PROMOTING QUALITY CARE & PATIENT SAFETY: THE CASE FOR ABANDONING THE JOINT COMMISSION'S "SELF-GOVERNING" MEDICAL STAFF PARADIGM

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I. Introduction and Overview

A confluence of issues—including rapidly evolving Quality/Safety standards,1 Quality/Safety-related reimbursement restrictions, and a relentless drive toward expansive Quality/Safety criminal, civil and regulatory liability exposures—mandate that the "American Model" of a "self-governing" medical staff, as embodied in the current and newly adopted hospital accreditation standards of The Joint Commission ("TJC"),2 has led and will continue to lead to such a high degree of dysfunction and paralysis within the governance structure of the modern American hospital that it is impeding material progress towards the achievement of a "zero-defect" hospital environment and is placing hospitals at profound legal and economic risk.

At the root of many of the challenges confronting hospitals today is the seemingly intractable problem of inadequate and unsafe patient care. Despite a decade of intensive hospital industry-wide efforts, the incidence of adverse events in too many hospitals remains, by many accounts, at or near the unacceptably high rates first reported by the Institute of Medicine ("IOM") in 1999.3 In its August 27, 2009 Sentinel Event Alert, TJC highlights that health

1. Reference throughout this article to "Quality/Safety" refers to and includes the broad spectrum of quality care and patient safety responsibilities for which governing bodies and their members, acting in a fiduciary capacity, are legally accountable. Included within this broad spectrum of responsibilities are, for example: (i) practitioner credentialing and privileging best practices, (ii) practitioner credentialing and privileging compliance and auditing best practices, (iii) mandatory evidence-based clinical practice parameters, (iv) practitioner appointment and reappointment criteria, (v) practitioner appointment and reappointment decisions, (vi) practitioner clinical privilege criteria, (vii) practitioner clinical privilege decisions, (viii) initiation and pursuit of practitioner corrective and disciplinary action, and (ix) quality assurance, resource utilization, performance improvement, and peer review processes and protocols.

2. See, e.g., THE JOINT COMMISSION (hereinafter TJC), STANDARD MS.01.01.01 (effective March 31, 2011) (formerly MS.1.20), http://www.jointcommission.net/standards/standards_overview/ms010101.pdf [last visited May 13, 2010] (hereinafter MS.01.01.01).

3. See, e.g., U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, National Healthcare Quality Report 2009, Publication Number 10-0003, Mar. 2010 (reporting that the pace of quality improvement nationally is slow, particularly with regard to medical error reduction and patient safety, and that in nearly 25% of the hospitals evaluated in 2009, the measures of patient safety were going in a negative direction); INSTITUTE OF MEDICINE, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 30 (Linda T. Kohn et al. eds., National Academy Press 2000). Roughly 3% of hospitalized patients experience adverse events. See DEPT. OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., ADVERSE EVENTS IN HOSPITALS: OVERVIEW OF KEY ISSUES 11 (2008), available at http://oig.hhs.gov/oei/reports/oig-06-07-00470.pdf [hereinafter OIG ADVERSE EVENTS OVERVIEW REPORT]. See also AGENCY FOR HEALTHCARE RESEARCH & QUALITY, NATIONAL HEALTHCARE QUALITY REPORT 2 (2008), available at
care leadership bears responsibility for failing to achieve the “zero-defect” safety interventions seen in other industries, and calls for a renewed commitment to developing a “safety culture.”

This article makes the case that one of the major impediments to material improvement in the quality and safety of our nation’s hospitals is the bifurcated leadership structure mandated by TJC’s “American Model” of a “self-governing” medical staff. The term “American Model” has been used by TJC representatives to describe the uniquely American system of medical staff “self-governance” in which the physicians practicing in a hospital “organize” themselves into a “self-governing” unit that exists outside the management structure of the hospital but which is nevertheless responsible for overseeing the quality of medical care rendered at the hospital.

As described in TJC’s
newly adopted Medical Staff Standard MS.01.01.01 ("MS.01.01.01"), this Model consists of (i) an "organized" and "self-governing medical staff that oversees the quality of care provided by all physicians and by other practitioners who are privileged through a medical staff process," (ii) an "organized medical staff [which] creates a written set of documents that describes its organizational structure and the rules for its self-governance," and, in notable contradistinction, (iii) a "governing body [which] is ultimately responsible for the quality and safety of care at the hospital."6

TJC’s stated mission is to “continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.”7 A central tenet of TJC’s long-standing hospital governance paradigm is that the “organized, self-governing medical staff” brings the medical staff’s collective medical expertise, independent judgment, and professional ethics to the task of establishing, implementing, and enforcing Quality/Safety standards in hospitals.8 However, hospitals’ inability to make meaningful inroads into the task of uniformly improving quality and performance outcomes—despite vast allocation of industry fiscal and human resources and a host of new quality care and patient safety initiatives by federal and state governments, payors, and trade organizations—challenges all hospital stakeholders to rethink whether TJC-mandated medical staff/hospital governance paradigm is fundamentally flawed.

Dramatic changes in health care generally, and in hospital-based health care specifically, especially over the past decade, increasingly have created adversaries among and between various members of medical staffs, and among and between medical staff members and governing bodies. For example, the (i) increasingly uniform recognition of the value and importance of evidence-based medicine and the resultant need to adopt and implement mandatory clinical practice parameters,9 (ii) searing focus on quality care and patient safety, its unmistakable growing positive correlation to reimbursement, and the responsibility to define, measure and enforce Quality/Safety standards,10 (iii) rapid expansion and diversification of physician-owned diagno-

6. MS.01.01.01, supra note 2, at 1.
8. See MS.01.01.01, supra note 2, at 1 (stating, “[t]he doctors of medicine and osteopathy and, in accordance with medical staff bylaws, other practitioners are organized into a self-governing medical staff that oversees the quality of care provided by all physicians and by other practitioners who are privileged through a medical staff process”) (emphasis added).
9. See discussion infra Section 3(A)(i).
10. See discussion infra Section 3(A)(ii).
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...tic, treatment and surgery centers,11 (iv) rapid expansion of physician office-based diagnostics and interventional procedures,12 (v) increasing affordability by physicians of medical and interventional technology,13 (vi) demise of state Certificate of Need laws,14 and (vii) increasing internecine competition among and between physicians of different specialties for identical hospital clinical privileges,15 collectively, create, and will continue to create, positional, economic and legal conflicts of interest among and between these stakeholders.

Exacerbating the palpable and myriad conflicts of interest permeating today's hospital stakeholders is TJC's continued advancement of the legally untenable and dangerous (to all hospital stakeholders — patients, physicians, management and governing body alike), governance notion that today's hospital medical staff is somehow "autonomous," that is, the "self-governing medical staff... oversees the quality of care provided by all physicians and by other practitioners who are privileged through a medical staff process."15 This JC-mandated notion of medical staff "self-governance" generally, and medical staff oversight of the quality of care provided by medical staff practitioners specifically, creates, in far too many medical staffs, a "false expectation" of decisional autonomy from the governing body and a denial of the definitive, unilateral role the governing body by law is required to play generally, and is required to play specifically with respect to the adoption, implementation and enforcement of Quality/Safety standards.17

This "false expectation" by the medical staff of decisional autonomy from the governing body, coupled with a JC-mandated standard prohibiting the unilateral amendment of a hospital's medical staff bylaws and rules and regulations,18 too often contributes to (i) inaction or inadequate action by the governing body due to its desire to avoid conflict with the medical staff, or, although rare, (ii) unilateral action by the governing body resulting in actual conflict between the medical staff and the governing body. Thus, the notional concept of medical staff "self-governance," or autonomy from the governing body, too often results in a paralytic environment characterized by the govern-

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11. See discussion infra Section 3(A)(iii).
12. See discussion infra Section 3(A)(iii).
13. See discussion infra Section 3(A)(iii).
14. See discussion infra Section 3(A)(iii). See infra note 175.
15. In our experience there are numerous specific procedures which generate competition between practitioners in different specialties. These include, for example: interventional radiology (radiologists, cardiologists and vascular surgeons), ultrasound (radiologists and obstetricians), and intensivist services (intensivists, pulmonologists, cardiologists, and critical care medicine physicians).
16. MS.01.01.01, supra note 2, at 1.
17. David B. Nash, M.D., Dean, Jefferson School of Population Health, Philadelphia, calls finding "the balance between physician autonomy and public accountability, or transparency" one of the "major challenges in health care." Laurie Larson, Physician Autonomy vs. Accountability: Making Quality Standards and Medical Style Main, Trustee, July 2007 at 14.
18. THE JOINT COMM'N, HOSPITAL ACCREDITATION STANDARDS 192 (MS.01.01.03) (2009) [hereinafter HAS 2009].
ing body either avoiding or inadequately pursuing aggressive compliance with Quality/Safety standards.

In the course of our many years counseling and representing hospitals in medical staff disputes and litigation, we have observed that the absence or inadequacy of aggressive compliance with Quality/Safety standards is often reflected operationally by, for example, (i) nonexistent, inadequate or un-enforced mandatory evidence-based clinical practice parameters, (ii) nonexistent, inadequate or un-enforced appointment and reappointment criteria, (iii) nonexistent, inadequate or un-enforced clinical privilege criteria, (iv) a reluctance or failure to render adverse or conditional appointment and reappointment decisions, (v) a reluctance or failure to render adverse or conditional clinical privilege decisions, (vi) a reluctance or failure to initiate and pursure corrective and disciplinary action, and (vii) nonexistent, inadequate or un-enforced quality assurance, resource utilization, performance improvement, and peer review processes and protocols.

TJC's stakeholders have been increasingly at odds over this dysfunctional governance paradigm. This is exemplified by the nine year debate over TJC's accreditation standard governing the required contents of medical staff bylaws.19 This debate started in 2001 (when TJC undertook to substantially re-vise the medical staff bylaws standard formerly known as MS.1.20) and was still ongoing as of March 18, 2010, when TJC finally adopted the new bylaws standard, relabeled MS.01.01.01.20 This new standard exemplifies and perpetuates the irreconcilable governance conflicts created by TJC's "self-governing" model of medical staff leadership.

TJC's American Model of medical staff "self-governance" provides an infrastructure which allows for, and perhaps fosters, the accentuation of material conflicts among and between medical staff members, physician leadership and physician committees, and the governing body relative to the definition, adoption, implementation and enforcement of requisite Quality/Safety standards.

Despite this flawed Model, there are medical staffs, physician leaders, management and governing bodies in health systems across the country which

are able to achieve a high degree of compliance with Quality/Safety standards. There are numerous stand-outs in this regard, such as the Mayo Clinic, Geisinger Health System, Intermountain Health Care, and Cleveland Clinic, to name a few. Most of these are fully integrated health care systems with unified medical/executive leadership and, critically important, the use of the physician staff employment model. Some of the specific factors that help promote success in such cases include: (i) a highly dedicated, proactive and unified medical/executive leadership fully committed to the Quality/Safety agenda, (ii) full alignment of interests between the governing body, management and medical staff through the use of the physician employment model, (iii) the absence or containment of intrusive and inhibiting conflicts among and between members of the medical staff and with the hospital, (iv) appropriate dedication of time and resources on the part of the leadership groups to the Quality/Safety program; and (v) a culture of mutual respect, cooperation and collaboration.

However, based on our national, “real-world” experience, far too many hospitals and their stakeholders, particularly the traditional, and very prevalent, not-for-profit community hospitals staffed largely with non-employed, independent practitioners, are profoundly challenged and prevented by the American Model’s dysfunctional governance structure in meeting and/or exceeding Quality/Safety standards on a consistent and long-term basis.

This article makes the case that the long-standing American Model of the “organized, self governing medical staff” should be abandoned as a governance principle, and outlines, in its place, a new paradigm which would integrate physician and non-physician expertise and judgment into a unified hospital governance structure, thus enabling hospitals and their stakeholders to intelligently and successfully meet and exceed the industry’s evolving Quality/Safety standards.

II. FAULT LINES AND FAILURES OF TJC’S “AMERICAN MODEL” OF A “SELF-GOVERNING” MEDICAL STAFF

A. Brief History of TJC Accreditation

Historically, TJC has played a defining role in developing, implementing and enforcing minimum standards of conduct by which hospitals and their stakeholders function. Created in 1951 by several physician professional associations and the American Hospital Association (“AHA”), TJC today is comprised of five corporate members: (i) the American College of Physicians (“ACP”), (ii) the American College of Surgeons (“ACS”), (iii) the American Dental Association (“ADA”), (iv) the American Medical Association...
TJC has its historical roots in the Hospital Standardization Program developed by the ACS in 1917. At that time, hospitals were undergoing a major transformation from being the “last, filthy refuge for the sick, dying poor” to being providers of clean, antiseptic environments where surgeons could practice safely. The ACS therefore had a large stake in promoting minimum standards. “In terms of quality, it is the physicians and the medical staffs, as well as organized medicine, who first insisted on quality in hospitals and created standards and monitoring to assure improved clinical environments for physicians to practice.”

TJC assumed the ACS’s hospital accreditation function in 1953. Over the decades since its inception, TJC has gradually expanded the scope of its accreditation services beyond hospitals to numerous other healthcare entities and geographic markets, and has launched many specific initiatives directed at improving patient safety. In 1986, TJC created a consulting subsidiary, Quality Healthcare Resources, Inc., and this became Joint Commission Resources, Inc. in 1998. In 1994, TJC launched Joint Commission International to provide Quality/Safety education, consultation, and accreditation for
foreign hospitals, and, since that time, has accredited more than 300 hospitals in 39 countries.\textsuperscript{31}

Through its Medical Staff Standards, TJC has dictated the organizational governance structure of hospitals it accredits in the United States for the past six decades.\textsuperscript{32} Eighty-eight percent (88\%) of the nation's hospitals are currently TJC-accredited.\textsuperscript{33} There are only two competing hospital accreditation programs — the National Integrated Accreditation for Healthcare Organizations developed by DNV Healthcare, Inc. ("DNV") and the Healthcare Facilities Accreditation Program of the American Osteopathic Association ("AOA"), each of which only has a tiny percentage of the market, as compared with TJC.\textsuperscript{34} TJC's near-universal accreditation program gives it virtually complete mandating authority over the governance structure and operational function of American hospitals.

TJC's hospital accreditation standards have such pervasive influence that they have become largely embedded in federal and state regulatory law as well. Medicare's original Conditions of Participation ("CoPs"), adopted on October 18, 1966,\textsuperscript{35} were based on, and equivalent to, the then-existing TJC standards, including the specific requirement that the hospital have a "medical staff organized under bylaws ... and responsible to the governing body of the hospital for the quality of all medical care provided patients in the hospital and for the ethical and professional practices of its members."\textsuperscript{36} The comparable CoP today requires that the "medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients."\textsuperscript{37} The CoP also requires that the medical staff adopt and enforce

\textsuperscript{31} See Joint Commission International, \textit{About Joint Commission International}, \url{http://www.jointcommissioninternational.org/about-jci/} (last visited Sept. 19, 2009); JCI INTERNATIONAL STANDARDS, supra note 5.

\textsuperscript{32} A Journey Through the History of The Joint Commission, supra note 24.

\textsuperscript{33} See The Joint Commission, \textit{Facts about Joint Commission Accreditation and Certification} (Aug. 18, 2009), \url{http://www.jointcommission.org/AboutUs/Fact_Sheets/facts_jc_accredit.htm}.

\textsuperscript{34} See Diane Meldi et al., \textit{The Big Three: A Side by Side Matrix Comparing Hospital Accrediting Agencies}, \textit{SYNERGY}, Jan./Feb. 2009 at 12.


\textsuperscript{36} \textit{Id}. at 13,428 (emphasis added). Except for utilization review, the 16 CoPs corresponded to the areas covered in TJC's (then known as JCAH's) 1965 hospital accreditation standards. See Institute of Medicine, \textit{MEDICARE: A STRATEGY FOR QUALITY ASSURANCE: VOLUME II SOURCES AND METHODS} 303 (Kathleen Lohr, ed., National Academy Press 1990). See also Dennis J. Purcell, \textit{Medical Staff in Need of Change: Explore a revolutionary way to reorganize your medical staff}, \textit{THE PHYSICIAN EXECUTIVE} Jan.-Feb. 2002, at 64 ("The initial Standards by the JCAH ... required accredited hospitals to have organized medical staffs. The medical staff was responsible for overseeing the clinical practice and quality of care provided by physicians at the hospital.").

