Part II

HOSPITALS AND QUALITY

Chapter 4

Whither Medical Staffs?: Rethinking the Role of the Staff in the New Quality Era

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§ 4:1 Introduction

The phenomenon of the "organized medical staff" within hospitals is a unique business model. A hospital has no business to conduct without the physicians who order its services and perform their own using the hospital's facilities. The accomplishment of significant portions of the hospital's mission depends upon the good will and actions of the disparate, mostly independent clinicians who come together in common cause only around their use of hospital resources. In well over twenty-five years of working on these issues, I have been unable to identify a similar or even analogous business structure that so defines an industry.

The hospital's lay board of directors, charged with the legal, fiduciary responsibility for the quality of care rendered under their stewardship are, as nonprofessionals, neither trained nor competent to assess complex technical matters of quality, including the competence of those who would provide services under the institution's rubric. Consequently, even though they are customarily not employed by those around whom they coalesce, the staff physicians are expected to organize themselves into an orderly mechanism through which they can effectively advise the hospital trustees and manage the quality functions the board delegates to them, based upon their professional expertise. This is a remarkably powerful responsibility.

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Despite the customary approach of the medical staff orienting itself through the use of bylaws, ironically the traditional medical staff is not even a legal entity separate from the hospital.[1] Rather, the staff consists of otherwise independent economic actors who often compete with each other within and across departments. Through pre-determined processes set forth in bylaws, the medical staff defines how it will exercise its vital advisory role. Through terms such as "self-governance" and "autonomy," the relative professional independence of the medical staff is recognized by commentators and physician advocates,[2] even though no one challenges the legal responsibility of the lay board for the operation of the institution.

Comparable to corporate practice of medicine doctrines which prohibit employment of physicians by unlicensed individuals and entities to ensure they can exercise unfettered professional judgment, the use of bylaws to facilitate this delegated responsibility acknowledges the very special nature of the necessary intellectual capital of otherwise independent professionals which must be brought to bear, in formal terms, for the benefit of the hospital. Obviously the matters at issue in medical staff processes are critical both in clinical and economic terms to the actors engaged in their undertaking. As the stakes are raised, so increases the potential for conflict.

Caselaw over medical staff matters abounds. Typical disputes which end up in court include termination of

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[Section 4:1]

[1]Although in several instances it has been recognized as an unincorporated association. Corleto v. Shore Mem'l Hosp., 138 N.J. Super. 302, 350 A.2d 534 (1975); St. John's Hosp. Med. Staff v. St. John's Reg'l Med. Ctr., Inc., 90 S.D. 674, 245 N.W.2d 472 (1976). Still other courts have explicitly rejected these theories. *See* Dallon, "Understanding Judicial Review of Hospitals' Physician Credentialing and Peer Review Decisions," 73 Temple L. Rev. 597, 658 (2000).

[2]*See* A.M.A. "Physician's Guide to Medical Staff Organization Bylaws" (2d ed. 2002).

or denials of clinical privileges or membership, on bases including due process, antitrust, sexual and racial discrimination arguments.[3] Confidentiality of peer review processes and data is another line of caselaw.[4] In truly egregious circumstances medical staffs and the boards of the hospitals at which they serve have gotten into litigation in power struggles which, ultimately, are always about a deep loss of trust between the actors.[5]

Without ending up in court, other types of controversies have always been present in the medical staff setting: There are issues that arise between the board and the medical staff organization. For example, struggles have surfaced throughout the country over the role of the board in controlling medical staff organization behavior—does the board approve the medical staff's elected officers or is the medical staff truly "self" -governing? Does the Credentials Committee of the Medical Staff report to the Staff Medical Executive Committee as all other medical staff committees do, and then the Executive Committee reports to the board, or does the Credentials Committee report its staff recommendations directly to the board? Board advisors have even emerged as advocates for various governance

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[3]*See* Dallon, "Understanding Judicial Review of Hospitals' Physician Credentialing and Peer Review Decisions," 73 Temple L. Rev. 597 (2000).

[4]*See* Rodriguez, "Peer Review Protection Revisited: The Challenge of Transparency with Improvement," *Health Law Handbook,* Ch. 5 (A. Gosfield, ed. 2003).

[5]*See, for example,* Exeter Hosp. Med. Staff v. Board of Trustees of Exeter Health Resources, Inc., No 2001-134 (N.H. 11-14-02), http://webster.state.nh.us/courts/supreme/opinions/0211/exete132.htm) where a lawsuit stemmed from the board's decision to remove the medical staff president from the Board, subjected him to a "gag order" and refused to provide members of the medical staff with the reasons for his removal unless they signed a confidentiality agreement. The court held the staff did not have standing. *See* 11 B.N.A. H.L.R. 1653 (Nov. 21, 2002), and LaFond, "The Relationship Between the Medical Staff and the Hospital Governing Board" in *AHLA Physicians and Physician Organizations Law Institute 2002*.

approaches, often couched in the guise of legal risk management or mandate.[6]

Controversies also arise within the medical staff. Does the Medical Staff Executive Committee wield too much control over the medical staff processes? Are the due process rights for new applicants to the staff different from those for members of the staff? Which adverse judgments generating a corrective action against a practitioner are subject to appeal? Can a physician employed by a hospital affiliate serve as a real medical staff representative on important committees or must each such physician be balanced by truly independent practitioners?

Depending on the medical staff culture, all of these issues are more or less important. Medical staffs have cultures;[7] and they vary. For example, whether the processes favor individual rights over the presumption of the proper functioning of the Medical Executive Committee, whether there are many or few medical staff committees, which categories of the medical staff have voting rights, and whether the bylaws are highly detailed and prescriptive or more generally oriented are differences which both define and reflect specific cultures.

No matter the specific culture, the types of skirmishes that engage medical staff tensions today, while no doubt absorbing to those whose ox is being gored, often miss the big picture. The real questions at hand are quite different from the provincial power struggles which I usually encounter within the staff and among them, the board and hospital administration: Given the increasing societal mandate in the American health care system to truly manage and improve clinical quality of

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[6]*See generally* Horty, Springer & Mattern, *ActionKit for Hospital Law*, and other resources, http://www.hortyspringer.com.

[7]For a discussion of how the bylaws define medical staff culture, *see* Gosfield, "Defining Institutional Culture: The Role of the Medical Staff Bylaws in Hospitals and HMOs," *Health Law Handbook*, 299-326 (A. Gosfield, ed. 1992).

care, increase patient safety and decrease medical errors, what ought be the role of the organized medical staff? Is the physicians' emphasis on the professional autonomy exercised by medical staffs an anachronism or a vital technique in a broader struggle to improve the quality of health care in the United States? Given what we know and are learning today about healthcare quality and mechanisms to improve it, are there new ways to think about the medical staff?

Any assessment of the role of the medical staff and its activities should be framed against increased public concern for the accountability of health care organizations generally, and particularly hospitals, for the quality and outcomes of care provided through and by them. To be considered accountable, an organization must explicitly focus on the extent to which its clinical culture is supportive of quality for which the hospital is willing to be evaluated, compared and held responsible. At a minimum, the hospital's clinical culture will determine the extent to which it makes improving quality over time the bedrock of its institutional mission. The clinical culture of the hospital is broader than the medical staff culture, and in the last analysis, is the reflection of the extent to which the operations and attention of the institution are focused around and supportive of ever improving clinical quality of care in all of the broader reaches of current definitions of quality.[8]

Taking quality improvement as its touchstone, this

[8]It is beyond the scope of this article to address the new ways of defining quality which are not just limited to whether the right service was provided at the right time—misuse, underuse and overuse. Patient centered views of the effectiveness of information transfer between doctor and patient, the flow of work within and between the operational units of hospitals, and whether care takes into account population-based notions of appropriateness are recent spins on the quality definition. All have risen to the fore some place in the quality zeitgeist. For the purposes of this article, however, at a minimum, quality means the effective application of science to the delivery of care in a way that fosters strong, healing relationships between patients and caregivers.

article will look at: (1) the legal influences which affect the medical staff's role in hospital quality improvement; (2) the contents and controversies in typical medical staff bylaws considered in light of how they relate to the essential quality mandates; (3) the values and forces which drive physician behavior and therefore define the context for medical staff activities; (4) current hot button issues which are challenging hospital boards and medical staffs and whether they have real meaning for efforts to improve quality and patient safety; and (5) then will consider some new ways to think about the medical staff mission in a more quality driven world. Informing these analyses will be my observations based on many years of working with medical staffs on their bylaws and operations.

§ 4:2 Legal influences

Three forces of law shape the interactions between hospital boards and medical staffs as well as the contents of medical staff bylaws, especially with respect to the focus on quality: (1) federal law in the form of basic Medicare conditions of participation for hospitals to be eligible to be reimbursed by the Medicare and Medicaid programs; and the Health Care Quality Improvement Act ("HCQIA") which influences the operation of hospital peer review activities; (2) the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") standards which rise to a legal standard by virtue of their incorporation into federal law where hospitals seek "deemed" status; and (3) state hospital licensing regulations.

§ 4:3 —Medicare conditions of participation

Medicare has long regulated the roles of the medical staff and the hospital board with respect to their responsibilities for assuring quality. These requirements

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are also incorporated into the Medicaid program.[1] Under Medicare, the governing body is "legally responsible for the conduct of the hospital as an institution."[2] Accordingly, the governing body determines which categories of practitioners may practice in the institution, appoints members of the medical staff after considering the recommendations of the staff, assures that the medical staff has bylaws and is accountable to the governing body for the quality of care provided to patients, and ensures that the criteria for medical staff selection are individual character, competence, training, experience and judgment.[3] These rules establish the fundamental responsibilities assigned to the medical staff in relationship to the board.

A separate Medicare regulation addresses the medical staff itself in greater detail. Here the medical staff must be organized, operate under bylaws approved by the governing body and be "responsible for the quality of medical care provided to patients by the hospital."[4] The medical staff is charged to periodically appraise its members, examine credentials and make recommendations to the board, and be organized in a manner approved by the board. The staff must "adopt and enforce bylaws to carry out its responsibilities."[5] The bylaws must be approved by the board, include the categories of the medical staff, describe the organization of the staff, the qualifications for medical staff appointment, the criteria for clinical privileges, and how to apply them.

These medical staff and board interactions are intended to permit the hospital to fulfill its further responsibilities for quality assurance generally. The governing body must ensure that there is "an effective,

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[Section 4:3]

[1]42 C.F.R. § 482.1(a)(5).

[2]42 C.F.R. § 482.12.

[3]42 C.F.R. § 482.12(a).

[4]42 C.F.R. § 482.22.

[5]42 C.F.R. § 482.22(c).

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hospital-wide quality assurance program to evaluate the provision of patient care."[6] The mechanisms by which this responsibility is accomplished are not stated. The standards merely require that the process be ongoing and have a written plan of implementation that addresses clinical issues, as well as integration and provision of other patient care services including social work, psychological and education services to meet the "medically-related needs of its patients." The hospital must take and document appropriate remedial action to address deficiencies found through the quality assurance program and must document the outcome of the remedial action. The specific role of the medical staff in conducting these activities is not stated.

§ 4:4 —HCQIA

The HCQIA establishes certain procedural requirements which, typically, are included in medical staff bylaws, because they relate to the process by which the medical staff and board interact in their review of the qualifications of medical staff applicants and the actions they may take in their ongoing implementation of their responsibilities to monitor quality of care in a professional review context. The implications of HCQIA for medical staff activities turns on the peer review nature of the activity addressed and the processes mandated in order to take advantage of the protections the law provides in the interests of improving quality.[1] The very purpose of the statute was to improve quality of care by protecting from civil liability participants in peer review undertaken in the good faith belief it was in furtherance of quality. The goal was to support and enhance the rigor of the review process by virtue of

[6]42 C.F.R. § 482.21.

[Section 4:4]

[1]For a more detailed discussion of the protections provided *see* Rodriguez, "Peer Review Protection Revisited: The Challenge of Transparency with Improvement," *Health Law Handbook,* Ch. 5 (A. Gosfield, ed. 2003).

some safety in undertaking aggressive and meaningful review.

The activities at issue in the HCQIA are "professional review actions" which means actions based on the competence or professional conduct of an individual physician and which affect adversely the clinical privileges or membership of the physician.[2] A professional review activity is an activity regarding an individual physician to determine whether he may have clinical privileges or membership, to determine the scope or conditions of such privileges or membership or to change or modify such privileges or membership.[3] The professional review body engaged in the professional review action means a "health care entity" conducting a professional review activity, any committee of such an entity conducting such an activity and specifically includes "any committee of the medical staff" when it is engaged in such activity.[4] Hospitals are specifically identified as health care entities.

To obtain the protections of the statute, the activity must provide procedural safeguards for the aggrieved physician in the form of due process rights (right to notice, right to a hearing, representation by counsel, right to cross-examine, submit additional briefs, and obtain a written decision[5]), but also the action must be taken in the reasonable belief it is in furtherance of quality health care, after a reasonable effort to obtain the facts of the matter, after adequate notice and hearing, and in the reasonable believe the action was warranted by the facts known after investigation and hearing.[6] The statute also imposes on hospitals the obligation to check the National Practitioner Data Bank ("NPDB") created by the statute at least every two years for adverse information on members and upon application for new

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[2]42 U.S.C.A. § 11151(9).

[3]42 U.S.C.A. § 11151(10).

[4]42 U.S.C.A. § 11151(11).

[5]42 U.S.C.A. § 11112(b).

[6]42 U.S.C.A. § 11112(a).

entrants.[7] Hospitals that do not check for such data, will be deemed in a medical malpractice action to have had knowledge of the information which was available.

The obligations of the HCQIA fall on hospitals themselves. The protections extend to individuals participating in the processes at whatever level—as reviewers, consultants, informants or decision makers. The medical staff committees and the individual members of them performing their delegated quality surveillance duties with respect to physicians are explicitly protected under the law. Taken together, although the HCQIA codified procedural due process rights which most medical staffs had offered anyway, its enactment linked with the reporting requirements, is a very powerful influence on the medical staff as it conducts its activities, as discussed more fully below.

