IS IT SAFE?

ADDRESSING THE LEGAL LIABILITY CONCERNS OF PHYSICIAN LEADERS

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****** This white paper is meant to provide general guidance and information to medical staff leaders and is not intended as specific legal advice. It is important to note that there are many exceptions within the law, much law is based on local statutes, regulations, and common law, and the law is constantly in flux. This brief white paper cannot convey the issues discussed on its pages in full detail or completeness. In considering any activity that might have legal implications, it is always prudent to consult a knowledgeable attorney well versed in the complexities of local and national health law.***

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INTRODUCTION: IS LEGAL LIABILITY A MYTH?

One of the most chilling movie scenes in twentieth century cinema is an interaction between Laurence Olivier and Dustin Hoffman in the film, "Marathon Man." In a scene of searing intensity, Laurence Olivier threatens to drill the nerve endings in Dustin's teeth unless he answers his enigmatic question: "Is it safe?"

Years ago this question was clearly on the minds of medical staff leaders as was evidenced by the publication of a seminal article, "The Myth of Legal Liability," written in 1973 by Charles Jacobs, J.D. and Susan Wegley, J.D. This article outlined the broad public good to be achieved through well-performed peer review and made the case persuasively that should personal liability arise from peer review, the effect would be detrimental to patient care and the healthcare profession. The authors outlined the various protections available to physicians at the time, including a Federal Court pronouncement, state laws, and the protections documented in the bylaws of most medical staffs. The authors' argument that physician leaders were reasonably shielded from legal liability for peer review has largely stood the test of time. There have been very few instances in which physicians engaged in good-faith peer review have been called to answer for their findings in court and even fewer in which they have faced the possibility of paying monetary damages. Yet the perceived threat continues to be a topic of considerable discussion and debate. Unfortunately, some courts seem to be taking positions recently that suggest need for greater caution as we pursue medical staff work in the future. This is true despite the greater statutory protections now available than were in place when "The Myth of Legal Liability" was first written three decades ago.

"Is it safe?" Today this question echoes in the meeting rooms of medical executive committees, peer review bodies, credentialing committees, and anywhere physician leaders are asked to assume responsibilities outside of the clinical sphere and the perceived protection of their malpractice insurance. This should hardly be surprising in the enormously litigious world of healthcare delivery. However, the concern it represents poses a huge barrier to the engagement of physicians in important work on behalf of hospitals and other healthcare organizations. Some physician fears result from an incomplete understanding of the legal protections that shield them from liability. Most physician leaders receive little education about the statutes, regulations, waivers, immunities, privileges, and precedents that are designed to facilitate the important work they perform. Likewise, physicians are rarely provided an orientation to recommended practices in their work that can reduce the risk of liability when they undertake medical staff or other organizational responsibilities. It is no wonder then that many physicians have an overdeveloped sense of liability.

This white paper is intended to provide physician leaders with information that can assist them in their medical staff work without stepping on legal landmines; to make them more confident in carrying out their responsibilities; and to arm them with information so they can make knowledgeable decisions about the risks they are willing to undertake. Healthcare is an enormous industry rife with legal conflicts and litigation. This white paper has intentionally narrowed the focus of discussion to the legal dangers associated with medical staff work. However, much of the discussion will be appropriate to the activities of physician leaders in group practices, physician organizations, insurance companies, and other institutions in our healthcare delivery system.

OVERVIEW

Over the past three decades, health law has grown into one of the largest specialties in the legal community. It's no wonder, given the range of health-related issues over which individuals and organizations sue. Physicians are most familiar with the nature of malpractice litigation for alleged instances of clinical negligence. These lawsuits have become ubiquitous and greatly distorted the delivery of healthcare while undermining the morale of the practitioner community.

Most doctors, however, don't realize the degree to which corporate negligence lawsuits now accompany these traditional legal actions against clinicians. Corporate negligence suits are levied against hospitals and their medical staffs and typically allege inadequate credentialing, privileging, or quality monitoring (peer review) resulting in patient harm. The malpractice premiums of hospitals have been rising rapidly as a result, with the dollars diverted from other important institutional and community needs.

Legal risk resides in numerous other corners if activities don't conform to the hugely complex web of laws and regulations governing healthcare.

There are federal and state anti-fraud laws, including the notoriously opaque Stark regulations, anti-kickback statutes, and statutes aimed at certain types of physician–vendor relationships. In recent years both federal and state governments have devoted huge resources to combat fraudulent billing practices. Indeed, the FBI has expanded the number of its agents dedicated to health fraud exponentially in the past decade. Billions of dollars of taxpayer money has been recouped through these efforts.

There are the federal and state antitrust laws and other initiatives to prevent anti-competitive behavior in the two trillion dollar healthcare industry. As competition has heated up between physicians and their colleagues and between doctors and hospitals, it is no surprise that antitrust lawyers are kept busy.

