amputation of his leg. Rejecting the hospital’s assertion that it had no obligation beyond using reasonable care in selecting its physicians, the court stated in what is now well-settled law, “Present day hospitals, as their manner of operation plainly demonstrates, do far more than furnish facilities for treatment.”

While Darling set a precedent that quickly changed legal expectations and potential liability for hospitals, courts continued to grapple with whether hospitals should bear potential liability for the actions

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78 Id. at 257, 332. While Darling involved failure to use reasonable care in credentialing, later cases have broadened the duties of the hospital board. See Oehler v. Humana Inc., 775 P.2d 1271, 1272 (Nev. 1989); Fridena v. Evans, 622 P.2d 463, 466 (Ariz. 1980) (discussing emerging trend imputing inherent responsibility to monitor overall quality of care to hospitals).

In 1981, in \textit{Johnson v. Misericordia Community Hospital}, the court held the hospital liable for negligence in granting privileges to an orthopedic surgeon whose privileges had been revoked or limited at other hospitals.\footnote{Johnson v. Misericordia Cmty. Hosp., 301 N.W.2d 156 (Wis. 1981).} While the case rested on negligent credentialing, the court cited to \textit{Darling} and the hospital’s broader duties to evaluate the care it provides.

Following \textit{Misericordia}, a long line of cases upheld hospital liability under the theory of corporate negligence, recognizing that the hospital owes an independent duty of care directly to the patient.\footnote{Oehler, 775 P.2d at 1272 (hospital and governing board may be liable for failure to supervise treatment by non-employed physicians under corporate negligence theory of liability); Insigna v. Labelle, 543 So. 2d 209, 214 (Fl. 1988) (recognizing the corporate negligence doctrine as the independent duty the hospital owes to patients, and finding that because the hospital is in “a superior position to supervise and monitor physician performance,” it is “the only entity that can realistically provide quality control.”); Elam v. Coll. Park Hosp., 183 Cal. Rptr. 156 (1982) (hospital held liable under the doctrine of corporate negligence where independent contractors negligently performed pediatric surgery at the hospital); Pedroza v. Bryant, 677 P.2d 166 (Wash. 1984) (expressly adopting corporate negligence theory); Zambino v. Hosp. of the Univ. of Pa., No. 06-3561 (E.D. Pa. 2006) (discussing application of corporate negligence to hospital trustees); Carter v. Hucks-Folli, 505 S.E.2d 177 (N.C. 1998) (negligent credentialing).}

In essence, courts have acknowledged the reality that hospitals have many avenues to control the quality of care, including treatment protocols, quality initiatives, and oversight of nursing and other services, as well as the fact that patients do not distinguish between employed and independent medical staff physicians in their expectations for hospital quality of care or oversight.

\section*{State Oversight and Enforcement}

Nonprofit healthcare organizations are regulated by two independent sources of state authority: state attorneys general and public health departments. Within state governments, the primary authority to oversee nonprofit corporations is vested in state attorneys general, who have broad authority in relation to nonprofit organizations, including...
management of assets, fulfillment of mission, and closure. Through licensure and regulation, state health departments directly oversee the quality of healthcare delivered in a wide array of settings, and by extension have authority to set standards and to sanction boards of directors for failure to oversee quality.

**Oversight by state attorney general offices**

In the wake of scandals entailing financial management, failure to fulfill mission, and self-dealing in the late 1990s, state attorneys general became more proactive in overseeing nonprofit boards. By and large, state attorneys general have continued to focus on mismanagement and self-dealing by nonprofit boards. Accordingly, in the healthcare arena, state attorneys general have intervened primarily in matters outside the purview of healthcare quality, such as conversion to for-profit status, closure, and merger of facilities.

In the most extreme cases, state attorneys general have the authority to sanction or remove board members. In a 1999 case involving Allina Health System, the Minnesota Attorney General asserted that the structure of Allina Health System, which included entities that provided health services and health insurance, led to conflicting missions between the HMO (“to manage health costs and control premiums”) and the hospitals (to “act as caregivers to patients”). He petitioned for the authority to appoint the board of a new entity, effectively removing the Allina board members for conflict of interest.

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82 Fishman, *Improving Charitable Accountability*, at 265.


84 Thomas Greaney, *New Governance Norms and Quality of Care in Nonprofit Hospitals*, *14 Annals Health L.* 421, 423–44 nn. 8–12 (2005) [hereinafter Greaney, *New Governance Norms*] (discussing increased activism by state attorneys general). In one significant case, New York State Attorney General Andrew Cuomo launched an investigation in 2007 into physician-ranking programs by health plans, asserting that the rankings could mislead consumers by confusing quality with efficiency or cost savings. See discussion, note 44.

The Allina case, as well as other actions to sanction or remove nonprofit board members, demonstrate the significant authority state attorneys general can exercise in relation to nonprofit boards.86 Indeed, states are much closer to healthcare institutions than the federal government; they oversee fewer institutions and are more knowledgeable about institutional leadership and the communities served. Despite the fact that state attorneys general are often in the most suitable position to oversee execution of the duties of care and loyalty, their efforts are hampered by limited resources.87 On issues posed by healthcare quality, state attorneys general lack the expertise of state public health authorities and CMS.

Oversight by state public health agencies

States’ public health agencies generally have authority to prescribe and enforce measures for hospital compliance with minimum quality standards. This authority rests in their control of licensure for healthcare institutions.88 The primary mechanism for oversight is surveys.89 Most states rely on Joint Commission surveys to evaluate hospital quality, but some conduct their own surveys. In addition to state surveys, many states have established incident reporting systems as a mechanism to track and respond to adverse events.90 By January 2008, twenty-six states had implemented adverse event reporting systems; twenty-three of those had established their own lists of reportable events, while the other three used the NQF’s list of never events.91


87 Greaney & Boozang, Mission, Margin, and Trust in the Nonprofit Health Care Enterprise, 1, 4. See also Fishman, Improving Charitable Accountability, at 268 (“It has long been demonstrated that state attorney general offices have neither the person-power, nor sometimes the will, to monitor nonprofits effectively”).

88 Most states rely on Joint Commission licensure standards and often accept such accreditation as the basis for a license.

89 However, recent findings demonstrate the infrequency of such surveys. In February 2009, the U.S. Government Accountability Office (GAO) criticized CMS’s oversight of Medicare and Medicaid participating facilities, finding the time between surveys for facilities without statutory survey frequencies too long, which can increase the risk for quality problems. For example, as of September 30, 2007, approximately 2700 facilities (thirteen percent) had not been surveyed in six years or more. GAO Report to Congressional Requesters, Medicare and Medicaid Participating Facilities: CMS Needs to Examine Its Approach for Funding State Oversight of Health Care Facilities 27, GAO-09-64, Feb. 2009, available at www.gao.gov/new.items/d0964.pdf. CMS also found that twenty-five percent or more of some nursing home surveys in seven states missed serious deficiencies. Id. at 14.


91 Id. at A2 for a list of the states, the year each state implemented its system, the agency receiving the reports, the reportable event list the states use, and the number of adverse events reported in each state in 2006.
Most states that collect adverse event data (twenty-three of the twenty-six) use the information to hold hospitals accountable, although state reporting has been inconsistent and varied.\textsuperscript{92} State public health authorities conduct administrative reviews of data, and in the most serious cases can use the data to support a decision to revoke a hospital’s license.\textsuperscript{93}

As part of the public health oversight framework, states set standards for hospital and healthcare system boards. Most states set general standards for hospital boards; they do not delineate how the boards should fulfill the obligation to oversee quality, although most recognize the longstanding premise that the board has “ultimate responsibility” for quality. In many states, boards must credential medical staff and appoint the chief executive officer (CEO).