§ 4:5 —JCAHO

From the inception of the Medicare program, the conditions of participation regulations have been deemed to have been met, if the hospital is accredited by the Joint Commission.[1] This mechanism obviates the need for a full survey to determine whether the hospital complies with Medicare's conditions and in many states the same judgment also precludes a full state survey for licensure purposes. Despite controversies over the years about the JCAHO and its programs,[2] deemed status remains a significant feature of hospital quality programs. This is all the more meaningful given the major changes in the contents, style and focus of the JCAHO standards in comparison with the Medicare

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[7]42 U.S.C.A. § 11135.

[Section 4:5]

[1]42 U.S.C.A. § 1395bb.

[2]*See* Morrissey, "On the Upswing," 31 *Modern Healthcare* 4 (Dec. 10, 2001); Morrissey, "Eyeing the Watchdog," 32 *Modern Healthcare* 8 (Apr. 22, 2002); Duff, "The Best Things in Life are Free," 32 *Modern Healthcare* 20 (Aug. 19, 2002); Morrissey, "Changing the Rules," 32 *Modern Healthcare* 8 (Oct. 7, 2002).

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Conditions of Participation. For many years they were similar in many respects, although generally the JCAHO was more prescriptive than the Medicare conditions.

In 1995, the Joint Commission completely revamped its standards to reflect its move to a greater emphasis on performance measurement. Entire chapters in the hospital accreditation manual are devoted to issues entailed in assessment of patients, care of patients, education, patients' rights and organization ethics, management of information, management of environment, management of human resources, infection control and nursing.[3] These categorizations are now very different from the time honored Medicare conditions. Of the matters at issue in this article, the relevant JCAHO chapters involve not only the traditional chapters dealing with governance and medical staff, but now also include "improving organization performance" and "leadership."

The governance standards explicitly require that the governing body provide for appropriate medical staff participation in governance[4] including the right to representation at governing body meetings and eligibility for full membership on the board. The medical staff chapter references "organized self-governing" medical staffs,[5] which develop and adopt bylaws approved by the governing body to establish a framework for self-governance and accountability to the governing body. Neither body may unilaterally amend the medical staff bylaws.[6] The standards require mechanisms for fair hearings and corrective action. They address the characteristics of the medical staff organization.[7] The bylaws must address the method of selecting officers,

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[3]All citations in this chapter are to the JCAHO, *Hospital Accreditation Standards* (2001 ed.).

[4]GO 2.2.

[5]MS 1.

[6]MS 2.1.

[7]MS 2.3.2.

their roles and responsibilities, how to remove them, and requirements for medical staff meeting attendance.[8]

The Joint Commission mandates that there be a mechanism designed to provide for effective communication among the medical staff, hospital administration and governing body.[9] A Medical Staff Executive Committee is required and is the primary vehicle for communication between the medical staff and the governing body.[10] The role of departments, if they exist, is addressed[11] as is the overall credentialing process,[12] the general management of patients as under the care of physicians,[13] and the role of the medical staff in performance improvement.[14]

Here the medical staff is charged with a "leadership role" with respect to process measurement, assessment and improvement when the performance of a process is dependent primarily on the activities of individuals with clinical privileges. The Commission requires attention to medical assessment and treatment of patients, use of medications, blood and blood components as well as operative and other procedures, efficiency of clinical practice patterns and significant departures from established patterns.

The overall chapter on improving organization performance is intended to ensure that the organization designs processes well and systematically monitors, analyzes and improves its performance to improve patient outcomes:

> Value in health care is the appropriate balance between good outcomes, excellent care and services and costs. To add value to the care and services provided, organizations need to understand the relationship be-

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[8]MS 2.3.4.1.

[9]MS 2.3.6.

[10]MS 3.1.6.

[11]MS 4.

[12]MS 5.

[13]MS 6.

[14]MS 8.1.

> tween perception of care, outcomes and costs and how these three issues are affected by processes carried out by the organization.[15]

The standards implementing this set of goals are designed to assure that planned, systematic, organization-wide processes are in place,[16] their design is carefully considered, data regarding concerns is collected effectively and then it is analyzed and aggregated well. These tasks are assigned to "leaders" without any special distinctions or delineation of tasks assigned to the medical staff versus other constituencies in the institution.

These concepts relate as well to the Joint Commission's general notions of "leadership" which now have their own standards. "Leaders" are defined to include at least the leaders of the governing body, the chief executive and senior managers, department leaders, the elected and appointed leaders of the medical staff and clinical departments, and other medical staff members in organizational administrative positions, along with the nurse executive and other senior nursing leaders.[17] The concept is that for the hospital to fulfill its mission it needs leadership to plan, design, direct, integrate, and coordinate services and improve performance generally:

> Building on the hospital's mission, effective leadership creates a clear vision for the future and defines the values that underlie the day-to-day activities carried out throughout the hospital. Effective leadership is inclusive, not exclusive; encourages staff participation in shaping the hospital's vision and values; develops leaders at every level who help to fulfill the hospital's mission, vision and values; accurately assesses the needs of patients and other users of the hospital's services; and develops an organizational culture that

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[15]JCAHO, *Hospital Accreditation Standards*, 157 (2001 ed.).

[16]PI.1.

[17]JCAHO, *Hospital Accreditation Standards*, 171 (2001 ed.).

> focuses on continuously improving performance to meet these needs.[18]

In fulfilling the standards for leadership, there are very few places where the medical staff is separately identified for any particular function. The medical staff approves sources of patient care provided outside the hospital.[19] "Health care professionals" (although not necessarily only medical staff members), with appropriate leaders, review and approve clinical practice guidelines selected for implementation.[20] Other than that, the leaders as defined are expected to fulfill the responsibilities of leadership among themselves.

The Joint Commission's standards relate to the same issues as those addressed in the Medicare conditions of participation but elaborate far more on the processes that are called into play to fulfill the responsibilities we are considering. However, they are not directive and there is some question as to how much guidance they actually provide. On the other hand, the medical staff standards which most define the context for bylaws and board and medical staff interactions have changed relatively little over the years, even in light of the complete revamping of the standards manual. What is clear is an expectation that medical staff leadership will be integrated into the broader functioning of the institution to meet new demands for quality.[21] How specifically that happens is up to the institution to determine.

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[18]JCAHO, *Hospital Accreditation Standards*, 171 (2001 ed.).

[19]LD 1.3.4.2.

[20]LD 1.10.2.

[21]In 2002, the Joint Commission convened a Medical Staff Standards Review Taskforce to identify more meaningful roles for physicians in assisting their organizations to maintain accreditation, "Physician Engagement in Accreditation," http://www.jcrinc.com/subscribers/perspectives.asp?durki=3301&site=10&return=187.

§ 4:6 —State hospital licensure laws

The fourth of the legal forces driving these relationships and responsibilities arises under the police powers of the states. Hospital licensure standards establish the baseline for an institution to be recognized to function as a hospital. Occasionally these regulations also address medical staff hospital interactions.

In Pennsylvania, the current hospital licensure regulations were published initially in 1975[1] to reflect the then state of the art of quality regulation. The regulations establish the overall responsibility of the hospital board "for the conduct of the hospital."[2] The board is to utilize the advice of the medical staff in granting and defining the scope of clinical privileges for individuals; and where the board disagrees with a medical staff recommendation, a joint conference committee is required.[3] Although the medical staff bylaws are to be approved by the governing body, "[s]uch approval shall not be withheld unreasonably."[4] Other specifications pertaining to board/medical staff relations include delegating to the staff the authority to evaluate professional competence, initial staff appointments, reappointments and curtailments of privileges, maintain effective communication with the staff, and requiring that the board ensure that the medical staff is provided with administrative staff and support for any medical staff functions required by the regulations or the hospital's own bylaws.[5]

The medical staff is accountable to the governing body

[Section 4:6]

[1]Under contract to the Department of Health, with Ed Shay, I wrote those regulations to reflect then state of the art quality standards. The regulations were based extensively on the then effective (1974) Joint Commission standards. The regulations have not been changed since.

[2]28 Pa. Code § 103.1.

[3]28 Pa. Code § 103.4(6).

[4]28 Pa. Code § 103.4(8).

[5]28 Pa. Code § 103.4(13).

and "has responsibility for the quality of all medical care provided to patients and for the ethical conduct and professional practice of its members."[6] The medical staff must have the authority to define conditions for membership, and delineation and retention of clinical privileges. Significantly for the current era, "[n]o applicant shall be denied medical staff privileges on the basis of sex, race, creed, color, or national origin or on the basis of any other criterion lacking professional or ethical justification, including association with a prepaid group practice."[7]

These regulations address the categories of the medical staff to be made available, affirmative due process requirements in rendering adverse appointment and reappointment decisions, appeals mechanisms for such decisions, how clinical privileges of non-physician practitioners are to be addressed and other issues to be included in the medical staff bylaws.[8] Specifically with regard to the medical staff's relationship with the board, the regulations establish that "[a] mechanism shall be provided by which the medical staff shall consult with and report to the governing body. . . . there shall be full communication between the two bodies. Both shall be adequately informed regarding hospital activities."[9] The organization of the medical staff, its officers, the role of committees and in particular the Medical Executive Committee, are addressed in these regulations, which, it should be remembered, are the threshold criteria to be a hospital in Pennsylvania.

Other states take similar approaches with more or less specificity. In the state of Washington, the regulations require that the governing body establish bylaws that "will provide for medical staff communication and

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[6]28 Pa. Code § 107.1.

[7]28 Pa. Code § 107.3(c). *See* discussion of loyalty oaths and economic credentialing in § 4:16.

[8]28 Pa. Code § 107.12.

[9]28 Pa. Code § 107.12(13).

conflict resolution with the governing authority."[10] The regulations establish that "[t]he purpose of the medical staff section is to contribute to a safe and adequate patient care environment through the development of a medical staff structure and mechanisms to assure consistent clinical competence."[11]

California also requires that the governing body address the appointment of the medical staff and its clinical competence.[12] "Each hospital shall have an organized medical staff responsible to the governing body for the adequacy and quality of the medical care rendered to patients in the hospital."[13] How non-physicians are to be granted a role in the clinical functions and even the hospital's establishment of an interdisciplinary committee to determine appropriate boundaries and functions is addressed;[14] but the political functions of the medical staff are not set forth in the regulations.

The point here is not an exhaustive survey of how states regulate hospitals, but to demonstrate that the interaction between the hospital board and the medical staff is often considered vital to the most basic activities of the hospital in these threshold to entry requirements. Essential functions related to the competence of clinicians and the quality of care provided, and particularly appointment, reappointment and corrective action are regulatorily assigned to medical staffs throughout America. Although this regulatory approach is not uniform, and some states are engaged in an even more dynamic process of establishing requirements associated more particularly with incident reporting, peer review and hospital-wide quality improvement programs, it should be noted that very often state hospital licensing regulations provide as a matter of law for the relationship between the medical staff and the govern-

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[10]Wash. Admin. Code § 246-320-125(1).

[11]Wash. Admin. Code § 246-320-185.

[12]22 Cal. Admin. Code § 70701.

[13]22 Cal. Admin. Code § 70703(a).

[14]22 Cal. Admin. Code § 70706.

ing body. All of these regulations require that the medical staff have bylaws to specify how it will implement its delegated responsibilities.

§ 4:7 Typical bylaws contents and current tensions

As we have seen, various legal requirements establish that the medical staff bylaws are adopted by the medical staff and then only become effective when they are approved by the hospital governing board. Still, I have seen power struggles between those groups on this most basic issue. I have seen paralysis set in when the board refuses to approve bylaws proposed by the medical staff because there is disagreement over philosophy, operation or specific bylaws provisions. Many of these issues never make it to court. The parties merely thrash about over time trying to arrive at some compromise, often failing, but expending considerable energies clashing over raw power issues rather than the substantive challenges they face.

The very structure of the bylaws has itself become a topic of controversy. One school of thought recommends a barebones, core bylaws document with essential functions such as credentialing, appointment, corrective action and fair hearing plan processes contained in separate 'policy' documents which purportedly are more easily amended if they do not require the type of medical staff vote required to amend the bylaws. Yet these are the most essential traditional functions in which the medical staff engages. Why would you want to change the processes governing them easily?

The bylaws usually open with some background observations which set the context for their interpretation and application. The respective roles of the medical staff and the board (for example that no physician will be appointed by the board without medical staff review; that the medical staff will be kept informed by the board of matters which affect its responsibilities) are stated here. In states where caselaw has confirmed that the

bylaws are a contract between the board and the medical staff[1] that may be explicitly stated; and sometimes that statement is made—in other settings as well—to provide a basis for construction of the bylaws in case of a future dispute. Although this recognition can prove important in a turf war, as a practical matter, what is the point of articulating a set of bylaws which have no effect without board approval if the board itself is not expected to follow those bylaws which fulfill its own obligation to assure quality?

Another bone of contention is sometimes the very language that is used to describe the individual physician in relationship to the medical staff and hospital. The traditional term has been "member" to connote that the physician is joining a medical staff organization with rules, processes and delegated responsibilities. This term usually appears in those bylaws which make reference to the staff actively "organizing itself" and engaging in "self-governance." Another approach which has appeared in the last fifteen years or so is use of the term "appointee." The point of this term is to denigrate the independence of the medical staff organization and to solidify the relationship between the individual physician and the hospital as one of mere appointment by the Board. Physicians often see these distinctions as significant. Their real significance, however, lies in the processes and functions to which they apply.[2] A hierarchy of documents—the board bylaws, the medical staff bylaws, rules and regulations, hospital policy—is also useful in almost every setting, and sometimes is articulated too. That the board cannot unilaterally amend the bylaws is often stated, has been a flashpoint

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[Section 4:7]

[1]*See* A.M.A. "Physician's Guide to Medical Staff Organization Bylaws," 3-5 (2d ed. 2002); and Dallon, "Understanding Judicial Review of Hospitals' Physician Credentialing and Peer Review Decisions," 73 Temple L. Rev. 597, 639-41 (2000).

