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# FENG SHUI AND THE RESTRUCTURING OF THE HOSPITAL CORPORATION: A CALL FOR CHANGE IN THE FACE OF THE MEDICAL ERROR EPIDEMIC

John D. Blum<sup>†</sup>

#### INTRODUCTION

FENG SHUI IS THE EASTERN ART and science of being in harmony with your environment. A current fad in the West, feng shui is often characterized as a method to place objects in physical space, but in a broader sense, it is a structural system designed to align an internal environment with the outside world.<sup>2</sup> The concept of feng shui can be applied to institutions, and while some may question such application, few students of organizational theory would quarrel with the need for an organization to be properly structured to meet internal and external objectives. Health care delivery is replete with organizational models created to achieve a type of structural feng shui. In particular, the American hospital has undergone significant structural changes to both facilitate internal operations and to meet the demands of external constituencies. Today's American hospital is a complex web of managerial and clinical parts, which often spill over into multicorporate structures. While the average hospital corporation is now far more complex than in the past, from a legal standpoint the fundamental corporate model, the so-called "three legged stool," board, administration and medical staff, has remained much the same for many years.3

<sup>&</sup>lt;sup>†</sup> John J. Waldron professor of Health Law at Loyola University Chicago School of Law, Institute for Health Law. This article is written as a tribute to the Case Western Reserve University School of Law, Law-Medicine Center and its Director, Professor Maxwell J. Mehlman, in recognition of the outstanding contributions made to the field of health law and policy.

ERIC SHAFFERT, FENG SHUI AND MONEY: A NINE-WEEK PROGRAM FOR CREATING WEALTH USING ANCIENT PRINCIPLES AND TECHNIQUES XVII (2002).

⁴ Id.

<sup>&</sup>lt;sup>3</sup> Richard L. Johnson, Revisiting "the Wobbly Three Legged Stool," HEALTH

This essay is written to consider the continuing viability of the basic legal structure of hospitals, namely the three legged stool, and to determine whether or not this legal framework retains its effectiveness in the current environment in which acute care institutions must function. More specifically, the article considers the question of whether or not hospitals can respond to pressures they are under in the areas of patient safety and quality, if they are locked into the traditional triad corporate legal model. Returning to the concept of feng shui, the question can be framed as an analysis of whether the three legged stool allows hospitals to achieve the necessary internal efficiencies to face the external pressures being placed on the hospital in the quality area. In view of the fact that this article is part of a broad symposium on health law, the consideration of the hospital legal structure will be developed in the broader context of hospital law generally.

The discussion will examine major trends in hospital common and statutory law that relate to quality of care concerns, and the ways hospitals have responded to quality pressures. The article will explore the implications of medical errors on hospital operations, sparked by the 1999 Institute of Medicine (IOM) Report, and in light of the IOM Report and its progeny, the piece will consider the inadequacies of the three legged stool. The article will end with a consideration of how the hospital corporate legal model might be altered to improve current and future quality or care challenges.

#### I. THE BIG PICTURE OF HOSPITAL LAW AND ITS NEXUS TO QUALITY

The goal of providing an optimal level of quality is a longstanding, perennial issue in American health care delivery. Quality, in and of itself, has become a complex multi-faceted concept, ranging from accountings of anecdotal impressions to studies that are multi-

CARE MGMT. REV., Summer 1979, at 15 (explaining that hospitals were referred to as "wobbly three legged stools" because they consisted of physicians, hospital executives, and hospital trustees all acting separately instead of as a unified organizational structure).

<sup>4</sup> COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Linda Krohn et al. eds., 2000) [hereinafter IOM REPORT] (reporting the high existence of medical error caused deaths in U.S. hospitals and recommending ways to counter medical error).

<sup>5</sup> See, e.g., Karen A. Butler, Comment, Health Care Quality Revolution: Legal Landmines for Hospitals and the Rise of the Critical Pathway, 58 ALB. L. REV. 843 (1995) (describing the rise of quality management and arguing that the use of the critical pathway "tool," a pre-planned course of treatment based on diagnosis for a hospital patient, will revolutionize hospitals' quality oversight). faceted and highly quantified.<sup>6</sup> It is common to see quality of medical care broken down into three primary elements: structure, process, and outcome, and each of these elements represents a primary approach to understanding and addressing quality issues in the hospital context.<sup>7</sup> For purposes of this article the concept of quality will be dealt with in a very broad manner, encompassing the full range of factors and techniques directed toward enhancement of individual and collective health. The consideration of quality in this essay is not, however, totally open-ended, as the first section focuses on how major developments in hospital law can be related to quality of care concerns. It is the premise of the article that most of the major developments in hospital law are concerned with quality of care, either directly or indirectly, and that concerns over quality will continue to be the driving force in the future development of law in the acute care setting.

#### A. Immunity

In constructing an overview of hospital law using quality as the vantage point, it is helpful to separate out common and statutory law developments in the discussion. It is also important to note that the focus of this essay is on law affecting non-profit, private hospitals, but much of what is discussed herein is equally applicable to for-profit and governmentally sponsored institutions. A very large body of case law has developed concerning hospitals in the second half of the twentieth century. Hospital common law can be divided into three general areas: safety-related issues, vicarious liability and agency, and corporate negligence.

In the early part of the twentieth century, hospitals were immune from suit as a result of governmental and charitable immunity principles. <sup>9</sup> Charitable immunity was rooted in trust law that characterized

<sup>&</sup>lt;sup>6</sup> See, e.g., Rushika Fernandopulle et al., A Research Agenda for Bridging the 'Quality Chasm,' HEALTH AFF., Mar.-Apr. 2003, at 178 (highlighting the gaps in knowledge and recommending research in areas identified in the IOM's Quality Chasm report that would meet the report's goals of building organizational supports for change, applying evidence to health care delivery, developing information technology, aligning payment policies with quality improvement, and preparing the workforce).

<sup>&</sup>lt;sup>7</sup> See generally Avedis Donabedian, A Primer of Quality Assurance and Monitoring in Medical Care, 20 U. Tol. L. Rev. 401, 411-14 (1989) (explaining the approaches to assessing the quality of care performance of physicians).

<sup>&</sup>lt;sup>8</sup> See, e.g., ARTHUR F. SOUTHWICK, THE LAW OF HOSPITAL AND HEALTHCARE ADMINISTRATION 539-40 (2d ed. 1988) (noting that until the common law changes in the 1940s & 1950s, hospitals used to enjoy immunity based on interpretations of trust law, theories of implied waiver of tort claims by beneficiaries of a charity, and/or public policy).

<sup>9</sup> BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND

the assets of a non-profit hospital corporation as being held to fulfill the institution's purpose as a charity.<sup>10</sup> To allow a financial recovery in tort against the hospital would jeopardize the entity's ability to carry out its charitable mission, and as a matter of public policy, such actions were barred. On the governmental immunity side, the principles of not allowing suits against government sponsored hospitals were rooted in difficulties obtaining insurance and financial resources prior to large-scale government financing.<sup>11</sup> Both forms of immunity, charitable and governmental, were abolished by statutory overrides and, while vestiges of sovereign immunity linger and continue to be a factor in a limited number of cases,<sup>12</sup> the immunity doctrine generally is remote from today's hospital world.

#### B. Safety and Employment

Prior to the development of corporate liability, hospital common law was focused on safety issues and vicarious liability. Hospitals were seen as shells within which medicine was practiced, and the hospital itself was legally akin to a hotel, bearing responsibility only for the physical structure and for its employees. Hospital liability was limited to what the corporation could directly control within its four walls, outside of the medical arena. Related to the notion of limited hospital liability is the corporate practice of medicine doctrine, which held that corporate entities, such as hospitals, could neither practice medicine, nor employ those who could. Thus, it followed that a hospital as an entity not licensed to practice medicine, or which did

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PROBLEMS, 416-17 (4th ed. 2001).

<sup>&</sup>lt;sup>10</sup> See id. at 416 (illustrating this notion via the historical reasoning found in Bing v. Thunig, 143 N.E.2d 3 (N.Y. Sup. Ct. 1957)); See also Thompson v. Nason Hosp., 591 A.2d 703, 706 (Pa. 1991) (explaining that hospitals had previously received absolute immunity from tort liability but can now be held to corporate liability standards).

<sup>11</sup> See FURROW, supra note 9, at 417.

<sup>12</sup> E.g., Moser v. Heistand, 681 A.2d 1322, 1325-26 (Pa. 1996) (noting that sovereign immunity applies in Pennsylvania and that in order to bring suit against the state in a medical action, a statutory exception must apply).

<sup>&</sup>lt;sup>13</sup> See SOUTHWICK, supra note 8, at 540-42 (arguing that hospitals and physicians should treat liability and risk management as joint problems and abandon prior adversarial roles of determining negligence based on corporate relationships).

<sup>&</sup>lt;sup>14</sup> See id. at 543 (explaining how the concept of respondent superior, in general, permits vicarious liability for the tort of an employee because an employer can "control the means and methods of the employee's work").