Besides these rather general standards, regulation of board oversight of healthcare quality varies state-to-state. For example, the New Jersey Department of Health and Human Services (DHSS) Code requires that “[t]he hospital shall have an established and functioning governing body responsible for establishing hospital-wide policy, adopting bylaws, maintaining quality of care, and providing institutional management and planning.”\textsuperscript{94} California law is unambiguous in vesting authority over quality of care in the board of directors, but it does not delineate how the board should implement this responsibility. The law requires hospitals to ensure that the medical staff is responsible to the governing body “for the adequacy and quality of the medical care rendered to patients in the hospital.”\textsuperscript{95}

New York’s law is more explicit.\textsuperscript{96} The New York Code states that the governing body is “legally responsible for the quality of patient care services, for the conduct and obligations of the hospital as an institution and for

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\footnote{92} Id. at 14. See also Modern Healthcare, Variation Seen in Adverse-Event Reporting (Dec. 16, 2008) (“Of the 26 states that operated event-reporting systems, 15 said hospitals don’t always report their adverse events, although all 26 states do use the information they collect in similar ways to improve patient safety”), available at www.modernhealthcare.com/article/20081216/REG/312169976. In addition, in many states, healthcare providers must report to the state when healthcare professionals commit egregious errors. See, e.g., N.Y. PUBL. HEALTH LAW § 2803-e, “Reporting incidents of possible professional misconduct; N.Y. PUBL. HEALTH LAW § 2805-l(1–2).

\footnote{93} However, as explained by public health staff in one state, “revocation could occur only after the hospital conducted an inadequate investigation of an event that was deemed ‘serious,’ did not develop an appropriate corrective action plan, failed to correct state-cited deficiencies, and was in the process of losing or had already lost its accreditation status.” DHHS OIG, Adverse Events in Hospitals: State Reporting Systems at 15 (Dec. 2008), available at www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf.

\footnote{94} N.J. ADMIN. CODE, § 8:43G-5.1(b), emphasis added.

\footnote{95} CAL. CODE REGS, tit. 22 § 70703(a), “Organized Medical Staff.”

\footnote{96} The New York Department of Health has the “central, comprehensive responsibility for development and administration of the state’s policy with respect to hospital and related services” due to the significance of providing health-related service “of the highest quality.” N.Y. PUBL. HEALTH LAW § 2800 (2008).}

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ensuring compliance with all Federal, State and local laws.97 The bylaws adopted by the governing body must specify how it and the medical staff interact, and how the governing body holds the medical staff accountable for its obligations to the community.98 New York law also requires that the governing body maintain “a coordinated program which integrates the review of activities of all hospital services for the purpose of enhancing the quality of patient care and identifying and preventing malpractice.”99 Like most states, New York requires the governing body to make the final decision to credential medical staff members and to appoint a medical director accountable to the governing body.100

States exercise oversight of board members in various ways, although generally there has been little discipline for poor quality of care by state attorneys general or public health agencies. Despite their disinclination to do so, states can impose penalties for board failures, although the most common penalty is a civil monetary penalty or fine imposed on the healthcare institution, not on the board members personally.101 For example, in 2007, California regulators imposed a $3 million fine on the nation’s largest nonprofit health plan for failure to provide adequate oversight of quality assurance programs, particularly with respect to patient complaint management.102 New Jersey adopted regulations in 2005 setting forth required periodic training for board members, including training on healthcare quality.103 In addition, the NJ DHHS may cite a hospital for a deficiency or impose monetary penalties, including for failure to have a functioning governing body responsible for maintaining quality of care. Legislation introduced in 2008 created an “Early Warning System” which provides the NJ DHHS with addi-
Federal Oversight of Healthcare Quality

Traditionally, the federal government exercised its responsibility to oversee quality with administrative surveys and sanctions, managed by CMS as the federal payor for healthcare. More recently, prosecution by the United States Office of Inspector General (OIG) and the Department of Justice have played an increasing role in federal oversight, as prosecutors have turned to enforcement of the False Claims Act (FCA) as a primary tool in combating poor quality of care. Moreover, under the Balanced Budget Act of 2005, states have financial incentives to pursue FCA enforcement. As a result, deferred prosecution and corporate integrity agreements have proliferated as a means to demand better performance of both institutions and the boards that oversee them.


105 The more interventionist steps include: (1) the Commissioner of Health meets with the board of directors; (2) the agency assigns consultants to participate in hospital board meetings; and (3) NJ DHHS appoints a monitor with the authority to override board decisions. Although NJ DHHS has not yet taken the most extreme of these steps, the agency has required organizations to create “management action plans” and has threatened further action which has led to quality improvement. New Jersey has not imposed sanctions for breach of fiduciary duty on any particular board members. In one instance, NJ DHHS sought relief from the State Attorney General, but no action was taken. Id. A list of New Jersey enforcement actions is available at http://nj.gov/health/healthfacilities/hospfines/summaries.shtml#bar043007.

106 See 10 N.Y. COMP. CODES R. & REGS. § 600.2(b)(2)(i) – (iii), “Requirements for Approval” (“The applicant must satisfactorily demonstrate to the council: that there is a public need for the facility or the proposed new facility; … if a nonprofit corporation, that the members of the board of directors and the officers of the corporation are of such character, experience, competence and standing as to give reasonable assurance of their ability to conduct the affairs of the corporation in its best interests and in the public interest and so as to provide proper care for the patients or residents to be served by the facility or the proposed facility”).
CMS standards

At the federal level, CMS has authority to set standards for hospital boards of directors as part of the Hospital Conditions of Participation (COP) in the Medicare programs. CMS standards established for boards of directors to date relate solely to the boards’ traditional role in overseeing the medical staff and granting final approval of medical staff credentials. Beginning in 1998, CMS set minimum health and safety standards for hospitals and providers to attain Medicare or Medicaid certification. In 2003, Medicare changed the COP standards to require hospitals to develop, implement, and maintain data-driven quality assessment and performance improvement programs, but did not include specific standards for boards of directors. However, institutions may be cited and penalized by CMS for a broad array of violations, including the failure of governance oversight.

Joint Commission accreditation is deemed sufficient to meet the requirements for Medicare participation and reimbursement. Like state statutes, the Joint Commission Leadership Standards vest ultimate responsibility for patient safety and quality in the governing body. Among other requirements, the Joint Commission standards require leadership to:

1. address conflicts among the leadership that could affect safety or quality;
2. create a culture of safety and quality, encourage teamwork, and provide education about quality to hospital employees;

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107 42 C.F.R. § 482.21 (2003); 42 C.F.R. § 488.5; 42 U.S.C. § 1395bb(a),(b), and § 1395x(e).
While CMS has authority to oversee hospital quality of care, it often does not actively do so, instead delegating compliance with such standards to the states. It has been argued that the federal government has been unable, “at a ground level,” to ensure quality of care. John P. Marren et al., The Hospital Board at Risk and the Need to Restructure the Relationship with the Medical Staff: Bylaws, Peer Review and Related Solutions, 12 Annals Health L. 179 (2003).