[2]Where two or more medical staffs have merged, issues pertaining to the transition process by which a fully unified operation will evolve is often set forth in the Preamble.

in a number of settings, and finds its acknowledgment in the JCAHO standard prohibiting such action.[3] Sometimes where conflicts have arisen, boards amend their own bylaws in an attempt to coerce the staff into their camp. While technically clever, this rarely works.

§ 4:8 —Membership, appointment/reappointment, clinical privileges

Membership, appointment and reappointment, credentialing and privileging are the central medical staff functions addressed in the bylaws. Whether all staff members are board certified, required response times in case of an emergency, whether members must take emergency on call coverage duties and the categories of medical staff membership are set forth. Historically, the numbers of medical staff categories have diminished, although there is usually a core group of physicians who primarily relate to the institution (the Active Staff), and then those who relate in a lesser manner (Courtesy Staff and Consulting Staff).

Some medical staffs have extremely detailed categories and in academic settings the category differentiations can verge on the byzantine. Common additional categories include: Associate Staff (often without the right to hold office or even vote) for new members to spend time learning the political ropes; Honorary Staff for long term members who are now relieved of certain responsibilities such as dues payment and/or emergency department coverage responsibilities; Emeritus Staff, which is often confused with Honorary Staff and actually ought be called Medical Staff Alumni and not members of any kind, since these individuals usually have no political rights, nor clinical privileges, and merely are permitted to attend medical staff and hospital functions to which they are invited by virtue of their past service to the institution. Not only do these

[3]MS 2.1.

categories of membership reflect clinical dedication to the facility but they also incorporate political rights to serve on essential committees, function as a department chair or staff officer, and vote in department, committee and staff meetings.

Despite the requirement that all medical staff members be evaluated initially as to their credentials, and surveilled on an ongoing basis as to their clinical performance, in recent years many medical staffs have permitted as members physicians who do not practice within the institution. These staffs believe these physicians must have privileges and/or membership because a managed care organization with which the physician contracts requires such privileges.[1] Unless there is some basis on which the medical staff can reach beyond the hospital's walls into the offices of these primary care physicians, there is little the staff can vouch for with respect to the ongoing quality of their performance as clinicians, other than in the once every two years reappointment process. The same concern arises with respect to Emeritus/Honorary staff when they have no privileges. Moreover, the mere fact of membership in a medical staff has been found to be a basis for hospital liability for activities of a physician off campus, off hours, having nothing to do with his activities in the hospital.[2]

The initial membership application process has evolved over the years to a fairly comprehensive investigation into the bona fides of the applicant as a

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[Section 4:8]

[1]This is frequently based on a misperception of NCQA's credentialing requirements. Many believe NCQA requires that accredited HMOs expect that physicians have hospital clinical privileges. In fact, the standards provide that if a clinician has such privileges, the HMO's credentialing process must address any loss or limitations on them. National Committee for Quality Assurance, *Accreditation of Managed Care Organizations, 2003 MCO Standards and Guidelines*, 328.

[2]Copithorne v. Framingham Union Hosp., 401 Mass. 860, 520 N.E.2d 139 (1988).

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physician. His past work, training, malpractice experience, and his exercise of clinical privileges elsewhere are typical matters which are evaluated. A major conundrum in this process, though, is that there is virtually no legal requirement that a potential information source provide meaningful data (*e.g.*, the chair of the department in another institution need not respond at all to a reference request). Fear of liability for saying anything negative in these settings impedes frank interchange, despite the presence of peer review protection acts in every state. Often a potential informant will believe that anything really negative will have made its way into the National Practitioner Data Bank. Any data beyond that, they believe, is likely not sufficiently substantiated to merit disclosure when measured against the risk of a lawsuit for defamation. Of course, if adequate information cannot be obtained to confirm the quality of the practitioner's care, the medical staff may reject the application as incomplete. Medical staffs are often reluctant to do so.

Some staffs have used temporary privileges as a way to accommodate a clinician whose application is wending its way through the review process—from the department, to the Credentials Committee, to the Executive Committee, to the board. As the hospital's potential liability for practitioner-created problems has increased, though, the temporary privileges approach has fallen into disfavor since, over the years, it was abused. It used to be very common to find physicians without membership exercising long term temporary privileges while their applications dragged through extended review processes. Still, nationally reputed clinician consultants, locum tenens physicians providing coverage for a staff member and a physician providing care to one or two patients a year, continue to be granted temporary privileges as long as basic information is verified including licensure and malpractice coverage.

The reappointment process is also set forth and not only evaluates interim changes since the last appoint-

ment, but is also expected to take into account the various sources of information within the hospital quality improvement processes which, by all rights, should be funneled into the physicians' credentialing files. Medical staffs vary widely in the rigor with which they seek out and incorporate this data. Reappointment is rarely as focused as the initial review.

It should be noted that membership entails rights and responsibilities of the medical staff member including citizenship rights in the medical staff organization, whereas approval of delineated clinical privileges is a separate clinical evaluation process. It is possible for a member to have limited political (membership) rights and extensive clinical privileges. The delineation of clinical privileges and continued monitoring of their exercise is potentially the most significant quality-relevant activity assigned to the medical staff. Here is where the real expertise of physicians in evaluating their peers comes into play. How information is gathered, the responsibility of staff members to proctor others, and the judgments made based upon information that feeds this process are essential quality functions. All are addressed in bylaws, but often with relatively little procedural detail.

§ 4:9 —Corrective action, fair hearing plan

The corrective action process is where the medical staff truly demonstrates its commitment to quality care by taking action against clinicians who fail to measure up. Because of the highly charged nature of the decisions made here, though, this section of the bylaws most reflects the influence of the law.

The first cut point for a medical staff is how a request for corrective action gets made and addressed initially. In some medical staffs, anyone can bring a request for corrective action and the ball is in play. In most medical staffs a request for corrective action may be brought to the Executive or Credentials Committee only by a department chair or officer of the medical staff. This

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filter is to assure that there is some failsafe mechanism to forestall completely frivolous or vindictive actions that do not merit the initiation of staff processes. By this mechanism, someone with a complaint has to be able to convince at least one medical staff leader that the concern merits investigation. In many medical staff bylaws there is recognition that informal collegial processes are also expected to be utilized, and that the Department Chair has responsibility for the ongoing handling of relatively routine problems before they rise to the level of a corrective action. The bases for corrective action also vary within medical staffs. Some bylaws enumerate a detailed range of problems from clinical performance, to violation of the bylaws themselves, to breaches of confidentiality or ethical proscriptions. Others are more general and sweeping.

Usually the investigation of an initial request is undertaken by the Executive Committee itself or someone appointed by the Executive Committee. The purpose of an investigation is to determine whether it is necessary to proceed further. Many potential formal processes are truncated here. Often the practitioner is given an opportunity to explain whatever circumstances led to the request. Some medical staffs recognize that a practitioner faced with an inquiry of this type, called to an informal meeting without benefit of counsel, may feel at risk. Their bylaws may say he has an opportunity to explain himself but that no presumption may attach to his failure to appear. In other words, a clinician choosing not to attend such a meeting could not, on that basis alone, be presumed to be at fault for the triggering behavior. Other medical staffs have a culture in which a critical value is that working together is essential; to safeguard the vitality of the process a practitioner requested to appear must do so and failure to appear is itself grounds for corrective action.

The inquiry may be dismissed. It may be sent to formal process. The "formal" process triggers the provisions of the HCQIA if the medical staff and the hospital hope to avail themselves of the antitrust and other

protections the Act offers. Consequently, the physician facing a formal request for corrective action is given the opportunity to present or explain his case. Whether he gets a full, "due process" hearing depends on what can happen to the practitioner based on a complaint which is decided adversely to him.

The HCQIA has become the driver of the elements of process made available where final action is taken by a peer review body in the good faith belief it is in furtherance of quality. This means that once an investigation is under way the medical staff must decide whether the problem complained of merits a sanction that will affect the practitioner's membership or clinical privileges or represents a lesser problem.

Because of the intense demands of the HCQIA's requirements, many lower level approaches to quality issues are considered and attempted. Typical actions which do not entail either reporting to the Data Bank nor the formal fair hearing process include a documented concern in the credentials file, a letter of reprimand, terms of probation where the practitioner is under watch for repeat episodes of the complained of behavior, mandated consultation with another practitioner, profiling of the practitioner on a more intense basis to study his patterns of care, terms of additional education, even mandated psychiatric evaluation. As long as these actions do not preclude or restrict the exercise of privileges unless they occur, they would not be reportable, even if related to quality, nor would they mandate a formal fair hearing under HCQIA.

By the same token, however, terms of mandated coprivileges with another practitioner, mandated consultation in the exercise of clinical privileges, limitations of privileges, suspension of privileges pending psychiatric evaluation, and additional continuing medical education in order to exercise privileges would all be reportable. Because physicians are extremely fearful about any report to the NPDB since they see these reports as career threatening, some medical staffs err on the side of more process rather than less; in other

words, some medical staffs will offer a full hearing, or a quasi-hearing for lower level problems because they favor a culture which works hard to protect individual rights.

The actual processes can be quite elaborate. Rules regarding pre-hearing discovery, challenges to the composition of the fair hearing committee, whether the fair hearing is to be conducted by a committee or a single fair hearing officer, whether the hospital counsel can serve as the fair hearing officer, whether the medical staff will itself be represented by counsel at the hearing while the hospital counsel advises the fair hearing process, or a separate lawyer who neither represents the hospital nor the medical staff is brought in, are all decisions that medical staffs have to make in deciding to proceed with a fair hearing.

Who has the burden of going forward? Generally the onus is on the medical staff to substantiate its position in favor of a recommended action. The aggrieved practitioner then has the burden of presenting his arguments against the determination. The burden of proof can vary and has some significance for the support of quality-relevant judgments. Sometimes there is a higher burden for initial applicants who are unknown to the staff and a lower burden for members of the staff. If presumptions are in favor of the Medical Executive Committee recommendation, meaning that the practitioner must overcome the judgment based on the fact that the staff action was arbitrary and capricious, or not supported by substantial evidence, these are high barriers to overcome. On the other hand, clear and convincing evidence is a somewhat lesser standard and the preponderance of the evidence is the lowest yet. Where the burden of proof is lower (*e.g.*, preponderance of the evidence) it is more difficult for the medical staff to sustain its corrective action.

The conduct of the hearing resembles a trial in many respects, and, although in the olden days some staffs precluded the presence of lawyers, now they are expected because representation by counsel is required

for the HCQIA protections. As a result, usually a medical staff panel sits in judgment of its peer who is under the gun. The lawyers defend and cross-examine. Memoranda of law may be presented subsequent to the closing of the hearing. The panel or hearing officer convenes to consider the evidence adduced, the arguments made and then makes a recommendation back to the Medical Executive Committee.

The story is still not yet over. The Executive Committee can remand for additional proceedings or can simply move to adopt, modify or reverse its original recommendation. The entire record then makes its way to the board, but the recommended action does not take effect until the board acts. If the board adopts the recommendation, the practitioner still has a right to appellate review by the board—a review of the record. Sometimes oral argument is permitted. Sometimes it is mandated. Briefs may be submitted. None of the appellate process is subject to the HCQIA. Some medical staff bylaws require that the appellate review, even though conducted under the board's authority, involve physicians among the decision makers, to sustain peer input into the review. Many medical staff bylaws assert no such requirements since it is a record review only.

If the board comes to a conclusion at variance with the Medical Executive Committee's recommendation, many medical staffs convene a Joint Conference Committee to consider the matter yet again. This process, which has somewhat fallen out of favor, represents a traditional effort to make sure the board understands the professional clinical judgments at issue and the reasons for the Medical Executive Committee recommendation. In these settings, the decision is not final until the Joint Conference Committee has acted.

Sometimes this committee advises the board and sometimes it acts for the board. No matter. By the time the board is reviewing a challenged corrective action which is recommended by the medical staff through the Medical Executive Committee, the matter has been reviewed by internal medical staff processes, hospital

internal processes which may be outside the medical staff as in the hospital-wide JCAHO mandated quality review process itself, the investigating committee, the Medical Executive Committee, the fair hearing review, the Medical Executive Committee again and then the board. The process usually takes many months, during which time the practitioner is functioning under a cloud—if he has not been summarily suspended, in which case he is not functioning at all in that environment.

The medical staff members who serve in the process are volunteers, generally unpaid, must take time from their clinical practice to perform these functions, are not trained to marshal evidence, present evidence or actually make a good case to support their position. Some of the most difficult situations arise when the medical staff knows a clinician is not up to par but they simply do not have the will or capacity to make a case which can withstand this type of evaluation.

The volunteers are often subject to persuasion by friends of the practitioner and other stakeholders in the institution. To give the process credibility they must remain free of coercion; and some bylaws even introduce the issue of attempted coercion as a separate basis for corrective action. Tensions run high even in the best of circumstances when there is general unanimity regarding the action proposed. The amount of time spent—both in substantive consideration of the matters at hand, and lost productive time for the clinicians engaged in these activities—can be astonishingly high.

Because the HCQIA also makes a resignation or voluntary relinquishment of privileges, even if only partial, reportable to the Data Bank, the medical staff processes are seen as leading to draconian possibilities. As a result, ironically, many quality relevant activities and evaluations within medical staffs no longer are as robust as they might be because of the fear of "there but for the grace of God go I" that is inevitable and natural in a peer setting. To avoid reporting to the Data Bank and because physicians fear whether their judg-

ment can withstand such intense scrutiny, many medical staffs choose not to exercise this chilling power in favor of lower level approaches or no approaches at all to quality problems.

With legal advice of variable quality when some is available or without a medical staff lawyer available to advise them, they take the low road. As a result, a law intended to bolster quality activities by providing protections to both sides—for the aggrieved practitioner with formal process and against antitrust liability for the medical staff—may, in fact, have the opposite effect.