Of course, there are the growing legal efforts to assure that hospital quality and safety practices are strengthened. Legal danger exists when physician leaders approve research protocols, undertake corrective action involving colleagues, struggle to help hospitals comply with the Emergency Medical Treatment and Active Labor Act (EMTALA), or recruit additional physicians to the community.

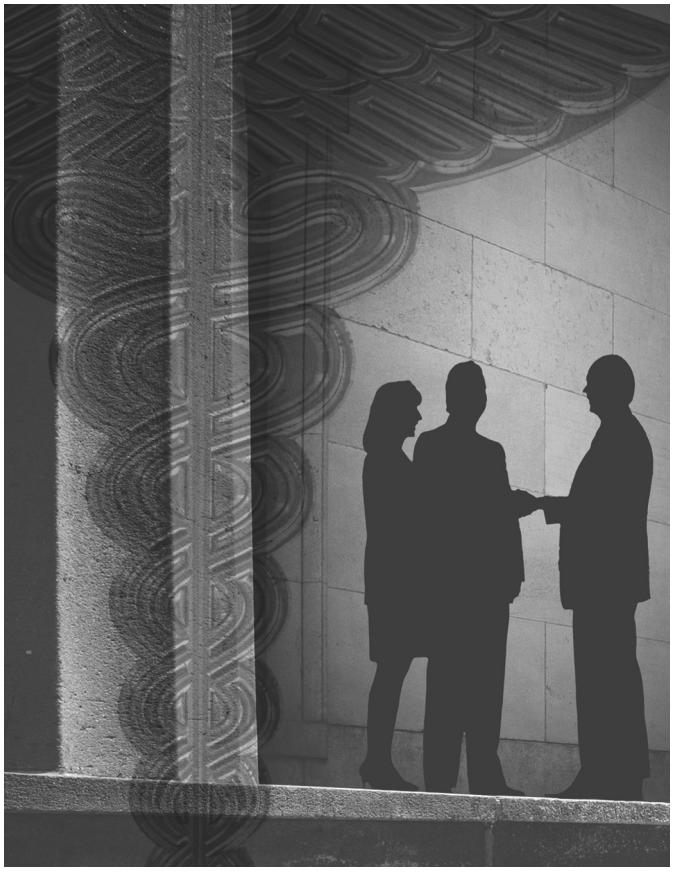
Heightened external scrutiny of hospital boards has raised concerns about conflicts of interest when physicians sit on the board.

There are the new laws aimed at protecting patient privacy, such as HIPAA (Health Insurance Portability and Accountability Act of 1996), which provide yet more fodder for lawsuits.

Indeed, this enumeration of areas of legal jeopardy for physicians and medical staffs could be extended several more paragraphs. However, the point has been made that the interaction between law and medicine is extensive in our modern society. Everyone in a leadership position today, including physicians, must familiarize themselves with a basic understanding of the greatest legal risks in their work and the best practices for avoiding them.

Examples of Legal Concerns in Healthcare

- Corporate negligence (often alleged for improper or inadequate credentialing, privileging, or peer review)
- Antitrust/anti-competitive behavior and/or conspiracy
- Anti-fraud laws (including anti-kickback statutes and the federal Stark laws)
- Due process concerns (especially those of physicians subject to peer review and corrective action)
- Privacy laws and the Health Insurance Portability and Accountability Act (HIPAA)
- Billing fraud (with increasing numbers of state and federal audits of government insurance programs)
- Rules relating to physician recruitment
- Physician–vendor relationships
- Emergency Medical Treatment and Active Labor Act (EMTALA)
- Private inurement (the improper diversion of monies from not-for-profit healthcare organizations to private individuals/entities)
- Compliance with state health regulations and accreditation standards
- Informed consent of patients
- Proper oversight of clinical research



WHO SUES?

Numerous parties bring lawsuits against hospitals and medical staffs for the work done by physician leaders. When clinical outcomes aren't what they hoped, patients and their families often hire attorneys. These suits usually begin as malpractice actions against the attending physician(s) who cared for the patient. Then the plaintiff's lawyer argues that the negligent attending should never have been allowed to practice on the medical staff in the first place. Clearly, he or she will argue, the credentialing process that led to the physician's grant of privileges must have been deficient. And in case this argument fails, for good measure the plaintiff's attorney will often throw in a claim of negligent peer review or negligent monitoring of the attending doctor. If such monitoring had been appropriately carried out, their argument goes, then the medical staff leaders would have detected the sub-standard performance of the attending physician and done something about it before the doctor harmed this patient who is now suing. We will discuss claims such as these later in this white paper, but they are the most common types of suits brought by patients against medical staffs and their leaders.

Increasingly we will see *patients* suing when they become victims of clinical "misadventures" that should not occur when good patient safety practices are in effect. As the public learns more about such practices they will be on the lookout for lapses that result in patient harm. It is likely, for example, that as more and more insurers and legislatures label certain outcomes "never events," lawsuits will inevitably follow in their wake. Since medical staffs play a major role in assuring the quality of care delivered by practitioners in the hospital, it will not be surprising to see physician leaders named in lawsuits when "never events" occur.