<sup>&</sup>lt;sup>15</sup> Brian Monnich, Note, *Bringing Order to Cybermedicine: Applying the Corporate Practice of Medicine Doctrine to Tame the Wild Wild Web*, 42 B.C. L. Rev. 455, 466 (2001) (explaining the doctrine).

not directly employ physicians, could not bear direct liability for medical care delivered within its four walls.

While the lack of institutional liability for medical care narrowed the acute care entity's legal exposure, the other avenues of legal responsibility, safety and vicarious liability, have proved to be significant and expansive. Much of the liability hospitals encountered in the safety and employment area can be related to quality of care in some fashion. The concept of safety includes a responsibility to adequately maintain premises, and that responsibility extends to visitors, employees, and patients alike. Safety duties related to patients may have their origins in hotel-like functions, but the nature of patient care involves numerous complexities that can create a broad spectrum of liability rooted in the duty to provide a safe environment. The range of patient safety issues extends from protecting the physical well-being of individuals in the different treatment areas of the hospital to maintaining a vast array of equipment.

The other long standing area of hospital liability concerns employer responsibilities under the doctrine of vicarious liability.<sup>17</sup> As a labor intensive institution that employs individuals with a wide range of backgrounds and responsibilities, a hospital's exposure under the doctrine of vicarious liability is extensive. While vicarious liability extends to responsibilities for the full range of activities engaged in by hospital employees, many of those activities will concern patient care issues, and, therefore, impact in some manner on quality of care concerns.

Of particular interest in the vicarious liability area are applications of this doctrine to physicians. As a result of the demise of the corporate practice of medicine, there has been an increase in the number of doctors directly employed by hospitals, the growth in hospital-based medical specialties, and the growing attractiveness of the acute care institution providing liability coverage. <sup>18</sup> If a hospital employs a phy-

<sup>&</sup>lt;sup>16</sup> See John J. Michalik, Annotation, Hospital's Liability to Patient for Injury Allegedly Sustained from Absence of Particular Equipment Intended for Use in Diagnosis or Treatment of Patient, 50 A.L.R.3d 1141, 1145 (1973) (explaining that the hospital's duty to maintain safe equipment for patient care was indirectly derived from its responsibilities to employees and third parties).

<sup>&</sup>lt;sup>17</sup> See, e.g., SOUTHWICK, supra note 8, at 542 (explaining that employers can be held liable, even when not directly at fault, if their employees commit a tort within the scope of their employment).

<sup>18</sup> Cf. HEALTHCARE FACILITIES LAW: CRITICAL ISSUES FOR HOSPITALS, HMOS, AND EXTENDED CARE FACILITIES 343-48 (Anne M. Dellinger ed., 1991) (listing indicators of an employment relationship and explaining that a hospital's liability for the negligent acts of its employee-physicians depends upon whether an employment relationship actually exists, and whether the employer controls the performance of the work).

sician, it will bear legal responsibility for the actions of that individual while he or she engages in medical practice within the institution. A related area of considerable interest in hospital law has been the expansion of hospital liability for the actions of independent contractor physicians under various agency doctrines such as apparent agency or agency by estoppel. 20

#### C. Corporate Liability

In 1965, with the Illinois Supreme Court decision in *Darling v. Charleston Community Hospital*, the limitations on hospital corporate liability were dramatically eroded.<sup>21</sup> The *Darling* court held that a hospital, based on its bylaws, licensure, and accreditation requirements, had an affirmative duty to monitor the quality of medical care in its institution, and could not use the argument that hospital duty was centered on custodial functions only within its four walls.<sup>22</sup> While not every state has followed the *Darling* case, the hospital law field experienced an erosion of the separation between administrative and clinical functions, not only through changes in common law, but also through changes in statutory law and accreditation requirements.<sup>23</sup> The hospital corporate responsibility for medical care is manifest in several ways, but two areas that are particularly noteworthy for the volume of legal actions generated include hospital medical malpractice actions and medical staff credentialing disputes.<sup>24</sup>

<sup>&</sup>lt;sup>19</sup> See John D. Hodson, Annotation, Liability of Hospital or Sanitarium for Negligence of Physician or Surgeon, 51 A.L.R.4th 235, 244 (1987) (invoking the doctrine of respondent superior in the context of employee-physicians).

Id. at 244-50. See generally Martin C. McWilliams, Jr. & Hamilton E. Russell, III, Hospital Liability for Torts of Independent Contractor Physicians, 47 S.C. L. Rev. 431 (1996) (describing, for example, actual agency, apparent agency and estoppel, non-delegable duty, and direct liability in the independent contractor physician context).

<sup>&</sup>lt;sup>21</sup> 211 N.E.2d 253 (III. 1965) (forbidding the hospital from limiting its liability as a charitable corporation to the amount of its liability insurance).

<sup>&</sup>lt;sup>22</sup> Id at 257

<sup>&</sup>lt;sup>23</sup> See Andrea G. Nadel, Annotation, Hospital's Liability for Negligence in Failing to Review or Supervise Treatment Given by Doctor, or to Require Consultation, 12 A.L.R.4th 57, 66 (1982) (discussing the role played by state-adopted hospital regulations and hospital accreditation standards in determining hospital liability in the Darling case).

Darling case).

24 See generally Michelle M. Mello & Troyen A. Brennan, Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform, 80 Tex. L. Rev. 1595 (2002) (tying the improvement in quality and safety to the deterrent effect of potential malpractice litigation); Jeffrey O'Connell & Christopher Pohl, How Reliable Is Medical Malpractice Law? A Review of "Medical Malpractice and the American Jury: Confronting the Myths About Jury Incompetence, Deep Pockets, and Outrageous Damage Awards" by Neil Vidmar, 12 J.L. & HEALTH 359 (1997-98) (book review).

The bulk of medical malpractice actions occur in hospital settings, and it is rare for the involved hospital not to be named in such actions, often because the entity is viewed as having a "deep pocket." Medical malpractice is directly related to clinical care issues, but whether such actions constitute a legitimate tool for enhancing quality is subject to considerable debate. It can be argued that medical malpractice shines a light on quality problems, and that fear of medical malpractice has a deterrent effect, forcing hospitals to be proactive in preventing medical errors. On the other hand, the argument can be made that malpractice actions are, at best, random, primarily driven by the prospect of a large financial award, having little to do with actually improving hospital care.<sup>25</sup>

The other area within the context of hospital corporate liability where there has been a considerable amount of litigation is medical staff credentialing: the appointment, reappointment, and delineation of privileges. Hospitals engage in credentialing as a result of common and statutory law mandates, and this area reflects the need of acute care institutions to ensure that its medical staff is qualified, continue to be qualified, and can deliver adequate clinical services. Credentialing is a quality assurance function, as it requires exercise of considerable clinical judgment; it is a function which has been delegated to the medical staff itself. But the ultimate legal responsibility for credentialing rests with the hospital board, reflecting the fact that the process is ultimately a corporate responsibility. Case law in credentialing typically concerns challenges brought by aggrieved physicians against hospitals, based on a range of legal theories, from breach of contract to alleged violations of antitrust law. With the expansion of creden-

<sup>&</sup>lt;sup>25</sup> See Paul C. Weiler, The Case for No-Fault Medical Liability, 52 MD. L. REV. 908, 915 (1993) (discussing the negative aspects of medical malpractice insurance and damages awards); Jack W. Shaw, Jr., Annotation, Hospital's Liability for Negligence in Selection or Appointment of Staff Physician or Surgeon, 51 A.L.R.3d 981, 984 (1973) (maintaining that proving proximate causation in negligent credentialing cases is, in fact, difficult and that it is utilized as only one of many possible litigation strategies for suing hospitals).

<sup>&</sup>lt;sup>26</sup> See Johnson v. Misericordia Comm. Hosp., 301 N.W.2d 156 (Wis. 1981) (affirming a hospital's duty to exercise reasonable care to grant privileges only to competent medical doctors); see also John D. Blum, Economic Credentialing: A New Twist in Hospital Appraisal Processes, 12 J. LEGAL MED. 427, 427-29 (1991) (noting the multiple suits brought by physicians against hospitals and exploring the latest phenomenon seen in hospital credentialing decisions, in which hospitals consider factors such as specific cost parameters or quality of care aspects of a physician's practice).

<sup>&</sup>lt;sup>27</sup> See Blum, supra note 26, at 433-36 (discussing the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards regarding credentialing processes to insure quality of care).

<sup>&</sup>lt;sup>28</sup> JOHN F. HORTY, HOSPITAL LAW § 1 (1988).

tialing into economic evaluation, it can be argued that the process has gone beyond only quality considerations. Credentialing is now a more expansive evaluative process that has changed as a result of the availability of more sophisticated information systems and the external market pressures faced by hospitals.<sup>29</sup>

#### D. Statutory Duties: Three Types of Regulation

The line between common and statutory law in the hospital arena is, at best, a rather artificial one, as so many hospital law principles have been codified or emanate from statutory law. For example, credentialing issues are not only manifest in common law, but are equally impacted by state and federal law, as well as private sector accreditation requirements. Common law is more concerned with redress in individual cases and its impact on quality is retrospective, whereas regulatory controls are designed to protect the public's health in a current and prospective fashion. In shifting the focus of inquiry to hospital statutory law, it is apparent that few entities have been subjected to more extensive regulatory controls from all governmental levels than the acute care hospital.<sup>30</sup> Though not all hospital regulations deal with quality, the bulk of government mandates have a direct or indirect bearing on quality concerns.