§ 4:10 —Other issues

The bylaws typically address the requirements for meeting attendance. Twenty years ago, medical staffs routinely required monthly meetings, then quarterly meetings and now many medical staffs require that members attend only one meeting a year. Most physicians experience a hospital primarily through their departments; and many hospital medical staffs have not sustained a clear vision for the general membership of the purpose of the medical staff organization as a whole. As financial constraints have affected physicians more and more, they often see no real value in their medical staff meetings. Frequently, simply raising a quorum has become difficult. Many physicians still attend department meetings, especially if they are required to do so. But as a practical matter, within many medical staffs, the bulk of the work is done by a core group of medical staff activists. Only in the case of some perceived clear and present threat does the general medical staff meeting emerge as a vehicle for real communication within the medical staff structures.

The bylaws usually confront establishment of departments, responsibilities of department chairs and election and removal of staff officers. The role of departments as the administrative focus for medical specialties is where much of the medical staff's work on quality originates. Even though the departmental

structure is ubiquitous, it is not mandated. When a hospital is departmentalized a raft of choices with both political and clinical significance must be made: Who has the authority to create or terminate a department—the staff alone; the staff with board approval; the board with input from the staff; or the board alone? Similar choices must be made regarding divisions. How is the department chair selected—medical staff elections; search committee of the staff; search committee of the board? Is the chair an administrator solely accountable to the board or is he or she expected to perform a representative and communicative function for the department members? Does the chair select division directors or are they chosen by political processes? The choices made on these issues can produce very different medical staff and clinical cultures. In academic settings, the relationships between these appointments and those with the affiliated medical school raise still further significant, quality relevant concerns for the staff, whether town or gown.

In many medical staffs, the committee structures may be complex with many committees performing a wide variety of functions. In recent years, greater simplification has been the hallmark of efforts to make these activities more efficient. Which non-physicians, if any, participate in medical staff committees and with vote or without vote occupies some medical staffs. Others differentiate clearly among committees which are specific to the medical staff, hospital committees which require medical staff chairs, and joint committees which involve slotted seats for medical staff representatives and other hospital stakeholders. The balance between the political desire to offer opportunities to participate to interested medical staff members with the real need to get the work done is a major concern in many medical staffs today. How physicians approach these and all other staff responsibilities is determined in part by the common values which motivate them.

§ 4:11 Physicians in medical staff organizations[1]

For a real understanding of how physicians function within medical staffs, it is important to reflect on: (1) their essential functions; (2) the forces and values which drive them; and (3) how these are manifest in medical staff behaviors. These can be seen both inherently in physicians as individual clinicians, distinct from all other actors on the health care scene, as well as in the dynamics that characterize their interactions with others. Some of these tenets and pressures are in flux and some are so immutable as to define starkly the essentials that compel physicians. All must be taken into account in understanding where tensions emerge in medical staffs, as well as how to improve medical staff operations in the context of the overall hospital clinical culture.

§ 4:12 —The essential role of physicians

The role of physicians in health care is so central as to define the parameters of major features of the rest of the system. They are plenary licensed—they have the broadest scope of practice of any other clinicians. Most other clinical professionals—nurses, therapists, technicians—function derivatively of an order given by a physician. Hospitals themselves can neither order, nor provide services, without a physician directive to do so.

For patients, physicians are the portal to the rest of the system. They are the formal and informal leaders of the care team. They perform many of the most critical and intimate procedures patients will experience. Much in the law makes the physician the captain of the ship in terms of personal responsibility for what happens based upon his orders.

Physicians are often the primary interpreters of the

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[1]The core of these ideas was first articulated in a white paper I wrote for the A.M.A. in 1998, "Quality and Clinical Culture: The Critical Role of Physicians in Accountable Health Care Organizations," http://www.ama-assn.org/ama/pub/category/8340.html.

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health care system to their patients. They are the principal sources of information about diagnosis and therapy, benefit coverages and limits, alternative sources of service and the quality of other services. For all the branding of hospitals and advertising of heart transplant centers, joint replacement programs and the like, for the most part, patients go to the facility to which their physician directs them.

The fundamental transaction which impels all of this is the doctor-patient encounter. A profound and elegant view of this relationship finds that the most essential task in which physicians engage is that they "transform information into meaningful explanations of the present, predictions of the future, and changed futures, mainly for individual patients and sometimes for whole populations."[1] This explanation has been adopted and recharacterized by another commentator as follows:

> [T]he fundamental nature of the transaction that takes place between physician and patient, as complex, multifaceted, and enigmatic as it is, can be captured in just three questions that people seek answers to when they are sick: ...[P]eople basically look to their physicians to (1) explain nature: What is happening to me?; (2) predict nature's future: What is going to happen to me?; and (3) alter nature's future for the better: What can be done to improve what happens to me?"[2]

As Reinertsen says,

> We take information about health and transform it to a higher order of information, not just as an intellectual exercise, but to satisfy the three fundamental needs of explanation, prediction and change. We can

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[1]Reinertsen, "Health Care: Past, Present and Future," *Group Practice Journal*, 38 (May/April 1997).

[2]Cohen, "Remembering the Real Questions," *Annals of Internal Medicine*, 128:563-566 (April 1, 1998).

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> do other things in the course of our day, but all are secondary to this primary task."[3]

The Institute of Medicine in its study of the policy needed to propel quality took up this view of the essentials of the doctor-patient relationship to observe that the "transfer of knowledge is care."[4] If that is so, then high quality care is care provided in a context in which that transfer is optimized. To enhance the transfer of knowledge, the physician must have a deeply personal relationship with the patient that permits an intimate understanding of how to convey the critical data most effectively. To do so requires time and touch.[5] Another definition of quality then, is the application of the best science available in a context of time and touch. This view of what physicians do is a consistent, although rarely articulated, value among them. Time to develop real relationships with their patients is what they crave more than anything in a world of decreased reimbursement and crushing administrative burdens, shaped ironically by regulations which purport to be aimed at improving quality.[6]

§ 4:13 —Their values

The values physicians bring to bear in their work are also relevant not only to how they interact with their patients but in relationship to all other aspects of the

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[3]Reinertsen, "Health Care: Past, Present and Future," *Group Practice Journal*, 38 (May/April 1997).

[4]Corrigan et al., "Crossing the Quality Chasm," Institute of Medicine, National Academy Press, 72 (Wash. D.C., 2001).

[5]Reinertsen, "It's About Time!: What CEOs and Boards Can Do For Doctors, Nurses, and Other Healthcare Professionals," 2 *Disease Management and Quality Improvement Report* (April 2002), at http://www.reinertsengroup.com/leadarticle.PDF.

[6]*See* Gosfield, "Making Quality Happen: In Search of Legal Weightlessness," *Health Law Handbook*, 609-78 (A. Gosfield, ed. 2002); and Gosfield, "Legal Mandates for Physician Quality: Beyond Risk Management," *Health Law Handbook*, 285-322 (A. Gosfield, ed. 2001).

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system. First and above all, physicians feel a direct one on one responsibility for the individual patient whose problem they are addressing. The law gives them this responsibility in terms of liability for malpractice, but they feel the mandate to consider the patient as an individual even in light of changing views not only of their responsibility for societal health care costs across populations, but even in their interpretation of controversial epidemiological data as in the recent disputes over hormone replacement therapies or when to initiate screening mammograms.

This responsibility for individuals, however, is most evident in the almost never discussed, searing responsibility each physician feels for the life and death of the patient he or she is treating. This is not an inconsequential driver of physician behavior. It imbues much of the unspoken physician culture. Most physicians can tell you thirty years into their career by patient name each incident in which they feel they might have killed or harmed a patient by virtue of their practice of medicine. They know the practice of their profession entails imperfect decisions, made based on imperfect information, usually without the benefit or luxury of time to reflect. It is this daunting, haunting accountability which generates such a strong physician cultural reliance on autonomy and individuality. In the last critical moment of clinical decision-making, no matter what else has been brought to bear to meet the patient's needs, an individual physician is often quite alone in deciding what to do for that patient. Having to trust so completely in their own judgment they do not easily give credence to others'.

Their sense of this raw accountability is such that they measure everyone, including other physicians, by it: the further a physician is from the risks of this accountability the less credible he is as a physician to other physicians. This is directly relevant to whom physicians trust within the physician culture. It also is relevant to whom they acknowledge as a leader.

That being said, over the years I have been struck

time and again about something which seems quite counterintuitive when their individual autonomous decision-making so compels their world view—physicians value collegiality. This is not a matter of friendly interactions for the sake of a brotherhood of the profession against the world (although there is certainly a separateness which comes from the life or death judgments they make). Rather, I have come to understand that collegiality is a reflection of the intellectual tradition of physician training.

Physicians continually draw on the intellectual capital of their peers as consultants in their treatment of the patient. There is a group-informed process, albeit rarely exercised in a group setting, by which the physician concludes how he or she will treat the patient, based on advice sought from and provided by colleagues with different expertise. Physicians of different specialties simultaneously treat the patient and cooperate in doing so. Similarly, throughout their careers physicians participate in grand rounds, an activity which exists in the most remote and far flung hospitals, as a way for them to interact about and share their views of new developments and the advancement of clinical practice.

Grand rounds as an intellectual undertaking is also a reflection of the strong physician tradition of evidence-based scientific decision-making (cast in modern terms) which finds its primary evidence in the widespread dissemination of peer reviewed literature as a hallmark of knowledge advancement. Physicians are subject to continuing medical education requirements by law in many states, by their profession in their board certifications, and within medical staffs. Their reliance on peer reviewed literature is yet another cultural manifestation of a belief in the need to test scientific thinking and safeguard its validity by virtue of evaluation by multiple similarly trained and experienced professionals.

By the same token, physicians are trained not to trust interpreted data. The physician progress note reads "Patient denies smoking or drinking." The implication

is that the truth will not be known until raw data is obtained based on analysis of fluids actually drawn from the patient's body. In the medical staff context, this translates into physicians' distrust of reports, whether analytical, interpretive, or in summary, presented to them by the board or administration—unless they have access to the underlying data. This value is essential to the ways in which the stakeholders communicate in the medical staff context.

This last value also relates directly to the very strong worth physicians find in due process. The administratively burdensome procedures they use to make the judgments they are charged with as a medical staff reflect, I believe, the concordance between due process and the scientific method.

Physicians are, in many ways, science-driven at their core. As Reinertsen has further observed:

> I think the distinction between the practitioners of so-called alternative medicine—chiropractors, homeopaths, naturopaths, and others—and those of us who claim our grounding in science is that the alternative practitioners are often very skilled at meeting the first two needs—explanation and prognosis—but they don't often actually change the future for their patients—at least not for those with meningitis, or insulin-dependent diabetes, or comminuted fractures of the tibia and fibula or infarction of two feet of their small bowel.
>
> For this is the real miracle that science brought to medicine. . .To truly alter the future, the doctor must have an effective craft—one worth knowing, not just a sham—and must use that craft with wisdom."[1]

Due process has features which correspond to certain aspects of the scientific method. Neither is efficient; both are intended to produce a "better" decision. In due process there is a hypothesis, as in science. The hypothesis posits a judgment about a physician, that

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[1]Reinertsen, "Health Care: Past, Present and Future," *Group Practice Journal*, 38 (May/April 1997).

his privileges should be curtailed, for example. In a due process hearing, the hypothesis is supported by the presentation of evidence. That evidence is challenged in the crucible of cross-examination, much the way a hypothesis in science is tested through repetitive experimentation. The resulting evidence is then evaluated to come to a conclusion.

Some argue that physicians are particularly drawn to a very narrow interpretation of the evidence because of their training in "the null hypothesis," which for due process purposes would be that the physician to be judged is not different from any other physician. To prove that the proposed curtailment of privileges is supportable, their training would tell them that the quality of the evidence that he is different must be very strong and unassailable with extremely high confidence.[2] This connection between the scientific method, medical training and due process can prolong already difficult judgments where the stakes are so high for the aggrieved practitioner. And then, ironically, even when there is a will to take action, often the medical staff still has not developed a very good record as to why corrective action is mandated.

§ 4:14 —Resulting medical staff problems

Against this background of values, it is not hard to understand how physicians end up disadvantaging themselves in their medical staff interactions and their interactions with the hospital board and administration. The first dilemma is the problem of physician leadership, which is compounded by profound problems in physician followership. Treating their patients as individuals, they function "politically" in a similarly atomistic way. Physicians frequently choose as leaders the individuals who most reflect their personal views rather than leaders who can best represent the needs of the medical staff or the department as a whole. The

[2]James L. Reinertsen, M.D., Personal Communication (Dec. 20, 2002).

chosen leader may be the most outspoken critic of some specific problem area about which the electorate is concerned. He may simply have the potential to be an ongoing thorn in the side for the administration with whom those voting have a grievance. Even where this common phenomenon is not present, once selected, the leader himself may choose to represent his own personal interests or parochially those of his department. He may fail to act as an information conduit to and from his constituents. It is difficult to eschew personal agendas in the medical staff setting if the value in doing so has never been explicitly considered or, even more importantly, articulated.

The followership problems stem from physician difficulty in trusting anyone—including their own representatives. As a result, medical staff undertakings often involve a "town meeting" culture in which physicians believe that all decisions should be made with all interested parties participating. When their leaders do take action, the physician membership will second guess them and try to both investigate and revisit the underlying judgments. This town meeting culture also leads to consensus decision-making where the same issue will be revisited *ad nauseum* on the theory that the one individual who persists in complaints about the group decision will somehow come to accept the group will if it is continually explained and reconsidered. It is astonishing how novel the notion of a majority vote and termination of discussion is to a physician group process.

Related common problems include the medical staff creation of redundant large staff committees to support the town meeting broad participatory value, yet without sanctions for those who fulfill their committee participation responsibility only sporadically—often, because they find it far more important in the moment to respond to a patient need or a perceived clinical practice need even where no patient emergency exists.