Lawsuits brought by patients against hospitals may be more common, but the plaintiff usually does not win them. Unless a medical staff has deviated significantly from common industry practices or regulatory requirements, it is likely to defeat these allegations of "corporate negligence" in the courtroom. An important element in a successful defense is a demonstration of compliance with the hospital or medical staff's own policies and procedures. Where physician leaders don't follow their own protocols they are much more likely to be found wanting by the courts and juries.

Who Brings Lawsuits?

- Patients and/or their families
- Physicians/medical staff members
- Other hospitals
- Federal Department of Justice/Office of the Inspector General (OIG)
- Centers for Medicare & Medicaid Services (CMS)
- State attorneys general
- Whistleblowers/*qui tam* relators
- Bondholders/shareholders in for-profit healthcare enterprises

Another group that sues medical staffs and their leaders are *disgruntled physicians.* Usually these doctors have been denied membership on the medical staff or not been granted some or all of the privileges they requested. Many have been the recipients of "corrective action" (i.e., a loss or restriction of membership or privileges as a result of peer review findings).

Particularly likely to sue are so-called "disruptive physicians" whose unprofessional conduct may have been the reason for an imposition of corrective action. To make matters worse, it often seems that disruptive physicians hire "disruptive" lawyers to represent them, making the ensuing legal proceedings particularly difficult and painful.

Physicians who sue the medical staff and/or its leaders typically make discrimination claims or believe they have been deprived of due process. They may assert antitrust conspiracy as the motivation for actions taken to discipline them or restrict their privileges. Physicians receiving bad peer review evaluations sometimes seek legal damages for defamation and slander, or they will claim tortious interference with their business and livelihood. When physicians bring these lawsuits they are particularly unsettling for medical staff leaders. Personal accusations are often leveled, the degree of acrimony high, and the damages requested can be very significant. On the relatively rare occasions when these lawsuits are lost, the plaintiff and plaintiff attorney can receive millions of dollars.

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Who else brings lawsuits against physician leaders? Don't overlook the *staff that supports physicians* in their offices or in the hospital. There are two types of claims most commonly arising from staff complaints. The first is the claim of sexual harassment, discrimination, or failure to correct a hostile workplace environment. Unprofessional physician conduct often leads to these suits. If it is clear that such conduct has gone on for some time without adequate intervention from leadership, the medical staff and hospital leaders may be accused of condoning the behavior through their passivity.

Staff members may also bring lawsuits through *qui tam* or whistleblower lawsuits. In *qui tam* suits, the government allows the staff member to bring a suit on the government's behalf under the federal False Claims Act. Congress passed this Act in 1863 as a response to widespread abuses by government contractors against the Union Army during the Civil War. The *qui tam* provisions are now used widely to fight healthcare fraud and have returned over 12 billion dollars to the U.S. Treasury since a legislative update was made to the Act in 1986. As an incentive to encourage workers in the healthcare marketplace to bring misdeeds to the attention of the authorities, private citizens who bring successful *qui tam* suits can receive between 15 and 30 percent of the total recovery from the defendant.

These suits gain traction when it is clear that leaders have been conveniently overlooking improper activities that can range from billing miscoding to inappropriate patterns of clinical care. In recent years the government has been very supportive of this type of lawsuit in its efforts to crack down on rampant healthcare fraud and abuse.

Of course, the *government* itself has lawyers prepared to bring suit where physician leaders fall down in their duties to assure safe, good quality care. For example, in 2002 the FBI raided Redding Hospital in California and the offices of a cardiologist and cardiac surgeon on the hospital staff. The United States brought legal action against the hospital after discovering that it was doing a brisk business in cardiac procedures that were not clinically indicated. The Office of the Inspector General (OIG) also asserted that the hospital failed to meet professionally recognized standards of care. The settlement with the government was for more than $50 million and the hospital owners were forced to relinquish the institution in 2003.

Another example is that of United Memorial Heath Center in Michigan, in which the Justice Department brought criminal charges against a number of the institution's leaders, including the chief of staff. (This case is described in the sidebar below.)

Finally, *other hospitals or healthcare organizations* may bring legal action against the medical staff and hospital. This is most likely where one institution fails to fully or accurately share information with another despite a legitimate request for that information. The most visible case of this nature was an action brought by Kadlec Hospital in Washington State (described in more detail later). It is likely that we will see more lawsuits such as this in the future since it is difficult for hospitals to responsibly screen candidates who wish to provide care when they can't get accurate information about their backgrounds.