109 Joint Commission Standard LD.01.03.01. See The Joint Comm’n, Accreditation Program: Hospital Leadership (2008), available at www.jointcommission.org/NR/rdonlyres/D53206E8-D42B-416B-B887-491B6D5AA163/0/HAP_LD.pdf [hereinafter Accreditation Program: Hospital Leadership]. The standards also clarify that the governing body is responsible for providing the resources required to maintain safe, quality care, treatment, and services. JCAHO Medical Staff Standard 2 states that a medical staff should develop and adopt bylaws and rules and regulations as both a framework for self-governance and as a framework for “accountability to the governing body.” JCAHO Medical Staff Standard 2.
3. use data to improve the safety and quality of care, treatment, and services; and

4. establish structures and processes that focus on safety and quality.110

The Joint Commission also encourages the reporting of “sentinel events” that require immediate investigation and response.111 It should be noted that although Joint Commission standards provide specific steps to promote the safety and quality of care within hospitals, the standards do not delineate responsibility between the three elements of leadership: the board, medical staff, and senior management.

Federal enforcement on quality

As healthcare quality has gained prominence in the public eye, it also has become the focus of mounting attention and action by government enforcement agencies.112 Armed with data that is publicly reported or mined from the government’s Medicare and Medicaid databases, the United States Department of Justice, the OIG, and state attorneys general have pursued healthcare providers for poor quality of care as a violation of the FCA. In addition to Medicare and Medicaid databases, federal and state prosecutors seeking to target quality of care investigations may examine data publicly reported on hospital and nursing homes, state adverse events reporting systems data, and sentinel events reported to the Joint Commission.113 Under the Recovery Audit Con-

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110 Accreditation Program: Hospital Leadership,
111 Joint Commission, Sentinel Events, available at www.jointcommission.org/SentinelEvents/ (“A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.”). The Joint Commission makes a point of distinguishing between “sentinel events” and “medical errors.” See also Joint Commission, Sentinel Event Policy and Procedures, available at www.jointcommission.org/SentinelEvents/PolicyandProcedures/se_pp.htm. The Joint Commission sets forth specific requirements for an organization or hospital reporting a sentinel event. If the hospital or organization does not follow up as required, the Commission can deny accreditation. The Joint Commission collects and aggregates data from the review of sentinel events, but makes only the statistics, not individual cases, public.
112 See Alice Gosfield & James Reinertsen, Avoiding Quality Fraud, TRUSTEE pp.12–15 (Sept. 2008) [hereinafter Gosfield & Reinertsen, Avoiding Quality Fraud]. As reported by Gosfield and Reinertsen, James Sheehan, former federal prosecutor and now New York State Medicaid Inspector General, asserted that the federal government will pursue boards of directors for poor quality under the FCA, and enumerated four questions that will direct the government’s inquiry: (1) Has there been a systemic failure by management and the board to address quality issues? (2) Has the organization made false reports about quality or failed to make mandated reports? (3) Has the organization profited from ignoring poor quality or ignoring providers of poor quality? (4) Have patients been harmed by poor quality or given false information about quality? Id. at 3.
113 CMS is using a variety of sources in its datamining efforts, including data from the Hospital Quality Initiative and the Physician Quality Reporting Initiative. For a fuller discussion of these sources, see Cheryl Wagonhurst et al., The Quality of Care Cerberus: Payments, Public Reporting and Enforcement, 20 HEALTH LAW. *3 [Dec. 2007] [hereinafter Wagonhurst et al., The Quality of Care Cerberus]. State attorneys general use the Medicaid

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tractor (RAC) Program, CMS pays contractors a percentage of the overpayments contractors identify from their examination of Medicare claims submitted by healthcare facilities, physicians, and suppliers.114 The sanctions for violations of the FCA range from exclusion from federal and state healthcare programs to stiff monetary penalties; violation of the FCA may encompass criminal as well as civil penalties.115

In the compliance context, providers generally have been found liable for substandard quality of care under the FCA based on one of two theories: (1) the treatment billed for was medically unnecessary or (2) the quality of care was so poor that the services were essentially not delivered or worthless.116 In addition, the government has pursued enforcement actions against hospitals for failure to properly oversee and credential the quality of medical staff, and for violation of regulations, such as limitations on use of physical restraints.117

In quality enforcement actions under the FCA, the government asserts that the claim submitted for reimbursement was fraudulent. Each
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time a hospital or nursing home submits a claim, it must certify compliance with government statutes and regulations that are a precondition for payment, including the requirement that the care is medically necessary and appropriate. A false certification may be either express or implied. The implied certification theory has been more controversial, and has not been accepted by courts in all jurisdictions.

Government enforcement actions have resulted in substantial penalties for healthcare providers. Under the FCA, courts can impose fines from $5,000 to $10,000 per claim, and a penalty of three times the value of each service that was fraudulently billed. The government can recover for claims brought within six years of the date on which a violation was committed, or within three years of the date on which the government knew or should have known that a violation was committed. DOJ reported FCA settlements and judgments totaling $3.1 billion in 2006, over 70 percent of which was attributed to healthcare case settlements, and $1.34 billion in settlements in 2008.

For the past decade, enforcement of substandard quality of care has been a priority for the OIG, which can pursue administrative remedies, including exclusion from the Medicare program. In 2000, the OIG

118 See Mikes v. Straus, 274 F.3d 687, 698–99 (2d Cir. 2001); Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 786 (4th Cir. 1999). See also Krause, Healthcare Fraud and Quality of Care. Express false certification occurs when the statute or regulation by its terms requires certification of compliance and establishes that compliance is a prerequisite for payment. Mikes, 274 F.3d at 697–98. An implied false certification claim is based on the premise that submitting the claim implies compliance with statutes and regulations that the government would perceive to be preconditions to payment. Id. at 699. See also James E. Utterback, Substituting an Iron Fist for the Invisible Hand: The False Claims Act and Nursing Home Quality of Care—A Legal and Economic Perspective, 10 QUINNIPAC HEALTH L.J. 113 (2007).

119 See Mikes, 274 F.3d at 698; 703 (acknowledging that a worthless services claim is valid under the FCA, but limiting the use of the implied false certification theory to cases where the “underlying statute or regulation upon which the plaintiff relies expressly states” that the contractor must comply to get paid).

120 31 U.S.C. § 3729(a); 3731(b)(1)–(2) (2004). See Krause, Healthcare Fraud and Quality of Care.


122 See Wagonhurst et al., The Quality of Care Cerberus, at *3, n. 19, citing OIG’s Morris Tells AHHA to Watch for Increases in False Claims Act Cases, 10 BNA HEALTH CARE FRAUD REP., 524 (July 5, 2006) (Lewis Morris, Counsel to the U.S. DHHS OIG, explaining OIG’s focus on using the FCA “to combat quality of care violations in hospitals and nursing homes.”). For example, in U.S. v. United Mem’l Hosp., the hospital entered into a federal plea agreement admitting overutilization of pain management surgical procedures and inadequate credentialing of a practicing physician. Plea Agreement, Docket No. 1-CR-238 (W.D. Mich. Jan. 8, 2003). Two years before Tenet entered into the 2005 CIA

118 See Mikes v. Straus, 274 F.3d 687, 698–99 (2d Cir. 2001); Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 786 (4th Cir. 1999). See also Krause, Healthcare Fraud and Quality of Care. Express false certification occurs when the statute or regulation by its terms requires certification of compliance and establishes that compliance is a prerequisite for payment. Mikes, 274 F.3d at 697–98. An implied false certification claim is based on the premise that submitting the claim implies compliance with statutes and regulations that the government would perceive to be preconditions to payment. Id. at 699. See also James E. Utterback, Substituting an Iron Fist for the Invisible Hand: The False Claims Act and Nursing Home Quality of Care—A Legal and Economic Perspective, 10 QUINNIPAC HEALTH L.J. 113 (2007).