A developing problem for physicians faced with shrinking revenues is the longstanding tradition of vol-

unteer service to the medical staff. One of the reasons fewer physicians are available to do the medical staff's work is that to do so takes away from revenue producing time. Juxtapose this problem against the absurdity that although medical staffs almost uniformly pay dues, most of that money is maintained to fund the annual staff dinner dance. Over and over again I have seen significant treasuries accumulated by medical staffs with the monies never dedicated to any meaningful activity that would support the hospital's needs or even those of the staff itself. Increasingly, staffs are finding that it is worth considering whether to pay physicians at least something for their service to the medical staff organization. Some hospitals consider this a way to bond with critical clinicians.[1] Others shy away from it completely, out of paranoid fears that the Stark statute precludes this approach. Yet, as long as the physicians who are paid are not those selected because of their referrals to the hospital, and the amounts paid reflect the fair market value of the work the physicians do, there is nothing in legal terms that precludes the hospital paying for these vital medical staff activities that are conducted truly to benefit the hospital.

The more difficult problem is the physician suspicion which has emerged in recent years as medical staffs have become bifurcated between the traditionally independent, entrepreneurial physicians in small or solo practices and the physicians who sold their practices or are employed by the hospital or its affiliated entities. In

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[1]Advisors who have long recommended significant board control over the medical staff structure and processes are now recommending that hospitals pay physicians for certain activities, but more importantly that they consider other techniques to make their physicians' lives easier such as making hospital rounds go faster, streamlining OR scheduling, getting physician offices ready for HIPAA and "bring physicians into the governance loop in a meaningful way." "10 Things You Can Do For Your Doctors—Without Going to Jail," Audio Conference (Dec. 18, 2002), http://www.hortyspringer.com.

these rearrangements, referral patterns are sometimes disrupted, generating real economic anxieties. The more prevalent fear, however, is that if a physician receives any money from the hospital he will be tainted, his decisions corrupted, and he will therefore be unable to represent the independents. In academic settings this is manifested in town/gown disputes; but more and more in community hospitals throughout the country the same bifurcation has occurred.

This level of suspicion and concern over the extent to which the hospital administration controls the employed physicians can significantly undermine efficient, meaningful medical staff processes by rejecting legitimate leaders on this basis alone, by removing from potential involvement in the medical staff those who cannot afford to participate meaningfully for no compensation given the economic demands on them, and the medical staff refusal to pay for or allow the hospital to pay for these services. Physicians ought to be able to understand that in today's world volunteerism has its limits.

The physician culture created by the interplay of these common values and the dynamics of their interactions is directly relevant to techniques for improved medical staff operations. Understanding these values and behaviors also provides insight into how to resolve tensions which arise from the challenges that hospitals and their medical staffs face. Let us now consider common flashpoints and hot spots in today's medical staffs all around the country.

§ 4:15 Current medical staff flashpoints

Against this background of legal influences, bylaws contents, physician culture and the general stresses of the health care delivery system, a number of controversies within medical staffs and between medical staffs and hospital administrations and boards have risen to the fore all over America. They reflect the strategic and financial challenges faced by most hospitals today; and they absorb considerable energies from boards, medical

staffs and hospital executives. This is not an exhaustive list but illustrative of challenges with import for quality.

§ 4:16 —Loyalty oaths, economic credentialing and conflict of interest policies

As the financial realities of shrinking resources have combined with improved and cheaper technologies, many physicians have become more businesslike and entrepreneurial in their approach to their work. They are far more active in seeking opportunities to increase their revenues through means other than their mere personal clinical productivity. In addition, for-profit companies have seen the opportunities for themselves in this arena by assisting physicians in these endeavors. As a result there has been a surge of interest in the physician community in owning more of the means of their own production from their own medical technologies like lithotripters, PET scanners and MRIs, to their own ambulatory surgery centers ("ASCs") and increasingly to include their own specialty hospitals often focused around cardiac care, orthopedics or women's services. In fact, the Stark statute has encouraged this through its recognition that physician investment in a hospital itself[1] and in-office ancillary services[2] are exempt from the statute's anti-referral proscriptions. Similarly the OIG's ambulatory surgery center safe harbor under the anti-kickback statute explicitly recognizes both physician and physician-hospital joint venture ASCs as specifically safe.[3]

In addition, physicians have joined into larger and larger groups to facilitate the acquisition of new technologies, to benefit from Stark law opportunities to generate revenues in this way, and to have greater bargaining power with managed care organizations. A

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[1]42 U.S.C.A. § 1395nn(d)(3).

[2]42 U.S.C.A. § 1395nn(b)(2).

[3]42 C.F.R. § 1001.952(r).

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corollary of this is that these groups also end up having more power in relationship to the hospital. Hospitals confronting these challenges often seek to avert this economic threat with their own proposals for physician joint ventures in equipment ownership, leasing services from physicians, and even gainsharing programs.[4] In some communities where multiple hospitals seek to bond with their physicians, bidding wars can arise at competing institutions where these larger group practices seek to be more and more important to the prized physicians.

What leads physicians to these initiatives? Often the physicians who are in a position to engage in competitive businesses are able to do so because they are good practitioners who command market recognition by their quality and their good organization. They are often the very types of physicians a hospital most wants involved in its critical medical staff functions. They have considered the hospital their business "significant other" for most of their careers. They generally respond to the siren lure of new undertakings only when they feel frustrated by lack of control at the hospital itself. When asked to consider in very real terms the potential upside of these initiatives (which command substantial expenditures of money, but even more importantly physician time to bring them to fruition), the physicians will talk more about control over their environment than anything else. While many of these projects are realized, and certainly the for-profit developers that assist in their creation fervently hope they will be, I have been involved in multiple situations where physicians left unsatisfying hospital contexts for new opportunities only to have the entire transaction collapse a year and a half after initiating it.

Some hospitals perceive these developments as profoundly threatening. They respond with a defensive

[4]*See* King and Louthian, "Gainsharing—Life Before and After the Bulletin," *Health Law Handbook*, 195-214 (A. Gosfield, ed. 2000).

posture which generates real animosity and anger among the physicians on the medical staff: namely loyalty oaths from the physicians—that they will not undertake such competitive actions; that they will offer the hospital, in effect, a right of first refusal to participate in these potential businesses; that they will dedicate a portion of their practice to the institution when their patients need hospitalization or other hospital services; that if they are to be given privileges to read echocardiograms at the heart station, for example, that they will not put competitive equipment in their own practices. These are only some of the versions of these loyalty oaths I have seen recently.

Some facilities are now requiring their physicians to disclose their health care investments, not only medical staff applicants' investments but also with respect to their family members and increasingly to include those already on staff who are up for reappointment. Some facilities legitimately fear that when physicians are invested in competing businesses, that they will cherry pick the best paying patients for their own facilities and bring the poorer paying patients to the hospital. There are major battles around the country on these points[5] and advocates on both sides argue whether the hospital's response to these threats raises fraud and abuse issues.[6]

Some hospitals have focused more on the competitive threats from others knowing what they are planning and have required confidentiality agreements from physicians who, because of their involvement in medi-

[5]*See* Taylor, "Doc Investors in For Profit Hospitals Denied Staff Privileges," *Modern Healthcare*, 12-13 (July 15, 2002); "Hospital System Pulls Staff Privileges For Doctors Who Invest in Competitors," 11 *BNA Healthlaw Reporter*, 1451 (Oct. 10, 2002).

[6]*See* Raspanti and Laigaie, "When Does Economic Credentialing Violate the Anti-Kickback Statute?," *Health Law Handbook*, 307-30 (A. Gosfield, ed. 2002); Nagele, "Hospital Privileges As Kickbacks?: The Economic Credentialing Debate Commands Renewed Attention" *Health Law Handbook*, Ch. 7 (A. Gosfield, ed. 2003).

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cal staff and/or hospital committees learn of the facility's strategic plans. In virtually every setting I have seen where these techniques are employed, the loss of trust and confidence between the hospital administration and/or board and critical elements of the medical staff has been long festering and unaddressed. The new approaches only crystallize the tensions which were already there.

These techniques also raise significant questions about how far they reach and what their impact might be with respect to quality. Looking more closely, it would seem that there is a real difference between the responsibilities of a physician serving on the board of a hospital as a trustee and fiduciary and a mere member of the medical staff. Therefore the confidentiality constraints on them ought vary. On the other hand, whether there is any legitimacy in competitive restrictions imposed in a non-profit hospital on physicians who practice there, even if they are in a leadership role is questionable. Between these extremes, the issues are more difficult.

Physicians in the leadership of the medical staff who sit on the Medical Executive Committee will, if the institution is operating appropriately, learn a lot about the hospital's finances and plans. The confidentiality of such information seems unassailable. But should physicians be excluded from leadership positions if they are invested in a competing business? How is such competition defined? Is the mere ownership of competing equipment competitive? And why should this analysis extend to family members? If strong physician practices which serve the hospital by bringing patients and participating in medical staff activities are excluded, who will serve in the medical staff leadership?

These political and strategic dilemmas are real and they are challenging, but they rarely are undertaken with consideration for their implications for quality which are not so obvious. The spurned lover approach of these loyalty oaths, economic credentialing, and disclosure documents can misfire completely so the most

critical physicians to the institution end up walking away from the very involvement the hospital would most desire.

There is a truly legitimate quality issue associated with the volume of services that certain critical physicians perform in the institution. Over and over again we learn that the best way to assure good outcomes, particularly for high risk surgical procedures, is to do many of them repetitiously[7] involving the same teams of practitioners—nurses, physicians, operating room technicians—who are used to dealing with each other in a team context.[8] It is entirely appropriate for a hospital to decide that for certain critical services it will only award clinical privileges to those physicians who perform a sufficient volume of procedures there to assure not only that the team approach to quality can be provided, but also that the number of procedures performed is sufficient to be able to effectively monitor the physician's quality over time. Even before the current era, this type of discrimination in hospital privileging has been upheld where a surgeon was denied privileges because his multiple memberships elsewhere would preclude his effective contribution to the hospital's teaching mission.[9] To do otherwise can put the hospital in a position where if a physician operates at multiple institutions and does not engage in enough activity at the hospital to permit a full evaluation of his skills over time, substantive quality may be impeded. In addition, the hospital must seek quality relevant

[7]This is the basis for the Leapfrog Group's movement to evidence based hospital referral. *See* "Bibliography," http://www.leapfroggroup.org/biblios/bibliography2.htm, for 43 citations on this point.

[8]That skilled teams working together over time produce better outcomes while seen primarily in observational studies, is also the foundation for the Leapfrog focus on ICU physician staffing. *See* http://www.leapfroggroup.org/Fact Sheets/icu-FactSheet.pdf, and Provonost et al. "Physician Staffing Patterns and clinical outcomes in critically ill patients 288 J.A.M.A. 2151 (Nov. 6, 2002).

[9]Robinson v. Magovern, 521 F. Supp. 842 (D.C. Pa. 1981).

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data about him from the other institutions where the physician provides these services. There is no guarantee the requisite clinical information will be made available since the other institution has its own constraints on sharing patient and/or peer review data.

The advent of the loyalty oath, economic credentialing, competitive disclosure epoch is yet another demonstration that the economic interests of the individual staff members and those of the hospital as an institution are not uniformly synchronized. Even so, these approaches to perceived economic threats likely will fade over time, especially as different models for medical staff and hospital interaction emerge. In addition, if and when the Office of the Inspector General ("OIG") fulfills its stated intention to consider the role of hospital privileges under the 2003 Work Plan,[10] more light may be shed on the potential legal implications of these undertakings. The OIG has now formally called for comments on these issues. Their concern turns on the implied demand for referrals in the preclusion of membership or privileges to those holding investments in competitive business, particularly where the hospital exercises discretion in granting membership or privileges in response to the information submitted.[11]

§ 4:17 —Communication between the board and the staff

Another flashpoint between medical staffs and boards is the manner in which, and the topics around which, the board communicates with the medical staff and even further, actively seeks its input. The challenges in these interactions have been recognized in the JCAHO standard which requires "a mechanism designed to provide

[10]DHHS, Office of the Inspector General, *2003 Work Plan,* CMS, http://oig.hhs.gov/publications/docs/workplan/2003/2-CMS%20fy03.pdf.

[11]67 Fed. Reg. 72,894 (Dec. 9, 2002). For my comments to the OIG on how economic credentialing implicates the antikickback statute, *see* http://www.gosfield.com/oigv2.pdf.

for effective communication among the medical staff, hospital administration and the governing body."[1] Additionally, the standard establishes that the medical staff be directly represented and participate in "any hospital deliberation affecting the discharge of medical staff responsibilities."[2] The leadership chapter in the JCAHO Manual would seem to expect the medical staff leadership to be seamlessly woven into the integrative processes by which the hospital itself assures that the other JCAHO mandates are fulfilled. There are, however, zero directives with respect to how any of this would occur.

Determining which topics merit physician involvement has been a frequent problem in hospitals. The role of the medical staff in insisting on pure self-governance and maintaining its autonomy, has in some ways ghettoized the physicians and created a boomerang effect. In response to the physician demanded separateness as the sine qua non of autonomy, often the board and administration isolate the credentialing, privileging, and corrective action activities to the medical staff, but fail to involve them in other critical decisions and processes which can significantly affect the quality of care in the institution.

Where the physicians' economic interests are at stake, and a risk of real medical staff restiveness lies in unilateral decisions by the board, some hospitals have found it useful to seek medical staff input on matters such as whether to close a department to new practitioners, whether to take a service which was previously open and make it subject to an exclusive contract with a single group of practitioners, whether to create a new clinical department in the hospital, whether to imple-

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[1]MS 2.3.6.

[2]MS 2.3.8.

ment a medical staff development plan,[3] when to add new services not previously offered at the facility and what those services might entail. These are issues with both strategic and economic significance both to the hospital as well as to the physicians, who may already be exercising the implicated clinical privileges or seek to have access to the new resources.

Although antitrust considerations come into play where otherwise competing practitioners speak to issues affecting their competitors, both within the institution and from outside, these matters have been at issue in struggles between boards and medical staffs for the last twenty years. There is no question that the scope of services to be made available by the hospital and who will be the practitioners utilizing them are critical quality issues. How to safely engage the medical staff on these topics is far less clear. Of even greater concern in some ways, is the failure of many hospitals to forge meaningful medical staff involvement in broader strategic and financial issues which not only directly affect quality but implicate the physicians who are so critical to providing it, maintaining it and safeguarding it on behalf of the institution.