CAN IMPROPER CONDUCT BY PHYSICIAN LEADERS LEAD TO CRIMINAL CHARGES?
Case Study of United Memorial Health Center

In the early 1990s, the 94-bed United Memorial Health Center in Greenville, Michigan was experiencing financial difficulties. To improve revenue from its surgical service line, it recruited a full-time anesthesiologist to its staff in 1993. Soon after joining the staff, Dr. Askanazi expanded his practice into pain management and within a year was primarily performing pain management procedures. When he came up for reappointment of his pain management privileges, Dr. Askanazi, who was then chair of anesthesiology, approved himself for expanded privileges in pain management. In 1994, the doctor's pain management procedures went from 24 per month in January to 230 per month by December. Nurses and some doctors on the staff complained that he appeared to be performing procedures too quickly and with poor results—even occasionally without sterilized technique. He performed the same procedures multiple times on the same patient. Apparently, he made no effort to conduct any type of examination to determine the advisability of the procedures he performed. Some complaints reached the medical staff peer review committee, but it did nothing to investigate.

With his business booming (and the hospital's bottom line improving), Dr. Askanazi sought additional business opportunities. He entered into business arrangements with two physicians on the medical staff, both members of the MEC (chief of staff and chair of the Emergency Department, respectively). Despite professional and financial conflicts of interest, neither of these doctors recused himself from discussions concerning Dr. Askanazi. The hospital CEO even resigned his position and took a job with Dr. Askanazi.

These concerns finally got the attention of the hospital board, which subsequently asked the medical staff quality committee to review the medical appropriateness of one of the pain management procedures done with great frequency by Dr. Askanazi. The quality committee initially failed to perform this review. The board apparently was loath to take further steps because, by this time, Dr. Askanazi's practice constituted approximately one-third of the hospital's income.

Eventually the quality committee arranged for an external peer review of Dr. Askanazi's procedures. The reviewer indicated he could not render an opinion because of the poor documentation in Dr. Askanazi's patient records. The quality committee then took eight months to decide to counsel Dr. Askanazi to keep better records.

In 1996, one of Dr. Askanazi's patients died. This patient had more than 22 pain management procedures administered by Dr. Askanazi in one year. She died from a puncture to her cervical spine. With this occurrence, the medical staff quality committee sent this case file and several others for external peer review (EPR). While the review was under way, Dr. Askanazi resigned voluntarily from the hospital staff. Three months later, the EPR report was issued and noted that the files it reviewed showed a "uniformly inadequate" evaluative process, no data or findings to support the diagnoses given, routine overuse of invasive techniques without clear indications, and procedures performed without evidence of efficacy or quality assurance.

The U.S. attorney investigated and found other examples of patients with adverse outcomes. Dr. Askanazi was subsequently convicted of thirty-three counts of mail fraud for falsely billing Medicare and other insurers for unnecessary pain management procedures and for anesthesia procedures he did not perform. He lost his license and was given a three-year jail term.

However, the U.S. attorney did not stop there. In 2001, federal prosecutors obtained indictments of the hospital and the two medical staff leaders who had been in business arrangements with Dr. Askanazi for conspiring with him to submit fraudulent billing claims. The crux of the government's argument was that in the face of the many complaints and the peer review findings regarding Dr. Askanazi, the hospital continued to bill and collect fees in connection with Dr. Askanazi's procedures. The two medical staff leaders were accused of intentionally blocking the peer review process to assure that the fraudulent billing continued.

A plea bargain was reached and the hospital paid a fine of more than $1 million and reimbursed Medicare for the improper billing charges. As part of the plea bargain, the federal criminal charges were dropped against the two medical staff leaders who so blatantly failed in their fiduciary responsibilities to protect patients at the hospital. Each apparently plead guilty to misdemeanor state charges of aiding and abetting larceny. They paid fines, performed community service, and participated in mandatory training in ethics, peer review, and the laws regarding fraud.

The former CEO of the hospital was charged with lying to a grand jury.

The important lesson from this case is that the federal government will seek out cases involving substandard care and prosecute them under the criminal fraud statutes. Medical staff leaders need to take their duties seriously and act responsibly to protect the welfare of patients. Department chairs should never approve their own privileges. Complaints to peer review bodies must be followed up and dealt with definitively, in a timely manner. Medical staff leaders who see something taking place that is improper must speak up and continue to speak up until there is an appropriate action taken. If necessary, they should bring their concerns directly to the hospital board. In the years ahead, financial times for hospitals and physicians may worsen. However, these will not be times for medical staff leaders to reduce the rigor of the important credentialing and peer review work they oversee.

WHY DO PLAINTIFFS SUE?

In the classic movie, "Dirty Harry," Clint Eastwood (playing Detective Harry Callahan) famously tells his adversary: "Go ahead, make my day!" What do those bringing actions against hospital medical staffs hope to achieve? The most common result of a successful action is monetary damages. Patients who bring corporate negligence lawsuits hope to reach into the deep pockets of hospitals. While the monetary results of a malpractice suit against a doctor may be capped by the limitations of his or her malpractice coverage, hospitals typically carry much more generous coverage or may be self-insured. On occasions where they win, plaintiffs can be awarded millions of dollars.