119 See Mikes, 274 F.3d at 698; 703 (acknowledging that a worthless services claim is valid under the FCA, but limiting the use of the implied false certification theory to cases where the “underlying statute or regulation upon which the plaintiff relies expressly states” that the contractor must comply to get paid).

120 31 U.S.C. § 3729(a); 3731(b)(1)–(2) (2004). See Krause, Healthcare Fraud and Quality of Care.


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1. absence of a comprehensive assessment of each resident’s functional capacity and a responsive care plan;
2. inappropriate or insufficient treatment to address residents’ clinical conditions, including pressure ulcers, dehydration, malnutrition, incontinence of the bladder, and mental or psychosocial problems;
3. failure to accommodate individual resident needs and preferences;
4. failure to properly prescribe, administer, and monitor prescription drug usage;
5. inadequate staffing levels or insufficiently trained or supervised staff to provide medical, nursing, and related services;
6. failure to provide appropriate therapy services;
7. failure to provide appropriate services to assist residents with activities of daily living (e.g., feeding, dressing, bathing, etc.);
8. failure to provide an ongoing activities program to meet the individual needs of all residents; and
9. failure to report incidents of mistreatment, neglect, or abuse to the administrator of the facility and other officials as required by law.

The recent proliferation of healthcare and pharmaceutical Corporate Integrity Agreements (CIAs) and Deferred Prosecution Agreements (DPAs) reflects the federal government’s escalating com-
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compliance scrutiny.\footnote{Commentators have predicted that the number of quality-based enforcement actions will continue to increase. Carl Jean-Baptiste, \textit{Dropping the "Boom" on Healthcare}, Mo. B.J. 32, 36 (Jan./Feb. 2009).} The agreements with hospitals, pharmaceutical companies, and other healthcare entities have clear implications for board leadership.\footnote{\textit{See November 2008 CIA with Bayer Corporation, which includes “specific requirements for the board of directors and management that will enable the OIG to closely monitor company practices affecting Federal health care programs and beneficiaries.” Press Release, U.S. D.O.J., Bayer Healthcare to Pay U.S. $97.5 Million to Settle Allegations of Paying Kickbacks to Diabetic Suppliers (Nov. 25, 2008), available at www.usdoj.gov/usao/fls/PressReleases/081125-01.html. In January 2009, Eli Lilly \& Co. entered into a five-year CIA with the OIG as part of a $1.4 billion settlement, with similar requirements. Press Release, U.S. D.O.J., Eli Lilly \& Co. Corporate Integrity Agreement (Jan. 14, 2009), available at www.usdoj.gov/civil/ocl/cases/Cases/Eli_Lilly/Corporate%20Integrity%20Agreement%20Eli%20Lilly.pdf.} Specifically, CIAs and DPAs have delineated the expectations and roles of the board and identified detailed oversight remedies.\footnote{Healthcare organizations and other entities enter into CIAs with the OIG (or DPAs with the U.S. Attorney’s Office) to settle investigations arising out of false claims and other legal violations. Some commentators assert that DPAs permit the federal government to take an intrusive role in “policing, and supervising, corporate America.” See Peter Spivack \& Sujit Raman, \textit{Regulating the ‘New Regulators’: Current Trends in Deferred Prosecution Agreements; 45 Am. Crim. L. Rev. 1, 3 (2008); Kathleen Boozang \& Simone Handler-Hutchinson, “Monitoring” Corporate Corruption: DOJ’s Use of Deferred Prosecution Agreements, Am. J. Med. (forthcoming 2009) [hereinafter Boozang \& Handler-Hutchinson, “Monitoring” Corporate Corruption].} Recent CIAs all set forth core requirements for the entities’ boards of directors, including the responsibility to oversee and certify that the corporation is in compliance with the agreement and federal law.\footnote{According to the OIG website, the most comprehensive CIAs have certain elements in common, such as the requirement to implement a comprehensive employee training program and provide an implementation report and annual reports to the OIG on the status of the entity’s compliance activities. U.S. H.H.S. O.I.G., \textit{Corporate Integrity Agreements, available at www.oig.hhs.gov/fraud/cias.asp. They also include specific requirements for board action, such as the requirement to hire a compliance officer or appoint a compliance committee, to establish a quality assurance monitoring committee as part of the board of directors, and to develop written standards and policies. For example, the Green Valley Pavilion CIA, discussed below, requires that “the Board of Directors may determine to appoint itself or a committee of its members to serve as the [Compliance] Committee.” Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Green Valley Pavilion et al. 3 (May 2007), available at http://oig.hhs.gov/fraud/cia/agreements/green_valley_pavilion_05012007.pdf [hereinafter \textit{Green Valley Pavilion CIA}]. However, CIAs are tailored to the particular circumstances of misconduct. A list of all CIAs, CCAs, and Settlement Agreements with Integrity Provisions for healthcare providers and entities is available at www.oig.hhs.gov/fraud/cia/cia_list.asp. As of February 2009, the site listed 480 entities with whom the OIG has entered into such agreements since 2000, including hospitals and nursing homes.}

While most CIAs address financial issues, prominent settlements have focused on healthcare quality. In 2001, Vencor, one of the nation’s largest operators of nursing homes and long-term hospital services, was accused of submitting false claims to Medicare, Medicaid, and TRICARE, the military’s healthcare program, based on poor quality
of care and failure to staff its facilities adequately. The company entered a five-year CIA mandating a comprehensive quality assurance infrastructure at the corporate, regional, and facility levels. The CIA required quality committees to collect and review quality-related data to identify problems, determine the root cause of the problems, develop corrective action plans to improve care, and monitor the effectiveness of the interventions to ensure overall improvement in the quality of care and services delivered.

The September 2006 CIA with Tenet Healthcare Corporation was a watershed agreement because of the broad sweep of provisions directing board conduct to oversee quality of care. The five-year CIA required the Quality, Compliance, and Ethics Committee of the board to review the effectiveness of Tenet’s compliance program and adopt resolutions summarizing its review of the company’s compliance with the CIA and federal healthcare program requirements. The Tenet officers were required to certify the Medical Center’s compliance with the CIA and submit annual reports to the OIG. In addition, the CIA required an independent entity to assess (1) Tenet’s compliance with its written policies and procedures to achieve compliance with federal healthcare program requirements, and (2) the “effectiveness, reliability, and thoroughness of Tenet’s quality management infrastructure and systems throughout Tenet.”