§ 4:18 Cross-department privileging

A third area which generates its own special torture between the staff and the board and very much among medical staff members is where physicians in different departments provide the same services and the corollary—allowing physicians to have privileges in more

[3]These plans used to be sought by the hospital when facilities were at risk of utilization to their full capacities. Now they are sought primarily by medical staffs seeking to consolidate their franchises. For a discussion of the legal issues in using a medical staff development plan *see* Gosfield, "Determining Medical Staff Composition: Legal Concerns and Practical Considerations," *DRG Monitor*, 1-8 (June 1987); and "Medical Staff Development: Planning and Managing the Process (co-authored with Hugo J. Finarelli, Ph.D., and Edward J. Schumacher, Ph.D.) *DRG Monitor*, 1-8 (Jan. 1986).

than one department. Increasingly the boundaries between medical specialties are blurring. Family physicians and obstetricians are a long standing example of practitioners who both deliver babies but are usually assigned to different departments. Interventional radiology is a prime example of the new challenges which arise around these issues. Although in many hospitals the radiologists have exclusive contracts to provide imaging services, other practitioners including vascular surgeons and cardiologists are moving into radiology territory even as the radiologists themselves are no longer merely diagnostically imaging but are more and more engaged in interventional treatment.

The Joint Commission has always required that there be uniform quality of care within the hospital. The current version of this directive reads as follows:

> The mechanisms provide for professional criteria that are specified in the medical staff bylaws and uniformly applied to all applicants for medical staff membership, medical staff members or applicants for delineated privileges. These criteria constitute the basis for granting initial or continuing medical staff membership and for granting initial, renewed, or revised clinical privileges.[1]

It is combined with recognition that clinicians do cross borders:

> There is a satisfactory method to coordinate appraisal for granting or renewal or revision of clinical privileges when an individual currently holding clinical privileges or applying for clinical privileges request privileges that are relevant to the care provided in more than one department or clinical specialty area."[2]

Among the difficulties here which relate directly to quality of care is that training has been the traditional threshold benchmark for granting privileges. As new procedures become available, the extent of the training

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[1]MS 5.4.

[2]MS 5.15.5.1.

required to be permitted clinical privileges for that service is a major decision within the medical staff. Yet different specialties, by definition, are trained differently in a manner which reflects their specific discipline; so to require board certification by one specialty over another as a measure of training adequacy precludes privileges to some who would claim to be adept. Moreover, the recommendation for the criteria for clinical privileges comes from the department itself and reflects its specialty's prejudices.

Many medical staffs confront this issue by including a bylaws provision which establishes that in cases of privilege criteria conflict, the resolution and in some instances even the final determination as to criteria for privileges is to be made by the Medical Executive Committee. Of course, depending on the size and composition of that committee additional controversies may arise. Still, in a number of settings even this approach does not go far enough.

Sometimes the board and administration would like to see the consolidation of certain services, thereby implicating the roles of disparate clinicians. Cancer centers, vascular centers of excellence, and women's health initiatives are examples of these strategies. Although depending on the constellation of physicians who provide the relevant services and the extent to which there are cross-referrals among them the Stark statute may be relevant, there are usually some other economic considerations at hand.

I have worked on multiple situations in the last few years where the approach to these dilemmas has been to have some physicians (*e.g.,* vascular surgeons) actually leave their (general surgery) practices to join an otherwise competing practice group (the radiologists). Not surprisingly, the mediation of the criteria for privileges becomes much easier once that has happened. Of course, the criteria issue has to be confronted before the merger takes place. I have had other situations where the solution is to use clinical practice guidelines agreed upon by the multidisciplinary clinicians as the

basis for treatment in the hospital. This deflects the focus from training to a focus on performance over time. Again, when this occurs, the privileging challenges are more easily met by using proctoring and performance assessment for the physicians newly rendering the subject services. In the last analysis though, sometimes these disputes cannot be resolved and the less powerful, aggrieved practitioners continue to grumble and be disruptive or begin to search for different practice venues. Neither of these results generally benefits the hospital, although when the complainers leave it can ease tension in the medical staff and sometimes ends up being the right result.

§ 4:19 —Non-physician practitioners

Another similar dilemma arises where some clinicians see a real value in the use of non-physician practitioners—most often nurse practitioners ("NPs"), physicians' assistants ("PAs"), nurse midwives, and certified registered nurse anesthetist ("CRNAs")—as functioning either as physician extenders or now more often as physician substitutes. Increasingly physician groups employ these individuals and seek to have them able to perform within the hospital, subject to medical staff privileging. Sometimes these non-physician practitioners ("NPPs") can be recognized for more independent practice under state law; and sometimes they are employed by the hospital itself. Hospital employment raises the question as to whether the medical staff wants to evaluate the clinical competence of these clinicians or to permit hospital job descriptions and employment contracts to determine their role in the hospital.

Other physicians see these individuals as real economic threats and do not want to permit them in the institution. For many years, on a good number of medical staffs these individuals were neither credentialed nor privileged. On the other hand, during that era, even lower levels of personnel ancillary to physicians—often

referred to as "medical assistants"—worked in the physician office, were not required to be licensed but still were given some limited level of permission by the medical staff, completely derivative of their employer physician's clinical privileges, to perform defined tasks within the institution to benefit those physicians who sought to use them.

Confronting how to deal with NPPs has now become a new hot spot for medical staffs because of these clinicians' increasing clinical sophistication and regulated independence. Moreover, their recent recognition by Medicare in a way that makes them far more useful to physicians to gain time, increase revenues and increase the physicians' clinical efficiency while enhancing their patients' satisfaction (since these individuals usually have more time to spend with the patients) will heighten this focus. Medicare now permits these clinicians to perform any service they are licensed to do for which Medicare would pay a physician, and they are reimbursed at 85% of the Medicare physician fee schedule.[1] Of potentially even greater significance, though, is the Medicare rule that if an NPP goes to the hospital, rounds on the patient and performs parts of the visit, and the physician then goes to the hospital and has an encounter with the patient (does not merely read the chart), then the combined service may be billed by the physician at 100% of the fee schedule.[2] As a result the pressure to confront the NPP issues will likely increase. Moreover, these clinicians are motivated themselves to seek larger roles, and their lobbying

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[1]NPs, PAs and CNSs are reimbursed at 85% of the fee schedule. *See Medicare Carriers Manual* (HIM 14-3) (MCM) 16001C, 16002C. CRNAs and nurse midwives are reimbursed differently by Medicare.

[2]Transmittal 1776, Oct. 25, 2002, amending MCM § 15501B.

organizations advise them on how to do so in the medical staff bylaws.[3]

More and more, medical staffs will have to determine the extent to which they want responsibility for surveilling the quality of the hospital's employed NPPs, the scope of the privileges any NPPs should exercise, and the extent of the process which will be made available in curtailing privileges and disciplining these individuals, since medical staff activities in this regard are not protected under HCQIA.

§ 4:20 —EMTALA[1] on-call responsibilities

Here, another point of tension turns on the emergency department ("ED") as a potential source of both business and liability—both professional and economic—to the physicians who serve on the on call schedule. Whether on call responsibilities are a boon or a burden, can vary significantly by specialty and tenure of the physician. For example, young orthopedic surgeons establishing themselves in a community eagerly desire the opportunity to be on the rotational schedule so they can capture unassigned patients. Depending on the community, though, many physicians view their EMTALA obligations as problematic since many of the patients are uninsured or Medicaid insured and by virtue of their treatment in the ED become patients of the on call clinician who may not want them in his private practice. The advent of and expanded roles of hospitalists as consultants to the emergency physicians and therefore in control of subsequent referrals also increasingly creates tension.

The first medical staff challenge is deciding who makes the judgment as to who is on the on call sched-

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[3]*See* "Guidelines for Amending Hospital Staff Bylaws," American Academy of Physician Assistants, http://www.aapa.org/policy/hospital-staff-bylaws.html.

[Section 4:20]

[1]42 U.S.C.A. §§ 1395dd et seq.

ule—is there a uniform standard for the medical staff as a condition of membership or is this determined at the departmental level, since the clinical implications of emergency services among specialties—dermatology patients versus cardiac patients, for example—are so distinct? Are the qualifications for being on the on call rotational schedule restrictive (*e.g.*, "no one can be on the on-call rotational schedule unless they have three years experience here and the fullest scope of delineated privileges this hospital offers in cardiology") or are they relatively light ("if you are licensed and on staff you may serve") or mandatory ("if you have Active membership you must serve")?

The EMTALA statute itself imposes on the hospital the responsibility to provide appropriate screening and treatment and not transfer for financial reasons.[2] This obligation does not belong to physicians or the medical staff. Once a physician is on the on call schedule, though, failure to respond appropriately will create personal liability for a $50,000 civil money penalty. In many hospitals, physicians chafe at the necessity to fulfill an obligation to meet these requirements imposed on the hospital. Hospitals are pushing for medical staff responses to EMTALA, which alter long standing policies. Physicians are angry. The hospital's "all or nothing" EMTALA demands and the physicians' ongoing obligations to treat patients whom they have encountered in the ED troubles them. Other problems can arise because of disparate policies among hospitals in a single community. Where there are relatively few specialists of a specific discipline available to meet patients' needs or one facility does not mandate that ENT physicians participate in the on call rotation, for example, patients end up being disproportionately transferred to the facility where the ENT physicians are obligated to be on call. Where specialists have priv-

[2]For a broader discussion of EMTALA generally *see* Boubelik, "The Expanding Reach of EMTALA: Analysis and Practical Tips" *Health Law Handbook*, Ch. 3 (A. Gosfield, ed. 2003).

ileges at multiple institutions, the on call obligations alone can preclude their ability to be on staff elswhere. The obverse is also true where a medical staff uses the requirements of on call coverage proactively to foreclose privileges to competitors.

Where some physicians do not want to be on the on call schedule the burdens may fall disproportionately on others on the staff. The resentments that arise in these settings invariably land at the feet of the Medical Executive Committee which must either step in or, if they choose not to, must recognize that the hospital board and administration will resolve the matter their own way. Hiring consultants directly is one way for a hospital to solve that problem. I have also seen instances in which the availability of employed hospitalists has been used by the hospital aggressively to punish clinicians who would seek the on call referrals of unassigned patients but whom the hospital sees as not sufficiently loyal to the institution to merit these referrals. The hospitalists are simply directed to refer to favored specialists. For the hospital to change the patterns for on call coverage to a quasi-exclusive contract approach by saying that where hospitalists are available they will perform the on call function and then refer raises the same issues as any other decision to close a department or make it exclusive.

These challenges arise in the context of a fairly traditional approach to medical staff/board and administration relationships. They are merely illustrative, although the strains they create within the medical staff and between the staff and board are significant. Their meaning in the quality debates varies considerably. In many hospitals, these types of issues will continue to erupt, exposing the inherent tensions in the divergent economic interests of the physicians as practitioners and the hospital as an institution. Today, though, the increasing policy concern for improved quality as the hospital's core mission compels us to reexamine the overall relationships which permit the hospital to fulfill its quality obligations through its reliance on the medi-

cal staff. The matters to which their attentions are addressed, the techniques of communication, and even more radically some very different ways of conducting privileging, fair hearings and motivating standardization of clinical care may spur the development of a true quality culture within those hospitals which decide to tackle in a new way this most essential relationship within their overall consideration of heightened quality demands.

§ 4:21 New considerations

The recent history of hospitals' relationships with physicians has been characterized as one of "integration." From the formation of physician-hospital organizations ("PHOs"), to purchasing medical staff practices into separate physician practice entities in which the hospital is a sole member, to gainsharing models, to non-purchase affiliation techniques to bond with key physicians,[1] the latter part of the twentieth century was characterized by attempts to bring more members of the medical staff directly under the control of the hospital. The frictions from this disparate treatment of some physicians by comparison with those who remained independent and how they have played out in medical staff politics have been alluded to above.[2] The economic viability of this approach has been disproven in most settings.[3] In fact, many hospitals which took these paths have now had to unwind them, resell practices back to physicians, confront the fraud and abuse challenges in both the initial purchase strategy and the

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[1]*See* McDowell and Crane, "Coping with Reality: Maintaining Control Through Restrictive Covenants, Letters of Intent, Rights of First Refusal and Other Contract Provisions," *Health Law Handbook*, 281-344 (A. Gosfield, ed. 1997).

[2]*See* § 4:5.

[3]The most spectacular failure was the collapse of the Allegheny Empire. *See* Burns et al., "The Fall of the House of AHERF," 19 *Health Affairs* 7 (2000).

unwind efforts,[4] recognize their PHOs have little business, and abandon gainsharing based on the Office of Inspector General's explicit denigration of the approach as violative of the law.[5]

The resulting new environment presents a different challenge—how to develop a collaborative process between the medical staff and the hospital which recognizes the longstanding bedrock value of physician professional expertise to be brought to bear in the interests of the hospital. Techniques which embrace the physician culture and all the physicians on the medical staff are likely to be far more productive than those which divide the medical staff into feuding camps with different economic value and significance to the institution. This is not to say that hospitals' employing physicians or otherwise engaging them is to be avoided. Rather, the role of the medical staff is quite distinct from the activities of employed or owned physicians and should be acknowledged as such. In that frame of reference, the following considerations reflect my prejudice for a collaborative, inclusive process for medical staffs.

§ 4:22 —The scope of the work

In considering the range of challenges confronted by

[4]McLeod Regional Medical Center recently agreed to pay $15,909,470 in settlement to the Department of Justice under false claims, antikickback and Stark allegations on account of submitting claims for services referred by physicians with whom the hospital had improper financial arrangements—"The government alleged that when McLeod purchased certain physician practices it agreed to pay doctors associated with those practices purchase prices and salaries that far exceeded the fair market value of the practices and services provided." Press Release, Department of Justice (Nov. 1, 2002), http://www.usdoj.gov/opa/pr/2002/November/02_civ_634.htm.