\textsuperscript{37} 42 C.F.R. § 482.22(c) (2009) (emphasis added). Notably, while the Medicare CoPs require that the medical staff be "well organized," they do not require that the medical staff be
a set of medical staff bylaws approved by the governing body.38 Most states have incorporated similar organizational requirements into their hospital licensing laws.39 Although the CMS requirements do not specifically mandate that the medical staff be "self-governing," there has been a general, albeit misguided, presumption that CMS and TJC were in lockstep with regard to the mandated governance model.

Moreover, from the beginning, TJC has had "deeming" authority with regard to the Medicare CoPs, thus making TJC accreditation, until very recently, a virtual necessity for any hospital seeking to participate in the Medicare program.40 Until mid-2008, TJC's deeming authority was predetermined.41 This changed when CMS decided that no accrediting agency should have automatic deeming authority, and that TJC would need to apply and be approved on an ongoing basis.42 On November 27, 2009, TJC was approved for hospital deeming authority through July, 2014.43 AOA's accreditation program has had deeming authority since its inception, but as noted above, accredits only a tiny percentage of the nation's hospitals.44 DNV's new accreditation program was granted deeming authority on September 26, 2008.

"self governing." It is the "self-governing" component of TJC's requirements that is particularly problematic for today's hospitals.

38. 42 C.F.R. § 482.22(c) (2009).
40. See Health Insurance Program for Aged, 31 Fed. Reg. 2,748 (proposed February 15, 1966); 31 Fed. Reg. 13,425 (Oct. 18, 1966) (to be codified at 20 C.F.R. § 405.1001(c)) ("Hospitals currently accredited by the Joint Commission on Accreditation of Hospitals will be deemed to meet all of the Conditions for Participation, except the requirement for utilization review . . . . Consequently, a JCAH approved general hospital will be able to establish eligibility to participate by furnishing adequate evidence that it has an effective utilization review plan."). See also A Journey Through the History of The Joint Commission, supra note 24.
41. Id. See also Medicare & Medicaid Programs, Approval of the Application by the Joint Commission for Continued Deeming Authority for Hospitals 74 Fed. Reg. 62,333 (Nov. 27, 2009).
42. 74 Fed. Reg. 62,333.
43. Id.
44. See Meldi et al., supra note 35 at 12. See also Health Insurance Program for Aged 31 Fed. Reg. 13,424-13,443 (Oct. 18, 1966) (to be codified at 20 C.F.R. § 405.1001). Notably, unlike with TJC, the rule stipulated that periodic re-evaluation of the implementation of the AOA accreditation program would be undertaken by the Federal government. Id. ("Likewise, hospitals currently accredited by the American Osteopathic Association . . . will be deemed to meet all of the Conditions of Participation, except the requirement for utilization review . . . . Recognition of the American Osteopathic Association accreditation program as provided for in this paragraph will be continued so long as there is continued assurance that hospitals accredited under the program meet the Conditions of Participation.")
thus establishing DNV, along with AOA, as a credible accreditation alternative to TJC.45

B. The American Model of a “Self-Governing” Medical Staff

The American Model of an “organized, self-governing medical staff,” which has become so firmly ingrained in our nation’s hospital governance structure and healthcare consciousness, has its origins in the early ACS standards developed in 1917.46 The ACS created the concept of the organized medical staff reporting directly to the hospital’s governing body, imbued with responsibility for credentialing, quality assurance, medical records standards, laboratory and radiology standards, and the monthly morbidity/mortality conferences for learning and improving practices.47 In 1919, the ACS mandated that hospital physicians must be organized into a “definite medical staff” as a pre-requisite for gaining ACS approval.48 Notably, while there were at that time quality justifications for requiring an “organized medical staff,” there were also, even then, clear economic motivations as well, in that it afforded insider physicians an ability to exclude their competitors.49

Over the years the American Model of the “self-governing” medical staff has come under serious criticism as mandating, if not resulting in, structural “silos” between medical staff and management, thus creating “obstacles to promoting quality in healthcare.”50 The medical staff silo consists of medical staff members, elected officers, department chairs, division chiefs, and medical staff committees including, most prominently, the Medical Executive Committee (“MEC”).51 The MEC traditionally has been and remains the medical staff’s singular communication conduit to the governing body.52 The hospital management silo consists of the typical chain of command that extends from operational line supervisors, up through hospital managers, department directors, administrators and senior executives.53 This latter group, which often includes a Chief Medical Officer on the senior executive team, are the professionals whom the hospital hires and pays to help design and implement its Quality/Safety standards and fulfill its accountability at an operational level.

45. See Jean DerGurahian, DNV Setting a New Standard, MODERN HEALTHCARE Oct. 27, 2008, at 6; Meldi et al., supra note 35 at 12.
46. See Marren et al., supra note 24, at 208.
47. Id.
48. Id. at 213.
49. Id. Marren et al. note that “[t]he physicians fortunate enough to seize this operational authority deftly organized themselves into closed medical staffs that excluded the vast majority of other practitioners from having the ability to practice within the hospitals, and thus from maintaining a living.” Id.
50. Marren et al., supra note 24, at 207.
51. Id. at 209.
52. Id.
53. Id.
In our experience, this bifurcation between medical staff and management isolates both of those groups from the governing body — thus creating yet a third leadership silo — that of the governing body. The governing body is imbued with clear “buck stops here” legal and fiduciary accountability for quality care and patient safety in the hospital. In a typical corporation, the governing body (comprised, in the not-for-profit hospital setting, of largely non-physician volunteers serving a community service mission), is expected to exercise its fiduciary responsibility through the direct and unilateral accountability of its senior management. However, we posit that the bifurcation of responsibility between management and the medical staff fragments the flow of information and accountability between these two groups and the governing body, thus impairing the governing body’s ability to hold either body accountable in any real-world sense.

Operationally, the structural “siloization” of the different leadership groups has too often promoted and institutionalized “dis-quality, rather than promoting quality.” These structural silos help perpetuate a misguided sense of physician/medical staff autonomy and a resultant expectation of entitlement to unilateral physician decision-making.

[The demand of physicians and organized medicine for physician self-governance, self-monitoring, and self-discipline creates an impenetrable barrier to the concepts of creating safe, efficient, and effective systems and processes of care. The architecture further isolates the physicians from any forces outside the medical staff to attempt to regulate the types of misconduct and potential incompetence concerns.

Moreover, the cumbersome committee structure helps perpetuate the notion that Quality/Safety oversight is a “democratic” process arrived at through consensus decision-making or committee vote. Our experience teaches us that, all too often, when suggestions are made for specific improvements in a hospital’s Quality/Safety processes or corrective action against an incompetent physician, those initiatives are discounted or abandoned out of a concern that “we’ll never get the physician vote.” Because there is no true “managerial” relationship between the governing body and medical staff, “the result is often a high-voltage, high-tension, emotionally laden relationship in which the two resort to using ‘governance weapons.”

54. Id. at 207.
55. The authors’ use of the vernacular term “siloization” is likely not found in a dictionary, but aptly describes the unfortunate perceptual, political and operational segmentation which too often takes place among and between the “medical staff,” “management,” and the “governing body.”
56. Marren et al., supra note 24, at 209.
57. Id. at 210.
Critics of the medical staff model note that it prevents any meaningful change that may impinge on medical staff autonomy.\textsuperscript{59} Notably, TJC, in its August, 2009 \textit{Sentinel Event Alert}, emphasizes the importance of hospital leadership in developing a "safety culture" and implementation of "zero-defect" patient safety interventions.\textsuperscript{60} TJC, drawing on commentary from the manufacturing industry, points out that "latent hazards or weaknesses" in an organization's defenses against hazards — such as "poor design, lack of supervision, and manufacturing or maintenance defects" — can create a "swiss cheese" effect, creating holes in systemic processes that contribute to consumer and— or patient — harm.\textsuperscript{61} Adverse events often can be "traced to a breakdown in systemic solutions intended to prevent harm." The development of a "safety culture" — which TJC identifies as the antidote to the "swiss cheese" effect — is achieved through an organization's "structures, practices, controls, and policies."\textsuperscript{62}

What TJC describes in its \textit{Sentinel Event Alert} is operationally difficult, if not impossible, to achieve in an environment wherein, despite the governing body's "ultimate responsibility" for quality care and patient safety, it is "the self-governing medical staff... [that] oversees the quality of care provided by all physicians and by other practitioners who are privileged through a medical staff process."\textsuperscript{63} The reality is that many "self-governing" medical staffs have responded with ambivalence when charged by their governing bodies with implementing organizational "structures, practices, controls and policies" in the delivery of clinical services, because those organizational controls threaten individual practitioner autonomy:

As practitioners of both the art and science of medicine, physicians have never wanted to be bound by standards, rules or mandates beyond the Hippocratic [O]ath. How can the new call for clinical protocols, including the increased incorporation of [Information Technology], reconcile itself with the age-old perception of the physician as the "captain of the ship"?\textsuperscript{64}

The "self-governing" medical staff, as to its purported oversight of the quality of care, is a descriptive oxymoron. How can a medical staff be truly "self-governing" as to its oversight of quality of care when it lacks the ultimate responsibility and accountability for safety and quality? The resultant non-alignment of expectations and other contradictions present in the American

\textsuperscript{59} Kanak S. Gautam, \textit{Bringing Quality to the Table}, in \textit{GOVERNANCE FOR HEALTH CARE PROVIDERS} 67, 79-80 (D. Nash et al. eds., CRC Press 2009) (noting that medical staff leaders are often elected as representatives, and not for their expertise in quality; they have short tenures, lack the legal mandate for change, and their processes are cloaked in peer review confidentiality).

\textsuperscript{60} Sentinel Event Alert No. 43, supra note 4.

\textsuperscript{61} Id.

\textsuperscript{62} Id.

\textsuperscript{63} MS.01.01.01, supra note 2 (Introduction) (emphasis added).

\textsuperscript{64} Larson, supra note 17, at 14.
Model cripple, in a real-world, day-to-day operational sense, hospitals' abilities to meet and exceed Quality/Safety standards when confronted either by medical staff opposition or intransigence.

Perpetuation and continued application of an antiquated, contradictory and dysfunctional paradigm that requires, on the one hand, a “self-governing medical staff that oversees the quality of care,” and, on the other hand, a “governing body [that] is ultimately [responsible] for the safety and quality of care, treatment, and services”65 more often than not creates misaligned expectations. It also results in governance conflict or paralysis, and prevents or disables hospitals from successfully implementing and enforcing Quality/Safety standards that either (i) they desire to adopt of their own accord, or (ii) are imposed on them by, inter alia, TJC, regulators, payors, juries and patients.

Today, TJC-accredited U.S.-based hospitals that seek the adoption and implementation of mandatory Quality/Safety standards may do so only by way of the collaborative, mutual consent of their medical staffs.66 In our experience, when such consent is not forthcoming or is unreasonably withheld, it leads to one of two outcomes, neither of which is desirable: either such standards are not pursued (to the demonstrable detriment of quality care and patient safety) or, very rarely, they are unilaterally adopted and implemented by the governing body. Such unilateral action by a hospital governing body, and the resultant oft-required unilateral amendment of medical staff bylaws and related policies, expose the governing body to negative medical staff animus, accreditation citation by TJC, and potentially destructive and costly litigation with and by the medical staff and related physician trade associations.67 Thus, absent preferable collaborative mutual consent of the medical staff, very few hospitals are willing to travel down the road of unilateral adoption and implementation of mandatory Quality/Safety standards. A typical result is unacceptable paralysis and inaction, or inadequate action, by the governing body and a resultant, and unacceptable, diminution of quality care and patient safety.

65. HAS 2009, supra note 18, at 101 (LD.01.03.01).
66. See, e.g., Alice G. Gosfield & James L. Reinetten, Sharing the Quality Agenda with Physicians, 60 TRUSTEE 12, 14 (Oct. 2007) (suggesting various strategies that governing bodies may employ in order to engage their physicians enthusiastically in their quality improvement initiatives).
67. See Med. Staff of City, Mem't Hosp. of San Buena Ventura County v. City, Mem't Hosp. of San Buena Ventura, No. CIV 219107 (Ventura County, Cal. Super. Ct) (In a suit for legal and equitable relief brought against a hospital by its medical staff for “breach of contract” in connection with unilateral amendments to the medical staff bylaws regarding physician conflicts of interest, the trial court denied the hospital’s motion to dismiss and upheld the medical staff’s standing as an organizational entity to sue the hospital). Contra Exeter Hosp. v. Bd. of Trustees of Exeter Health Res., Inc., 810 A.2d 53, 56 (N.H. 2002) (hospital’s medical staff is “not a legal entity separate and apart from the hospital, but rather a subordinate administrative unit dependent upon and accountable to the hospital.”).
Although TJC-mandated medical staff bylaws recite that the medical staff is "accountable" to the governing body for the quality and safety of services provided, the "real-world" reality is that the governing body is largely powerless to hold an otherwise intractable medical staff accountable in any meaningful sense. The American Model dictates that (unlike any other industry in the United States), the "service" that brings patients to the hospital (healthcare) is "delivered" by individuals (predominantly non-employed independent staff physicians) over whom the governing body has no direct control. Although there are certain inherent conflicts that will always be present by virtue of this service delivery model, the delegation of Quality/Safety authority to a "self-governing" medical staff exacerbates such conflicts. Volunteer, non-hospital-employed physicians serving on the "self-governing" medical staff are naturally motivated by their own self-interest, and therefore can be expected to act in the interests of the hospital only to the extent that those interests are aligned, and not in direct conflict, with the physicians' self-interests. Such conflicts give rise to organizational dysfunction. It is not surprising, therefore, that "few believe that [the voluntary, "self-governing" medical staff model] is well suited to improving the quality or controlling the costs of medical care." Even strong advocates of the American Model recognize that it is not functioning optimally in the current environment. For instance, Dr. Gerald Eisenberg, then-President of the Medical Staff of Lutheran General Hospital in Illinois, pointed out in 2003 a variety of ways in which he felt that the independent medical staff structure needed strengthening. Dr. Eisenberg notes that physicians perform critically important Quality/Safety functions for hospitals, including credentialing and clinical oversight functions. Dr. Eisenberg also points out a variety of factors that contribute to flawed Quality/Safety processes in many hospitals, including: (i) inadequate outcome measurement systems, (ii) intense pressure on hospitals to adequately manage cost to remain competitive, (iii) personal conflicts among medical staff members that lead them to either under-emphasize quality issues among their colleagues or to be overly critical of quality issues among their competitors, (iv) decreased availability of physicians to perform medical staff functions on a voluntary basis.

68. Gautama, supra note 59, at 75 (observing that "the medical staff often claims it is a self-governing body with exclusive authority over quality-related issues, yet by law, the medical staff can only self-govern in consonance with policies and purposes promulgated by the board").

69. Lawrence P. Casalino et al., Hospital-Physician Relations: Two Tracks and the Decline of the Voluntary Medical Staff Model, 27 HEALTH AFFAIRS 1305, 1313 (Sept. 2008). See also Ken Smithson & Stuart Baker, Perspective: Medical Staff Organizations: A Persistent Anomaly, HEALTH AFFAIRS w76, w78 (Dec. 2006) (SPECIAL ONLINE ISSUE).


71. Id. at 257.
due to their own economic pressures, and (v) decreased amounts of time ac-
tually spent by physicians in the hospital setting.  

Notwithstanding these deficiencies, Dr. Eisenberg opines that preserving
the independent medical staff structure is important for Quality/Safety be-
cause it provides a “critical balance” to hospital management’s drive towards
cost reduction. Dr. Eisenberg argues that, while employed physician-
administrators may be pressured to put the financial “bottom line” above
patient safety, the “independent medical staff organization” can advocate
more “freely” in favor of quality patient care. In fact, Dr. Eisenberg’s pro-
posed solution to the current deficiencies in the American Model is for hos-
pitals to promote an even higher degree of autonomy for the medical staff, by
funding its activities and giving it greater access and influence at the governing
body level. In this way, medical staff organizations can be revitalized and
can “recognize and assert their role and responsibility in leading care im-
provement initiatives.”