In 2007, the OIG charged that Green Valley Pavilion, operated by the Green Acres Health System, had forged and altered patient charts to maximize reimbursement from Delaware’s Medicaid Program. The Health System entered into a four-year CIA requiring creation of a board Quality Assurance Compliance Committee to address allegations of neglect and poor quality of care. The CIA also mandated a board Quality Assurance

130 Id. The 2005 CIA with HealthSouth also contained provisions requiring board of director oversight, but the CIA is not as far-reaching as the Tenet CIA in outlining the requirements. HealthSouth Corporate Integrity Agreement (Jan. 1, 2005), available at www.oig.hhs.gov/fraud/cia/agreements/healthsouth_corporation_01012005.pdf.
131 Tenet CIA, at 60–64; Gosfield & Reinertsen, Avoiding Quality Fraud.
Monitoring Committee to “review the adequacy of Green Acres’ system of internal controls, quality assurance monitoring, and patient care.” 132 Finally, the CIA required a nurse consultant/monitor to inspect Green Valley Pavilion (and five other facilities owned by Green Valley Pavilion’s parent company) and report to Green Acres and the OIG on the facilities’ compliance with applicable regulations and standards of care. 133

A more recent CIA entered into by Corona Care Convalescent Corporation obliged the organization to create a board committee to oversee the quality of care. 134 This committee is required to:

- review the adequacy of [Corona]’s system of internal controls, quality assurance monitoring, and patient care;
- ensure that [Corona]’s response to state, federal, internal, and external reports of quality of care issues is complete, thorough, and resolves the issue(s) identified; and
- [make sure] that [Corona] adopts and implements policies and procedures [ ] designed to [provide] each individual [with] the highest practicable physical, mental, and psychosocial level of care attainable. 135

The board committee must be readily available to the compliance officer and the independent monitor. As under the Green Valley CIA, the monitor is responsible for assessing the effectiveness of the Corona Care internal quality control system and the facility’s response to quality of care issues, and for reporting to Corona Care and the OIG on the facility’s compliance with regulations and standards of care.

Outside the quality arena, CIAs and DPAs entered into for violation of federal and state laws demonstrate both the breadth of remedies that government may demand in relation to boards of directors and the concomitant loss of board authority over governance and operations. 136 For example, in 2005, the University of Medicine and Dentistry of New Jersey entered into a Corporate Integrity Agreement with the OIG of the HHS. 137

132 Green Valley Pavilion CIA.
135 Id.
136 For a discussion of the trend in CIAs and DPAs, as well as the breadth of remedies incorporated into the agreements, see Boozang & Handler-Hutchinson, “Monitoring” Corporate Corruption.
New Jersey (UMDNJ) entered into a DPA for violation of the anti-kickback law, hiring practices that favored those with political connections, and other matters.\textsuperscript{137} The DPA required appointment of a federal monitor with substantial authority to conduct ongoing investigations. The U.S. Attorney’s Office for the District of New Jersey appointed a federal monitor to oversee the activities of the leadership (board, CEO, and senior medical staff), including governance procedures and structures, cost reporting and billing, and conflicts of interest.\textsuperscript{138} When the monitor was eventually released, the board had been reconstituted from six members to a more diverse eighteen, and the CEO, general counsel, and chief compliance officer had all been replaced, with input from the monitor.

**Mounting federal expectations for boards**

Heightened federal and state enforcement for poor quality of care has occurred amidst rising standards for board oversight of corporate compliance and financial management. Issued in 1991, the *Federal Sentencing Guidelines for Organizations* (the Sentencing Guidelines) was one of the earliest federal statements to underscore board obligations to prevent corporate misconduct.\textsuperscript{139} Applicable to nonprofit as well as for-profit corporations, the Sentencing Guidelines expressly recognize that an effective compliance and ethics program can mitigate the sentence for a corporation. Setting forth principles that may undergird future government compliance guidance and enforcement action, the Guidelines stress that a necessary element of a compliance program is a board that is knowledgeable about the organization’s compliance program and exercises reasonable oversight of the program’s effectiveness.

In 2006, the Department of Justice amplified the importance of board conduct in prosecutorial decisions about corporate culpability in a memorandum by Deputy Attorney General Paul McNulty.


\textsuperscript{138} Vasilios J. Kalogredis, *N.J. University and Hospital Released from Monitorship*, 237 LEGAL INTELLIGENCE 45 (2008). UMDNJ was required to adopt the monitor’s recommendations for improvement unless the U.S. Attorney’s Office agreed with UMDNJ that such a recommendation should not be adopted.

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The McNulty Memorandum advised prosecutors that in deciding about charges against a corporation and penalties, they should take into account certain enumerated factors, including the pervasiveness and history of the problem, and the corporation’s pre-existing compliance program. Citing the Caremark decision, the McNulty Memorandum turned to the role of the board, advising that prosecutors can take into account:

1. governance practices to identify wrongdoing;
2. whether board members exercise independent judgment in reviewing transactions;
3. whether they receive sufficient information to do so; and
4. whether the directors have established an information and reporting system reasonably designed to provide the board with timely and accurate information to make an informed judgment about legal compliance.

In February 1998, OIG issued its Compliance Guidance for Hospitals, setting forth expectations for the goals and operation of an effective compliance program and enumerating the basic elements of any such program. The Compliance Guidance for Hospitals underscored the importance of culture and leadership for compliance, with specific guidelines for boards. At the outset, the Compliance Guidance for Hospitals noted, “The OIG believes that every effective compliance program must begin with a formal commitment by the hospital’s governing body to include all of the applicable elements . . . .” Among


141 While recognizing that the existence of a corporate compliance program is not sufficient by itself to justify a decision not to charge the corporation with criminal conduct, the memorandum stated that an active, well-designed program—or its absence—could play a role in prosecutorial decisions. Paul McNulty, Deputy Attorney Gen., U.S. Dept of Justice, Principles of Federal Prosecution of Business Organizations, at 4 (Dec. 12, 2006), available at www.usdoj.gov/dag/speeches/2006/mcnulty_memo.pdf.

142 Id. at 14.


144 Id. at 8,989. The seven elements cited were: (1) written standards of conduct as well as policies and procedures to promote compliance; (2) a Chief Compliance Officer charged to operate the compliance program who reports to the CEO and Board of Directors; (3) training programs for all employees; (4) a process to receive complaints; (5) a system to respond to allegations of wrongdoing and disciplinary action against employees who violate compliance policies or federal or state law; (6) audits or other methods to monitor compliance; and (7) investigation and remediation of identified systemic problems and policies addressing sanctioned individuals. These same basic elements were set forth in the Compliance Guidance for Nursing Homes. Publication of the OIG Compliance Program for Nursing Facilities, at 14,289.
the elements cited is the designation of a Chief Compliance Officer who reports directly to the CEO and the governing body. The document also highlights the importance of accountability, asserting that the evaluation of managers and supervisors should include their performance in promoting and adhering to compliance. Two years later, the OIG issued the Compliance Program Guidance for Nursing Facilities, reiterating the importance of the board’s role and the need for direct reporting about compliance to the board.145 Updated revised compliance guidance statements were issued for hospitals and nursing homes in 2005 and 2008, respectively. Notably, both statements emphasize that, among other benefits, implementation of a voluntary compliance program “may significantly reduce the risk of unlawful conduct and corresponding sanctions.”146

Adopted in 2002 in the aftermath of corporate scandals such as Enron, Worldcom, and Arthur Anderson, the Sarbanes-Oxley Act sought to create more stringent standards for board accountability for financial management. While Sarbanes-Oxley applies only to public companies, it carried over into the nonprofit arena, establishing expectations for best practices, although not for legally mandated change.147 Among other actions, Sarbanes-Oxley required boards to appoint an independent audit committee, include financial expertise on the board, train board members in financial literacy, and oversee the credentials and work of the auditing firm retained by the corporation.