It is far beyond the scope of this essay to present a detailed review of the myriad regulations affecting hospitals that have a quality nexus, but for purposes of this analysis quality-related regulation can be characterized as broadly focusing on hospital structures and processes. Regulation in the hospital sector can be viewed in various ways, with initial regulatory efforts centering on organizational and structural matters. The second generation of regulation was spawned by large public programs, primarily Medicare and Medicaid, and most of the regulation in this context falls into the broad category of reimbursement regulation. The third level of hospital regulation is more eclectic in that it tends to be driven by governmental responses to specific and

<sup>&</sup>lt;sup>29</sup> E.g., John D. Blum, *The Evolution of Physician Credentialing into Managed Care Selective Contracting*, 22 Am. J.L. & MED. 173, 180-87 (1996) (noting that economic pressures have altered the role of medical staff as isolated professionals).

<sup>&</sup>lt;sup>30</sup> See, e.g., AM. HOSP. ASS'N, PATIENTS OR PAPERWORK?: THE REGULATORY BURDEN FACING AMERICA'S HOSPITALS, at http://www.hospitalconnect.com/aha/advocacy-grassroots/advocacy/advocacy/content/FinalPaperworkReport.pdf (last visited Nov. 24, 2003) (describing the paperwork tasks required of health care workers as an example of the effects of excessive governmental regulation).

broad based problems and is generally directed by the winds of politics.

#### 1. Structure-Organization-Licensure

In the area of structure and organization, licensure stands out as the most basic form of regulation.<sup>31</sup> Licensing statutes and regulations specify basic services and functions which must be provided by an acute care facility.<sup>32</sup> Licensure, at its core, is driven by the state's desire to ensure that entities providing acute care services meet necessary, basic requirements to deliver adequate quality of care. Medicare Conditions of Participation details basic requirements hospitals must comply with to participate in the Medicare program and are akin to licensure laws.<sup>33</sup> In addition, the private sector requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have had a profound impact on the structure and organization of hospitals, and should be viewed as quasi-governmental in their impact.<sup>34</sup> Licensure and accreditation requirements are not static, but change over time, reflecting the attitude of regulators as to what the core of the acute care facility needs to be in lieu of changes in medicine and health care delivery generally. To an extent, the requirements serve as a template for understanding the panoply of regulatory mandates directed at this sector.

Beyond licensure one area that directly concerns structural issues of acute care facilities is certificate of need (CON) laws. While CON has fallen out of favor in the current market oriented climate, these laws represent an attempt by regulators to rationalize the behavior of health care delivery entities, in particular, hospitals.<sup>35</sup> CON laws may be motivated in large part by economic considerations, but ultimately they reflect concerns about the quality of health care in a region, which is affected directly by service availability and expansions.

<sup>32</sup> See, e.g., id. at 85/6 (permitting licensure only if the facility is able to meet proper community, financial, and safety standards).

 $<sup>^{31}</sup>$  E.g., Hospital Licensing Act, 210 ILL. COMP. STAT. ANN. 85/1-16 (West 2000 & Supp. 2003).

<sup>&</sup>lt;sup>33</sup> See Health Insurance for Aged Act, 42 U.S.C. § 1395x(e) (2000) for a definition of the standards to which institutions wishing to be considered a hospital are held, and 42 C.F.R. § 482 (2002) for hospitals' conditions of participation in Medicare.

<sup>&</sup>lt;sup>34</sup> See Butler, supra note 5, at 846-47 (explaining JCAHO's creation and its effect on the organization and management of hospitals).

<sup>&</sup>lt;sup>35</sup> E.g., ROBERT D. MILLER & REBECCA C. HUTTON, PROBLEMS IN HEALTH CARE LAW 65-66 (8th ed. 2000)

#### 2. Reimbursement

Reimbursement regulation may be the one area where the argument can be made that the requirements are strictly driven by cost considerations, and any link to quality can be characterized as incidental. This analysis, however, is misguided, as reimbursement matters are very much related to quality considerations. The fact that the Medicare Conditions of Participation require hospitals to have quality improvement, credentialing, and utilization review programs in place prior to being eligible to treat Medicare patients demonstrates that public insurance programs regulate far more than the mechanics of payment.<sup>36</sup> In fact, Medicare and Medicaid have expended considerable effort in controlling many aspects of the delivery of institutional health care, such as the current proposal that Medicare providers who meet quality standards in five clinical areas would receive performance bonuses.<sup>37</sup> Medicare has been consistently involved in mandated quality improvement, starting with utilization review in the 1960s and moving through a wide range of hospital quality evaluation programs, adopting directive to more open ended approaches.<sup>38</sup>

Even where the focus of the Medicare regulation is reimbursement, the impact on quality is still present. Perhaps the best example of the link between cost and quality can be seen in Medicare's adoption of prospective payment through use of Diagnostic-Related Groups (DRGs) in the 1980s.<sup>39</sup> On its face, the DRG system establishes prospective payment levels for hospitals for medical treatment, but implementation of the system has resulted in more careful analyses of diagnosis and treatment, caused changes in the actual delivery of medical care, and was the spark that resulted in a new approach to data collection and analysis.<sup>40</sup> Whether DRGs have improved medical care is a matter of speculation, but few could disagree with the notion

<sup>&</sup>lt;sup>36</sup> 42 C.F.R. §§ 482,21-482,22, 482,30 (2002).

<sup>&</sup>lt;sup>37</sup> See Kendra D. Casey Plank, Hospitals to Earn Performance Bonuses Under New CMS Quality Initiative Demo, 12 Health L. Rep. (BNA) No. 29, at 1132-33 (July 17, 2003) (describing a demonstration project launched by the Department of Health and Human Services to improve hospital quality).

<sup>&</sup>lt;sup>38</sup> R. Heather Palmer, Securing Health Care Quality for Medicare, HEALTH AFF., Winter 1995.

<sup>&</sup>lt;sup>39</sup> Social Security Amendments of 1983, Pub. L. No. 98-21 (codified as amended at 42 U.S.C. § 1395ww (2000)).

<sup>&</sup>lt;sup>40</sup> See Larry A. Oday & Allen Dobson, Paying Hospitals Under Medicare's Prospective Payment System: Another Perspective, 7 YALE J. ON REG. 529, 529-44 (1990) (discussing the generally successful effects of Medicare's prospective payment system on health care delivery despite Congressional manipulation).

that this system of prospective payment is linked to quality considerations.<sup>41</sup>

In the problem-based approach to regulation, there are numerous examples of initiatives specifically directed at quality concerns. Over time many of the changes in licensure regulations can be attributed to specific quality concerns. State laws dealing with risk management and hospital data reporting requirements are examples of directives motivated by quality considerations.<sup>42</sup> On the federal level, the most visible regulation of hospitals is driven by professional and public concerns over quality. The 1986 Health Care Quality Improvement Act was sparked by organized medicine's concerns over the integrity of the hospitals' medical peer review process. These concerns, coupled with broader societal worries about medical malpractice, led to the creation of the National Practitioner Data Bank, which directly impacts hospital medical staff credentialing.<sup>43</sup> The Emergency Medical Treatment and Active Labor Act (EMTALA), the outgrowth of a 1985 Consolidated Omnibus Budget Reconciliation Act provision, deals on its face with access to hospital emergency care. 44 EMTLA. however, concerns medical screening, stabilization and treatment, and has a clear bearing on the quality of emergency medicine in the hospital setting.<sup>45</sup> The recent Health Insurance Portability and Accountability Act (HIPAA) privacy rule, which seeks to safeguard patient electronically transferred medical information, can be seen as another regulatory initiative that ultimately is directed to the quality of patient care in a very broad sense. 46 An example of a very specific and highly

<sup>&</sup>lt;sup>41</sup> Medicare fraud and abuse enforcement also can be viewed as ultimately concerned with quality of care and regulatory initiatives in this area appear to be overtly moving in such a direction. See James G. Sheehan, Federal Enforcement of Minimum Quality Standards, Remarks at Widener University's Health Law Teachers Meeting (June 2003).

<sup>&</sup>lt;sup>42</sup> E.g., 210 ILL. COMP. STAT. ANN. 85/6.17 (West 2000 & Supp. 2003) (protecting the confidentiality of medical records); OHIO REV. CODE ANN. § 2305.251 (Anderson Supp. 2003) (providing immunity from liability for peer review committees); FLA. STAT. ch. 395.3025 (2003) (mandating the copying of medical records upon request and their provision to authorized parties).

<sup>&</sup>lt;sup>33</sup> Health Care Quality Improvement Act of 1986, Pub. L. No. 99-660, 100 Stat. 3784 (codified as amended at 42 U.S.C. §§ 11101-11152 (2000)).