We disagree with Dr. Eisenberg’s central two-pronged premise that (i)
financial “bottom line” interests trump Quality/Safety goals, and (ii) a “revita-
lized” medical staff organization is the mechanism for assuring that this result
does not occur. As to the first premise, today’s healthcare environment de-
mands that financial considerations and Quality/Safety goals not be mutually
exclusive. As discussed later in this article, increasingly hospitals’ reimburse-
ment is being tied directly to their quality performance and outcomes, and
thus it is unrealistic to suggest that hospitals, even if they were so inclined,
could successfully place financial considerations ahead of Quality/Safety
goals. Moreover, Dr. Eisenberg’s premise overlooks the fact that a unified,
sequential governance approach to Quality/Safety may enable hospitals to pro-
vide higher quality care more efficiently, and therefore, at lower cost.

As to the second premise, we disagree that what is needed is to “revital-
ize” the medical staff through greater funding and a higher degree of autono-
my from, and influence with, the governing body. On the contrary, this en-
hanced “siloization” of the organized medical staff from hospital management
and the governing body creates barriers to the implementation of systemic,
evidence-based Quality/Safety programs. It serves only to perpetuate both a
continuing conduit for dysfunction and an inability, absent full medical staff
consensus, of the governing body to pursue and enforce unilaterally Quali-
ty/Safety standards consistent with its level of accountability.

TJC representatives have acknowledged the controversy surrounding the
American Model of an “organized, self-governing medical staff,” and the
question as to whether it can survive the pressures being brought to bear by

72. Id. at 253-56.
73. Id. at 257.
74. Id. at 260.
75. Id. at 263.
76. Id. at 264.
the fundamental changes occurring in the industry and the increased accountability for quality care and patient safety. As candidly opined by TJC's General Counsel, Harold Bressler, Esquire, in a 2007 educational teleconference about MS.1.20:

The concept of an organized medical staff is something that is organized and is supposed to, in an organized fashion, further the interests of quality and safety and works with the governing body and not solely represent the individual interests of medical staff members. It's something, of course, that is derived back from the 1919 American College of Surgeons standard. It's in all the laws and regulations across the country. I know that there are experienced people, people who I believe are thoughtful, who believe that that concept is ridiculous. Who believe that if it ever existed it does not work now and that you can't expect there to be anything organized as a medical staff to enhance quality and safety. The Joint Commission disagrees. Others disagree. There is going to be a lot of discussion, in my view, in the next five, ten, fifteen years about whether that American Model works.

Notably, TJC's International Accreditation Standards for Hospitals nowhere require accredited hospitals to have an "organized, self-governing medical staff." To the contrary, these Standards emphasize the importance of a unified, integrated approach to quality and safety which, we suggest, is far too often not achievable under the governance model reflected in the U.S. hospital accreditation standards.

77. Teleconference Standard MS.1.20, supra note 5, at 16.
78. Id.
79. JCI INTERNATIONAL STANDARDS, supra note 5.
80. The International Standards regarding Quality Improvement and Patient Safety emphasize that "continuously planning, designing, monitoring, analyzing, and improving clinical and managerial processes must be well-organized and have clear leadership to achieve maximum benefit... Efforts to improve [clinical care] processes must be guided by an overall framework for quality management and improvement activities in the organization, overseen by a quality improvement and patient safety oversight group or committee." Id. at 139 (Quality Improvement and Patient Safety ("QPS") Overview) (emphasis added). TJC's Hospital Accreditation Standards do not contain a comparable statement anywhere in the Leadership ("LD"), Performance Improvement ("PI"), or Medical Staff ("MS") chapters. The closest analogy in the current U.S. standards that we could find is located in LD.03.01.01, which specifies that "[l]eaders create and maintain a culture of safety and quality throughout the hospital." Its Rationale section further specifies that "[s]afety and quality thrive in an environment that supports teamwork and respect for other people, regardless of their position in the organization. Leaders demonstrate their commitment to quality and set expectations for those who work in the organization... Leaders encourage teamwork and create structures, processes, and programs that allow this positive culture to flourish." HAS 2009, supra note 18, at 108-09. The U.S. standard, as compared to the International one, reflects amorphous expectations in a diffused leadership environment which, we submit, is far less likely to produce measurable improvement in patient safety.
Likewise, although DNV and AOA Standards are constrained by current federal and state law to mandate an "organized" medical staff, neither accreditation program requires that the medical staff be "self-governing." Rather, the accreditation guidelines emphasize the governing body's ultimate authority, and the medical staff's accountability, for effective Quality/Safety processes.81

The DNV accreditation standards incorporate the principles articulated in the generic International Quality Management Standard ISO 9001.82 ISO 9001 has a section on "Management Responsibility," in which it describes the functions and responsibilities of "top management." The first of these elements is "Management Commitment," which specifies as follows:

5.1 Management Commitment.

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

(a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements;
(b) establishing the quality policy;
(c) ensuring that the quality objectives are established;
(d) conducting management reviews; and
(e) ensuring the availability of resources.83

The ISO Standards go on to discuss, in considerably more detail, top management's responsibilities in the areas of (i) setting policy, (ii) planning, (iii) ensuring that responsibilities and authorities are defined and communicated within the organization, (iv) designating a specific member of management who has the authority and responsibility to ensure that the quality man-


agrement processes are established, implemented and maintained, (v) ensuring appropriate internal communication processes throughout the organization, and (vi) conducting periodic audits and reviews to ensure continuing suitability, adequacy and effectiveness of the quality management system, and of assessing opportunities for improvement within the quality management system.84

The DNV Standards have integrated and adapted the ISO model to the hospital setting, including developing consistency with the CMS requirements for an "organized" medical staff. The first four of the DNV’s Medical Staff Standards provide a striking contrast to TJC’s "self-governing medical staff" model both in their simplicity and their clear recognition of Board authority to match its accountability. The standards are as follows:

**MS.1 ORGANIZED MEDICAL STAFF**
The organization shall have an organized medical staff that is composed of fully licensed doctors of medicine or osteopathy. In accordance with State law, the medical staff may also include other practitioners.

**MS.2 ELIGIBILITY**
The governing body shall determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

**MS.3 ACCOUNTABILITY**
The medical staff shall be organized in a manner approved by and accountable to the governing body and shall be responsible for the quality of the medical care provided to patients.

**MS.4 RESPONSIBILITY**
The responsibility for organization and conduct of the medical staff must be assigned to an individual doctor of medicine or osteopathy or, when permitted by State law, a doctor of dental surgery or dental medicine.

Interpretive Guidelines:
The medical staff must be accountable to the hospital’s governing body for the quality of medical care provided to patients.

Surveyor Guidance:
Validate the process by which the governing body monitors the quality of medical care provided to patients.

Verify that an individual doctor of medicine or osteopathy is responsible for the conduct and organization of the medical staff.85

84. Id. at 2-5.
85. DNV STANDARDS, supra note 81, at 18-19 (MS.1 — MS.4) (emphasis added).
In a special subsection of the medical staff standards devoted to the governing body, DNV reinforces the importance of the governing body's role in overseeing medical staff affairs. The standards reinforce that it is the governing body that "appoint[s] members of the medical staff and approve[s] clinical privileges after considering the recommendations of the existing members of the medical staff and ensure[s] that the medical staff is accountable to the governing body for the quality of care provided to patients." The interpretive guidelines reiterate that "[t]he governing body, with the advice of the medical staff, is responsible for the appointment and reappointment of the individual practitioners of the medical staff and their respective delineation of privileges." The DNV standards also change the emphasis of the medical staff's role in quality oversight functions from "leadership" to "participation."

In a myriad of ways, the DNV standards create a more unified, integrated approach to Quality/Safety, which de-emphasizes Medical Staff autonomy, and emphasizes the ultimate accountability and leadership role of the governing body.

C. How TJC’s New Standard MS.01.01.01 Exemplifies the American Model’s Organizational Dysfunction

In September, 2001, TJC initiated a comprehensive review of its medical staff standards that resulted in a proposal for major changes initially targeted

86. Id. at 23 (MS.11 Governing Body Role).
87. Id.
88. Id. (MS.11 Governing Body, Interpretive Guidelines) (emphasis added). The DNV standards also elevate the nursing function, requiring that the hospital’s primary Nurse Executive be a "member of senior leadership" and serve on the Medical Executive Committee (with or without vote). Id. at 20 (MS.5 Medical Executive Committee) & 33 (NS.2 Nursing Executive). The comparable TJC Standard specifies that the "nurse executive directs the delivery of nursing care, treatment, and services," and an Element of Performance related to that standard specifies that the nurse executive "functions at the senior leadership level." HAS 2009, supra note 18, at 253 (NR.01.01.01 & EP 1) (emphasis added). Importantly, TJC Standards do not require the Nurse Executive to be a member of the MEC. Id. at 192-93 (MS.02.01.01). Further, under the DNV standards, the Nursing Staff is responsible for developing a Plan of Care for each patient within 24 hours of admission that reflects an interdisciplinary planning process that encompasses the care of the patient from admission through discharge. DNV STANDARDS, supra note 81, at 34-35 (NS.3 Plan of Care). The comparable TJC Standard merely specifies that "[t]he hospital plans the patient’s care." HAS 2009, supra note 18, at 268 (PC.01.03.01).
89. Compare HAS 2009, supra note 18, at 197 (MS.05.01.01) ("the organized medical staff has a leadership role in performance improvement activities to improve quality of care, treatment, and services and patient safety") (emphasis added), with DNV STANDARDS, supra note 81, at 20 (MS.6 Medical Staff Participation) (requiring medical staff participation in the following quality-related activities — medication management oversight, infection control oversight, tissue review, utilization review, medical record review, and quality management systems) (emphasis added).
for implementation starting in January, 2004. The overall thrust of the changes was to (i) prescribe the essential medical staff organization and function with much greater specificity than previously, and (ii) explicitly recognize and confirm the medical staff's autonomous existence as a "self-governing body" operating within the hospital governance structure.

A proposed new MS.1.10 formally interjected the term "self-governing" into the phrase "organized medical staff" to create the descriptive phrase "organized, self-governing medical staff." At the same time, a proposed revised MS.1.30 strengthened TJC's then-existing prohibition against "unilateral" governing body amendment of the medical staff bylaws, rules and regulations by barring any text authorizing unilateral amendment from both the medical staff bylaws and the governing body bylaws.

While these changes to MS.1.10 and MS.1.30 were controversial, the implications of the proposed new MS.1.20, specifying the content of the medical staff bylaws, were even more profound. Accreditation requirements for medical staff bylaws have significant consequences for hospitals because, once adopted and approved, they are deemed to be legally binding on the hospital and its practitioners. Courts in the majority of states bind hospitals to the terms of their medical staff bylaws, either as a "contract" between the hospital and the medical staff, or on the basis of a quasi-contractual, constitutional, regulatory or common law "due process" theory. A hospital is legally required to comply with all of the procedural and other requirements of its medical staff bylaws in carrying out its Quality/Safety functions, with substan-

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90. The Joint Commission, Background on Medical Staff Standard MS.01.01.01 at 5, Apr. 2010, http://www.jointcommission.org/NR/rdonlyres/81AOE2F3-CA04-4DC6-905B-6449A753395B/0/MS010101FINAL40810.pdf (last visited May 13, 2010).

91. See Joint Commission on Accreditation of Healthcare Organizations, Hospital Accreditation Standards 298-301 (2004) [hereinafter HAS 2004], which reflects the standards that were originally proposed in 2003, at MS.1.10 and MS.1.20. See also Barbara A. Blackmon & Phil Zarone, The 2004 JCAHO Medical Staff and Leadership Standards and New Survey Process (2004) (Pennsylvania Bar Association 10th Annual Health Law Institute Materials) (on file with the authors).


tial liability exposures flowing from the failure to do so. Therefore, by specifying the content of the medical staff bylaws, TJC actually dictates, as a binding mandate, an accredited hospital’s method and manner of performing its Quality/Safety functions.

Prior to 2004, the content of MS.1.20 had been found in MS.2, which articulated general requirements for medical staff bylaws such as, for instance, that they (i) make provision for an MEC, (ii) establish mechanisms for corrective action, (iii) create categories of medical staff membership, (iv) set forth the procedures for selecting officers, (v) specify the requirements for meeting frequency and attendance, and (vi) contain provisions for adoption and amendment. Even this formulation was much more descriptive than the current DNV Standards, whose sole prescriptive content is as follows:

SR.3 The medical staff bylaws shall describe the organization of the medical staff and include a statement of the duties and privileges of each category of medical staff to ensure that acceptable standards are met for providing patient care for all diagnostic, medical, surgical and rehabilitative services.

SR.4 Medical staff bylaws shall include provisions for mechanisms for corrective action, including indications and procedures for automatic and summary suspension of medical staff membership or clinical privileges.

The proposed 2004 version of MS.1.20, by contrast, prescribed, in twenty new Elements of Performance (“EPs”), what content must be contained in the medical staff bylaws, including:

- Detailed specification of the structure and function of clinical departments;
- Requirements regarding the composition and role of the MEC, and the aspects of its organizational structure that must be contained within the bylaws;

95. A recent, dramatic example of such potential liability exposure is the case of Poliner v. Texas Health Systems, 2006 U.S. Dist. LEXIS 13123 (N.D. Tex. Mar. 27, 2006), rev’d, 537 F.3d 358 (5th Cir. 2008), in which a Texas jury awarded cardiologist Lawrence Poliner, M.D., damages of $366 million against a hospital and several of its medical staff leaders. The hospital and its medical staff leaders were alleged to have violated the procedures of the hospital’s medical staff bylaws in addressing quality concerns, resulting in a six-month restriction of Dr. Poliner’s interventional cardiology privileges. Although the huge jury verdict was reversed on appeal two years later based on the Fifth Circuit’s conclusion that the defendants were protected in their decision-making by their compliance with the minimum “due process” requirements established by the Health Care Quality Improvement Act, 42 U.S.C. § 11101 et seq., it was, nevertheless, shocking to the hospital industry and sent up a major red flag as to the potential liability exposures that could arise out of actions taken to address quality concerns. 537 F.3d at 381.


97. DNV Standards, supra note 81, at 21.
• Detailed requirements regarding what the bylaws must contain regarding corrective actions, summary suspensions, automatic suspensions, and the mechanism for recommending termination, suspension or reduction in privileges;
• Specification that the mechanisms for fair hearing and appeal be defined in the bylaws;
• Specification that the credentialing, privileging, appointment and membership processes be contained within the bylaws.98

The overly prescriptive nature of MS.1.20, coupled with the strengthened prohibition against unilateral governing body amendment, generated immediate concern among TJC’s hospital stakeholders (and their counsel) because of the apparent erosion of governing body authority to match its legal accountability for Quality/Safety. Two commentators, speaking directly to the enhanced unilateral amendment prohibitions, noted:

The Standard prohibiting unilateral amendment has always been contrary to the fundamental principle of corporate law that the Board is the ultimate authority in the corporation and has full authority to manage the property, business and affairs of the corporation, in the view of hospital counsel. . . . The Board is also ultimately responsible for everything that is done by or in the name of the corporation.

Regardless of what [TJC] may state, hospital counsel believe that a Board cannot abrogate this authority or responsibility.99

There was also a strong negative reaction to the introduction of the phrase “organized, self-governing medical staff” as a formal construct.100

In November, 2003, TJC, well-aware of the controversy surrounding the new proposed Medical Staff standards, withdrew the prohibition against bylaws language that would permit unilateral amendment of the medical staff bylaws.101 TJC’s then-President, Dennis S. O’Leary, M.D., in an open letter to the hospital industry, acknowledged the “tensions” existing between the three leadership groups and advised that, rather than move forward with that particular EP, TJC had instructed its staff to:

work through its consensus-building process to create a new leadership framework that would re-define the respective responsibilities of hospital management, the governing body, and the medical staff in relation to each other; establish new expectations regarding conflict resolution; and focus priority attention on the collective accountability of the three groups to the patients and the communities they serve.102

98. HAS 2004, supra note 91, at 298-301.
101. Id. at 35-38.
102. Id. (Appendix, Dennis S. O’Leary, M.D., “Dear Colleague” Letter).
TJC's action with regard to MS.1.30, however, did not resolve the concerns regarding the new proposed MS.1.20, including that the overly prescriptive requirements would invalidate, what had become a quite the common practice among many hospitals, of placing many of the procedural components of credentialing, corrective action and fair hearings into supplemental documents that could be amended more flexibly to meet rapidly evolving regulatory and legal imperatives, without the full vote of the medical staff. Over the course of 2003-2005, TJC issued multiple clarifications, amendments and new formulations of the proposed MS.1.20 and its EPs to address the stakeholder concerns, but its efforts were contradictory and confusing.