Over recent years, the IRS has steadily increased both its focus and standards for board governance of tax-exempt organizations.148 Central to tax-exempt status is the notion that the organization must serve public and not private purposes. In 2002, the IRS issued final rules prohibiting “excess benefit transactions” for those in a position to influence corporate decisions, including explicit guidance for a process to

145 Publication of the OIG Compliance Program for Nursing Facilities at 14,289.
148 IRS rules for tax exemption have broad and complex application to nonprofit entities, with issues such as the requirement to provide community benefit that have particular salience for healthcare facilities. It has been argued that in recent years, the IRS “has become the primary regulator of nonprofit behavior.” James Fishman, Improving Charitable Accountability, 62 Mo. L. REV. 218, 265 (2003). See also Thomas Greaney, Nonprofit Governance, Norms and Quality of Care in Nonprofit Hospitals, 14 ANNAALS HEALTH L. 421, 426 (2005) (“The IRS has long served as a de facto monitor of corporate governance in the nonprofit sector.”).
set executive compensation that would create a rebuttable presumption of reasonableness.\textsuperscript{149} In February 2008, noting the strong link between good governance and tax law compliance, the IRS released a detailed memorandum recommending good governance practices for tax exempt organizations.\textsuperscript{150} The recommended practices cover significant ground, calling for, among other steps, an explicit statement of mission, a clear framework for governance, independent board members, and written policies on conflicts of interest and protection for whistleblowers. The emphasis on transparency and executive compensation was amplified by the release later in 2008 of the revised 990 tax form for nonprofits, which significantly expanded disclosure of governance practices and executive compensation.\textsuperscript{151}

Drafting a roadmap for boards: the OIG-AHLA Joint Statement and the NQF guide

The most explicit federal guidance about board fiduciary duties on quality issued to date is set forth in a 2004 joint statement issued by OIG and the American Health Lawyers Association (the Joint Statement).\textsuperscript{152} Identified as an educational resource for boards, the

\textsuperscript{149} IRS Code § 4958.


\textsuperscript{151} IRS Code § 4958. Executive compensation has been a sustained area of focus for the IRS. In 2007, it released the results of a study of executive compensation by nonprofit entities, indicating significant problems with reporting of the compensation on 990 tax forms. Report on Exempt Organizations Executive Compensation Compliance Projects Parts I and II (March 2007), available at http://www.irs.gov/pub/irs-tege/exec._comp._final.pdf. In August 2008, the IRS finalized the new Form 990, which requires, for the first time, reporting on specific board governance practices such as board composition and transparency, in addition to seeking more information about executive compensation. The 2008 Form 990 is available at http://www.irs.gov/pub/irs-pdf/f990.pdf.

Joint Statement sets forth proactive best practices by boards. It does not specify grounds for enforcement in terms of poor or prohibited conduct.\textsuperscript{153} Nonetheless, the actions recommended in the Joint Statement may inform federal and state prosecutors as they weigh enforcement decisions. The Joint Statement recognizes the heightened focus on quality and concomitant heightened expectations for boards, “[w]ith a new era of focus on quality and patient safety rapidly emerging, oversight of quality also is becoming more clearly recognized as a core fiduciary responsibility of health care organization directors.”\textsuperscript{154}

At the outset, the Joint Statement summarizes board fiduciary duties for quality, asserting that boards are responsible for overseeing patient safety and healthcare quality. The Joint Statement urges that as attention is increasing on quality of care, boards adjust their practices to be responsive to a changing national environment.\textsuperscript{155} In addition, the Joint Statement stresses that quality has emerged as an enforcement priority for federal and state regulators. Accordingly, it advises boards to seek regular reports about compliance risks posed by poor quality, and about the organization’s system to minimize and monitor these risks. The Joint Statement points to new financial arrangements at the intersection of quality and compliance that require oversight, including pay-for-performance, gainsharing, and outcomes management.\textsuperscript{156}

The core of the Joint Statement is a series of questions designed to shape the board’s duties in overseeing healthcare quality. The questions guide a board’s inquiry into the design and implementation of the organization’s program on patient safety and quality, and the means to fulfill the board’s oversight obligation. The questions cover the following issues:

1. the goals for quality and the measures to assess those goals;
2. the means to improve patient care and quality, and accountability among key management and clinical staff for process and outcomes;

\textsuperscript{153} The Joint Statement lacks the weight of regulation, an opinion letter, or a formal guidance statement. Referring to the questions delineated to inform board inquiry in overseeing quality, the Joint Statement asserts that the questions raised in the document “are not intended to set forth any specific standards of care ...” OIG & AHLA, CORPORATE RESPONSIBILITY AND HEALTH CARE QUALITY: A RESOURCE FOR HEALTH CARE BOARDS OF DIRECTORS at 1 (2007), available at www.oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf.

\textsuperscript{154} Id. at 1. The Joint Statement notes that the heightened focus on quality “increasingly impacts the responsibilities of corporate directors.” The Joint Statement implicitly recognizes that board oversight of healthcare quality has not been central to the board duties of care and obedience.

\textsuperscript{155} Id. at 4.
\textsuperscript{156} Id. at 3.
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3. operational policies and practices to support and monitor quality of care;
4. the board’s own competence to oversee quality, focusing on board training and expertise;
5. the information essential to the board to oversee quality, and a timetable for reports to the board;
6. coordination between the corporate compliance program and patient safety, and integration of quality concerns into corrective action plans;
7. mechanisms to foster internal reports of quality problems;
8. the allocation of resources for quality improvement and patient safety;
9. the alignment of medical staff credentialing standards and peer review with the organization’s quality goals and measures; and
10. the response to adverse events both by the organization and by the board, so that the events are identified, analyzed, and addressed effectively.

In relation to this last goal, the Joint Statement notes the growing body of data that can point to patient safety concerns, including hospital quality data reported to CMS, adverse events reported to many state governments, and peer review reporting conducted in accord with the Health Care Quality Improvement Act.\(^{157}\)

In 2004, the National Quality Forum (NQF) also released a guide for hospital boards of directors on fiduciary duties to oversee quality and patient safety.\(^{158}\) Hospital Governing Boards and Quality of Care: A Call to Responsibility begins with the statement that “board members often express confusion and uncertainty about what exactly they need to do to fulfill their responsibilities” to oversee healthcare quality.\(^{159}\) The NQF guide urges board engagement in many of the oversight actions proposed by the Joint Statement, with some additional guidance. The guide emphasizes that hospital governing boards must develop “quality literacy,” including familiarity with the structures in place to support patient safety, quality improvement, and measurement. It also under-

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\(^{157}\) Id. at 11. While recognizing that these sources of data are a resource to the board, the Joint Statement cautions boards to seek legal counsel about the confidentiality protection accorded some of the information, and to proceed in a way that does not unnecessarily increase the organization’s exposure to liability.

\(^{158}\) NAT’L QUALITY FORUM, HOSPITAL GOVERNING BOARDS AND QUALITY OF CARE: A CALL TO RESPONSIBILITY (Dec. 2004), available at www.qualityforum.org/pdf/reports/call_to_responsibility.pdf. The recommendations in the document were prepared with input from experts in board fiduciary duties, healthcare measurement and quality, hospital leadership, and consumer organizations.

\(^{159}\) Id. at 1.
scores the board’s role in following up on poor performance on quality or safety measures, and the value of incentives for hospital executives to advance high performance.