<sup>&</sup>lt;sup>44</sup> 42 U.S.C. § 1395dd (2000) (stating the requirements and regulations of hospitals when dealing with emergency patients).

<sup>&</sup>lt;sup>45</sup> Michael J. Frank, *Tailoring EMTALA to Better Protect the Indigent: The Supreme Court Precludes One Method of Salvaging a Statute Gone Awry*, 3 DEPAUL J. HEALTH CARE L. 195, 210-11 (1999-2000) (noting that the primary purpose of the screening requirement is to ensure that all patients have access to the same quality of examination).

<sup>&</sup>lt;sup>46</sup> Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 262 (1173), 110 Stat. 1936, 2025-26 (codified as amended in scattered

political regulation can be seen in the Baby Doe rules, which mandate that hospitals post notices concerning the need to provide treatment to medically compromised newborns—a targeted example of a federal regulation that presumably was intended to impact the quality of care in hospitals.<sup>47</sup>

#### 3. Responses to Legal Realities Affecting Quality

The avalanche of regulation and common law liability pressures that impact the quality issue in the hospital context has resulted in multiple responses, from mandated changes to self-generated operational structural and policy alterations. More recently, major regulatory initiatives, such as Medicare fraud and abuse enforcement<sup>48</sup> and HIPAA privacy regulation, have spawned specific compliance initiatives.<sup>49</sup> It has been more typical for hospitals to respond to regulations by making internal changes in less directive ways than the current noted compliance initiatives demand.

On the common law side, liability pressures have resulted in hospital-wide risk management programs that are geared to identify, evaluate, and minimize medical problems, focusing on a wide range of operational matters. Over time these efforts have been codified into law and accreditation requirements. In addition to responses to common and statutory law, hospitals have developed elaborate intradepartmental and hospital-wide programs to focus on various quality issues, and these efforts have been integrated into the hospital operational culture. Acute care facilities have responded to growing governmental pressure regarding patient satisfaction and most institutions are performing patient surveys to monitor their quality of care from a consumer perspective.

sections of 42 U.S.C.)

<sup>&</sup>lt;sup>47</sup> Child Abuse Treatment and Prevention Act, 42 U.S.C.S. § 5102 (2003).

<sup>&</sup>lt;sup>48</sup> 42 U.S.C. § 1320a-7b (2000).

<sup>&</sup>lt;sup>49</sup> Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (listing monetary penalties for failure to comply with the regulations).

<sup>&</sup>lt;sup>50</sup> See generally FLORENCE KAVALER & ALLEN D. SPIEGEL, RISK MANAGEMENT IN HEALTH CARE INSTITUTIONS: A STRATEGIC APPROACH (2d ed. 2003) (covering areas of concern, strategic approaches, and specific areas in need of risk management).

<sup>51</sup> E.g., Stanford Hospital and Clinics, New Patient Satisfaction Survey Will Help Improve Service, MEDICAL STAFF UPDATE ONLINE, at http://www-med.stanford.edu/shs/update/archives/MAR2003/survey.html (Mar. 2003) (announcing Stanford Hospital's use of new survey to learn patient assessments of care).

### II. THE IOM REPORT: A TSUNAMI HITS HEALTH CARE

In the abstract, it could be concluded that the law has had a very positive effect on the quality of hospital care because of the many changes that have occurred due to direct and indirect legal pressures. In 1999, however, the hospital world experienced the equivalent of its own perfect storm as the Institute of Medicine (IOM) in its well known report, "To Err is Human," concluded that hospital-based medical errors resulted in 44,000 to 98,000 avoidable deaths per year.<sup>52</sup> While the wide range in estimated deaths may give some pause, and has led to arguments about the validity of the IOM study, subsequent studies have confirmed that the problem of avoidable hospital errors is a troubling reality. The IOM itself followed up its original report with two subsequent studies that in a more comprehensive manner demonstrated the pervasive overuse, misuse, and under use of care in hospital settings.<sup>53</sup> Leading medical journals have carried articles detailing various aspects of the medical error problem and the voices of concern over medical errors have emanated from some of the nation's leading health service researchers. It was noted by a health services researcher, Dr. Donald Berwick in the New England Journal of Medicine, that, based on the IOM Report, 100 patients will die in hospitals each day as a result of preventable errors.<sup>54</sup> Berwick. in another piece, chronicles the care his wife received in leading teaching hospitals, concluding that "[t]he errors [in her care] were not rare; they were the norm." A study conducted by Rand Health Care in twelve metropolitan areas found that physicians provided appropriate care in about 55% of patient encounters and that percentage did not vary with the level of treatment being provided.<sup>56</sup>

<sup>52</sup> IOM REPORT, supra note 4, at 1.

<sup>&</sup>lt;sup>53</sup> COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., CROSSING THE QUALITY CHIASM: A NEW HEALTH SYSTEM FOR THE 21<sup>ST</sup> CENTURY (2001) (discussing methods for improving the quality of the current health care system). *See also* COMM. ON RAPID ADVANCE DEMONSTRATION PROJECTS: HEALTH CARE FINANCE AND DELIVERY SYSTEMS, INST. OF MED., FOSTERING RAPID ADVANCES IN HEALTH CARE: LEARNING FROM SYSTEM DEMONSTRATIONS (Janet M. Corrigan et al. eds., 2003).

<sup>&</sup>lt;sup>54</sup> Donald M. Berwick, *Errors Today and Errors Tomorrow*, 348 NEW ENG. J. MED. 2570, 2570 (2003) [hereinafter Berwiwk, *Errors*].

 $<sup>^{55}\,</sup>$  Donald M. Berwick, Escape Fire: Lessons for the Future of Health Care 23 (2002).

<sup>&</sup>lt;sup>56</sup> Rita Rubin, *Patients' Care Often Deficient, Study Says*, USA TODAY, June 26, 2003, at A1 (reporting on a study's caution that deficiencies in care pose serious threats to the American public).

The IOM reports, and subsequent findings concerning medical errors, have resulted in a great deal of reflection from public and private quarters about why the numbers of avoidable medical errors in American hospitals are so high. Blame has been attributed to the diverse and ever complex organizational structures within which medicine is practiced.<sup>57</sup> In addition, medical education has been criticized for failing to encourage collaboration with health professionals from varying backgrounds.<sup>58</sup> A frequently cited criticism of hospital care is the lack of communications and coordination among caregivers, as well as the inability of professionals to reach consensus in developing consistent plans of care. 59 Also, it has been argued that the medical error problem is driven by inadequate medical information systems. characterized by a combination of disjointed paper and electronic records.<sup>60</sup> Still others point to the nursing shortage and lack of adequately trained nurses as the central issue in the medical error epidemic.61

Beyond formulating insights into the problem of medical errors, considerable attention has been focused on how best to address the problem. A popular response to the medical error problem has been some type of reporting system for medical errors. JCAHO has led the way with the development of a sentinel reporting program, in which accredited hospitals voluntarily report major adverse events to the Commission. There have also been several legislative proposals calling for the creation of a federal reporting system. But reporting

<sup>58</sup> See id., at 73-75 ("[W]e persist in using age-old, even medieval, strategies and methods for training physicians.").

<sup>59</sup> Berwick, *Errors*, *supra* note 54, at 2570-71 (discussing coordination and communication problems in hospitals as observed by residents).

Jane Roessner, *Making Doctors Computer Literate*, in REDUCING MEDICAL ERRORS AND IMPROVING PATIENT SAFETY 12-15 (Steven Findlay ed., 2000) (explaining how the implementations of computerized "order entry" system dramatically helped reduce medical errors due to medication errors).

61 Your Health: Medical Errors Linked to Nurses, CNN.COM HEALTH, at http://www.cnn.com/2000/HEALTH/09/15/your.health/index.html (Sept. 15, 2000) (addressing the notion that nursing mistakes, due in large part to staffing shortages, cause a significant portion of medical errors).

62 See, e.g., Memorandum from Dan Field, Oregon Association of Hospitals and Health Systems, to the Chief Executive Officers (Jan. 8, 1999), at http://www.aracnet.com/~oahhs/issues/jcaho/sentnl13.htm (last modified May 10, 2001) (providing a legal analysis of the revised JCAHO Sentinel Events Policy announced October 1998).