103. Blackmond & Zarone, supra note 91, at II-5-II-6. See also Newman et al., supra note 93, at 35-37.

104. On December 23, 2003, TJC “clarified” that a hospital’s processes for credentialing, privileging, appointment, and the fair hearing/appeal process could be referenced in the bylaws but “described in detail” in other documents that could be approved and amended through a delegated process outlined in the medical staff bylaws such as, for example, MEC and governing body approval. Blackmond & Zarone, supra note 91, at II-5-II-6. However, in two subsequent “E-Blasts” issued by TJC on September 24, 2004 and October 21, 2004, TJC reversed course. The first E-Blast articulated a proposed revised EP 19 specifying that when administrative procedures are described in supplemental documents, (i) the bylaws must contain the approval mechanism for the administrative procedures and the criteria for determining which administrative procedures may be in the supplemental documents, and (ii) the administrative procedures must actually be approved by the medical staff and governing body through the processes identified in the bylaws. Joint Commission Resources Inc., E-mail Blast re: EP 19 (Sept 29, 2004). The October 21 E-Blast distinguished between those procedures related to process steps that would need to be in the bylaws and those that would not. Specifically, procedures that would involve evaluative conclusions or have a major impact on the outcome of a decision were required to be contained within the four corners of the medical staff bylaws. Other administrative procedures such as scheduling, verifying information, soliciting information from the applicant, and so forth, could be in supplemental documents. Joint Comm’n Resources Inc., E-mail Blast re: Official Publication of Clarification to Requirements: Additional Information on MS.1.20, EP 19 (Oct. 21, 2004). Taken together, the September and October, 2004 E-Blasts appeared to be a substantive reversal of TJC’s December, 2003 straightforward guidance that credentialing, privileging and fair hearing procedures could be detailed in supplemental documents so long as the approval mechanism for such supplemental documents was set forth in the bylaws. In March, 2005, TJC assembled an ad hoc Advisory Committee to help it address stakeholder concern on both sides, and issued a new proposed formulation of MS.1.20 in April, 2005. It also pushed the implementation date of controversial EP 19 back to January 1, 2007. Joint Comm’n on Accreditation of Healthcare Orgs., Revisions to 2005 Requirements for Hospitals, http://www.jointcommission.org/Standards/FieldReviews/fr_ms120.htm (last visited Oct. 16, 2006) (website no longer available). This new version was submitted to TJC’s Leadership Accountabilities Task Force, which recommended additional changes. 2006 MS.1.20 Field Reviews and Draft Standards, supra note 92. On September 20, 2005, TJC published the new proposed revision to MS.1.20. This version reaffirmed that the MEC, rather than the full medical staff, could be delegated the authority to approve administrative procedures contained in supplemental documents, but then introduced a complex set of requirements regarding the composition and election process for the MEC, which was abandoned in a subsequent version. Joint Comm’n on Accreditation of Healthcare Orgs., Proposed Revisions to MS.1.20 (Sept. 20, 2005) (on file with the authors). The September, 2005 version was submitted for field review
In February, 2006, TJC announced that, based on its field review of a proposed 2005 draft revision, there were ongoing concerns with the formulation of MS.1.20, which included:

- Disruption of effectively functioning organizations by requiring a time-consuming process of bylaws revision to meet the new standard;
- Over-prescription of the bylaws content;
- Interference with the hospital's right to design and structure the MEC;
- The challenge to the governing body's authority;
- Undermining of medical staff authority; and
- A broadening of TJC's interests beyond patient safety and health care quality.  

Based on these concerns, TJC revised MS.1.20 yet again, and issued a new proposed version in August, 2006. The August, 2006 version (i) specified that the MEC could be given authority to create rules, regulations and policies addressing the procedural elements of credentialing, peer review and corrective action without a full vote of the medical staff, (ii) created a specific method for non-MEC medical staff members to develop bylaws amendments and submit them directly to the governing body for consideration, and (iii) for the first time, formally incorporated the concept of a conflict resolution process in the event of impasses arising between the "organized medical staff" and the governing body. This new formulation failed to resolve the concerns of the various stakeholders and, therefore, the standard was revised again the following year.

In June, 2007, TJC Board of Commissioners approved yet a new proposed version of MS.1.20, pushing the implementation date back to July, 2009 to give the hospital industry a full two years to make the necessary changes in their medical staff bylaws, and to give TJC the opportunity to hold educational sessions with stakeholders from the physician and hospital communities. This 2007 version: (i) specified that the requirements of the credentialing, corrective action and fair hearing processes must be in the medical staff bylaws, approved by the organized medical staff but, at the organized medical staff's option, the procedural details associated with those requirements could be located in separate rules, regulations and policies, with approval to adopt the procedural later that year, and generated more push-back both from physician and hospital stakeholders.

2006 MS.1.20 Field Reviews and Draft Standards, supra note 92.

105. Id.
107. Id.
108. TJC, Revisions to Standard MS.1.20 Approved, http://www.jointcommission.org/AccreditationPrograms/Hospitals/revisions_std_ms120_approved.htm (last visited July 11, 2007) (website no longer available) (on file with the authors).
details delegated to the MEC; (ii) required that a process be developed whereby the medical staff could develop its own procedures and present them directly to the governing body for approval; (iii) specified that all elements of the organizational structure must be in the bylaws themselves, and subject to the vote of the entire organized medical staff; (iv) addressed, at great length, the potential for conflict between the MEC and the "organized medical staff" and "urged" the "organized medical staff" to consider what action it would take if it disagreed with the actions of the MEC; and (v) specified that conflict between the organized medical staff and governing body must be submitted to conflict resolution as set forth in the new Leadership Standards. 109 The Leadership Standards, issued the same year and currently effective, specify that the hospital "manages conflict between leadership groups to protect the quality and safety of care" and articulate five EPs setting forth the requirements of the hospital's conflict resolution process. 110

At an educational teleconference on MS.1.20 conducted by a panel of TJC representatives in November, 2007, Dr. Robert Wise, TJC's Vice President for Standards and Survey Methods, noted that there were several ongoing points of controversy over MS.1.20, including:

- Concern over the decreased authority of the MEC;
- Concern over who is on the "voting medical staff" with authority to vote on medical staff bylaws; and
- Concern that a full vote of the medical staff and governing body would be required for "every single document that relates to quality and safety." 111

The transcript of this teleconference reveals that the concerns about proposed MS.1.20 went to the heart of the hospital's governance authority and anomalies created by the "self-governing" medical staff paradigm. The questions posed to TJC panel by hospital stakeholders reflected a pervasive and growing frustration that TJC's efforts were making it increasingly difficult for hospital governing bodies to fulfill their legal accountabilities for Quality/Safety, particularly in the face of medical staff intransigence or inaction. The following comments reflect some of the major concerns expressed during this teleconference:

**Issue One: Governing Body Authority**

We all agree that the governing board is the ultimate authority and yet when I read the introductory paragraph as we've discussed, all of the requirements from standard MS 1.20 must be jointly approved by the medical staff, the medical exec [sic], and governing board. If the governing body is the ultimate authority and they cannot make decisions

109. Id.
110. See HAS 2009, supra note 18, at 106-07 (L.D.02.04.01).
111. Teleconference Standard MS.1.20, supra note 5, at 2-3.
in the interest of patient care which may be at odds with the medical staff, aren't we giving them the responsibility without the authority?\(^\text{112}\)

Issue Two: Role of Medical Staff in Bylaw Amendment Process

With the new revision, our bylaws committee and medical staff felt that the whole medical staff could dilute the power or the voice of those of our active members. The committee felt that non-active members have little investment with the governing structure of the hospital and put the active staff at risk in granting votes to a pool of individuals unfamiliar with the day-to-day effects of the bylaws of the medical staff. They felt with the new guidelines there'd [sic] be no future changes to the medical staff bylaws, and rules and regulations. So, if we propose something to the board, the board approves it, goes through the process, gets it approved, then the medical staff in whole can then go and try and change it. Then you put an animosity between the medical staff and the board of the hospital. This doesn't make sense.\(^\text{113}\)

Issue Three: Role of the MEC

[First caller]. You keep talking about the need for the medical staff and board to work through these issues and so... if we're talking the active medical staff, how do you envision the active medical staff and the board discussing this as a whole?... Because I think traditionally people had thought that that's why the active medical staff voted in its [MEC] members so that they could, in fact, engage in these functions on behalf of the entire active staff. I'm just having a hard time understanding how the active medical staff is supposed to engage in all of these discussions with the board and what the role of the MEC is in relation to all of that.\(^\text{114}\)

[Second caller]. In any organization, when you've got an empowered leadership and voice if you're creating a work around, then you're essentially disempowering that leadership structure, and as I read it, spending my entire career in a hospital, you're just creating a dysfunctional system by creating a work around to the leadership structure.\(^\text{115}\)

Issue Four: Influence of Competing Physicians on the Medical Staff

Many of our physicians practice not only at our hospital, but also practice in other hospitals and facilities. A number of those physicians who are on our medical staff also are owners-investors in a specialty hospital. And those same physicians who are owners-investors and those who practice elsewhere are often times the most difficult for us to work with, relative to compliances, delinquent medical records or other safety and quality initiatives that MEC and the board have adopted. And as ridiculous as it may seem, they've even been

\(^\text{112}\) Id at 28-29.
\(^\text{113}\) Id at 8.
\(^\text{114}\) Id at 13.
\(^\text{115}\) Id at 37.
successfu\l in passing resolutions to do away with The Joint Commission survey and to no longer be an accredited facility, as their facilities are not accredited. Can you help me understand how giving the organized medical staff as a whole the ability to adopt bylaws, rules and regulations and policies and amendments will not undermine the MEC who are elected by their departments in my facility, nor challenge and undermine the authority of the board or the governing body?

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It just appears to me that via this proposed standard change that my competition will have a louder and stronger voice and create more chaos than actually further the cause of safety.\textsuperscript{116}

In January, 2008, two months after the teleconference, TJC appointed an Implementation Task Force comprised of prominent members of the health care community, to examine the potential impact of implementing proposed revised MS.1.20.\textsuperscript{117} The Task Force met twelve times, and focused its discussions on several key issues, including:

- What needs to appear in the medical staff bylaws and how such decisions are made;
- The relationship between the organized medical staff and the MEC;
- How to foster a collaborative and positive relationship among the organized medical staff and the governing body; and
- How to manage conflict that may arise between the organized medical staff and the governing body, or between the organized medical staff and the MEC, regarding medical staff bylaws, rules and regulations, and policies.\textsuperscript{118}

After several delays (causing TJC to postpone indefinitely the implementation date for the new MS.1.20), the Task Force, on March 27, 2009, issued a "Working Draft" of a proposed new standard, renumbered as MS.01.01.01, which was unanimously supported by the members of the Task Force.\textsuperscript{119} Between March and October, 2009, TJC circulated the Working Draft of

\textsuperscript{116} Id. at 21-23.


\textsuperscript{118} Id. 

\textsuperscript{119} Id. As noted above, the new MS.01.01.01 underwent Field Review between December 17, 2009, and January 28, 2010. Throughout this period, hospitals have had to comply with the version of MS.01.01.01 that appears in the 2009 standards (which appears to be one of the 2004 versions), with the exception of EP 19 (pertaining to what elements of credentialing, privileging, corrective action and fair hearing processes must be in the bylaws as opposed to supplemental governance documents), as to which there is a moratorium. Id.
MS.01.01.01 among its own stakeholder groups for comment, and on December 17, 2009, the Working Draft of MS.01.01.01 was released for Field Review. On March 18, 2010, The Joint Commission adopted the Working Draft of MS.01.01.01 without further revision, to become effective on March 31, 2011.

We submit that, over the past nine years, as TJC has issued successive drafts of MS.1.20 culminating in the newly adopted MS.01.01.01, it has not achieved a realistic resolution of its hospital stakeholders' concerns over the dysfunctional governance structure, and instead, has developed “workarounds” and terminology changes that do not address the root problem. In the process, TJC and its Task Force have introduced some new and highly questionable assumptions, including: (i) that an “organized medical staff” can successfully limit its voting membership to those members who are truly interested in providing medical leadership; and (ii) that issues dividing the MEC, the “organized medical staff” and the governing body can best be managed through “conflict resolution.” Moreover, the new EPs themselves are so numerous (there are now 36), lengthy and difficult to apply that they create ambiguity where clarity is required.

The core weaknesses of the new MS.01.01.01 are that it:

- Perpetuates the failure to recognize the governing body’s ultimate unilateral authority, thus preventing it from fulfilling its legal accountability for the adoption, implementation and enforcement of Quality/Safety standards in the absence of full and uniform voluntary consensus from its medical staff.


121. TJC News Release, 'Joint Commission Approves Revised Medical Staff Standard MS.01.01.01' (Mar. 18, 2010), http://www.jointcommission.org/NewsRoom/NewsReleases/nr_031810.htm' (last visited May 13, 2010).

122. See infra note 128.

123. HAS 2009, supra note 18, at 104-07 (LD.02.01.01 - LD.02.04.01).

124. The lack of ultimate, unilateral governing body authority is most evident in the disjointed, conflict-laden and confusing formulation of how medical staff bylaws are created and adopted, as reflected in EP 2: “The organized medical staff adopts and amends medical staff bylaws. Adoption or amendment of medical staff bylaws cannot be delegated. After adoption and amendment by the organized medical staff, the proposed bylaws are submitted to the governing body for action. Bylaws become effective only upon governing body approval. (See the Leadership chapter for requirements regarding the governing body’s authority and conflict management processes. See Element of Performance 17 for information on which medical staff members are eligible to vote.)” [Sic] MS.01.01.01, infra note 2 (EP 2). We submit that the only legally defensible formulation that gives appropriate recognition to the need for a collaborative process between all leadership groups, subject to the governing body’s ultimate legal accountability and responsibility is as follows: “The medical staff, in close collaboration with hospital management and the governing body, develops and recommends medical staff bylaws, subject to the ultimate unilateral review, revision, adoption and implementation by the governing body.”
• Diminishes and weakens the role of the MEC — which historically according to TJC hospital accreditation standards served as the principle medical staff committee directly accountable to the governing body for Quality/Safety standards; 125

• Invests the organized medical staff with the sole authority to determine the qualifications, roles and responsibilities of departmental chairs, who serve a critical role in the development, adoption and implementation of Quality/Safety functions. Pursuant to MS.01.01.01, inasmuch as the organized medical staff is solely responsible for the qualifications, roles and responsibilities of chairs, if the Chairs are not performing or are underperforming any of their Quality/Safety duties, the governing body is without authority to hold them accountable in any suitable fashion; 126

• Invests more power into the hands of the “organized medical staff” — which, in reality, is an amorphous, disorganized and disparate group of largely self-interested and, often, conflicted private practitioners; 127

125. The MEC’s leadership role and authority is substantially weakened by (i) the enhancement of the voting rights of the “organized medical staff,” (ii) correspondingly diminished scope of authority of the MEC to establish and implement medical staff policy and procedure without submitting it to a vote of the “organized medical staff,” and (iii) in a new requirement that there must be a conflict resolution process to resolve differences between the MEC and the organized medical staff. See, e.g., Id. (EPs 1, 2, 3, 8, 9, 10 & 11). Specifically, EP 10 requires that “the organized medical staff has a process which is implemented to manage conflict between it and the medical executive committee on issues including, but not limited to, proposals to adopt a rule, regulation, or policy or an amendment thereto.” Id. (EP 10) (emphasis added).