**The Role of Health Systems on Healthcare Quality**

In general, a board of director’s statutory obligation to oversee quality and common law fiduciary duties of care and mission are non-delegable. Thus, parent boards of a health system of hospitals, nursing homes, and other entities that deliver healthcare services cannot supplant the boards of the facilities in overseeing quality. In some states, parent boards can share this responsibility with the entity board, subject to the express approval of state public health authorities. While health system boards in general do not assume direct responsibility for overseeing quality of care, it is conceivable that they could be held accountable for poor quality if they exercise corporate authority to interfere with the subsidiary entities’ efforts to improve quality or address quality-related compliance risks.

Some health systems have adopted mirror boards for parent and (one or all) subsidiary entities, establishing that the parent and subsidiaries have the same members on the boards of directors. In this governance model, the parent and subsidiary entities do not share responsibility for healthcare quality. The board of the facility, observing corporate formalities of separate meetings, minutes and resolutions, oversees quality at the facility. While this model of corporate governance reduces conflict between entities within the system, streamlines the number of meetings, and centralizes control, it presents serious challenges to a board in fulfilling its duties to oversee matters as complex and demanding as finance, quality, and compliance for numerous entities throughout the health system.

160 For example, in New York state, hospitals can delegate or share operating authority with a parent entity if that entity has applied for and received state approval to serve in effect as a co-operator of the facility under Article 28 of the Public Health Law. In this process, proposed certificates of incorporation and bylaws for the parent entity and subsidiary facility must delineate the respective responsibilities for the entities on healthcare quality and other areas of operation.

161 For example, if the parent entity demanded budget cuts that reduced staffing to a level that created risks to patient safety, or insisted on policies that led to poor care, state public health authorities might seek to hold the entity accountable.

162 In some states, such as New York, the health system board can share responsibility for healthcare quality, subject to the governance documents and state approval. See Edward Kornreich, *Corporate Governance Issues Faced by Orchard Health*, 9 HEALTH LAW J. 20, 22 (2004).

163 However, as found in a recent study, boards of health systems are more likely than hospital boards to have a separate committee on quality, which could undertake oversight of numerous entities. J. Jiang et al., *Board Engagement in Quality: Findings of a Survey of Hospital and System Leaders*, 53 J. HEALTHCARE MGMT. 121 (2008) [hereinafter Jiang et al., *Board Engagement in Quality*].
Expertise and leadership on quality will vary from institution to institution in any health system. Although health system boards do not have direct responsibility for quality of care, they can play an important role in improving quality by providing expertise, setting benchmarks for performance, and holding the subsidiary boards accountable for high performance on quality.164 The health system can offer training and protocols to enhance quality, and establish system-wide quality improvement initiatives and goals. Like the subsidiary boards, the health system board can contribute to a culture that values and recognizes high performance on quality.

Board Engagement on Quality: What the Data Show

Several recent studies provide insight into the level of board involvement, specific activities boards undertake, and the attributes of board activity associated with higher-performing hospitals.165 Overall, the data show a high level of board involvement in terms of review of quality measures and setting goals on quality, with more equivocal findings on board effectiveness as evaluated by chief executive officers.

Board time devoted to quality varies widely, ranging from less than five percent to more than twenty-five percent.166 Most hospital and health system boards use quality dashboards to review quality performance, and most dashboards include the CMS Quality Compare Measures. There is wide variation, however, in how boards and institution-based leaders use the dashboards.167 Health system boards are more likely than hospital boards to use quality dashboards, to incorporate national benchmarks in those dashboards, and to have a committee of the board devoted to quality.168

Hospitals or health systems where boards use dashboards with fewer measures and review them more frequently perform better in terms of quality of care.169 Board use of the dashboards for two years or longer

164 Many health systems may be doing so, given the preponderance of quality committees at the board health system level. Id. The health system’s role in quality for subsidiary organizations should be delineated in its mission statement and corporate documents.


166 Vaughn et al., Engagement of Leadership in Quality Improvement Initiatives, at 3.

167 The study of 139 hospitals by Kroch et al. found that 87% of hospitals used a dashboard on quality; the study of 562 hospitals and health systems by Jiang et al. found a virtually identical percent, 86.7.

168 Jiang et al., Board Engagement in Quality, at 129. 86% of health system boards have a committee of the board devoted to quality vs. 58% of hospital boards.

169 Kroch et al., Hospital Boards and Quality Dashboards, at 18.
is also associated with higher hospital performance on quality. In addition, the involvement of a board quality committee in developing the content of the quality dashboard is associated with a significant difference in quality outcomes. One study examined the association between the existence of a board committee devoted to quality of care and other markers of board engagement on quality, concluding that boards with a quality committee performed significantly better on all measures of engagement; the boards were more likely to:

- use quality dashboards (91% versus 79%);
- set strategic goals for quality (89.5% versus 68.2%);
- set the agenda for the board discussion on quality (48.8% versus 32.6%);
- include measures of quality and patient safety in executive performance evaluation (61% versus 45%); and
- issue a written policy on quality communicated throughout the organization (34% versus 26%).

Larger hospitals and those in the northeast were more likely than smaller hospitals to have board quality committees.

Another study that examined different potential correlates between quality outcomes and quality leadership found that the following four factors were associated with better outcomes:

1. facilities with boards that spend more than twenty-five percent of board meeting time on quality;
2. a high level of interaction between board members and medical staff leaders in setting the hospital’s quality agenda;
3. identification of the CEO or COO by hospital leaders as the person with the “greatest impact” on quality; and
4. compensation of senior executives based in part on quality improvement performance.

Interestingly, the same study found a sharp difference in perception between CEOs and chief medical officers (CMO)/quality improvement (QI) executives about the most significant change that could improve quality. CEOs were more likely to cite physician engagement as the change factor. CMOs and QI executives ranked health information

170 As stated by the study authors, “Perhaps the most important finding of this study is that hospitals in which the board quality committees are strongly involved with the development of the dashboard content had significantly higher performance ….” Id. at 16.
171 Jiang et al., Board Engagement in Quality, at 129.
172 Id. at 129.
technology as more significant. In the one study that asked CEOs about board performance on quality, less than half the CEOs rated the board’s performance highly.

**Where Do Boards Go From Here?**

Devised as a platform for improvement and pay-for-performance, scientific advances in quality measurement and reporting have changed both the tools and expectations for board oversight of healthcare quality. A passive role for the board in reviewing credentialing decisions has been replaced by an emerging paradigm of a board that is better informed, better able to lead, and more accountable for quality of care. Significantly, recent studies of board engagement on quality all suggest that many hospital boards are actively undertaking quality oversight.

As set forth in the roadmap laid out by the joint OIG-AHLA statement on board fiduciary duties, boards should undertake an array of tasks ranging from regular review of quality measures, training to understand the metrics for quality, creation of goals, and evaluation of resources and staff assigned to quality of care. In the traditional governance model, board members often were recruited primarily for their financial expertise and capacity to donate or raise funds. In the face of far more data and rising expectations for board oversight of quality, it is critical that boards evaluate their membership to determine if they have the expertise and passion for quality to drive board engagement and leadership. As suggested by the study by Kroch et al., boards that have a quality committee perform better on all measures of engagement and leadership.