<sup>63</sup> See, e.g., Melissa Chiang, Note, Promoting Patient Safety: Creating a Workable Reporting System, 18 YALE J. ON REG. 383 (2001) (offering a plan for a Federal reporting system, including the suggestion to protect the confidentiality of

<sup>&</sup>lt;sup>57</sup> Elise C. Becher & Mark R. Chassin, *Improving Quality, Minimizing Er*ror: Making it Happen, HEALTH AFF., May-June 2001, at 68, 72-73.

proposals have been stymied by concerns over confidentiality and discovery of reported information.<sup>64</sup> At the state level, programs have been launched that focus on the collection, analysis, and public dissemination of key hospital quality data. 65 A number of states have enacted laws to address medical error issues directly, with efforts ranging from statewide study commissions, to mandatory reporting by hospitals.<sup>66</sup> It has been proposed that institutions that positively address medical error issues should be rewarded through increases in reimbursement, based on demonstrable improvements in quality.<sup>67</sup> As noted. Medicare has launched an experimental program to increase hospital reimbursement in several treatment categories for institutions that meet certain quality outcome measures. 68 Ouestions concerning why errors occur, and how to bring about positive changes have become a priority of the Department of Health and Human Services (DHHS), Centers for Medicare and Medicaid (CMS), as well as the federal Agency for Healthcare Research and Ouality (AHRO), and several projects in the area have been launched by these entities.<sup>69</sup> More broadly, health service researchers have been engaged in attempting to study and extrapolate lessons from safety science garnered in other industries, particularly aviation and nuclear safety, and apply results of those analyses to hospital settings.<sup>70</sup>

On the individual hospital level there has been considerable activity directed at addressing medical error issues. Typical responses include developing better management information systems to address problems in medication errors, and particular emphasis has been placed on infection control, equipment errors and even routine slip

quality review information).

<sup>65</sup> See id. at 15 (noting that in 2000, after the release of the IOM report on medical errors, 15 states introduced 45 bills related to medical errors).

<sup>&</sup>lt;sup>64</sup> See Damon Adams, State Legislatures Tackle Medical Error Reporting, AMNEWS, March 12, 2001, at 15, 17, available at http://www.amaassn.org/amednews/2001/03/12/prsb0312.htm (reporting that the American Medical Association is against reporting that does not protect physicians).

<sup>&</sup>lt;sup>66</sup> Id. See also Helen Altonn, Hawaii Health Care Addresses Errors, HONOLULU STAR-BULLETIN, June 30, 2001, at A2, available at http://starbulletin.com/2001/06/30/news/story9.html (discussing how Hawaii is attempting to address and minimize medical errors).

<sup>&</sup>lt;sup>67</sup> See, e.g., David A. Hyman & Charles Silver, You Get What You Pay For: Result-Based Compensation For Health Care, 58 WASH. & LEE L. REV. 1427 (2001).

E.g., Plank, supra note 37, at 1132-33.
 See Carolyn M. Clancy & Thomas Scully, A Call To Excellence, HEALTH AFF., Mar.-Apr. 2003, at 113 (evaluating the federal government's actions to help improve patient safety).

<sup>&</sup>lt;sup>70</sup> E.g., Paul Barach, The End of the Beginning: Lessons Learned from the Patient Safety Movement, 24 J. LEGAL MED. 7, 20-24 (2003).

and fall issues.<sup>71</sup> A group of Boston teaching hospitals has developed an Information Technology (IT) system to enable it to more closely track the status of patients in the emergency room, and provide more timely reports on diagnostic test results.<sup>72</sup> Hospitals are now cautioning patients about safety issues and stressing the need for better communication between staff and patients.<sup>73</sup> In spite of such changes, a noted medical error expert issued word of caution, observing that many hospitals and physicians alike have not confronted the problems of medical errors in a meaningful way and that medical staffs have resisted initiatives in this area.<sup>74</sup>

#### III. CONSIDERING LAW AND MEDICAL ERRORS

Interestingly enough, in the recent literature concerning speculation and study of the genesis of avoidable medical errors, the role of law as a causative element has not been considered. Rather, the law is often cast as a tool to positively address some of the causes of medical errors. It has been speculated that medical malpractice actions have a positive impact on quality beyond any one individual case. It can be argued that hospital regulatory law largely evolved as a mechanism to redress specific problems, or lay the foundation for an environment which has a positive impact on the delivery of medical care, thus minimizing errors. It seems most likely that law would be seen as a neutral element in reference to medical errors, a type of backdrop that does not have an immediate link to the actual delivery of medical care, and thus is not a cause of medical errors. The recognized phenomena of defensive medicine which motivates treatment, as a defen-

<sup>&</sup>lt;sup>71</sup> See, e.g., CENTRAL MAINE MEDICAL CENTER, QUALITY MANAGEMENT REPORT: PATIENT SAFETY, at http://www.cmmc.org/qualityreports/patient\_safety.html (last visited Nov. 25, 2003) (indicating ways the CMMC has attempted to address patient safety).

Matt Hicks, Hospitals Getting IT Prescription, E-WEEK, at http://www.eweek.com/article2/0,4149,1247411,00.asp (Oct. 15, 2001).

<sup>&</sup>lt;sup>73</sup> E.g., YALE-NEW HAVEN HOSPITAL, PATIENT SAFETY: STAYING SAFE IN THE HOSPITAL, at http://www.ynhh.org/choice/safety.html (last revised May 19, 2002) (encouraging communication between the patient and health care professional as a fundamental aid to patient safety).

<sup>&</sup>lt;sup>74</sup> See Michael L. Millenson, *The Silence*, HEALTH AFF., Mar.-Apr. 2003. "The virulent resistance by many in the medical profession to confronting evidence about systemic failings is neither new nor an aberration." *Id.* at 107.

<sup>&</sup>lt;sup>75</sup> IOM REPORT, *supra* note 4, at 127-29 (advocating legal solutions, including that Congress should enact legislation to protect peer review and patient safety data).

<sup>&</sup>lt;sup>76</sup> See Mello & Brennan, supra note 24, at 1607-24 (discussing studies of the deterrent effects of medical malpractice suits and the factors, such as non-experience-rated insurance, which preclude a direct correlation).

sive legal strategy rather than for clinical reasons, can certainly be classified as an area where responses to the law can generate medical errors, both if the treatment is unwarranted or improperly administered, resulting in patient harm.<sup>77</sup>

Outside of defensive medicine, it may be rather extreme to postulate that law in the hospital arena is a variable in fostering a climate that has resulted in quality problems. The rush to comply with everescalating legal mandates, ironically, may have forestalled creative ways to address system-wide delivery problems, as institutional resources are drained by pursuit of compliance and avoidance strategies. It, therefore, can be concluded that hospital common and statutory law in the quality area has not succeeded in creating the necessary incentives to prevent medical errors. Some may say, with justification, that it is unrealistic and unfair to expect a legal system to act as a mechanism to impact the complexities of hospital-based medical care when, in fact, the viability of long-standing acute care clinical quality assurance programs must be seriously questioned. Nonetheless, the law needs to be considered as a variable in the mix of elements leading to medical error.

Consideration of whether failings in law have resulted in medical errors, or not played a role in reducing the numbers of hospital-based errors, is largely a matter of speculation and, with all due respect to the forum within which this article is placed, is frankly an academic question. Of more immediate and practical import, is consideration of how the law can be used proactively to address medical error issues. and to create a climate within which patient safety can be enhanced. Indeed, the law could mandate the creation of legislative study commissions, establish mechanisms for medical error reporting and analysis, and provide legal safeguards against the discoverability of error reporting data.<sup>78</sup> As mentioned, these ideas have all been proposed in one manner or another, and some have been legislated at the state level. It is the contention of this essay, however, that law can do more to foster hospital quality, but doing more will require fundamental changes that undoubtedly will be controversial. It appears that for medical error issues to be seriously addressed at the institutional level, key elements of the institution must work together to address quality problems in ways that do not seem to be occurring yet. A major bar-

<sup>&</sup>lt;sup>77</sup> See generally Alan Feigenbaum, Note, Special Juries: Deterring Spurious Medical Malpractice Litigation in State Courts, 24 CARDOZO L. REV. 1361, 1370-71 (2003) (discussing defensive medicine).

<sup>&</sup>lt;sup>78</sup> See DIANE L. KELLY, APPLYING QUALITY MANAGEMENT IN HEALTHCARE: A PROCESS FOR IMPROVEMENT (2003) (providing practical quality control advice to health care managers).

rier in fostering the necessary collaboration in the hospital setting is the current corporate structure which is mandated by law and accreditation, namely the three legged stool structure of board, administration, and medical staff.

#### IV. EXPLORING THE TRIPARTITE ARRANGEMENT

The tripartite corporate arrangement of hospitals has a long-standing basis in operations and law, with its most unique variable being the independent, self-governing medical staff. In theory, the three parts of the hospital, board, medical staff, and administration, are well-integrated and interface at many levels, in particular through a complex committee structure. Hospitals have managed to operate through the tripartite structure, and for some time have used such an arrangement to provide patient care. The problems concerning quality manifested through recent findings about patient safety, however, call into question the viability of the current corporate arrangement, and particularly the ability of such a structure to satisfactorily address quality of care issues.