126. MS.01.01.01’s new EP 36 contains an explicit requirement that the “qualifications and roles and responsibilities of the department chair . . . are defined by the organized medical staff.” Id. (EP 36) (emphasis added). The Department chair function is a critically important one. Department chairs are relied upon by governing bodies and management relative to (i) oversight, through peer review and other performance improvement mechanisms, of the professional performance of all practitioners within the Department, (ii) recommendations on appointment and reappointment to the medical staff and delineation of clinical privileges, (iii) recommendation of criteria governing evaluation and award of clinical privileges, (iv) assessment and improvement of the quality of care, treatment and services provided by Department practitioners, (v) provision of necessary recommendations for the initiation of corrective or other disciplinary action based on competency, quality, ethical or behavioral criteria, and (vi) maintenance of quality control programs. EP 36 thus, in the absence of uniform consensus, effectively strips the governing body of the ability to perform and fulfill its Quality/Safety fiduciary mandate sit a sit Department Chairs, because the governing body cannot hold Department Chairs accountable if it lacks direct control and authority over the “roles and responsibilities” which form the basis of that accountability.

127. MS.01.01.01, as noted above, limits the authority of the MEC and increases the authority of the amorphous, ill-defined group known as the “medical staff.” The TJC Task Force, in evident response to expressed stakeholder concern about the diffusion of leadership authority, has developed an elaborate new construct known as the “Medical staff, voting members of the organized” — which is defined in a new Definitions section as: “Those practitioners within
- Requires “conflict resolution” processes that only further para-
  lyze hospital decision-making and denude the governing body of
  the authority it needs to fulfill its accountability for Quality/
  Safety.\textsuperscript{128} and

- “Micro-manages” the content of the medical staff bylaws — creat-
  ing inflexibility and divesting the governing body of any unila-
  teral authority over the bylaws, thus tying the hands of the go-
  verning body and retarding or diminishing promotion and com-
  pliance with Quality/Safety standards.\textsuperscript{129}

MS.01.01.01 avoids dealing with the central contradiction represented by
the presence of the “self-governing” medical staff, and instead creates a series
of proposed “fixes” which ultimately diffuse hospital governance authority
and foster paralysis when unilateral action may otherwise be required.

the organized medical staff who have the right to vote on adopting and amending medical staff
bylaws, rules and regulations, and policies. (See also, medical staff, organized)” [Sic]. Id (Intro-
duction, EPs 9 & 17). Although unremarkable on its face, this newly defined term can be
understood, in the broader context, as TJC’s attempt to articulate a method by which hospitals
can ensure that only the “engaged” members of their medical staffs actually have input into
medical governance issues such as the text of their bylaws, rules and regulations. This was
reflected in the comments of Dr. Robert Wise at the 2007 TJC Teleconference, in which he
acknowledged that medical staffs around the country often give privileges to a large number of
licensed independent practitioners who rarely ever come to the hospital campus, and that it is
important for hospitals to “try to focus on who is actively involved and who really has a signifi-
cant interest in the working of the organization” in terms of carrying out medical leadership
functions. Teleconference Standard MS.1.20, \textit{supra} note 5, at 6-9, 22. The dichotomy of “en-
gaged” versus a “disengaged” medical staff was further expanded on by Mr. Bressler in discuss-
ning and re-affirming the concept at a teleconference entitled “MS. 1.20 or MS.01.01.01 — By Any
Name (or Number) Is It Any Sweeter? hosted by the law firm of HortySpringer on July 9, 2009.

128. MS.01.01.01, in the Introduction and at EP 10, expands the requirements for conflict
resolution that first appeared in the 2007 MS.1.20 and are also embedded in the new Leadership
Standards (I.D.02.02.01). The reality is that governing bodies cannot fulfill their legal accoun-
tabilities while facing the need for a defined conflict resolution process with regard to every
issue that the medical staff finds unpalatable. Further, if the defined conflict resolution fails to
resolve the conflict, the governing body cannot resolve it on its own, leading to paralysis or
inadequate “compromise” action.

129. Whereas the original 2004 version of MS.1.20 contained 20 simply worded EPs, the
new MS.01.01.01 contains 36, many of which consist of entire paragraphs, further enlarged by
reference to other EPs, Leadership Standards and explanatory notes. MS.01.01.01, \textit{supra} note 2
(EPs 2, 3, 4, 9, 10, 11, 15, 16 & 20). Moreover, the Introduction to the new MS.01.01.01 is so
lengthy and discursive that it now consumes nearly two pages. The new MS.01.01.01 appears
to be “micro-managing” the content of the medical staff bylaws to an unwarranted degree,
creating a rigid and inflexible governance framework.
III. OPERATIONAL & LEGAL QUALITY/SAFETY "DRIVERS" FOR A NEW PARADIGM

The inherent structural flaws of TJC’s medical staff/governing body governance paradigm are acutely evident, and disabling, to hospitals and their stakeholders in light of the major operational and legal Quality/Safety “drivers” that require hospitals to adopt a “comply or die” imperative. In order to survive, hospitals must respond successfully to these various “drivers,” either (and preferably) in close collaboration with their medical staff physicians, or, in the absence of successful collaboration, unilaterally. Otherwise, they risk suffering “death from a thousand cuts” emanating from substandard quality, denied and diminished reimbursement, and costly and/or catastrophic regulatory, criminal and civil liability exposures.

On the business side, the recognition of the need to implement systemic change in order to eradicate medical errors, coupled with the radically shifting reimbursement environment, the escalating costs of healthcare, and the increasingly competitive environment, collectively, are requiring hospitals to assert and enforce tight control over all aspects of the service delivery system, both as a matter of legal accountability and pure economic survival. On the regulatory side, the industry has seen vastly increased legal accountability and exposure for hospitals and their individual directors, officers, and physician leaders for substandard, albeit medically necessary, care. Notwithstanding the profound impact of these fundamental industry changes, hospitals are still required by TJC to function within a governance paradigm that cedes major decision-making authority for “quality of care” to a “self-governing” medical staff, over which hospital governing bodies, absent mutual consent, have virtually no leverage, exercise little to no actual control, but who are pursuant to accreditation standards and the law, “ultimately responsible for the quality and safety of care at the hospital.”

A. Fundamental Changes in the Operational Environment

1. Demand for System-Based Approach to Quality/Safety

Since the landmark IOM study in 1999, improving patient safety has become a national priority embraced by physicians, hospitals, and the entire

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130. The March, 2010 passage of the Patient Protection and Affordable Care Act, Public Law 111-148 (March 23, 2010) as amended by the Healthcare and Education Reconciliation Act, Public Law 111-152 (March 30, 2010) (“PPACA”), lends new urgency to the call for full alignment between hospital governing bodies, management and medical staff. While detailed discussion of PPACA’s impact is beyond the scope of the present article, its new mandates and incentives for achieving higher quality and efficiency will exert increasing pressure on hospitals to confront the challenges posed by their existing, siloized leadership structure.
health care community. The main thrust of the patient safety movement over the past decade has been to develop an evidence-based systems approach to reducing medical errors, based on the recognition that "safety is primarily a systems problem." Systemic solutions, however, require, by definition, a fully integrated and coordinated commitment to Safety/Quality — such as that which has been effectively implemented by the aviation industry. As explained by Dr. Lucian L. Leape of Harvard School of Public Health:

[The aviation industry] relied on the widespread implementation of hundreds of small changes in procedures, equipment, training, and organization that aggregated to establish an incredibly strong safety culture and amazingly effective practices. These changes made sense; were usually based on sound principles, technical theory, or experience; and addressed real-life problems. . . .

In a recent article from the Journal of the American Medical Association ("JAMA"), Dr. Stephen Shortell succinctly articulates the critical relationship between the (i) clinical and (ii) systemic organizational components for improving Quality/Safety. Characterizing these components as "Evidence-Based Medicine" ("EBM"), and "Evidence-Based Management" ("EBMgt"), Dr. Shortell concludes:

Two components are necessary to improve the quality of medical care: advances in evidence-based medicine (EBM), which identify the clinical practices leading to better care, i.e., the content of providing care, and knowledge of how to put this content into routine practice. These advances in evidence-based management (EBMgt) identify the organizational strategies, structures, and change management practices that enable physicians and other health care professionals to provide evidence-based care, i.e., the context of providing care. [Citation omitted]. Until both components are in place — identifying the best content (i.e., EBM) and applying it within effective organizational contexts (i.e., EBMgt) — consistent, sustainable improvement in the quality of care received by US residents is unlikely to occur.

In the United States and internationally, many of the health systems that receive the highest marks for quality have been able to achieve evidence-based

132. Id. at 504 (citing numerous references, including J. Reason, A Systems-Based Approach to Organizational Error, 38 ERGONOMICS 1708-21 (1993); R. Cook et al., MEDICAL DISASTERS AND LATENT SYSTEMS FAILURES: BLAME, GUILT, AND CAUSALITY 1-6 (Cognitive Systems Engineering Laboratory, The Ohio State University 1992); R. Cook, How Complex Systems Fail 1-3 (Cognitive Technologies Laboratory, University of Chicago 1998)).
133. Id. at 505 (emphasis added).
134. Stephen M. Shortell et al., Improving Patient Care by Linking Evidence-Based Medicine and Evidence-Based Management, 298 JAMA 673, 673 (2008) (citing K. Walshe et al., Evidence-Based Management: From Theory to Practice in Healthcare, 79 MILLBANK Q. 429-57 (2001)).
135. Id. (emphasis added).
management most successfully through a *physician employment model* that completely eliminates, for all practical purposes, the concept of a “self-governing” medical staff. Although the vast majority of hospitals in the country do not employ their staff physicians, there are important lessons that can be learned from the integrated health care delivery systems that do operate on that basis.

The Mayo Clinic, Cleveland Clinic, Geisinger Health System, the Veterans’ Administration, Intermountain Health Care, Marshfield Clinic, the Henry Ford Clinic, and Kaiser Permanente are all examples of high quality integrated health systems that employ large numbers of physicians, and have strong and cohesive leadership structures integrating physician and non-physician executive leadership at the highest levels. 136

The Mayo Clinic exemplifies the system-wide, integrated approach to Quality/Safety. Mayo Clinic has grown exponentially from a single outpatient physician practice into a highly complex, integrated health system, operating in numerous different geographic locations. All Mayo Clinic physicians are salaried, which removes any personal financial incentives to practicing in a particular way. 137 Mayo’s four part approach to quality includes (a) optimizing its culture for safety, (b) significantly enhancing a supportive infrastructure, (c) streamlining coherent engineering efforts, and (d) delivering disciplined effective execution. As to the culture, the Mayo physician leadership reports that “[m]edicine cannot become highly reliable as long as autonomy, steep hierarchy, blame, independence, and opaqueness characterizes an organization’s culture.” 138 They explain:

Leadership must acknowledge that its organization must transform from a “cottage industry” to a standardized and interdependent delivery system. A basic tenet of a culture of safety is acceptance of a core standard work based on best practice; this must be the rule and

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137. Swensen et al., supra note 136, at 429.

138. Id.
deviations from it are appropriate and expected only for patient-centered reasons, not ones that are physician-centered (e.g., a warfarin regimen that is different from the organization's recommended standard because "this is how I like to practice.") A work environment with needless variation is one that increases the likelihood of medical errors by the health care personnel involved. There is an inherent tension between standardization to excellence and physician autonomy that must be understood and confronted.139

Likewise, the Veterans Affairs New England Healthcare System, which has been recognized as an industry leader in delivering high quality healthcare services, employs most of its physician leaders, which "makes a difference in physician engagement."140 The System's Quality Manager notes that "[w]e are very thoughtful about who we select for physician leaders and participants, and we are also very clear about endpoints and expectations."141

The Henry Ford Health System, also a noted quality leader, has large numbers of employed and non-employed physicians in its System, and demonstrates the contrasting cultures that that dichotomy creates even within a single system. Henry Ford has approximately 900 employed physicians staffing its flagship Henry Ford Hospital, and approximately 1,000 affiliated physicians practicing at the numerous other hospitals in its System.142 One observer has pointed out a striking difference in the system's ability to implement quality-driven improvements at the flagship Henry Ford Hospital as compared with one of the System's community affiliates, the Wyandotte Hospital:

Because Henry Ford Hospital physicians are employees, that facility's department chiefs and heads may have more leverage than would be the case if the physicians were independent contractors. At Henry Ford Hospital, for example, changes are incorporated as part of the physicians' performance expectations and reviews. The Wyandotte Hospital, in contrast, has community physicians with privileges, and its CEO said they are considered to be "customers."143

Intermountain Healthcare ("IHC"), another industry leader in quality, employs only about one-third of its 3,200 affiliated physicians.144 However, one of the critical components of its success in achieving a superior track record of delivering high quality and efficient services has been the successful integration of physician leadership into the overall leadership structure:

In 1993 leaders took . . . steps to more formally integrate physicians, hospitals and health plans in an effort to "improve the total process of care." A task force explored and recommended options for physician relationships with IHC. The system's leadership hoped to give

139. Id.
140. Baker et al., supra note 136, at 85.
141. Id at 84.
142. Id at 190.
143. Id at 202 (emphasis added).
144. Id at 155.
physicians an organizational voice and to bring clinical sciences into prominence. The task force endorsed a new relationship for physicians that would enhance their integration into the IHC system, including a medical division for physicians who chose to be employed by IHC. As a result, the Intermountain Medical Group was created and physicians were invited to play a more significant role in IHC's management and operations. [Citation omitted.] The Intermountain Medical Group proved to be strategically important for engaging physicians in improvement by providing a laboratory for clinical innovation and holding physicians accountable for results.

The highly successful employment-model systems provide the exception rather than the rule. The vast majority of hospitals nationwide continue to be staffed by independent practitioners as opposed to employed physicians. The challenge, therefore, is to translate the successes of the employment-model systems to the majority of hospitals or health systems that have medical staffs comprised of independent staff physicians.

One clinical area in which hospitals across the board have been able to achieve success in improving quality through evidence-based protocols is anesthesiology — where hospitals typically achieve a higher degree of management control through exclusive contracting or employment arrangements. As explained by Harvard's Lucian L. Leape, M.D.:

Anesthesia is the only system in health care that begins to approach the vaunted “six sigma” level of perfection that other industries strive for. Mortality from elective anesthesia has declined 10-fold in the past several decades as a result of a concerted effort to improve safety. This outstanding achievement is attributable not to any single practice or development of new anesthetic agents or even any type of improvement (such as technological advances) but to application of a broad array of process, equipment, organization, supervision, training and teamwork.

The “siloized” governance structure represented by the American Model too often stands as a material barrier to the development and implementation of effective “Evidence Based Management” of hospital Quality/Safety. It requires a hospital’s governing body to build consensus with a diverse and conflicted medical staff and leadership, without realistic recourse if consensus is unable to be achieved regarding the EBM protocols or practices that the governing body (through hospital management), is seeking to implement.

The governing body of a typical community hospital with an independent, (i.e., non-employed) medical staff is too often presented with a Hobson’s choice, of either (i) avoiding conflict with its medical staff by abandoning its effort to implement the disputed protocols or practices, thus jeopardiz-

145. Id. at 156.
146. Leape et al., supra note 131, at 505-06 (citing E. Pierce, The 34th Raventhon Lecture, 84 ANESTHESIOLOGY 966-75 (1996)) (emphasis added).
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ing quality care and patient safety and risking the hospital's demise qualitatively and financially, or (ii) attempting to force implementation unilaterally, thus generating controversy and/or outright hostility from the "self-governing medical staff," and thereby undermining the cooperative relationship that an effective systems approach requires. This "Hobson's Choice" is illustrated by the following, real-world examples drawn from our private practice experience:

- A hospital clinical division follows, on a trial basis, mandatory evidence-based clinical practice parameters. At the conclusion of the trial, all agree that the new practice parameters resulted in the desired quality outcomes; yet, a group of physicians within the division refuse to adhere to them on a going-forward basis and demand that future adherence to the parameters be permissive, not mandatory. The governing body may either (i) unilaterally mandate the adoption and enforcement of the parameters or, alternatively (ii) make compliance a matter of individual discretion, thus impacting adversely quality outcomes. Anticipating negative physician reaction, and confronting the reality that it cannot unilaterally amend the medical staff bylaws to articulate, and mandate compliance with, these practice parameters, the governing body elects to permit voluntary compliance.