Boards should understand the measures used across all three dimensions of quality and require a strategic plan for how the institution will improve performance in each area, including accountability for improvement among administrative and medical leadership. Boards also should set priorities for patient safety and quality, in consultation with executive and medical staff leadership. Public quality measures provide key information for boards and must be part of an overall strategy for quality measurement and improvement. Boards should rely upon serious adverse or never events and near misses, as well as assessment of quality concerns by the medical and nursing leadership, to identify other areas for improvement. Priorities also should establish

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174 *Id.* at 5.
175 The CEOs were asked to rate board performance on a scale of 1 to 6, with less than half the boards receiving a score of 5 or 6. Jiang et al., *Board Engagement in Quality*, at 125.
176 See Kroch et al., *Hospital Boards and Quality Dashboards*; Jiang et al., *Board Engagement in Quality*; Vaughn et al., *Engagement of Leadership in Quality Improvement Initiatives*.
177 Kroch et al., *Hospital Boards and Quality Dashboards*. 
priorities or maintain practice areas of excellence key to the institution’s reputation and brand.

Boards will need to evaluate where their institution stands on quality in a comparative sense, i.e., compared to the peer group for their institution in terms of academic or community hospital, size, and/or region. Boards should ask management for dashboards on quality that present the information in an actionable, concise form, and should be engaged in determining which measures are provided in the quality dashboard. For serious adverse events, boards should take an active role in seeking a corrective action plan and monitoring by appropriate staff to prevent further similar incidents.

Finally, boards should seek data to evaluate risks and seek needed improvement at the intersection of quality and compliance. With CMS undertaking datamining to pursue and target investigations for poor quality, boards should seek information that can be generated from financial and care delivery databases to flag quality of care deficiencies that would trigger enforcement. To undertake the task, the board should seek a coordinated approach from leadership in quality and compliance.

Recommendations for Government Oversight

Comparative quality measures and public reporting give government new information and tools to oversee quality. While most states have relied on periodic Joint Commission surveys and self-reporting of serious adverse events to drive investigation of serious quality concerns, states can now use quality measures to identify facilities that might have serious deficiencies in care. Measures of quality for medical treatment and certain measures of patient satisfaction (such as those that focus on adequate treatment for pain and acknowledgement of a patient’s treatment choices) should be reviewed by government to determine if patient care is so deficient that it places patients at risk. State governments and the Joint Commission should reevaluate the timing and nature of surveys in light of available quality data, giving consideration to more targeted assessments that focus on either poorly performing institutions or areas of care delivery where the data indicate poor care.178

At the state level, attorneys general have the most direct oversight responsibility to oversee board performance in fulfilling their fiduciary duties of care, loyalty, and mission. Unquestionably, quality is core to

mission for healthcare institutions, and a state attorney general could choose to reprimand or even replace a board of directors in an institution with severe, persistent quality problems that place patients at risk. At the same time, attorneys general are not familiar with quality of care metrics or delivery, which fall under the oversight of state health departments and CMS as payors and regulators of quality. For this reason, oversight of board performance on quality should rest with the agencies most able to carry out the responsibility.

The government’s approach to evaluation of board leadership should follow a pattern similar to compliance; demonstration that the board has focused on quality to provide leadership should be exculpatory or reduce the size of any penalty, while board failure to address serious, persistent problems should be taken into account. The connection between leadership, quality, and culture is well recognized, and boards should be held accountable for serious quality problems if data available to the board suggest that the problem has persisted over time without attempts to improve.

**Conclusion**

Legal doctrines enunciating board fiduciary duties, as well as state statutes vesting ultimate oversight of the quality of care in the board of directors, had little impact on the board’s role in improving patient safety and quality throughout the twentieth century. As reflected in the landmark report, *To Err is Human*, as well as in studies that preceded and followed it, serious medical errors leading to patient death or injury routinely occurred in healthcare facilities. The legal doctrine recognizing hospital responsibility for quality of care first handed down in *Darling v. Charleston* in 1965, and the rising tide of malpractice litigation that followed, did remarkably little to change the structure and nature of leadership on quality within healthcare institutions. Boards provided final approval for credentialing decisions, but mostly deferred to the organized medical staff as the locus of control and oversight of quality.179

Until recently, systemic barriers impeded quality improvement, including the independence of the medical staff, the lack of reliable, comparative measures of quality, the lack of transparency in quality, and, most significantly, the absence of a business case for quality, with

healthcare financial incentives misaligned to reward quality improvement. In many respects, public and private payors, frustrated by the lack of national and institutional progress on quality, have driven the quality agenda.

Medical staff control over quality rested in part on physicians’ exclusive access to information about the quality of care. With the movement toward publicly reported measures, healthcare boards of directors are no longer dependent on the medical staff for information about performance across all three dimensions of quality: patient safety, quality improvement, and patient satisfaction. The expanding use of information systems, including the electronic medical record and bar coding that generate significant databases on quality under administrative control, add to institutional capacity to develop quality reports and increase board access to information.

Courts have not held healthcare boards to a duty to investigate to identify quality of care problems, recognizing that board members could rely on the CEO and other senior officers to bring problems to their attention, including poor quality of care. Once notified of a concern, however, boards are obligated to undertake an inquiry, inform themselves about the problem, and seek corrective action. It can be assumed that boards have notice of problems revealed in publicly reported quality measures or publicly reported patient safety errors. Where quality scores fall well below performance measures for institutions comparable in size, patient mix, and region, boards should assume that the fiduciary duty to ask questions, seek an explanation, and demand solutions has been triggered.

While quality always has been core to healthcare facilities’ mission, financial incentives from public and private payors, transparency, and potentially large financial penalties tied to compliance sanctions for poor quality have changed the stakes for boards and their institutions. Although facilities previously may have given quality of care initiatives lower priority in the face of financial challenges and difficult choices about investment of limited capital, pay-for-performance will make quality integral to financial goals and revenue.

In the past, serious adverse events, when splashed across the headlines, had the potential to affect reputation on quality but were relatively rare and, absent specific warning signs, unanticipated by the board. In general, consumers continued to rely on word of mouth rather than

quality data to select hospitals.\textsuperscript{181} However, years of experiments and experience by business coalitions and national quality organizations seeking to make quality measures salient and actionable by the public may bear fruit. As suggested by one recent study, public measures combined with public reporting that provides a summary score or recommendation may influence both reputation and consumer choice of hospital.\textsuperscript{182} Reputation may now be tied to quality measures in a tangible way, with explicit data that can prompt board inquiry and action to protect and promote the institution’s reputation.

Finally, heightened government enforcement of poor quality, combined with financial incentives for compliance recoveries under the Deficit Reduction Act, create another powerful incentive for boards to focus on patient safety. Federal and state enforcement has not only raised the financial costs of poor compliance, but increased expectations for board oversight, with direct implications for board duties on quality: enhanced board expertise and literacy, better reporting systems to identify problems, and increased accountability of senior management for outcomes. At the same time, OIG compliance guidance and Department of Justice Sentencing Guidelines make clear that board performance in overseeing quality can have a direct impact on the price paid by institutions—in prosecutors’ decisions about violations and penalties.\textsuperscript{183}

It has long been a truism that the board of directors has the ultimate responsibility for the quality of care. The absence of reportable quality measures, immature information systems, and the independence of medical staffs meant that the truism often was devoid of content. Transparency in quality, comparative measures, and the rising stakes for healthcare quality have given boards powerful new incentives and new tools to lead on quality.


\textsuperscript{182} Judith H. Hibbard et al., \textit{It Isn’t Just about Choice: The Potential of a Public Performance Report to Affect the Public Image of Hospitals, 62 Med. Care Res. & Rev.} 358 (2005). The study by Hibbard et al., suggests that consumers will use quality information for choice if the information: (1) clearly identifies high and poor performers; (2) is concise; and (3) is widely disseminated.

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