In a recent article concerning the hospital corporate structure, authors Marren, Paddock, and Feazell, cite the work of Dr. Martin Merry MD, a noted physician health care consultant. Herry characterizes hospital organizations as being split into silos, with the medical staff and administration as separate silos that, in effect, operate independently of one another. Merry's concept of silos is perhaps best illustrated in the quality arena, as there appears to be a disconnect in the respective efforts of the medical staff, administration, and, to a lesser extent, the board. Under a delegated arrangement, the medical staff is largely responsible for clinical quality matters such as credentialing, quality improvement, utilization management, and infection control. Hospital administration, on the other hand, has responsibility for quality in the managerial context, as administrators are frequently engaged in operational changes designed to make the hospital run more smoothly. A popular innovation on the managerial side

<sup>&</sup>lt;sup>79</sup> John P. Marren, G. Landon Feazell & Michael W. Paddock, *The Hospital Board at Risk and the Need to Restructure the Relationship with the Medical Staff: Bylaws, Peer Review and Related Solutions*, 12 Annals Health L., 179, 207 (2003) (citing to a letter from Dr. Merry to Landon Feazell).

<sup>&</sup>lt;sup>80</sup> *Id.* at 207-10.

<sup>&</sup>lt;sup>81</sup> See Mark A. Kadzielski et al., The Hospital Medical Staff: What is its Future?, 16 WHITTIER L. REV. 987, 993-94, 1000 (1995) (discussing an expanded role of the medical staff to monitor quality of care).

<sup>&</sup>lt;sup>82</sup> ROBERT D. MILLER, PROBLEMS IN HOSPITAL LAW, 34-39 (5th ed. 1986) (discussing how hospital administrators are chosen, evaluated, and the liability they

has been total quality management (TQM) a process which is a teambased approach to operational improvement, but largely the process has focused on non-medical staff aspects of hospital operation. <sup>83</sup> While the board has final authority for the entire operation, its posture is somewhat distant from the medical staff, and administration alike, as it relates to quality matters.

One area in the quality context which presumably bridges the administration and the medical staff is risk management, a hospital-wide program designed to respond to, and minimize, damages from liability episodes. Risk management is quite broad in scope, dealing with the full range of hospital operational and clinical areas. While the medical staff may be involved in various clinical aspects of risk management, the process is one that has remained largely within hospital administration, tends to be a function dominated by nursing, and has been coopted by concerns over insurance and litigation strategies. Risk management activities have not created a bridge between liability control and clinical quality improvement, largely because of a cultural divide that underpins Merry's concept of silos, and this failure in coordination may be a major factor contributing to hospital-based medical errors.

In theory, the hospital board, which has the ultimate legal authority in the acute care setting, should be the one part of the corporate triad to bring administration and medical staff together. Both the medical staff and the administration perform their respective responsibilities under a system of delegated authority that emanates from the board. Boards have sufficient authority to pressure the other two corporate parts to work in a more integrated fashion, but the exercise of authority outside of traditional norms is highly unusual for boards. Hospital boards have evolved from the days in which membership

face).

<sup>&</sup>lt;sup>83</sup> See Ken Jennings et al., Changing Health Care: Creating Tomorrow's Winning Health Enterprise Today 219-20 (1997) (explaining TQM as one method for structuring task performance to stimulate improvement).

<sup>&</sup>lt;sup>84</sup> See Richard R. Balsamo & Max Douglas Brown, Risk Management, in LEGAL MEDICINE 223, 223 (Susan Baxter ed., 4th ed. 1998) (covering the origin and scope of risk management; risk identification, prioritization, control, prevention, and financing; and also external risk management requirements).

See Richard L. Johnson, HCMR Perspective: The Purpose of Hospital Governance, HEALTH CARE MGMT. REV., Spring 1994, at 81, 82 (stressing the necessity of selecting board members who are able to forge strong physician-hospital relationships); see also Patrice L. Spath, The Hospital Governing Board's Role in Quality Management, BROWN-SPATH & ASSOCIATES, at http://www.brownspath.com/original\_articles/board-role.htm (last visited Nov. 25, 2003) (asserting that the hospital board should not be a passive observer in quality management activities.

was a matter of community status and philanthropic potential, as the current scope and complexity of issues faced has increased dramatically, and in some instances hospital board roles are complicated by the presence of separate hospital system boards. In a period in which for-profit corporate boards have become the focus of attention, as a result of scandals in corporate oversight, and the subsequent passage of the Sarbanes-Oxley Act, there is considerable pressure placed on non-profit acute care institutional boards to perform better. Hospital boards must, in particular, be attentive to oversight of senior management, fiscal responsibility, confidentiality, conflict of interest policies, regulatory compliance, as well as institutional quality. In light of these current duties, it seems unrealistic for hospital boards to launch initiatives to fundamentally restructure the hospital tripartite arrangement, particularly without strong support to do so from the medical staff. 88

Assuming that the three corporate pieces which compose the hospital corporation operate distinctly from one another, one may question why these pieces are alienated from each other and why medical staff and management are not better integrated. The legal structure which underpins the hospital has fueled a sense of independence of the medical staff from the operation, and fostered the concept of selfgovernance. Linked to self-governance is the status of most physicians as independent contractors, whose loyalty to the institution can be characterized as fickle at best. In order for hospitals to foster a sense of loyalty with members of its medical staff, institutions must actively court physicians, and the quality of care in the facility is only one element in binding doctor to hospital. 89 A key underlying factor in the dynamics of the organized medical staff is autonomy.<sup>90</sup> strong sense of professional independence, individually and collectively, permeates the character of the medical staff. Any inroads into traditional medical staff functions by administration or the board

<sup>87</sup> See Johnson, supra note 85 (discussing the skills needed of hospital board members, including managerial, financial, and operational expertise).

<sup>&</sup>lt;sup>86</sup> Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, 116 Stat. 745 (codified as amended at 15 U.S.C.A. § 7201 (Supp. 2003)).

<sup>&</sup>lt;sup>88</sup> Cf. Marren et al., *supra* note 79, at 223-26 (laying out a possible restructuring scheme, including redefining bylaws and integrating a hospital's governing body with its medical staff).

<sup>&</sup>lt;sup>89</sup> Randall L. Culbertson, Location of Office Space Affects Physician Loyalty, CLICK (June 2001), at

http://www.acpe.org/click/archive/index.cfm?fuseaction=display&ID=57 (listing incentives such as parking, technology services, and favorable clinical schedules as other factors to enhance physician loyalty).

<sup>&</sup>lt;sup>90</sup> See Marren et al., supra note 78, at 217, 220-21.

quickly meets resistance, largely because such incursions are seen as challenging physicians' professional independence, an area that is guarded zealously by organized medicine.<sup>91</sup>

While the effects of autonomy and professionalism should not be underplayed in assessing the alienation of the medical staff from the hospital operation, an even stronger element which motivates medical staffs, individually and collectively, appears to be economics. Medical practice in many parts of the country has become highly competitive, and membership on a given medical staff is likely to be driven as much by business considerations as matters concerning professionalism and quality. Buffeted by escalating medical malpractice rates, and pressures from third party payers, even the most altruistic physician is hard pressed to devote significant time to broader institutional matters, such as assessing and correcting systemic quality problems.

Hospital administrators, likewise, function within the confines of highly competitive local markets, and their attention is directed toward ways to enhance institutional status with payers, purchasers, regulators, clinicians, and the public alike. While hospital managers are undoubtedly concerned with the quality of the medical staff, that concern is heavily underscored by business considerations. To an extent, management sees the medical staff as an economic unit, which individually and collectively refers and attracts patients, and can solidify relationships with third party payers.

## V. ECONOMIC CREDENTIALING: A CONTINUING STORY OF CONFLICTING GOALS

An illustration of the gulf and tensions that exist between hospital management and the medical staff in the current acute care climate can be seen in the long standing dispute over economic credentialing. Economic credentialing is the application of fiscal criteria to the appointment, reappointment, and delineation of clinical privileges.<sup>94</sup>

<sup>&</sup>lt;sup>91</sup> See, e.g., Tanya Albert, Mounting Tension Over Autonomy: Courts Referee Doctor-Hospital Battles, AMNEWS, July 21, 2003, available at http://www.amaassn.org/amednews/2003/07/21/prl10721.htm (reporting a California medical staff decrying their loss of autonomy); Medical Staff of Community Memorial Hospital of San Buenaventura v. Community Memorial Hospital of San Buenaventura, No. CIV-219107 (D. Cal. Apr. 24, 2003).

<sup>&</sup>lt;sup>92</sup> See generally, James C. Robinson, The Corporate Practice of Medicine: Competition and Innovation in Health Care (1999); see also Wendy Leebov & Gail Scott, The Indispensable Health Care Manager: Success Strategies for a Changing Environment (2002).

<sup>&</sup>lt;sup>93</sup> See, e.g., Marren et al., supra note 79, at 209.

<sup>&</sup>lt;sup>94</sup> E.g., Jon H. Sutton, Economic Credentialing: A Growing Concern, BULL. AM. COLL. SURGEONS, Dec. 2002, at 15-17.