- A primary care physician, both personally popular and an extremely large referral source to a variety of specialists, engages in multiple serious incidents of disruptive conduct in violation of the hospital's physician disruptive conduct policy, thus impacting adversely patients and other physicians and nurses. Physician leadership investigates the incidents and finds them all credible; however, it refuses to initiate action against the disruptive physician because he is an influential physician. The governing body may either (i) unilaterally initiate adverse action, fully expecting the MEC to rally to the physician's support and attempt to defeat the governing body's effort, or alternatively, (ii) through inaction, be a passive participant in perpetuating an environment harmful to both patients and staff.

The experiences of such integrated health care systems such as the Mayo Clinic, Intermountain Healthcare and Geisinger Health System, coupled with our own extensive, real-world, national experience, suggest that hospitals cannot realistically succeed in implementing the systemic, evidence-based reforms necessary to achieve acceptable Quality/Safety standards of practice except through an integrated management structure that combines both clinical and management expertise, and operates under the ultimate, unilateral oversight and decisional authority of the governing body.
2. Quality/Safety Driven Reimbursement Environment

The need for effective management of Quality/Safety is also being driven by dramatic changes in the reimbursement environment. The national health insurance reform debate has helped shine a light on the extent to which substandard care drives up the overall cost of healthcare, because avoidable adverse events such as iatrogenic infections, readmissions, falls, wrong-sided surgery, and the like all increase the intensity, and therefore the cost, of healthcare delivery.\textsuperscript{147} Because of this linkage between quality and cost, payors increasingly are using their economic leverage through “pay-for-performance” (“P4P”) and “never events” reimbursement policies to pressure hospitals to dramatically improve the quality of care.

P4P refers to a range of reimbursement tools being developed and used by payors to establish incentives for hospitals to deliver care that the payors deem is necessary and appropriate to achieve the highest quality standards and best outcomes.\textsuperscript{148} Prominent examples include the Leapfrog Group’s Hospital Rewards Program,\textsuperscript{149} and the Prometheus payment system.\textsuperscript{150}

The Leapfrog Group is an employer consortium that was formed for the specific purpose of “mobilizing employer purchasing power to alert America’s health industry that big leaps in health care safety, quality and customer value will be recognized and rewarded.”\textsuperscript{151} The Leapfrog Group has developed a number of P4P initiatives, including its annual Hospital Rewards Program, by which participating hospitals are, on an annual basis, rated on a host of quality and efficiency-related objective measures (65% quality and 35% resource utilization) and those that score well are then eligible for specific financial rewards from participating payors.\textsuperscript{152}

The Prometheus payment model reflects a new payment methodology based on an “Evidence-informed Case Rate” or “ECR.”\textsuperscript{153} An ECR is an evidence-based global payment for an entire episode of medical care for a particular payor-provider-patient triad, as informed by clinical practice guide-
lines and/or expert opinion.\textsuperscript{154} In other words, an ECR will be developed for each specific chronic or acute condition (such as asthma, diabetes, or acute myocardial infarction (AMI)) based upon sophisticated analysis of cost and quality data, and physicians will receive, instead of a series of discrete fees for specific services, one global payment based on the ECR.\textsuperscript{155} The intent is to achieve higher quality, transparency, and coordination of care — and also to reduce administrative burden.\textsuperscript{156} The motivating principle is to employ an evidence-based payment methodology which will promote higher quality, as well as more efficient, care.

P4P programs are now firmly embedded in the payment systems of U.S. public and private insurers across the spectrum.\textsuperscript{157} As of February 2007, it was reported that more than half of commercial health maintenance organizations had P4P programs.\textsuperscript{158} In 2007, CMS initiated the Physician Quality Reporting Initiative ("PQRI"), an ongoing program that provides financial incentives to participating physicians who meet specific quality indicia established by CMS.\textsuperscript{159}

Despite the evident popularity of P4P incentives, the consensus view appears to be that, as of this time, they have had only limited success in improving patient safety.\textsuperscript{160} In particular, researchers have noted that the impact of the quality incentives becomes less dramatic, and can even level off after baseline targets for quality have been met.\textsuperscript{161} Among the various critiques of P4P is the recognition of the limits of its effectiveness given lack of

\begin{itemize}
\item \textsuperscript{154} Id.
\item \textsuperscript{155} Id.
\item \textsuperscript{156} Id.
\item \textsuperscript{158} Id.
\item \textsuperscript{160} See, e.g., Meredith B. Rosenthal, \textit{What Works in Market-Oriented Health Policy?}, 360 New Eng. J. Med. 2157, 2159 (2009) ("Studies have found modest effects of pay for performance on process measures of quality and intermediate health outcome measures"); Meredith B. Rosenthal, \textit{Beyond Pay for Performance — Emerging Models of Provider-Payment Reform}, 359 New Eng. J. Med. 1197, 1197 (2008) [hereinafter \textit{Beyond Pay for Performance}] (noting that some in the industry have characterized P4P as "putting lipstick on a pig"); Peter K. Lindauer et al., \textit{Public Reporting and Pay for Performance in Hospital Quality Improvement}, 356 New Eng. J. Med. 486, 486 (2007) ("Hospitals engaged in both public reporting and pay for performance achieved modestly greater improvements in quality than did hospitals engaged only in public reporting"); Rosenthal & Dudley, supra note 157, at 740 ("Despite purchasers' enthusiasm for pay-for-performance, it has become clear that it should not be a foregone conclusion that these programs will benefit patients or even significantly assist providers who want to improve care.").
\item \textsuperscript{161} Lindauer et al., supra note 160, at 490; Stephen M. Campbell et al., \textit{Effects of Pay for Performance on the Quality of Primary Care in England}, 361 New Eng. J. Med. 368, 375 (2009).
\end{itemize}
centralized coordination and control in the health care delivery system: "Aligning provider incentives with [p]ayer goals will require organizational forms that can coordinate care more effectively than the fragmented current system."

The flip side of P4P is the withholding of payment from hospitals for hospital-acquired conditions or "never events," a growing movement at the federal and state levels, and among commercial payors as well as hospitals. According to the OIG, the first reported "never events" payment policy was adopted in 2005. Since then, numerous large, national payors (as well as hospitals) have implemented such policies, and as of October 2008, CMS initiated its "never events" policy for a set of eight hospital acquired conditions. CMS has encouraged state governments to adopt such policies as part of their Medicaid reimbursement systems, and an increasing numbers of states are doing so. This payment approach has become a fixture of the new reimbursement environment.

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162. Beyond Pay for Performance, supra note 160, at 1200 (citing Elliott S. Fisher et al., Creating Accountable Care Organizations: The Extended Hospital Medical Staff, 26 HEALTH AFFAIRS w44, (2006)).

163. The term "never events" was originally created by the National Quality Forum [hereinafter NQF] in developing its list of events that "should never occur in a [hospital] setting" and which are primarily associated with death or serious physical injury. OIG ADVERSE EVENTS OVERVIEW REPORT, supra note 3, at 1 (citing National Quality Forum, About NQF, http://www.qualityforum.org/about (last visited Oct. 21, 2008)) (internal quotations omitted). NQF has subsequently changed its terminology to "serious reportable events," but the term still retains broad colloquial usage as a general reference to those hospital acquired conditions for which reimbursement may be withheld. Id.

164. Id. at 16-17 (citing HealthPartners, HealthPartners hospital payment policy, http://www.healthpartners.com/portal/866.html (last visited Sept. 8, 2006)).


166. On July 31, 2008, CMS issued State Medicaid Director Letter #08-004, which discussed the Medicaid payment implications of "never events" as a means of encouraging and supporting the states in the adoption of similar plans for Medicaid. As of December 2008, CMS reported to OIG that there were seven states that had pending State Plan Amendments to adopt such policies, and CMS was hopeful that these could serve as models for a national system. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., OEI-06-07-00471, ADVERSE EVENTS IN HOSPITALS: STATE REPORTING SYSTEMS IV, 29 (2008) [hereinafter OIG STATE REPORTING SYSTEMS REPORT]. On August 31, 2009, New Jersey Governor Jon S. Corzine signed into law S.2471, which will prohibit New Jersey hospitals from seeking reimbursement for costs associated with a set of specified "never events." In a related state quality/safety initiative, on September 24, 2009, the California Department of Health [hereinafter DOH] announced that it had assessed administrative penalties of $25,000 per violation against 11 hospitals for practices or procedures that had caused, or were likely to cause, serious injury or death, bringing the total fines assessed for the month of September to $575,000, and well over $3 million since the California DOH started its new enforcement program in 2007. Patient Safety: California Public Health Agency Fines 11 More Hospitals for Dangerous Practices, 18 HEALTH L. REP. (BNA), Oct. 1, 2009.
“Never events” payment policies are placing increased pressure on hospitals to dramatically improve quality and bring their policies and practices into alignment with quality-driven industry guidelines. In a February 2008 article published in the Joint Commission Journal on Quality and Patient Safety, its authors predicted that “never events” payment policies will place more financial pressure on providers to improve patient safety and, specifically, will change clinical practice and hospital procedures to more closely follow recommended guidelines for quality of care and patient safety. 167

Similarly, Dr. Arnold Milstein, M.D., M.P.H., a member of the Medicare Payment Advisory Committee (“MedPAC”) and a prominent physician leader, opined in the June 2009 issue of the New England Journal of Medicine that “fundamental changes” will be required in clinical training and health care delivery as a result of the “never events” reimbursement policies. 168 He cautioned, however, that it is unclear how such changes will be facilitated. In the short term, physicians can expect “more urgent requests from hospitals for cooperation in addressing large shortfalls in implementing the National Quality Forum’s best practices for hospital safety.” 169

These quality-driven payment initiatives at the federal and state levels and among commercial payors are forcing hospitals to take control of the quality and delivery of care to an unprecedented extent as a matter of economic survival — thus potentially bringing them into direct conflict with the “self-governing” medical staff which often has neither the requisite tools nor the collective will to implement the systemic changes that are required to meet the new Quality/Safety imperatives.

3. Competition from Outpatient, Specialty and Foreign Providers

Compounding the challenges presented by the changing Quality/Safety reimbursement environment is the dramatically decreasing revenue base experienced by many hospitals over the last decade, increasingly as a result of competition from domestic outpatient centers and specialty hospitals, and foreign hospitals — all of which have the option of operating free of the cumbersome American Model of medical staff governance.


168. Arnold Milstein, Ending Extra Payment for “Never Events” – Stronger Incentives for Patients’ Safety, 360 New Eng. J. Med. 2388, 2390 (2009). Dr. Milstein noted that the recent “never events” payment policies are part of a larger movement by which the government, in tandem with employers, consumers, and labor leaders, frustrated by the industry’s slow pace in bringing down the medical error rate, increasingly is demanding more accountability for clinical performance.

169. Id.
The drain on hospital revenues started in the 1980s with the proliferation of outpatient diagnostic centers, independent laboratories, and finally, ASCs. In 2006 the AHA reported that 37% of all outpatient surgeries in the United States were being performed at ASCs. Even more dramatic has been the proliferation of specialty hospitals capable of siphoning off hospitals’ most lucrative services such as cardiology, orthopedics and general surgery, with which they have historically subsidized their unprofitable but vital services to the community such as emergency medicine, trauma, obstetrics, and “safety net” care of the uninsured. Although the proliferation of specialty hospitals has been hampered by federal legislation and state certificate-of-

need laws, the movement continues to threaten the inpatient revenue base of community hospitals.

The most recent developing threat to hospitals’ revenue base is the dramatic rise of medical tourism. Although statistics vary, the most recent figures from Deloitte Center for Health Solutions are that 750,000 Americans outmigrated overseas for elective surgical procedures in 2007. That figure is projected to rise to nearly 1.6 million by 2012, with sustainable annual growth thereafter of thirty-five percent. India alone is projected to grow 30% annually between 2009 and 2015 in its medical tourist capability. The major driver for foreign elective medical tourism is the escalating cost of American healthcare, with private hospitals in less developed countries being able to provide comparable services at a cost which is 20% to 80% lower than in the United States.

Like specialty hospitals, foreign hospitals, and now a small number of domestic “tourist” hospitals, target some of American hospitals’ most lucrative service lines, such as cardiac and orthopedic surgery. On November 21, 2009, The Wall Street Journal reported that Indian cardiologist Devi Shetty, M.D. is producing high volume, high quality heart surgery at his 1,000-bed cardiac hospital in Bangalore, India, at a small fraction of the cost that would be charged at comparable American hospitals. Dr. Shetty reports that the high volume of procedures enables him to achieve economies of scale, and enable his forty-two employed cardiac surgeons to develop a high degree of specialization through repetitive performance of highly complex procedures. Dr. Shetty also has a 1,400-bed cancer hospital and a 300-bed eye

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175. Medical Tourism: Update and Implications, DELOITTE CENTER FOR HEALTH SOLUTIONS 3 (2009) [hereinafter DELOITTE UPDATE].


177. DELOITTE UPDATE, supra note 175, at 7.

178. Reed, supra note 176, at 1435.


181. Id.
hospital, and is working on plans to reproduce his model at a new 2,000-bed hospital in the Cayman Islands—"an hour's plane ride from Miami."182

The escalating loss of hospitals' revenue base, first to competing ASCs and specialty hospitals, and now increasingly to competing foreign hospitals capable of providing comparable quality service through a more efficient governance structure and at a significantly discounted cost, is creating yet more economic stress for hospitals. Despite U.S. hospitals' urgent need to compete to the greatest extent possible on Quality/Safety grounds, they are inhibited from doing so through the perpetuation of the American Model.

B. Hospital Quality/Safety Liability & Accountability

With the increased public mandate for comprehensive Quality/Safety reform comes increased liability exposure when performance falls short of reasonable expectations. The American Model must therefore be viewed through a prism which includes evolving federal and state criminal and civil common law, federal and state criminal and civil statutory law, and federal and state regulatory law. The American Model of medical staff self-governance was developed at a time when hospitals were largely immune from legal liability for substandard medical care.183 In today's radically changed legal and business environment, hospitals and their directors, officers, and physician leaders, individually, are being held financially accountable and face escalating civil and criminal exposure for substandard care.

1. Federal & State Enforcement Initiatives Targeting Hospital Directors & Officers for Substandard Quality

Accountability for the health care industry's inadequate quality record is increasingly being assigned to hospital directors and officers. For instance, a board's failure to take action to halt the submission of claims to Medicare (and other payors) for care that is known to be substandard has been characterized as tantamount to 'quality fraud' by the hospital's leadership, including its trustees.184

182. Id.
183. See, e.g., Thompson v. Nason Hosp., 591 A.2d 703, 706 (Pa. 1991) ("Hospitals in the past enjoyed absolute immunity from tort liability. See McDonald v. Mass. Gen. Hosp., 120 Mass. 432 (1876). The basis of that immunity was the perception that hospitals functioned as charitable organizations. See Forrest v. Red Cross Hosp., 265 S.W.2d 80 (Ky. 1954), overruled by 348 S.W.2d 930 (Ky. 1961). However, hospitals have evolved into highly sophisticated corporations operating primarily on a fee-for-service basis. The corporate hospital of today has assumed the role of a comprehensive health center with responsibility for arranging and coordinating the total health care of its patients. As a result of this metamorphosis, hospital immunity was eliminated.") See also Gregory T. Perkins, Note, Medical Malpractice — Ostensible Agency and Corporate Negligence, 17 St. Mary's L.J. 551 (1986).
In a joint publication of the United States Department of Health and Human Services Office of Inspector General ("OIG") and the American Health Lawyers Association ("AHLA"), authored by, inter alia, Lewis Morris, Chief Counsel to the OIG, and entitled Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors, the authors note that "the American health care delivery system is in need of fundamental change . . . quality problems are everywhere affecting many patients."185

Citing a scorecard developed by the Commonwealth Fund in 2006, the OIG/AHLA publication notes that the U.S. healthcare system, as compared with that of other industrial nations, scored in the lowest 25% for some key indicators (such as mortality and use of electronic health care records), and was in the lowest third overall.186

The OIG/AHLA publication emphasizes governing body accountability for improving patient safety:

With 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. Health care organization boards have distinct responsibilities in this area because promoting quality of care and preserving patient safety are at the core of the health care industry and the reputation of each health care organization.187

Board accountability for healthcare quality has guided the OIG’s recent enforcement activities. For instance, on July 13, 2009, the OIG announced that Emmanuel Bernabe, President and Chairman of the Board of the Pleasant Care Corporation in California, had agreed to his permanent exclusion, as an individual, from participating in the federal health care programs. Mr. Bernabe’s agreement was in resolution of the OIG’s allegations that the nursing home residents had received substandard care consisting of, inter alia, (i) insufficient

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186. Id (citing Why Not the Best? Results From a National Scorecard on U.S. Health System Performance, THE COMMW. FUND COMM’N ON A HIGH PERFORMANCE HEALTH SYSTEM, Sept. 2006). The Commonwealth Fund’s findings included the following: (i) for 37 key indicators for quality, access, equity, outcomes and efficiencies, the overall U.S. score was 66 out of a possible 100, with efficiency being the single worst score; (ii) the U.S. scored 15th out of 19 countries in health care mortality; (iii) the U.S. ranked 16th out of 20 countries in use of electronic health care records; (iv) basic tools such as healthcare IT are missing to track patients through their lives; (v) the U.S. ranked highest worldwide in health care cost; and, (vi) improving performance in key areas would save 100,000 to 150,000 lives and $50 — 100 billion annually. Notably, an updated Commonwealth Fund study issued in 2008 showed that, overall, U.S. healthcare had not improved over the two year period, and in certain key areas had lost ground. Why Not the Best? Results From a National Scorecard on U.S. Health System Performance, THE COMMW. FUND COMM’N ON A HIGH PERFORMANCE HEALTH SYSTEM, July 2008.