Similarly, physicians who sue for damage to their careers may garner very large monetary awards, including large sums for punitive damages. In the Poliner case (see sidebar on the next page), a jury awarded Dr. Poliner $366 million after he sued over the suspension of his cardiac catheterization privileges by a Texas hospital. This decision was eventually overturned, but it illustrates the magnitude these judgments can reach.

Although it is a quasi-legal action, we should list the "fair hearing" as a process that physicians can insist upon when the proper medical staff bylaws provisions are triggered. Fair hearings can be quite burdensome in time and money. Often acrimonious, they can run from days to years (the latter usually implies a poorly run process). Such hearings can be expensive and some have cost hospitals more than a million dollars to carry out.

Plaintiffs can also seek injunctive relief or some other equitable remedy. For example, a suspended physician may ask the court to reinstate her privileges or seek a temporary restraining order (TRO). A doctor who believes she has been subject to an antitrust conspiracy may get an exclusive contract nullified. A medical staff member who believes he has been mistreated in violation of the organization's bylaws may get a court to order that proper procedure be followed.

The government has a number of solutions at its disposal when it finds wrongdoing. It can levy fines and exact other economic penalties. It can exclude practitioners and hospitals from participation in government insurance programs such as Medicare. It can require providers to enter into Corporate Integrity Agreements (CIAs) in which the hospital or offending organization agrees to a set of future behaviors. Under a CIA, the institution agrees to report regularly on its adherence to the agreement and its compliance is monitored. In general these agreements are considered a major burden on an organization and its reputation.

The government can also bring criminal charges where particularly egregious behavior occurs. (See the case study on United Memorial Health Center, beginning on page 4.)

When financial impropriety occurs, the IRS may remove the tax-exempt status of a not-for-profit institution. In extreme cases the government can take away an institution's license and shut its doors.

As long as we are cataloguing the damage that legal actions can inflict on a hospital and medical staff, we should note the harm that can occur to the reputations of the institution and its doctors. In this day and age, there is little that occurs that doesn't reach the public's attention. When word of these lawsuits hits the news, the hospital is often at a disadvantage because the details underpinning the hospital's actions are often confidential. Under such circumstances it is difficult to publicly defend against the allegations being made by the plaintiffs.

Even when plaintiffs lose their cases, the defendants often have spent considerable amounts in legal fees defending themselves. In addition, individuals often have to give significant amounts of their time in the defense process with the attendant costs to the institution or persons involved. And regardless of the expense, defending against lawsuits is always a dispiriting process that undermines morale and confidence of those affected.

It should be clear that it is better to avoid legal landmines than to deal with the damage they inflict. Knowing where the dangers lie should allow thoughtful and careful physician leaders to avoid many of the legal pitfalls articulated above. The pages that follow provide some guidance regarding good prevention practices.

THE POLINER ODYSSEY:
The Story of a $366 Million Judgment for Improper Peer Review

Dr. Lawrence Poliner, an invasive cardiologist, was a staff member at Presbyterian Hospital of Dallas and, in 1997, had several cases awaiting peer review after the hospital's cath lab nurses reported them to medical staff committees. Poliner was a solo practitioner in a hospital dominated by several very large cardiology groups. In May 1998, Poliner was involved in another concerning case at the hospital, which was considered by the medical director of the cath lab to be potentially life threatening. He reported the incident to the chief of cardiology and chair of internal medicine. The latter, with the cath lab director and chair of cardiology present, asked Poliner to accept "abeyance" of all procedures until an *ad hoc* committee could review the cases. This request was not made on behalf of any medical staff committee and Poliner was told that if he did not accept it immediately his lab and echocardiography privileges would be summarily suspended. (The hospital bylaws required that a physician must agree to an abeyance. Poliner later asserted in court that he was forced to sign this document).

An *ad hoc* committee of six cardiologists was appointed by the chair of internal medicine and, after reviewing 44 of Poliner's cases, determined that the care was substandard in 29. The *ad hoc* committee reported to the peer review committee of the internal medicine department, which considered its findings and recommended additional reviews, including use of an outside reviewer. Poliner was given an opportunity to address the committee but with less than three days notice to prepare his rebuttal to the *ad hoc* committee report. After hearing from Poliner, the internal medicine advisory committee voted unanimously to recommend suspension of Dr. Poliner's privileges. He was then given an expedited hearing under the medical staff bylaws. The hearing committee of the medical staff heard evidence over portions of three days and recommended unanimously that Poliner's privileges be restored. It also concluded that the suspension of Poliner's privileges had been nevertheless justified under the circumstances existing when it was issued. The hospital medical board accepted the recommendation, but Poliner appealed to the hospital's committee on professional affairs. He believed that the summary suspension on his record would be harmful to his career and wanted it reversed. The committee hearing the appeal determined it had no authority to set aside his summary suspension.