Motivated by the need to attract and retain physicians who positively affect the bottom line, economic credentialing criteria were adopted by hospitals around the country. While the extent of overt economic credentialing has never been fully measured, it has pitted the interests of organized medicine and medical staffs against hospital managers and boards. 95 Physician interests against economic credentialing were rooted in two arguments: One, that such a practice is mandated by the hospital board, thereby usurping the self-governing rights of a medical staff. The other argument against economic credentialing is that the practice improperly injects financial variables into a process that should only assess medical quality. The justification for economic credentialing is that the governing entity, as a fiscal fiduciary, has a right, driven by a legal mandate, to protect the fiscal viability of the operation. The initial economic credentialing controversy that erupted in the early to mid-1990s dissipated as the practice was barred in some places by legislation, but even more significantly, as the realities of the health care market place bypassed this controversy. 96 Physicians engaged in joint ventures with hospitals, and specialists created their own hospitals, developments that required physicians themselves to focus on individual physician economic performance.

Recently, economic credentialing has reared its head, but in a slightly different context, namely in matters involving financial conflicts of interest. Hospital boards and management are questioning the appropriateness of appointing and retaining physicians on medical staffs who have financial interests in entities which compete with the hospital. There is currently a controversy involving Community Memorial Hospital of San Buenaventura California in which a hospital board has stripped the medical staff's right of self-governance,

<sup>&</sup>lt;sup>95</sup> See Blum, supra note 29, at 182-83 (discussing the resulting conflicts between hospitals and their medical staffs).

<sup>&</sup>lt;sup>96</sup> See generally Elizabeth A. Weeks, The New Economic Credentialing: Protecting Hospitals from Competition by Medical Staff Members, 36 J. HEALTH LAW 247 (2003) (discussing the causes and effects of hospitals' use of economic credentialing).

<sup>&</sup>lt;sup>97</sup> *Id.* at 252-53 (referring to policies based on a physician's ownership, investment, affiliation, etc. with competing health care facilities).

<sup>&</sup>lt;sup>98</sup> E.g., Ohio Hosp. Ass'n, OHA Position on Conflict of Interest Legislation, at http://www.ohanet.org/advocacy/state/issues/position/position\_conflict.pdf (last visited Nov. 25, 2003) (favoring an expansion of state law to prohibit physicians with investments interest from making treatment decisions); see also, Am. Hosp. Ass'n, Promises Under Pressure: Safeguarding Community Access to Health Care Services, at

http://www.hospitalconnect.com/aha/annual\_meeting/content/03mtgpaper\_Niche.pdf (last visited Nov. 25, 2003) (discussing the growing conflict of interest of doctors via their ownerships of "niche" service facilities).

because the medical staff leadership has a financial interest in a competing entity. 99 Community Memorial adopted a "Medical Staff Code of Conduct" that prohibits economic conflicts of interest and requires members of the medical staff to sign a lovalty oath, a trend that appears to be occurring in other hospitals. 100 Other controversies over economic conflicts are occurring around the country and have triggered questions about whether hospital corporate bylaws supercede medical staff bylaws, reflecting on the ultimate power of the hospital board itself. 101

Interestingly enough, the current economic credentialing dispute over conflict of interest in California has been characterized by both sides, hospital management and the medical staff, as a dispute that is ultimately about quality. 102 From the management standpoint, economic conflicts on the part of medical staff members, weaken the operation, and in a broad sense jeopardize quality. From the medical staff perspective, the current attempt to usurp the role of the physician organization jeopardizes the doctor's role in protecting patients, and places the interest in finances above medical care. For purposes of this essay, it does not particularly matter which side in the California dispute is correct in its assessment about economic credentialing. Rather, what is significant is that such a dispute is occurring. Sadly, the Community Memorial Hospital controversy over economic credentialing reflects the type of tensions spawned by economic realities that now separate medical staffs from boards and administration. While not every acute care institution faces such profound divisions as seen in the Community Memorial case, the three parts of the hospital structure are being stretched by economic pressures, and responses to such pressures may not be viewed as being in the best interests of the entire operation. In light of such fundamental, divisive economic tensions, it becomes hard to imagine that the acute care institution is structurally poised to deal with major institution wide challenges, such as medical errors.

#### VI. FORGING A NEW CORPORATE STRUCTURE

While it is likely that not every reader will agree that the tripartite hospital corporate structure needs to be altered to meet the current quality challenges, that is the premise of this piece. The question, therefore, becomes one of determining how best to rearrange the hos-

<sup>99</sup> Albert, supra note 90.

E.g., Manvar et al. v. Brooklyn Hospital, No. 23001 (N.Y. Sup. Ct. 2003).

See. e.g., Albert, supra note 90 (reporting an accusation that the hospital unilaterally amended the bylaws).

pital corporation to achieve a more cohesive structure that can address medical error issues in a comprehensive fashion. There are two broad, generic possibilities which emerge in considering hospital restructuring. The first generic approach to hospital reorganization calls for changes within the context of the current structure, by more sharply delineating authority, or by creating a committee mechanism to unify the interests of the corporate triad in the quality area. The other generic approaches to hospital reorganization are more extreme in that they would either alter the roles of the three parts of the corporation, or actually abolish one of the parts, and thus, would require a fundamental change in the hospital laws.

#### A. The Lesser, More Practical Solution

From a practical standpoint, the less radical the approach to hospital reorganization, the more feasible it will be to implement. One possibility is to redraft hospital and medical staff bylaws to more clearly state the roles and boundaries which govern the behavior of the board, hospital administration, and medical staff in the quality area. <sup>103</sup> Such a restatement, while not changing current realities, would be a way to more sharply clarify legal responsibilities, and as bylaws have been viewed as contractually binding, such alterations would have clear import. <sup>104</sup> In addition to clarifying the respective roles of the three corporate elements for quality purposes, bylaw changes can mandate more affirmative quality measures such as the adoption of measurable quality initiatives for individual medical staff members, and specific quality goals could be mandated for inclusion in board development plans.

A second approach to reorganizing the hospital corporation that could occur within the present legal structure was identified by Marren, Paddock, and Feazell. The Marren article recommended the creation of a total quality committee that would act as a bridge between the medical staff executive committee and the hospital board. The multi-disciplinary total quality committee would have institution-wide responsibility for quality matters including board education, review and analysis of data, the duty to take affirmative action to ad-

<sup>103</sup> See Dennis J. Purtell, Medical Staff in Need of Change: Explore a Revolutionary Way to Recognize Your Medical Staff, THE PHYSICIAN EXECUTIVE, Jan.-Feb. 2002, at 64, 67 ("[T]o avoid falling into existing patterns of complexity, documents establishing the new format should not attempt to parallel or merely amend existing medical staff bylaws, rules, and regulations.").

<sup>104</sup> Marren et al., supra note 79, at 221.

<sup>&</sup>lt;sup>105</sup> See id. at 223-24.

<sup>&</sup>lt;sup>106</sup> Id. at 224-25, 233.

dress suboptimal care, and the responsibility for integrating quality matters into strategic institutional and board planning. While the creation of such a committee change, as suggested by Marren, would require amendments to institutional and medical staff bylaws, they don't appear to be alterations which necessitate state licensure laws and regulatory amendments.

#### B. Over the Top: A More Radical Approach

#### 1. Revamping the Board

An alternative path in the area of hospital corporate rebalancing would entail a far more radical restructuring of the enterprise. One approach would be to revamp the hospital board by allocating designated slots for medicine, business, and law, with the goal of creating a professional group of institutional overseers, whose involvement would be far more than occasional. There have been proposals for enhancing board effectiveness in light of Sarbanes-Oxley, such as corporate trust programs. 107 But while enhancement of governance is desirable, it does not address the realities of coping with operational complexities. A professionalized board would be engaged to a greater extent in the day-to-day activities of the facility and would demand greater accountability from management as well as the medical staff. A professionalized board also would be in a better position to address institution-wide problems such as medical errors, not only because such a board would better appreciate its role and legal authority, but more importantly, it would have the requisite expertise to oversee current complexities. Slots on a professional board may be difficult to fill particularly in non-urban settings and board members would likely need to be reimbursed, as such a level of service could not be anticipated from volunteers. In addition, the slotted board would pose a special challenge to hospital management in deciphering the respective lines of authority, but a professional board could diffuse some of the pressure administrations now face in their relationships with medical staffs.

#### 2. Downgrading the Medical Staff

A second, even more extreme approach to hospital restructuring, centers on the medical staff's status as an independent self-governing entity. As noted, the existence of the self-governing medical staff is

<sup>107</sup> See John P. Vail, Responding to the Crisis in Health Care: Do You Have a Corporate Trust Program?, THE HEALTH LAWYER, July 2003, at 19, 27.

long-standing in law and practice, but as a distinct entity, the medical staff's independence from the hospital is nebulous. 108 Whatever power the medical staff invokes through its bylaws is delegated power that flows from the hospital board. At best, a medical staff is a type of unincorporated association, which has no independent legal identity outside the four walls of the hospital. The courts have, by and large, rejected the idea that medical staffs are somehow legally separate from the hospitals within which they exist. 109 The medical staff could be dissolved through changing licensure laws and accreditation policies, and in turn replaced by a medical affairs committee, that clearly would be an operational unit of the hospital. Although such a change would be extremely difficult to undertake and would involve other business considerations, it would directly address the core division in the hospital setting, which makes movement on clinically related issues so difficult. This is not to suggest that physicians, individually and collectively, should not be intimately involved in quality efforts at every level, but the structure within which that involvement occurs must diffuse the barriers that prevent unified approaches to hospitalwide problems.