[5]For a discussion of the OIG's Alert and its implications for quality *see* Gosfield, "Making Quality Happen: In Search of Legal Weightlessness," *Health Law Handbook*, 609-78 (A. Gosfield, ed. 2002).

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the twenty-first century hospital, one can well posit a continuum of issues which implicate quality around which to determine appropriate roles for the medical staff. There are some matters which are imbued so obviously with clinical significance as to create an *imperative* for substantial, meaningful, directive physician involvement in their undertaking to safeguard fundamental quality. There are closely related matters which support the imperatives of clinical culture for which physician involvement would be *important* to sustain a strong clinical culture. Of lesser priority are other matters where the incorporation of physician perspectives might be *useful*; and then finally there are many matters on which physician input is hardly relevant.

While somewhat artificial as a logical construct, to contemplate where various issues fall on this continuum or spectrum of concerns, can offer guidance in forging new approaches. The discussion which follows is only one taxonomy of these issues. It is neither immutable nor prescriptive. Rather, specific hospitals will and should parse these issues differently. Every hospital will have its own continuum reflecting or driving its particular clinical culture. An ordering of priorities in a carefully crafted and explicitly articulated statement of the applicable continuum can be a very powerful first step in new relationships.

The traditional privileging, credentialing and corrective action processes fall within the imperatives for medical staff involvement. That case has already been made as the reason for a medical staff organization in the first place and will not be further elaborated here. Going further though, the operation of medical management programs—utilization review, disease management, demand management—are all activities which demand medical staff involvement to assure their clinical legitimacy and the maintenance of the clinical rationales supporting them. The adoption, processes, implementation and refinement of all of these programs and activities are matters on which medical staff input is vital. Increased standardization of care is a lynchpin

of the Leapfrog Group's efforts as well as the multitude of patient safety error prevention programs that characterize the new environment.[1] Standardization is also important to finding time for physicians to devote to their interactions with their patients.[2] In fact, standardization is fundamental to any performance measurement activity to assure that what is measured is consistently evaluated. For these and many other functions, increasingly clinical practice guidelines ("CPGs") are the basis upon which these activities rest. CPGs can be used just in performance measurement and assessment, but they also can serve to literally standardize the care itself through standing orders and the like, to inform the documentation of care, to determine the hospital's health manpower resource needs, to drive capital budgets and even to bargain for global payment rates. These applications will only be effective if the medical staff is not only involved in the CPG selection, but actively champions their implementation in these and other creative ways.

The potential uses of CPGs by facilities are myriad and relatively unexplored. The data drawn from an analysis of conformity with CPGs can drive operational quality improvement initiatives, profiling of physicians, negotiations with payers, as well as the design of administrative processes that make the hospital work more effectively. Because these guidelines, by definition, reflect the application of clinical science, they fall within the purview of the professional expertise of physicians. The critical role of physicians in the selec-

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[1]http://www.leapfroggroup.org.

[2]*See* Reinertsen, "It's About Time!: What CEOs and Boards Can Do For Doctors, Nurses, and Other Healthcare Professionals," 2 *Disease Management and Quality Improvement Report* (April 2002), http://www.reinertsengroup.com/leadarticle.pdf; and Gosfield, "Making Quality Happen: Confronting The External Challenges to Time and Healing Relationships," *Healthcare Leadership and Management Report* (Aug. 2002), http://www.gosfield.com/leadaug.PDF.

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tion, implementation, sweep of their scope, and analysis of data based upon their application cannot be overstated.

Important related activities within the hospital include issues pertaining to the infrastructure which supports the clinical culture. So critical as to verge on an imperative is the role of information systems in a quality driven hospital. No quality improvement activity can be undertaken without data upon which to choose a course of action. Consequently, the utility and functionality of the information systems which drive quality improvement will turn, in part, on the ability of the physicians at the hospital to understand the applications of these systems. Moreover, whether, how and when these systems are able to speak to each other, while technically beyond the realm of physicians, still would benefit from their views as to the proposed system's capacity to produce data which they will use. Their input is most valuable prior to the hospital spending large sums of money on systems acquisition. The single most common infrastructure failure I have seen in the last five years is the purchase by hospitals of expensive information systems whose utility can only be maximized if the physicians use them but the physicians can neither use them nor understand the reports they generate.

Another important challenge emerged as hospitals moved to "integrate" more with physicians and other hospitals into "systems." The common fantasy was that this would strengthen the hospital's bargaining position for improved payment rates. As a matter of fact, commentators today assert that in instances where there has been successful consolidation of hospitals with integration it has increased their power in relationship to managed care organizations and all payors.[3] Even as these systems have expanded to include physician pay-

[3]*See* "What's Behind The Rise: A Comprehensive Analysis of Health Care Costs" Blue Cross Blue Shield Association (Oct. 2002); http://bcbshealthissues.com/costpressconf/materials.vtml.

ments in their rates, though, they have often neglected to involve the physicians in the analysis of whether the payment rates at issue are adequate to support appropriate clinical care. While the costs incurred in providing services turn on financial analyses of resource consumption, determining the appropriate resources to bring to bear in the treatment of disease states rests on clinical premises. Consequently, while physicians ought not control payment negotiations, their judgments certainly are important to the validity of the critical financial assumptions. Patient safety efforts (a new spin on risk management) entail hospital capital expenditures as well as reengineering and reorganization. The Leapfrog demand for computerized physician order entry ("CPOE")[4] will require a shift in how hospitals orient their technologic relationship with the physicians' systems. However, CPOE will never work if the physicians are not bought in and supportive of its implementation. Successful risk management activities and patient safety activities within the hospital will turn on physician support for the appropriate clinical orientations. Consequently, the involvement of the physicians in these activities is more important than ever.

Three broad planning responsibilities within hospitals are essential to a quality driven culture. While none ought be primarily the responsibility of physicians, each has profound implications for medical staff activities: (1) Strategic planning is the process by which the hospital declares the business it is in and how it will engage in those activities—which services it will add or reduce, which related businesses to enter, which sources of new business to seek. Given the essential purpose of a hospital, strategic planning cannot be effective without the involvement of the medical staff who will have to share the hospital vision to make the plan real; (2) Hospital budgeting in terms of whether the resources allocated are appropriate to support the strate-

[4]http://www.leapfroggroup.org/consumer_intro2.htm.

gic goals and mission of the institution, obviously, relate directly to the capacity of the medical staff to provide high quality care. Again, although the medical staff ought not be the sole determinant of how budgets are allocated, and controversies always arise as to which department deserves more new capital expenditures than another, still, the typical exclusion of physicians from this process other than at a board meeting (or a meeting of a committee thereof) denies the hospital the full capacity to effectively coordinate its resources to fulfill its ultimate goals.

Of the three critical planning activities, manpower planning—whether the hospital has the right constellation of practitioners to accomplish the tasks it has set for itself—is most isolated from physician dialogue even though in a quality driven environment, it ought reflect patient needs. Manpower planning can benefit significantly from physician input with respect to the scientific predicates that determine the highest and best use of the relevant actors to meet the needs of the patient. Which functions are performed by which professional in a team setting merits physician consideration. Each of these critical planning activities draws first on the expertise of other stakeholders in the hospital. However, physicians are so fundamental to the hospital's business, that a hospital which would claim to have a clinical culture cannot do so with credibility without strong, vocal physician contributions.

Of a lesser priority but still relevant to a clinical culture are activities around which it is useful to involve physicians from time to time, but in more limited ways. Financial and administrative reporting on the hospital's operations as a whole is of interest to physicians and can provide the medical staff with a more complete understanding of their relationship to the overall enterprise. Sharing the relevant data with them can produce unexpected insights into its significance. Public relations and marketing activities which lay claim to professional expertise among the medical staff and high quality performance also benefit

from physician evaluation. Any public statements about physicians should be reviewed by them before publication.

Related to marketing is the use of and publication of customer satisfaction data and hospital generated report cards. Where the data is reported will implicate physicians. To improve performance will require physician support and involvement. Consequently, this is another arena in which it is useful to involve physicians although they certainly ought not be the sole determinants of what, where, and how to report.

Then there are operational issues for hospitals where physician involvement is not relevant. Broad human resources issues, materials management, overall marketing and public relations, hospital claims payment management, housekeeping, and the retail businesses (*e.g.,* gift shop, restaurants) are examples of such operational areas.

Missing from much of the dialogue involving how hospital boards and administration relate to the medical staff has been an explicitly articulated clear philosophy and vision with respect to these essential interrelationships. While "integration" strategies characterized post-failed Clinton health reform, the collaboration of the relevant stakeholders—recognizing that each has significant value to be brought to bear in the hospital's overall interest—will allow each of the contributors to the hospital's quality of care to perform at their highest and best use. Where these overarching principles and the techniques to implement them are directly tackled, a different context can be created, one with far better implications for advancing the quality agenda.

§ 4:23 —Principles of engagement

The fundamental need to involve physicians in specific hospital strategic challenges has been observed by multiple commentators confronting today's demands on hospitals. "It is simply not possible to achieve any

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measurable level of clinical integration for patients without a close relationship of physicians with an organized delivery system."[1] For the stakeholders to contribute to the hospital's quality undertakings at their highest and best use, the physicians' sphere of influence must be given meaning through structure and process. Both sides of the transaction must come to the table with the willingness to reorder their interactions.

Identifying effective techniques for staff, board and administration relationships and recognition of the simmering tensions throughout the country have characterized the hospital governance and management literature for the last few years.[2] Taking into account both their operating values and the sought after contributions the physicians may make, to truly activate a collaborative process, clear principles of engagement are necessary. I have derived the following principles from observing and assisting in both failed and successful collaborative efforts. There are certainly others which could be propounded or added to these. The point is that some explicit statement of overarching principles can go a long way to facilitating new initiatives.

A. To make the collaborative process credible, the physicians not only must be involved at the earliest stages of any initiative around which collaboration is sought, their involvement must be visible. Often I encounter situations in which the Chief Executive or

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[1]Shortell, Gillies, and Anderson, "The New World of Managed Care: Creating Organized Delivery Systems," *Health Affairs*, 53 (Winter 1994).

[2]*See, for example,* Ashmos et al. "Organizational Responses to Complexity: The Effect on Organizational Performance," *Healthcare Executive*, 20-25 (July/Aug. 2001); Ashmos et al., "Physicians and Decisions: A Simple Rule for Increasing Connections in Hospitals," *Health Care Management Review*, 109-15 (Winter 2000); Hoff, "The Physician as Worker: What It Means and Why Now?," *Health Care Management Review*, 53-70 (Fall 2001); Purtell, "Medical Staff in Need of Change," *The Physician Executive*, 64-67 (Jan./Feb. 2002); Rice, "Developing a Partnering Culture," *Healthcare Executive*, 6-10 (May/June 2002).

the Vice President for Medical Affairs will have had side-bar conversations with perceived medical staff leaders without making it known that these communications are occurring, nor that they have meaning for the formal communication process. Although informal interaction is certainly expected in a well functioning hospital environment, the physicians' faith in the legitimacy of the process will turn, in part, on the formalized visibility of the interactions.

B. Where those external to the medical staff seek physician involvement, it is critical that they identify the real leaders within the physician culture. Although there are many facets to physician leadership, in the physician culture the leaders are, generally speaking, physicians who continue to practice in the trenches, enjoy peer respect for their clinical care, and demonstrate integrity as perceived by the physicians whom they would lead. They avoid personal or specialty specific goals and agendas and function as good communicators and conduits of information in both directions—to their constituency and from their constituency to those with whom they are collaborating. Good physician leaders have a willingness to learn and also to teach their roles as leaders to the next generation.

In the best circumstances, the real leaders are the elected leaders of the medical staff and their acknowledgement by the physicians is mirrored in respect from the hospital leadership at the board and administration. Unfortunately, the real physician leaders are not always the individuals who bear the organizational title that would seem to give them that mantle. Sometimes the process develops best when it does not rely exclusively on participation by titled representatives. In addition, to permit the collaboration to unfold smoothly, the non-physicians must recognize the physicians' need for a collegial, group platform from which to obtain legitimacy for the positions they would represent.

C. The one question that is asked of me more than

any other in projects involving the principles set forth in this article is how to develop trust between the collaborating stakeholders, particularly when trust has been lost. This question is posed by hospital administrators, board members and physicians. My answer does not vary by inquirer. Trust is developed based on the respective parties doing what they say and saying what they do consistently over time. Trust is earned; it is neither merely claimed, nor purchased.

D. In order to develop trust, and for collaboration to proceed as an ongoing proposition, there must be open, frequent and candid communication between the parties. This means not only the sharing of raw data, but the sharing of difficult and negative information from all sides. But, if the processes are to be so revealing as to allow a real understanding of the challenges confronting the hospital, there must be a commensurate sensitivity on the part of the physician participants with respect to the privacy such disclosure merits. This is not a matter of a punitive or restrictive approach to medical staff membership or leadership. It is about how if the physicians seek to be at the table for the critical decisions which will order their world, they must recognize the vulnerability this creates for the hospital as an economic actor in a turbulent health care environment.

E. By the same token, to earn trust and credibility in collaboration on the very sensitive and significant matters at issue as imperative and important spheres of attention, everyone must be willing to be held accountable for their participation. This means accountability both within the collaborative process as well as accountability to their constituency. Those who seek to participate in collaborative exercises should expect to be held accountable for consistent, ongoing participation in the process. The matters at hand here are so significant that a commitment to engage this way must take precedence over other obligations. Physician unwillingness or inability to maintain a schedule of meetings and attend consistently thwarts

the trust they desire to engender in their collaborators. Non-physician failures in this regard send a message that the administrators do not take the process seriously.

F. The medical staff itself must learn to trust their leaders, accept the decisions the process produces and permit the process to work.

G. Both the staff membership and the medical staff leaders participating in collaboration must be willing to accept the inevitability of change and the dynamism of these processes. Decisions made today may have to be revisited in eighteen months. This is not a matter of perfidy, or incompetence, but reflects a fast changing environment.