187. Id at 2.
icient hydration and nutrition, (ii) inappropriate wound care, and (iii) a failure to maintain adequate staffing levels.\textsuperscript{188} In a press release, Inspector General Daniel R. Levinson advised that "[t]he critical that boards and management make compliance with professionally recognized standards of care a priority at all levels of their organizations."\textsuperscript{189}

The OIG's settlement with Mr. Bemabe in the Pleasant Care matter is consistent with, and reflective of, a deliberate policy initiative that has been in force at the federal level for a number of years, and is now gaining a foothold at the state level as well of holding governing bodies and individual directors and officers accountable for substandard quality in healthcare institutions through False Claims Act ("FCA") enforcement.

On May 15, 2008, the OIG's Chief Counsel, Lewis Morris, testifying before a U.S. House Subcommittee, noted that, since at least 2003, the OIG has been working to raise awareness and provide educational resources for hospital board members regarding their direct legal and fiduciary accountability for the quality and safety of the care delivered.\textsuperscript{190} Mr. Morris noted that "[w]ith a new focus on quality and patient safety, oversight of quality is a core fiduciary responsibility of health care organization boards of directors."\textsuperscript{191}

In 2006, James G. Sheehan, who at the time was Chief of the Civil Division of the U.S. Attorneys' Office in Philadelphia, and who currently is the Inspector General of the New York State Office of Medicaid, articulated four critical questions to guide prosecutorial decision-making as to whether a healthcare organization and/or its directors and officers, may be prosecuted for substandard care:

- Has there been a systemic failure by management and the board to address quality issues?
- Has the organization made false reports about quality or failed to make mandated reports?
- Has the organization profited from ignoring poor quality or ignoring providers of poor quality?
- Have patients been harmed by poor quality or given false information about quality?\textsuperscript{192}

\textsuperscript{188} Press Release, Office of Inspector Gen., Nursing Home Executive Agrees to Permanent Exclusion in Settlement with OIG (July 13, 2009).
\textsuperscript{189} Id. (internal quotations omitted).
\textsuperscript{191} Id. at 10.
Mr. Sheehan is now aggressively pursuing and implementing the same public policy approach at the state level for the New York State Medicaid Program. The 2009-2010 Medicaid Work Plan, issued by the New York State Office of Medicaid Inspector General ("OMIG"), articulates in specific terms the compliance and oversight obligations of governing bodies and warns that individual directors may be sanctioned for failure to satisfy their compliance and oversight obligations. Specifically, the Work Plan states that:

Under state law and regulation, most health care providers . . . are obligated to have a governing body with responsibility for setting policy, for assuring that processes and systems are in place to provide a reasonable assurance of compliance with governing law, and for exercising reasonable oversight over information and reporting systems on an ongoing basis to detect potential violations of law or corporate policy.

When OMIG identifies a significant compliance or control weakness at a health care provider in the course of an audit, investigation, or match project, OMIG will inquire into the board's actions in assuring that compliance processes and systems are in place, and whether board members have exercised reasonable oversight over information and reporting systems.

In appropriate circumstances, OMIG will consider sanctions, including censure and/or exclusion against individual members of the governing body for significant failures to comply with their duties with respect to compliance and oversight.

In a written Statement submitted in April 2009 to a Subcommittee of the U.S. Senate's Committee on Homeland Security and Governmental Affairs, Mr. Sheehan emphasized that his agency will seek to hold "senior executives and board members accountable" for failing to maintain adequate systems to prevent improper billing. The focus of program integrity efforts must be on "systems control failures by management and the board as well as wrongful intent."

Federal and state regulators have thus given clear guidance that substandard care is an enforcement priority — in nursing homes, hospitals, home care,
hospice and skilled nursing facilities.\textsuperscript{197} It is equally clear, and not subject to debate, that legal accountability for substandard quality care does not fall onto a hospital's "organized medical staff" but, rather, rests squarely with the hospital itself, and its directors and officers individually.\textsuperscript{198}

2. Statutory Basis for False Claims Act Enforcement for Substandard Care

The Federal False Claims Act (along with its numerous state analogues) has proven to be a particularly potent weapon for enforcement efforts directed at substandard care. The FCA is a criminal and civil statute that makes it illegal to intentionally or recklessly submit a false claim for payment to the federal government.\textsuperscript{199} Penalties include imprisonment, criminal fines, civil damages, forfeitures, civil monetary penalties and exclusion from the federal or state health care programs.\textsuperscript{200} In the healthcare context, the most commonly invoked civil FCA provisions impose liability on persons or corporations who knowingly: (i) present or cause to be presented a false or fraudulent claim for payment to the government, (ii) use a false record or statement to obtain payment on a false or fraudulent claim, (iii) use a false record or statement to conceal, avoid or decrease a payment obligation to the government, or (iv) engage in a conspiracy to defraud the government by getting a false or fraudulent claim paid.\textsuperscript{201} The term "knowingly" encompasses having actual knowledge of the falsity of the claim or acting with deliberate ignorance or in reckless disregard of the truth or falsity.\textsuperscript{202}

Suits can be initiated by the federal government, or by private \textit{qui tam} relators (whistleblowers) — usually insiders to the organization — who are incentivized to bring such suits in the name of the government by the potential rewards that can be reaped of up to thirty percent (30\%) of the entire recovery, plus costs and attorney fees.\textsuperscript{203}

"The Department of Justice ("DOJ") and \textit{qui tam} relators increasingly have turned to the [FCA] to address egregious failures to oversee or provide quality care,"\textsuperscript{204} employing creative legal theories that, while relatively untested judicially in the substandard care context specifically, have provided the basis

\textsuperscript{197} Belmont et al., supra note 192, at 1-2 (citing U.S. Dept. of Health & Human Servs., FY 2008 Agency Financial Report, Management Issue 4: Quality of Care; Melanie Evans, Raising the Bar for Boards, MODERN HEALTHCARE (Mar. 2, 2009)).

\textsuperscript{198} TJC explicitly recognizes, through its Leadership Standards, that "[t]he governing body is ultimately accountable for the safety and quality of care, treatment, and services." HAS 2009, supra note 18, at 101 (LD.01.03.01).


\textsuperscript{200} Id.; 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law).

\textsuperscript{201} 31 U.S.C. §§ 3729(a)(1)(A)-(C), (G).

\textsuperscript{202} Id. § 3729(c).

\textsuperscript{203} Id. § 3730.

\textsuperscript{204} Belmont et al., supra note 192, at 4.
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for FCA prosecutions and substantial monetary settlements. The legal theories include:

- **False Certification.** It is well-accepted by the courts that a FCA claim can be predicated on an express or implied “false certification” of compliance with all applicable laws and regulations submitted as part of the claim for payment. As applied in this context, the theory is that the provider has “falsely certified” compliance with minimum quality standards and/or specific state or federal patient safety regulations.

- **Worthless Services.** The government has taken the position that a claim is “false” if the services for which payment is claimed are “worthless services.” Care that is rendered in a manner that is far below acceptable quality standards can be deemed “worthless” for purposes of FCA enforcement, along with medically unnecessary services.

In addition, the government is aggressively employing new methods of analysis, such as data mining of utilization statistics, to proactively identify and prove what services are so substandard or unnecessary as to be deemed “worthless” and therefore capable of FCA enforcement.

3. Quality of Care Case Law

The government’s quality-based FCA enforcement initiatives have resulted in substantial and well-publicized settlements, including:

- **$54 Million Settlement for Redding Medical Center, California.** In 2004, Tenet Healthcare Corporation entered into a $54 million civil settlement with the federal government arising out of claims

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205. Id. at 4-5.
against the Tenet-owned Redding Medical Center, based on the Medical Center’s failure (i) to identify aberrant utilization patterns by certain physicians on its medical staff, and (ii) to prevent these physicians from performing medically unnecessary invasive cardiac procedures, including open heart surgery.  

- **$200,000 Settlement for Central Montgomery Medical Center, Pennsylvania.** In 2005, Central Montgomery Medical Center paid $200,000 in resolution of the federal government’s allegations of improper use of restraints on psychiatric patients.

- **$3.8 Million Settlement for Our Lady of Lourdes Regional Medical Center, Louisiana.** In 2006, Our Lady of Lourdes Regional Medical Center paid $3.8 million to the federal government in settlement of allegations arising out of a cardiologist’s performance of allegedly unnecessary invasive cardiac procedures, such as angioplasty and stent placement. The cardiologist himself went to trial and was convicted of 51 counts of healthcare fraud.

Importantly, the government has utilized federal mail and wire fraud statutes to pursue hospitals and their medical staff physician leaders for gross failures in the credentialing, privileging and quality oversight processes that create and perpetuate significant risk to patient safety.

Most notable in this regard are the three federal criminal indictments against not-for-profit United Memorial Hospital and two of its senior medical staff leaders for alleged gross failures in credentialing, privileging and peer oversight of a pain management physician whose serious competency issues ultimately led to the death of a patient. According to the stipulated facts set forth in the plea agreement, United Memorial Hospital (“UMH”) had been experiencing financial difficulties in the early 1990s, when it recruited anesthesiologist Dr. Jeffrey Askanazi to chair the department of anesthesiology.

Soon after joining the hospital’s staff, Dr. Askanazi expanded his practice to

209. Press Release, Doctors Accused of Performing Unnecessary Heart Surgeries at Redding Medical Center Agree to Pay Millions to Settle Fraud Allegations and Accept Restrictions on Their Medical Practice (Nov. 15, 2005) (on file with the authors), available at http://s181943702.onlinehome.us/campbell/dojre12.pdf.


213. Id. at 5.
include pain management, notwithstanding his lack of training or experience.214 By September of 1994, UMH's management team began receiving complaints from nurses, physicians and patients that Dr. Askanazi was performing pain management procedures that lacked medical benefit and endangered the welfare of patients.215 By May, 1995, these concerns reached UMH's Board of Trustees.216 Despite such complaints, virtually nothing was done to restrict the number or type of procedures that Dr. Askanazi was performing. Instead, actions were taken to discourage complaints against him, as his practice was financially lucrative to UMH.217 It was not until one of Dr. Askanazi's patients died in July, 1996 that UMH's management obtained a substantive review of Dr. Askanazi's practice, which revealed that Dr. Askanazi was providing substandard and unnecessary care.218 The case resulted in a plea agreement by which the community hospital pled guilty to wire fraud and paid $1.75 million in fines.219

This is but one example of the potentially draconian exposures that face hospitals, their directors, officers, and medical staff physician leaders for failing to ensure the development of, and compliance with, applicable Quality/Safety standards.

4. Corporate Negligence

Another substantial source of legal exposure for hospitals arising out of substandard quality is corporate negligence exposure for negligent credentialing, privileging and peer oversight of physicians practicing on their medical staffs. In 2004, Tenet Healthcare Corporation paid $395 million to resolve corporate negligence, breach of fiduciary duty, and other civil legal exposures arising out of allegations that it had failed to provide proper credentialing and quality oversight relative to a cardiologist and cardiovascular surgeon on the medical staff of the Redding Medical Center, alleged to have performed unnecessary coronary procedures.220 This was not an isolated case.

214. Id. at 3-4.
215. Id. at 4.
216. Id. at 6.
217. Id. at 6-8.
218. Id. at 8-9.
219. Id. at 1, 11-14. In October 2001, federal prosecutors obtained indictments of UMH, Dr. Daniel Seward, UMH's Chief of Staff, and Dr. Matthew DeWys, UMH's Chief of Emergency Medicine, for conspiring with Dr. Askanazi to submit fraudulent billing claims from 1995 to 1997. Francis J. Serbaroli, Fed Snag Hospital in Physician Fraud Case 229 N.Y.L.J. 1, 2 (2003), available at http://www.cadwalader.com/assets/article/SerbaroliNYLJ012803.pdf. In 2003, UMH pled guilty to one count of wire fraud, agreeing to (i) reimburse approximately $750,000 to Medicare, Medicaid and two private insurers, (ii) pay a fine of over $1 million, and (iii) implement a compliance plan and annual independent audits of its coding and billing practices. Id. As part of the agreement, the federal criminal charges against Dr. Seward and Dr. DeWys were dismissed. Id.
For example, Pennsylvania Health Care Cost Containment Council's ("PHC4") public interactive database on Total Hip and Knee Replacements tabulates the post-surgical rate of (1) deep joint infection or device problems, (2) blood clot in the lung/leg, (3) wound infection, and (4) readmission, organized by both hospital and by surgeon.224 Anecdotally, when a Pennsylvania hip surgeon has a bad outcome leading to a corporate negligence lawsuit, the local plaintiff's bar can be expected to search the PHC4's website and, if the surgeon's quality statistics are below the norm, use that as a basis for challenging the hospital's credentialing of that surgeon on the basis of the PHC4 data.

Furthermore, with the increasing use of Electronic Medical Records, the industry is developing ways of mining data directly from the EMR to assess
quality. One published article reports on the use of a radiology information system containing medical images and associated patient data in digital form as a tool to assess the performance of radiologists over various quality parameters.\textsuperscript{225} As other medical records are increasingly converted to electronic form, the information they contain could similarly be mined in order to assess performance in other areas of practice.\textsuperscript{226}

The increased transparency resulting from these many new technologies, coupled with state adverse event reporting requirements, may have the impact of increasing these corporate negligence exposures. Skillful plaintiffs' attorneys are becoming increasingly sophisticated at mining negative quality data that is now regularly published on public and commercial websites, and at using the readily available "industry best practices" data to argue for more rigorous standards of care.\textsuperscript{227}

5. Staff Privilege Litigation Exposures Arising from Board Quality/Safety Enforcement Efforts

The bifurcated governance responsibility arising from TJC-mandated "self-governing" medical staff paradigm exacerbates the separateness of the "self-governing" medical staff from the management and the governing body, thereby creating the potential for increased antitrust liability exposure for those hospitals seeking to invoke and rely upon JC-mandated peer review and corrective action processes to resolve issues of physician competence, ethics, behavior and quality.

Disciplined physicians frequently resort to antitrust litigation to challenge adverse decisions. In fact, the vast majority of antitrust actions filed in the healthcare arena — whether by private civil litigants or by the federal government — are filed by physicians challenging adverse privileging decisions made


\textsuperscript{226} Booz Allen Hamilton, One Organization's Experience Automating Quality Measurement using a Commercial Electronic Medical Record (study on file with the authors). Notably, there are limitations as to the capability of automated quality measurement systems keyed to EMRs. Specifically, in this study, a health care organization wanted to install an EMR systemwide, in order to automate quality reporting and eliminate chart review. The study found that, of the data elements that the organization desired to automate, approximately 60% could be fully automated, another 17.5% could be partially automated, and the last 22.5% could not be automated, largely due to documentation requirements. The study concluded that automating 50% of the data elements would result in automation of only 4 quality measures.