Poliner filed a lawsuit against the hospital, the committee physicians, and the non-committee physicians (including the cath lab director and the chairs of cardiology and internal medicine). He alleged:

- A conspiracy in violation of the Sherman and Texas Antitrust Acts
- Breach of his contract due process rights under the medical staff bylaws
- Business disparagement, slander, and libel
- Tortious interference with business
- Intentional infliction of mental anguish and emotional distress

He also alleged that the Health Care Quality Improvement Act (HCQIA) and Texas Medical Practice Act were unconstitutional as enacted into law. He asked the court to deny immunity under these Acts because of actual malice evidenced by the hospital players against him.

The trial court found that all of the committee physicians involved in the case were entitled to be dismissed because of their immunity under HCQIA and the Texas Medical Practice Act. This was because there was evidence that these doctors had met the four criteria for immunity under HCQIA (see page 10) and there was no evidence of actual malice.

The non-committee physicians were not dismissed, the court ruling that it was for a jury to determine if they had acted reasonably and without actual malice in issuing the suspension. At trial, the jury decided that these doctors did ***not*** act in the reasonable belief that their action was in furtherance of quality healthcare; did ***not*** act after a reasonable effort to obtain the facts of the matter after procedures that were fair to Dr. Poliner under the circumstances; did ***not*** reasonably believe failure to immediately suspend would result in imminent danger to the health of any person; and acted with ***actual*** malice. Thus they were not immune from the judgment of $366 million they awarded.

In a pretrial hearing, a federal judge dismissed Poliner's antitrust claims. Poliner had privileges at several other hospitals and could not show that Presbyterian dominated the Dallas market, which might have made the suspension anti-competitive.

At trial, damages were awarded to Poliner because the court found that the due process rights in the hospital bylaws had not been properly afforded to Poliner. The hospital and non-peer review committee doctors were found liable for defamation and intentional infliction of emotional distress because the jury found actual malice in their actions.

In August 2004, Poliner was awarded a jury verdict of $366 million against Presbyterian Hospital and the three non-committee physicians. The stunning amount was a product of the punitive damages the jury believed were warranted. The chair of cardiology settled with Dr. Poliner. The judge ordered the remaining parties to mediate after the trial.

In 2006, a federal district court in Texas reviewed the trial court findings and determining its judgment excessive, modified the award to $22 million.

In July 2008, the 5th U.S. Circuit Court of Appeals reversed the Poliner jury award. The three-judge panel noted that HCQIA immunity from money damages afforded to participants in peer review requires only a "reasonable belief that the action was in the furtherance of quality healthcare." They determined that the hospital and physician defendants were entitled as a matter of law to immunity for issuing the abeyance to Poliner. The court also noted that "a failure to comply with hospital bylaws does not defeat a peer reviewer's right to HCQIA immunity from damages."

Lessons from the Poliner Case

The Poliner case was certainly an aberration in the case law—but one that sent shockwaves through the peer review community. What could have been done differently at Presbyterian Hospital to avert this horrendous detour through the courts?

The use of an "abeyance" is a problematic option. It is too easy, as it was for Poliner, to make this appear as a coerced suspension. If your bylaws incorporate this procedure, consider making a change. It is cleaner to have clear indications for suspensions and clear procedures for their imposition and subsequent adjudication.

Always consider external peer review early in any corrective action. Poliner felt that the other cardiology groups at Presbyterian were out to eliminate him as a competitor. The consolidation of cardiologists at the hospital into a limited number of groups made this appear plausible to a jury. By obtaining an objective outside review it would have been much easier to argue that the goal was to make the right decision to protect patients. Consider EPR whenever there is risk of litigation over actions resulting from peer review.

It is always good practice to have suspensions ordered by a peer review committee (ideally the MEC) rather than by an individual. Sometimes, if time is of the essence and a suspension needs to occur immediately, it must be done by an individual. In this case, consider having this person be a medical staff officer or VPMA/CMO—someone who is not in the same specialty as the offending doctor. Then have a committee ratify the decision as soon as possible.

Watch the language in your bylaws. The Presbyterian bylaws apparently had 'present danger' to patients as the criterion for suspension. At trial, defendants admitted they did not know if Poliner was a present danger at the time of the suspension because the investigation to determine this had not yet taken place. Consider bylaws language that allows suspensions when there is reason to suspect patients may be in danger, to protect patients from potential harm, or as a precaution.

Finally, consider moving peer review out of department silos. The best contemporary approaches to peer review use multidisciplinary medical staff committees that are not tied to specific departments or specialties. These committees access the appropriate subject matter expertise on the medical staff as needed.

PROTECTIONS FOR MEDICAL STAFF LEADERS

In "Dirty Harry," Detective Harry Callahan asks his opponent in a shoot-out, "…You've got to ask yourself one question: 'do I feel lucky?'" Well, as a medical staff leader, do you feel lucky? The answer may depend on how familiar you are with the various legal protections that exist for individuals carrying out medical staff work.