H. Similarly, physicians engaged in these kinds of initiatives will have to learn to practice respect for diversity of opinions and multidisciplinary values. Acceptance of the will of the collaborative process is also important to avoid protracted, unnecessary and repetitive power struggles.

I. Finally, to secure a platform for action, the players should engage in the formal exercise of documenting what the process and vision of the collaborative relationship will be. Whether in bylaws or otherwise, a document which memorializes the intentions of the parties can be significant both to clarifying the initial understandings as well as to assuring a common view by the participants. A documented process mitigates conflicts over the respective roles of the stakeholders, even as it speaks to other internal constituencies within the hospital. While this article is about the significant role of the medical staff to the hospital with respect to quality, their responsibility within the institution and the centrality of their role will drive consequences for other stakeholders too, professional and not. The documentation of the process makes real the visibility of engagement of the parties and gives them both a touchstone to be revisited with respect to the commitments they make to each other. In addition, a document of this type can be used to speak to

external stakeholders who care about the hospital's clinical culture.

§ 4:24 —New approaches to traditional issues

As we have seen, many of the skirmishes and disputes that trouble medical staffs today have implications for quality but also turn on the economic interests of the parties involved. Some, like the loyalty oath, economic credentialing, and investment disclosure policies not only do not reflect quality mandates, they may affirmatively undermine quality. There is no question that these conflicts threaten the fabric of the medical staff-hospital relationship. Cross-department privileging and the roles of non-physician practitioners have greater direct import for quality and raise interesting possibilities to rethink essential approaches to privileging and other functions—even where teams of practitioners are not at issue. The following are some new ways to approach traditional medical staff functions with the goal of improving quality of care, and physician quality of professional life.

§ 4:25 — —Privileging on guidelines

Among the challenges for medical staffs is how to determine what privileges should be delineated and then who should exercise them. Although this judgment is made throughout the country, given what we now understand about quality, there is an argument to be made that the process functions poorly. The theory of delineating clinical privileges is that physicians vary in their abilities to perform different services. To enumerate explicitly those services for which a physician's competence has been established enhances the quality of care and protects patients. Typically, when privileges are granted to a clinician by a medical staff, there is the baseline credentialing function of making sure the individual practitioner has the right tickets to get in line—as licensed, certified, and trained. All of that is verified. Then there is the issue of actual competence to

perform requested, delineated procedures. Here is where the system falls short in many ways.

References will be sought. Whether they provide meaningful information is questionable.[1] If there are egregious competence problems that might be discerned, but despite a desire to know whether any clinician is truly competent, the capacity of the medical staff to make such a judgment on paper is relatively limited. Often the department chair simply approves what is requested. In other settings, those granted privileges initially are proctored and evaluated in practical terms. However, even where proctors are performing their functions, what they are to review and how is rarely specified. With multiple physicians within a department sharing these responsibilities, there can be interrater reliability issues which are never addressed by the staff because no one has specified what is to be evaluated in accordance with any consistent standard.

The use of CPGs to define what is to be evaluated might well be more effective and focused than the hit or miss proctoring process which depends on the haphazard presentation of patients needing services which entail requested privileges, judged idiosyncratically by the proctor who volunteers or has volunteered for that job. Although a CPG will not speak to whether a physician has golden or even adequate hands, it does speak to the cognitive decisions in play in providing care. In addition, using a common CPG across departments can resolve cross-department privileging controversies.

Well organized medical group practices with real focus in terms of the types of patients seen, conditions treated, and services rendered, could simply step forward and state what they will do as documented in a well elaborated CPG. The medical staff could choose to evaluate that practice assigning privileges to reflect the proposed treatment algorithm. In more aggressive settings, hospitals might adopt such an approach through

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[1]*See* discussion at § 4:8.

the collaborative processes just discussed so that there is standardization and consistency in clinical practice within the institution. This would make the entire accountability of the privileging mechanism more reflective of specific tenets of quality, more standardized and more focused in terms of what the proctors are to consider.

Another aspect of this privileging on guidelines could address the use of non-physician practitioners. As noted above, we now know that team treatment of patients enhances quality outcomes. In addition, given the profound challenges that physicians face with respect to the administrative burdens upon them[2] any technique which can save the physicians time for their highest and best use in their healing relationships with their patients is an improvement. Increased non-physician involvement in delivering care will salvage physician time. In the privileging function, teams of practitioners could be evaluated to treat patients in accordance with a CPG. Whether the non-physicians are employed within the physician practice or employed by the hospital, conceiving of privileging in a team frame of reference would represent a more quality grounded focus.

For example, if a specific group practice employing multiple physicians and ancillary personnel were to seek to be recognized by the medical staff to treat their patients in accordance with a specific CPG, as long as the baseline credentialing functions have been performed, it might be possible to leave to the specific proposing group the determination of who would perform which function on which day. Could this streamline the privileging process and make it more quality driven? Could this not also create more unifor-

[2]*See* Gosfield, "Making Quality Happen: In Search of Legal Weightlessness," *Health Law Handbook*, 609-78 (A. Gosfield, ed. 2002); and Gosfield, "Legal Mandates for Physician Quality: Beyond Risk Management," *Health Law Handbook*, 285-322 (A. Gosfield, ed. 2001).

mity in the actual delivery of care? Even where physicians do not employ NPPs but use those employed by the hospital, consistent views of what the relevant clinicians bring to bear in serving the science applicable to the patient's condition can not help but improve not only actual quality of care but also post-hoc judgments about performance. Privileging would then be consistent with an overall approach to standardized care throughout the hospital enterprise.

§ 4:26 ——Farming out corrective action and FHP

As discussed above, the role of the medical staff in disciplining its own is a crucial piece of the quality puzzle. The processes by which this happens, though, are enormously time consuming, fraught with evidentiary peril, and unpleasant for the participants who may be subjected to persuasive lobbying if not outright coercion in fulfilling this medical staff role. Medical staffs have always clung tenaciously to the notion that these processes must be controlled by them to maintain the legitimacy of both the technical judgments made and the procedures to arrive at them.

This belief may no longer be worth the tenacity with which it has long been asserted. Given the enormous demands at hand, and the real positive potential which exists in a more standardized, more quality driven, procedurally fair hospital setting, why shouldn't the marshalling of the evidence, the making of the case and even the fair hearing itself not be contracted out to a peer review body, accountable to the medical staff in terms of the standards applied and the report made?

If the medical staff adopted standards, guidelines or protocols to be used to judge its members, and the apparent failure of one of them to conform raised questions, why not let an external group of qualified peers marshal the evidence regarding the clinician, hear his (and his attorneys') arguments, and then make a finding as to the extent of deviation from the standards?

The medical staff would receive the report and make its own judgment regarding the appropriate response to the data adduced, thereby fulfilling the values of its own culture. In this way, all the legal requirements would be met, the medical staff values sustained, but the worst of the internal medical staff processes would no longer distract the staff leadership over long periods of time from more positive roles and activities.

§ 4:27 ——Helping the physicians help themselves

As the physician members of the medical staff conduct their clinical activities providing services in the hospital for which they will bill and be paid directly by the applicable payers, they define major portions of the quality provided by the hospital. In their roles as medical staff members their actions can create hospital fraud and abuse liability sounding in quality. For example, providing information that can lead to a premature discharge,[1] and providing services that do not meet professionally recognized standards of care,[2] are quality relevant behaviors for which a hospital can be excluded from Medicare or be assessed civil money penalties along with the physician. In addition, the Office of the Inspector General has identified a range of quality issues in the Work Plan for 2003, including hospital quality oversight, certification of heart transplant centers, medical necessity of emergency department diagnostic testing, and medical necessity of allergen testing.

Physicians as economics actors in their own right are also subject to a raft of fraud and abuse penalties which relate to quality, and more which do not, particularly those for false claims liability. I have contended in other

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[1]42 U.S.C.A. § 1320a-7a(a)(3).

[2]42 U.S.C.A. § 1320a-7b(6)(B).

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publications[3] that the effect of these laws on physicians has impeded their ability to be fully engaged in the quality agenda. I have also posited that using CPGs as the foundation for much of what they do can save time for physicians which can then be redirected to their highest and best use—to bring to bear the best science available in truly healing relationships with their patients. To launch such initiatives, I have argued would significantly advance the application of science and standardization of care, and could be used to make their payment systems more clinically relevant. The broader the application of CPGs, the more it would simplify the physicians' environment, and as a result, they would be more willing to be held accountable for their performance.

While these observations have been made in discussions as to why physicians would want to be engaged in a quality agenda, the implications for hospitals to support such undertakings would be very much in their own interests. It is therefore, quite astonishing to find that in the final Stark regulations, there is the recognition of the appropriate role of the hospital in assisting its own physicians with respect to compliance. The hospital is explicitly authorized to provide "compliance training" which means:

> [T]raining regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, reporting) or specific training regarding the requirements of Federal health care programs (for example,

[3]*See* Gosfield, "Making Quality Happen: In Search of Legal Weightlessness," *Health Law Handbook*, at 609-78 (A. Gosfield, ed. 2002 ed.); Gosfield, "Legal Mandates for Quality: Beyond Risk Management," *Health Law Handbook*, at 285-322 (A. Gosfield, ed. 2002 ed.); and Gosfield, "Making Quality Happen: Confronting the External Challenges to Time and Healing Relationships," *Healthcare Leadership and Management Report* (Aug. 2002) (http://www.gosfield.com/leadaug.pdf).

billing, coding, reasonable and necessary services, documentation, unlawful referral arrangements).[4]

Relating these issues to quality is not difficult. The compliance issues that physicians face are in many ways mediated by the use of CPGs which can streamline documentation, substantiate medical necessity, manage malpractice risk and protect against overuse, underuse and misuse.

Under this regulation, the hospital can pay for and provide training to assist physicians in understanding their compliance responsibilities. To the extent that compliance can be linked with the medical staff's quality mission so its functions reflect systematized consistency throughout the enterprise, the hospital would benefit in many ways while assisting its physicians in their own practices.

§ 4:28 Conclusion

This consideration of the role of the hospital medical staff in an emerging, newly defined, quality driven world was intended to answer the question as to whether the basic concept of an organized medical staff has continuing vitality. Based on: (1) the unique and fundamental functions physicians perform and the values they manifest in doing so; (2) the legal mandates that they assist the hospital board in its fulfillment of its fiduciary responsibility for quality of care; and (3) the substantial concern for improving quality in the current policy debates, there is no question that the medical staff is the key significant other to the hospital. The physicians' aggregation into an organized medical staff systematizes their role so it can be effectively utilized by the hospital, orders their interactions in a meaningful way, and fulfills their need for collegiality. That said, we have also seen that there are many traditional aspects of what goes on in medical staffs which merit new scrutiny in light of the new

[4]42 C.F.R. § 411.357(o), 66 Fed. Reg. 962 (Jan. 4, 2001).

environment. A more expansive view of medical staff-hospital collaboration could significantly advance the hospital's fundamental quality mission, while it would diminish the territorial power struggles between the staff and the hospital which impede real efforts to improve the quality of care.

I have considered here not only a broader organizational approach to collaboration, but also some discrete problem areas that could benefit from more radical treatment. There likely are still other creative ways to address what medical staffs do which could streamline their activities through a crisper focus, give them back more time to devote to better uses and also diminish still further parochial power struggles within the staff in favor of more significant quality initiatives. For example, the organization of medical staffs into departments, while relevant to teaching programs for those hospitals so engaged, in many ways seems an anachronistic reflection of the academic fiefdoms that characterize physician training. As we move more toward multidisciplinary, "highest and best use," team based, disease state management of care, medical staff and even hospital departments may become more and more obsolete.

The real economic skirmishes which underlie but far too often dominate medical staff behavior, may, in turn, be better mediated by moving from a less structurally focused approach to medical staff organization to a far more content and process driven design. Instead of concentrating on structure—*e.g.*, what committees shall we name? which representatives should sit on them? who should vote?—I am increasingly convinced that it is time to engage in a deconstructionist assessment of medical staff activities, to reorder them with a clear guiding purpose that reflects something more than lip service to "we're the quality guardians of the hospital." It is time to go back to the most basic aspects of the potential contributions of the medical staff to reconsider how hospitals and physicians would ideally interact and toward what specific ends. Assume that all tradi-

tional functions are up for grabs, articulate the overarching operating principles of the hospital in clinical terms and then articulate how such clinical principles could drive a systematic reorientation of how the hospital and medical staff can relate to each other.

Looking at the same technique from a different perspective, through such an explicit process (which is not about the strategic vision but rather the operational reality of the institution), the value of the individual components of medical staff activities can be evaluated and redesigned in a way that can give more substance to the role of the medical staff in the institution. The result will also help the medical staff help itself. Such a focused, institution-specific reevaluation cannot help but revitalize the medical staff organization itself. Abundant clarity about the hospital's specific clinical goals and the mechanisms by which they will be achieved, combined with simple principles of engagement, will speak to physicians in new, meaningful and powerful ways. Their resulting reengagement may yield a far stronger partnership between the collaborators.

The glory of health care today is that we are learning more and more about the clinical validity of what ought be done. Evidence based medicine, more systematic techniques of improvement, and enterprise-wide multidisciplinary initiatives are hallmarks of a very new hospital world. While physicians are often threatened by the implications of these developments, I would argue that greater standardization, more applied science on the ground and reengineered systems to make it easier to do this in optimal ways, are what physicians ought to and actually do want for themselves quite apart from their functions in the medical staff. To the extent they can contribute to these changes through their activities in the medical staff, they will not only improve the hospital's quality of care, but with the hospital's carefully crafted support, they will better fulfill their own desires in meeting their patients' needs.

The beginning of the twenty-first century has offered turbulent and difficult times for hospitals. Their

pathway to a successful future is by no means clear. The reason for their existence is, though. It is that most fundamental mission—to deliver ever improving clinical services to acutely ill patients and others in need, applying the best science at hand in compassionate and patient responsive ways -that can only be fulfilled with an engaged medical staff. It is time to refocus on this most essential relationship. All the rest is tactics.