#### 3. No More Independent Contractors

A less drastic, but no less controversial, proposal in altering medical staff status would be legislative changes in the law which would recast the non-employee physician medical staff member as an agent of the hospital, not an independent contractor. Principles of agency would extend to physicians on the medical staff, both within the hospital and in hospital affiliated ambulatory settings. It is likely that acute care institutions will balk at characterizing non-employee physicians as independent contractors, as such an extension will remove a standard institutional defense to medical malpractice. But, in effect, independent contractor physicians, for purposes of institutionally-based medical malpractice, are more often than not treated as agents of the hospital, leaving the outpatient areas as the battleground for

<sup>&</sup>lt;sup>108</sup> See Kadzielski, supra note 81, at 993-94 (pointing out that the medical staff is one of the four leadership entities in a hospital and noting that it must participate in all aspects of hospital operation due to the pervasiveness of clinical issues). See also Exeter Hosp. Med. Staff v. Bd. of Tr. of Exeter Health Res., Inc., 810 A.2d 53, 56-57 (N.H. 2002) (concluding that the medical staff is not a legal entity separate and apart from the hospital).

See, e.g., Malanowski v. Jabamoni, 688 N.E.2d 732, 736-38 (III. App. Ct. 1997) (holding that even though the defendant-doctor was not an employee at the hospital, the hospital may be held liable because the hospital had an apparent agency relationship with the defendant-doctor).

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extension of agency doctrines. Changing the legal status of physicians from independent contractors to agents has broader significance than just liability. From an organizational standpoint, having independent contractor physicians become legal agents, calls into question the appropriateness of a self-governing medical staff, in light of the hospital's even clearer responsibility for the individual and collective actions of its doctors. Indeed, the distinct establishment of physicians' as agents, in reference to quality and medical errors, provides a hospital corporation with an even more powerful mandate to take the lead in developing requisite actions to enhance patient safety and to develop clear accountability measures for physician staff members. An alternative to changing physician legal status, would be for all hospitals to directly employ physicians, but the current economic realities for both clinicians and institutions may preclude that option in the short term.

#### 4. A Medical Liability Insurance "Quid Pro Quo"

The politics of medicine are such that proposals to abolish the independent, self-governing medical staff, or to change laws to alter the legal status of doctors as independent contractors will be highly contentious. Medical practitioners have seen dramatic erosions of their power through managed care practices in particular, and further assaults on autonomy, even if motivated by attempts to improve overall quality, will be viewed negatively. If the medical staff structure is going to be altered, there will have to be some type of "quid pro quo" provided for doctors. One possible approach for gaining physician support for changing current hospital structure is, in fact, the medical error issue, as it relates to the current problems in medical malpractice. As a result of the escalation in medical malpractice premium rates, individual practice costs in most specialties have risen dramatically. 110 The trade-off for diffusing the power of the medical staff is the creation of a legal mandate for hospitals to provide medical staff members with comprehensive medical malpractice coverage, as a benefit of staff membership. Provision of liability coverage would become a lever to reduce the independence of the of the selfgoverning medical staff, and more importantly, such coverage would be coupled with mandatory quality requirements, such as adhering to clinical protocols as a requirement for continued staff membership and coverage. Hospitals may reject the proposal to pay for medical

<sup>110</sup> Massachusetts Medical Society, Massachusetts Physician Practice Environment Index Plunges 3.9% in 2002, Marking Nine Consecutive Years of Decline, at http://www.massmed.org/pages/062403pr mmsindex.asp (July 18, 2003).

staff member's medical malpractice insurance as being too costly, but such an additional expense would need to be factored into public and private reimbursement formulas. The outgrowth of hospitals offering credentialed physicians malpractice coverage will be a type of enterprise liability that could spark meaningful controls to address quality issues in a more direct manner, and certainly such a development would require legal modification in areas such as Medicare's Anti-kickback law.<sup>111</sup>

#### 5. A Very Different Tact: The Medical Staff Becomes the Board Or An Owner Of Parts

Another possible tact in restructuring the hospital's medical staff would be to move in a dramatically different direction, and make the medical staff the hospital board. The medical staff as board would have the ultimate authority for hospital governance, and presumably could use its collective expertise to more effectively address quality issues. By abolishing the lay board, and directly ceding control of hospital operations to the medical staff, physician staff members would be invested with power for running all aspects of the acute care facility. Indeed, there is precedent for physician control in medical group practices, doctor-owned hospitals, and, more recently, in specialty care hospitals. Whether or not physicians would be willing to take on this expanded role in the current competitive climate of medical practice is an open question. To an extent, by replacing the voluntary lay board, doctors would be directly responsible for addressing all matters of institutional health care delivery, including quality. Related to the idea of turning board control over to the medical staff is for a hospital to sell off operational units to physician specialists. In a sense, hospitals would "condominiumize" the hospital, vesting clinical and operational control to physician owners. Such a development follows a natural progression from the joint venture arrangements hospitals have engaged in with specialists in the outpatient area, and that are now seen on the inpatient side, most typically in the creation of "hospitals within" hospitals. 112 In addition, it may be possible to structure an arrangement using the sale of bonds by a non-profit hospital to its medical staff members to finance hospital expansions and, in so doing, link physicians more closely to the hospital.

<sup>111 42</sup> U.S.C. § 1320a-7b (2000).

Timothy Lake et al., Something Old, Something New: Recent Developments in Hospital-Physician Relationships, 38 HEALTH SERVICES RES. 471, 479 (2003).

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#### 6. A Needed Regulatory Shift

Undoubtedly there are other radical changes that can be made in hospital corporate structures, but the more extreme changes suggested here, would each require amendment to federal and state laws affecting hospital, changes in accreditation standards, and, in the case of agency, even broader alterations. If such changes are going to occur in the law, there must be a commensurate change in the attitude of legislators and regulators alike toward acute care institutions. notion of hospitals as private entities largely shaped by the vicissitudes of the marketplace, with only significant controls at the entrylevel, may need to change. Licensure, the primary area of hospital regulation, is focused on core requirements that create a quality floor, and allows for intervention only if dramatic problems arise beyond mandated relicensure processes. Licensure has not been seen as a process to motivate fundamental change, and the view that hospitals, aside from tax status, are quasi-public entities has been usurped by the notion that these entities should be shaped primarily by market forces. To effectuate structural change, regulators must be more willing to view the law as a vehicle to stimulate internal corporate changes. somewhat akin to what has occurred in the area of government reimbursement regulation. In the case of medical errors, hospital law should be liberalized to allow institutions to make basic corporate changes to adjust the organization to better address quality challenges. Accreditators too, must be willing to depart from established hospital models, and run the risk of backlash for the sake of ushering in more effective acute care structures.

The question, then, becomes what state regulators and accreditators should mandate in reference to hospital restructuring. It seems that articulation of any specific model, or set of models for altering the three legged corporate stool may be premature. Rather than recommending a particular format, it is the suggestion of this essay that the regulatory mandate be one that affords hospitals freedom to determine how best to restructure operations in ways that better meet quality challenges. Licensure laws should be liberalized both to allow hospitals to initiate corporate restructuring, and to justify such restructuring through selection of measurable quality factors. Some institutions may decide to make minor corporate adjustments, while others may pursue one of the more radical paths mentioned in this piece. The important point is that hospitals will be free to select an appropriate organizational model, and that such selection must produce measurable results. In the event that hospital restructuring fails to impact patient safety, regulators must actively intervene to assist in creating more appropriate operational models. No doubt regulators in the

United States will balk at such an interventionist role, but if meaningful changes are going to occur in health delivery, regulators must use their leverage, and not behave as though licensure is a pro forma process.

#### CONCLUSION

To return to the analogy of feng shui that was introduced at the beginning of this piece, to achieve the necessary balance between internal operations and external pressures generated by concern over medical errors, hospitals must be allowed to break the mold that was cast in the early twentieth century. There is nothing sacrosanct about the three legged concept of the hospital corporate structure, and while it may have been a platform on which legal and economic developments occurred in the hospital world, it is a foundation that is eroding. Medical staffs, boards, and administrations need to develop a unitary front to meet the profound challenges in quality raised by the medical error studies, and that united front cannot be achieved when the three parts of the hospital structure are alienated from one another. In a sense, the premise of this article takes us back to the work of Avis Donnabedian, where quality is divided among structure, process, and outcome. The responses to the medical error epidemic have, for the most part, focused on process and outcome, but it is important not to overlook the core element of structure which must not be viewed as an area settled by tradition and practice. It is in altering the hospital corporation, where the law can play its part in addressing one aspect of the current quality dilemma. The history of hospital law has been rooted in matters involving regulatory control of operations and legal liability so the changes suggested herein do not depart from the spirit of this body of law. It is now necessary for the law to return to the more fundamental matters of structure and to be a lever of change that can enhance the acute care hospitals future viability, giving these institutions the necessary foundations to achieve corporate feng shui and, as such, better address matters involving the quality of hospital care.