\textsuperscript{227} More than half of the states now have some form of mandatory reporting system for medical errors. OIG STATE REPORTING SYSTEMS REPORT, supra note 166, at 7. The greater availability of such data may generate more, and more successful, corporate negligence suits against hospitals that compile and report such data but fail to act upon the substandard quality issues that the data reveals. Barry R. Furrow, Symposium: Privacy Law in the New Millennium: A Tribute to Richard C. Turkington: Article: Data Mining and Substandard Medical Practice: The Difference Between Privacy, Secrets and Hidden Defects, 51 VILL. L. REV. 803, 821 (2006).
on the basis of competence, ethics, behavior or quality concerns.\textsuperscript{228} It is common for physicians to include not only the hospital entity, but also individual medical staff leaders, directors and officers as defendants in these actions.\textsuperscript{229}

TJC-mandated "self-governing" medical staff makes governing bodies and their "self-governing" medical staffs needlessly vulnerable to antitrust challenges pursuant to Sections 1 & 2 Sherman Antitrust Act concerted action claims.\textsuperscript{230} In the case of staff privilege antitrust litigation, the fact that credentialing, privileging, peer review and corrective action are, by TJC mandate, delegated to and overseen by the "self-governing" medical staff gives rise to claims (ultimately valid or not) that adverse privileging decisions allegedly resulted from concerted action between the governing body and its medical staff.\textsuperscript{231} In some jurisdictions (the minority), courts have held that a hospital entity is \textit{capable} of concerted action with its medical staff, thus exposing both to antitrust liability under the Sherman Act.\textsuperscript{232} However, the majority of courts have found that, in carrying out quality and peer review activities, the interests of a hospital entity and its "organized medical staff" are so closely aligned that they are \textit{incapable} of conspiring with each other.\textsuperscript{233} As the Fourth Circuit Court of Appeals explained:

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229. In \textit{Poliner}, for instance, the plaintiff sued and obtained jury verdicts against the hospital and its Chairman of Internal Medicine, its Director of the Cardiac Catheterization Laboratory, and its Chief of Cardiology. Numerous other physicians involved in the peer review process were also sued but ultimately dismissed from the case. \textit{Poliner v. Tex. Health Sys.}, 2006 U.S. Dist. LEXIS 13125 (N.D. Tex. Mar. 27, 2006), rev'd, 537 F.3d 368 (5th Cir. 2008).

230. "Every contract, combination in the form of a trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal." 15 U.S.C. 5 1. "Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony ..." \textit{Id} at § 2.

231. \textit{See infra} notes 233-234.


Proof of concerted action requires evidence of a relationship between at least two legally distinct persons or entities. [Plaintiff] contends that this plurality requirement is met in this case because the medical staff and the hospital are legally discrete entities. We think, to the contrary, that the staff is acting as an agent of [the hospital] during the peer review process and as such is indistinct from the hospital.

In reaching this result, courts generally rely upon the Copperweld intra-corporate immunity doctrine, which protects against antitrust liability arising from concerted action between legally distinct entities within a corporate network. However, we express concern that the enhanced separation and autonomy of the self-governing, organized medical staff, in contradistinction to the governing body, reflected in MS.01.01.01, makes it increasingly difficult to argue in the future, as a matter of public policy, that the quality/safety interests of medical staffs and hospitals are so closely aligned as to warrant Copperweld immunity.

Additionally, even in the majority of jurisdictions which apply Copperweld intra-corporate immunity to physician staff privilege disputes, there is a significant exception to Copperweld immunity known as the “independent personal stake exception.” Under this exception, even if the “organized medical staff” is not capable of conspiring with the hospital, individual medical staff members motivated by their own economic self-interest can engage in concerted action for purposes of Sherman Act liability even while purportedly fulfilling their designated medical staff functions. Given the extensive and increasing sources of financial and other conflict between hospitals and their medical staff physicians, the “personal stake exception” is taking on increasing significance as a means of attempting to circumvent Copperweld immunity.

The propensity of disciplined physicians to file antitrust suits — seeking treble damages, attorneys’ fees and equitable relief — too often operates as a powerful disincentive for hospitals and medical staffs to take requisite adverse action related to substandard care. Even in the absence of federal antitrust allegations, the threat of costly and contentious medical staff litigation alleging breach of contract, tortious interference, unfair competition, defamation, emotional distress, and other state law claims, frequently deters a fragmented hospital leadership from taking needed disciplinary or corrective action.

234. Oksanen, 945 F.2d at 702-03.
236. See, e.g., Oksanen, 945 F.2d at 705.
Based on our national litigation experience, we acknowledge that, with the adoption and implementation of the Health Care Quality Improvement Act ("HCQIA"), which provides, *inter alia*, limited immunity from damages in antitrust and other claims, physician staff privilege lawsuits arising over Quality/Safety standards are often defeated after the completion of lengthy discovery at either summary judgment or at trial. Notably, however, HCQIA limited immunity from damages neither prevents health care providers from being sued, nor typically protects defendant health care providers from having to participate in emotionally grueling, contentious, disruptive and costly discovery. Moreover, in our experience, as increasingly conflictual and disparate economic interests develop among and between hospital stakeholders, HCQIA limited immunity is becoming less available because of the propensity of aggrieved physicians to allege that the adverse action resulted from the furtherance of particular economic interests as opposed to the "furtherance of quality healthcare." Even though many of these suits are defeated after discovery at summary judgment or at trial, they continue to be filed in significant numbers and result in extremely costly, contentious, and disruptive litigation, and many times very significant monetary settlements.

Collaterally, the threat of being named a party-defendant in antitrust (and other) litigation, regardless of the ultimate substantive merits, chills the willingness of too many medical staffs to properly investigate and pursue aggressively issues of practitioner incompetence and/or disruptive behavior. A typical result is that the governing body either (i) acts independently, without medical staff support, thus enabling the aggrieved physician to utilize the absence of medical staff support to materially challenge and undermine the *bona fides* of the governing body’s action, or (ii) elects not to act at all, or inadequately, thus permitting an incompetent and/or disruptive practitioner to continue to practice. Our real-world, national litigation and counseling experience teaches us that, regrettably, too many governing bodies find themselves confronted with "chilled" medical staffs and thus too often elect the latter course of action.

With this type of accountability and legal exposure arising out of failures in their quality standards and compliance processes, it is untenable that U.S. hospitals are prohibited by TJC accreditation standards from exercising the control and authority needed to decisively address Quality/Safety issues effectively.

6. Insurance Coverage: Availability, Cost & Increased Scrutiny

Diverse and profound regulatory and liability exposures faced by hospitals and their stakeholders are resulting in an increasingly sophisticated health
care insurance market which provides hospitals and their stakeholders with requisite insurance coverage, especially directors and officers ("D&O") and professional liability indemnity and defense coverage.

Insurers generally, and D&O and professional liability insurers specifically, have taken keen note of both the regulatory and litigation quality care initiatives, as well as the results of DOJ and State Attorneys General investigations and prosecutions (criminal and civil), regulatory investigations and administrative enforcement proceedings, and private civil litigation, all of which have rocked the hospital-provider industry with incredibly disruptive, reputationally harmful, and extremely costly litigation, settlements and verdicts. These insurers, by way of their indemnity and defense insurance coverage, have witnessed first-hand the "cost" of these defenses, settlements and verdicts.

As a result, insurers generally, and healthcare D&O and professional liability insurers specifically, necessarily will become much more penetrating and sophisticated, for example, in their underwriting scrutiny and analysis. Rather than simply inquiring into, and reviewing, potential policyholder-hospitals' medical staff bylaws, hospital accreditation surveys, state department of health surveys, and claims history, these insurers increasingly will apply a heightened level of underwriting scrutiny to hospitals examining, for example:

- The existence, content and enforcement of medical staff physician conflict of interest policies;
- The existence, content and enforcement of mandatory, as opposed to permissive, evidence-based clinical practice parameters;
- The existence, content and enforcement of credentialing and privileging "best practices;"
- The existence, content and enforcement of credentialing and privileging compliance and auditing "best practices;"
- The existence, content and enforcement of governing body-driven systems designed to verify independently the integrity and credibility of quality care and competency decisions and recommendations emanating from key "informational gatekeepers" such as, for example, Department Chairs, Division Chiefs, Chief Medical Officers, the Credentials Committee, and the MEC;
- The procedure(s) by which Department Chairs are selected, evaluated, and retained, and whether Chairs are elected by their Departments, or whether they are appointed, evaluated and reappointed by the governing body for the responsible performance of their diverse and critically important Quality/Safety duties and responsibilities;
- The procedure(s) by which medical staff physicians are appointed, evaluated and reappointed as members of the governing body, and whether such physician members of the governing
body act as fiduciaries or as "representatives" of the medical staff;
- The existence, content and enforcement of systems designed to audit the credentialing and privileging recommendations emanating from "exclusive contract" departments and "single groups" divisions; and,
- The hospital's record of investigating and pursuing corrective and other disciplinary action based on Quality/Safety, ethical and behavioral standards.

Insurers are also paying greater attention to applicable exclusions in physician credentialing disputes. In recent contentious federal and state litigation between a hospital and physicians on its medical staff arising out of an economic credentialing policy, the hospital's insurance carrier retroactively denied coverage of the hospital's defense costs based on the hospital's failure to notify the insurer that its prior adoption of the credentialing policy was likely to lead to litigation. The insurer's denial of coverage was upheld in court. The federal district court determined that the hospital's adoption of the economic credentialing policy should have been disclosed to its insurer, based on the evidence presented that (i) the hospital was aware that similar policies at four other hospitals had been challenged legally, (ii) the OIG had raised questions about whether "economic credentialing" violates the anti-kickback statute, (iii) the hospital had sought extensive legal review before adopting the policy, and (iv) the hospital knew that specific physicians who would be impacted by the policy had complained about its adoption. The insurance policy was therefore declared void by the court.

Physician-driven litigation, including qui tam, antitrust, physician staff privilege, and litigation arising out of conflicts of interest among a hospital's physician directors, is responsible for increasing numbers of claims filed under D&O policies. Hospital and insurance industry benchmarking suggest that the volume of professional liability cases has been increasing, potentially as a result of the increased publicity and awareness surrounding hospital "never events." Escalating insurance premiums help escalate the cost of health care for hospitals, and, ultimately, for consumers.

TJC accreditation standards must keep pace with the new business realities by affording hospitals the tools needed to develop and implement a fully

240. Id. at 31-32.
241. Id.
aligned hospital/medical leadership structure – which is the only way that hospitals will ultimately, absent successful physician collaboration, be able to gain control of the quality and cost variables for which they are legally accountable.

IV. FOUNDATIONS OF A NEW DISCUSSIONAL PARADIGM

The American Model of the “organized, self-governing medical staff,” created seventy years ago under a completely different set of social, economic, regulatory and legal conditions, is now a prohibitive barrier to real progress in achieving a “zero-defect” “safety culture” advocated by TJC and mandated by government regulators, payors and patients. In particular, TJC’s continuing misguided emphasis on physician autonomy and “self-governance” seriously detracts from, and operates as a barrier to, the industry’s overall move towards coordination and integration of care as a way of producing both higher quality and greater efficiency in the health care delivery system.

Although the American Model has become firmly entrenched in our American health care culture, there are viable alternatives that warrant serious consideration. Specifically, the DNV standards, which integrate ISO’s International Quality Management Standards with the CMS requirements, offer a more unified and integrated quality management model which recognizes the Board’s ultimate authority and emphasizes medical staff accountability to the Board for quality and safety. Likewise, the numerous healthcare systems that have received international acclaim as high achievers in the areas of both quality and efficiency of service delivery – such as the Mayo Clinic, Geisinger Health System, Cleveland Clinic, Intermountain Health Care and the Veterans Affairs New England Health System – in contradistinction to the typical community hospital that is staffed by independent, non-employed staff physicians, have done so in large part through successfully integrating the physician, governing body and executive leadership to develop a unified, system-wide approach to quality and safety.

The lessons that can be learned from these integrated models are that hospitals need to move away from the “siloized” governance model created and perpetuated by TJC accreditation standards, towards a unified hospital/medical staff leadership structure that is capable of driving change in a coordinated fashion across the full spectrum of health care services delivered by a hospital or health care system.

In our view, some key foundational aspects of such a governance paradigm must include:

* Elimination of the “self-governing medical staff” structure, and integration of physician clinical expertise and judgment into a streamlined departmental structure operating under the management oversight of a Chief Medical Officer or other like position reporting directly to the CEO (who in many instances may
also be a physician), so that there is a unified, fully accountable, management structure reporting to the governing body;

- Integration of all Quality/Safety functions into the hospital's unified management structure, so that physician and non-physician executive leadership can, under the direct management authority of the CEO and ultimate, unilateral authority of the governing body, efficiently promulgate and enforce standards of competence and conduct and address and resolve chronic quality care deficiencies, using an evidence-based systems approach to Quality/Safety;

- Integration into the unified management structure of various participatory conduits through which physician expertise and judgment is obtained relative to (i) Quality/Safety issues, and (ii) strategic planning activities related to the full spectrum of clinical and operational endeavors, to be considered and resolved ultimately by the governing body, thus obviating the need for the notional concept of "physician representation;"

- Explicit recognition of the governing body's ultimate unilateral authority over the development, adoption, implementation and enforcement of all Quality/Safety standards and functions relative to the delivery of all hospital-based services.

As the numerous examples of successful quality-driven hospital systems show, physician expertise and judgment is critically important to a hospital's ability to develop, implement and enforce Quality/Safety standards. Specifically, by way of example, this expertise and judgment is necessary in requisite areas such as (i) performance improvement, (ii) recommended mandatory evidence-based clinical practice parameters, (iii) clinical peer review, (iv) competency-based appointment and reappointment, (v) competency-based corrective and disciplinary actions, and (vi) development of appointment, reappointment and privileging criteria.

Physicians who provide such expertise and judgment need to be selected, evaluated and retained through an appropriate unified management structure and, concomitantly, appropriately reimbursed in a manner commensurate with the critically important roles that they play. Inasmuch as governing bodies are legally accountable for quality/safety issues, we acknowledge and recommend that they have to commit the necessary financial and human resources to enable them to attract and retain suitable physicians in the performance of these activities. It is contemplated that this structure will invest physicians with the necessary time and resources to enable them to credibly and materially further the hospital's Quality/Safety program, while at the same time being free from the deep-seated conflicts and performance barriers inherent in TJC's bifurcated governance structure.

Indeed, in the Mayo Clinic example (among others), which has its roots in a single physician practice group, the physician leadership has driven the
evolutionary growth of the organization into the highly sophisticated and integrated health care delivery system it is today, and has driven the development of its highly successful Quality/Safety program. One of the critical ingredients of success in the Mayo Clinic example, as well as the others cited in this article, is the integration of the physician and the executive leadership into a single management structure, accountable to, and operating under the ultimate, unilateral authority of, its governing body.

Whether a health system’s executive leadership is predominantly physician or non-physician, it is evident that the greatest health system success stories to date in achieving Quality/Safety standards are largely those built on a physician employment model — in whole or in substantial part. However, we do not accept the premise that the employment model offers the only means of achieving measurable improvement in Quality/Safety functions.

The vast majority of health systems in the country, which do not employ their physicians, are in need of new governance paradigm that will facilitate the same degree of integrated management and control that the employment-model health systems have been able to achieve. TJC’s American Model of medical staff “self-governance” stands as a major barrier to the development of such a paradigm. Fortunately, the evidence from TJC’s own international standards, as well as the DNV standards and ISO 9001 suggest that more effective Quality/Safety processes can be achieved in a health care system staffed by independent practitioners so long as the management of and accountability for Quality/Safety processes is in the hands of physicians who are not “self-governing,” but who are, to the contrary, fully integrated into the hospital’s management structure and who possess genuine, real-world, accountability to the governing body.