Despite the risks of legal action, physician leaders who carry out their work properly have little reason to worry. There are numerous layers of protection available to shield such leaders from the dangers of lawsuits. Familiarity with these protections can provide leaders a sense of security and confidence when they carry out the important work they undertake on behalf of patients, their colleagues, and their communities.

INDEMNIFICATION AND INSURANCE

Physicians who assume leadership positions in health organizations should request indemnification for the work they do on the organization's behalf. As described, the barriers that protect physician leaders from lawsuits are multiple and formidable. However, the risk of liability cannot be eliminated completely. For medical staff leaders, the hospital should agree to cover any legal expenses incurred by such leaders for work done in their medical staff roles. Such indemnification may include the costs of any legal defense, compensation for time lost from patient care, and coverage for any monetary damages or claims levied against the leader. Occasionally, medical staff bylaws will explicitly articulate the hospital's duty to provide such indemnification for medical staff members engaged in medical staff/hospital work. When this is not the case, a commitment to indemnify can be expressed through a letter from the CEO to new leaders (e.g., as part of their orientation) or to the medical executive committee (MEC). A statement from the CEO or board chair recorded in medical staff minutes, or a resolution to this effect adopted by the hospital board, may serve adequately.

Physicians should be aware that they could lose the benefit of hospital insurance or indemnification if they fail to carry out their duties consistent with their fiduciary responsibilities.

Most hospitals purchase some type of Directors & Officers insurance (typically referred to as D&O insurance) that covers the work done by the hospital leadership. When acting in medical staff and hospital leadership roles, physicians are considered to be agents and officers of the hospital. Nevertheless, it is prudent for medical staff leaders to inquire whether the hospital holds D&O insurance and whether its policy explicitly includes them as insured parties. Such policies often have limitations in their fine print and it is always wise to ask the hospital to state its commitment to indemnify physicians whether or not D&O insurance kicks in adequately in the face of a legal action.

Physicians should be aware that they could lose the benefit of hospital insurance or indemnification if they fail to carry out their duties consistent with their fiduciary responsibilities. Physicians acting in leadership roles must perform their duties in "good faith" and they owe a duty of "loyalty" to the institution that they expect to indemnify them. This means they must act reasonably to protect the interests of the hospital and must carry out the work they perform with proper due diligence. Failures in this regard may release the hospital and its insurers from a duty to cover a physician's legal fees in the event of a suit.

For example, physicians who fail to maintain proper confidentiality of peer-protected information may find a hospital refusing to indemnify them should a lawsuit result. Another example might be if a medical staff officer conspired with other physicians to destroy the practice of a competitor by inappropriately using the peer review process or inappropriately releasing damaging confidential peer review information.

WAIVERS, CONSENTS, RELEASES, AND IMMUNITY PROVISIONS

The use of consents and waivers is a common practice in medicine. Patients typically sign general consents to treatment when admitted to a hospital and more specific informed consent for designated diagnostic and therapeutic interventions. To be valid, consent must be given by an informed individual who has been given the information a reasonable person would expect when making a decision. Physicians are sometimes asked to give consent to make inquiries of third parties about their clinical performance, their abilities to serve as team members, or their health and ability to exercise specific privileges. Indeed, as a general rule, no information about a medical staff member should be released to any third party without the written consent of that individual.

Similarly, the use of waivers is a common practice. Virtually any privilege or claim can be expressly waived by the person for whose benefit it exists. In executing a waiver document, the party signing agrees to relinquish some legal privilege such as a right to privacy or a right to bring a lawsuit. It is common to find waivers in medical staff policies and procedures and in application forms for medical staff membership and privileges. For example, it is customary for applications for medical staff membership to include a waiver granting hospital staff permission to inquire about the applicant from third parties or to share peer review information when requested from an appropriate healthcare body. It is important that waivers be crafted carefully and cover both the hospital and all individuals who may be involved in credentialing and peer review activities.

Express waiver: The intentional or voluntary relinquishment of a known right.

Release: The relinquishment, concession, or giving up of a right, claim, or privilege, by the person in whom it exists or to whom it accrues, to the person against whom it might have been demanded or enforced.

(Definitions from Black's Law Dictionary, Fifth Edition.)

The concept of a release is closely related to that of a waiver. A release is the giving up of a right, claim, or privilege. It means that the individual authorizing the release will not hold the released party liable for any type of legal action that results from an action covered by the release. For example, if a medical staff applicant releases the hospital from liability for making inquiries about her background, she cannot later sue when it turns out making such inquiries put a current employer on notice of her intentions to move on. It is common for medical staff applications to contain general releases and waivers to cover the broad activities relevant to good credentialing practice. These clauses should indicate that they give immunity and release hospital and physician leaders from "any and all liability" relating to peer review and credentialing.

General releases do not always provide adequate assurance to a third party that it is safe to disclose confidential or sensitive information. In such cases, a release can be crafted to more specifically name that party and expressly release that party to share specific information.

Example of a Consent for Release of Information

I hereby request that _____ [the Facility] provide _____ [the inquiring Hospital] with all information relevant to my application for membership and/or clinical privileges at _____ [the inquiring Hospital]. This includes information relevant to my professional qualifications, credentials, clinical competence, character, ability to perform safely and competently, ethics, behavior, or any other matter reasonably having a bearing on my qualifications for initial and continued appointment to the medical staff. This authorization includes the rights to inspect or obtain any and all communications, reports, records, statements, documents, recommendations or disclosures of _____ [the Facility], the Facility's medical staff, their authorized representatives or appropriate third parties that may be relevant to such questions. In addition, I specifically authorize _____ [the Facility] to release the information to the Hospital, its medical staff, and their authorized representatives upon request.

I hereby release from liability and grant absolutely immunity to _____ [the Facility] and any physician on the Facility's medical staff who is or was involved in reviewing my practice and qualifications for membership and/or clinical privileges for providing information that will assist _____ [the inquiring Hospital] in making a decision regarding my appointment and/or request for clinical privileges.

_____ _____

Signature of Practitioner Date

Remember, it is always reasonable to put the burden on the applicant to provide information leaders require to fully vet appropriateness for medical staff membership and privileges.

The language in a specific release often reinforces the agreement of the physician signing it to waive any right to legal action or to explicitly agree to forgo any legal options against the third party. Specific releases may give "absolute immunity" in an effort to encourage the third party to release important information.

An example where a specific release is often helpful is when soliciting information regarding an applicant or staff member who you believe has engaged in unprofessional conduct elsewhere. Such "disruptive physicians" frequently threaten litigation against anyone suggesting they have a "problem." Third parties may not be willing to discuss their history with that physician unless he/she is willing to explicitly agree not to sue under any circumstances.

Why would a "disruptive physician" agree to sign a specific release? Because medical staff leaders should inform them that receipt of information from the third party is necessary to the further evaluation of her application at appointment or reappointment. Failure to sign the release and facilitate release of the critical information will result in a stop to the processing of her application. Remember, it is always reasonable to put the burden on the applicant to provide information leaders require to fully vet appropriateness for medical staff membership and privileges.

As a general rule, medical staff leaders should not use waivers, releases, and immunity provisions that limit their application to "good faith" activities or have some similar limitation articulated. These qualifications leave too much subjectivity in the process and not enough security to those engaged in medical staff work. Allegations of "bad faith" are easy to make and then everyone must travel down the path of litigation to resolve the difference of opinion.

Closely related to waivers and releases is the use of authorizations in which a physician or other individual expressly provides permission for a third party to undertake the authorized action. It is also common to see immunity provisions in medical staff bylaws; these provisions work in a fashion similar to waivers and releases. When an applicant for medical staff signs an agreement to abide by the bylaws, he is agreeing to the provision contained therein.

Some hospitals have gone beyond the traditional use of waivers and releases to provide additional obstacles to frivolous lawsuits. These come most commonly in the form of bylaws language that states if a practitioner brings a lawsuit, despite signing the waivers/releases in the medical staff application form, he will be liable for all the costs incurred by the hospital and its leaders if his case does not prevail.

STATUTORY AND REGULATORY PROTECTIONS

Federal Laws

In the 1970s healthcare was plagued by a "malpractice crisis" much as it is today. Hospitals and physicians were under pressure to do more rigorous peer review but they were loath to do so given the risk of lawsuits from disgruntled physicians. Of particular concern were certain judicial decisions at the time holding participants in the peer review process liable for antitrust violations. Under pressure to provide hospitals and medical staffs some protection from the rising tide of litigation, Congress passed the Health Care Quality Improvement Act (HCQIA) in 1986 (42 U.S.C.). This is a seminal piece of legislation and it is important for medical staff leaders to understand its scope and its limitations.[1]

HCQIA provides healthcare organizations and their peer review bodies immunity from monetary damages as a result of "adverse professional review actions" that relate to the competence or professional conduct of an affected physician or dentist. It is important to note that HCQIA does not prevent other types of legal action (e.g., injunctions or restraining orders) and it does not convey protection of peer review documents from discovery in legal proceedings. As will be discussed later, other statutes may provide such protections. HCQIA also created the National Practitioner Data Bank and established reporting requirements for hospitals that restrict or terminate the privileges of physicians.

HCQIA immunity applies to every jurisdiction in the United States and has proven to be a highly effective shield from litigation for those who undertake peer review responsibly. This immunity is given to "professional review bodies" when they undertake "professional review actions." HCQIA does set out several requirements that must be met in order for immunity to be granted. Specifically, peer review actions must be taken:

1. In the reasonable belief that the action was in the furtherance of quality healthcare;
2. After a reasonable effort to obtain the facts of the matter;
3. After adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances; and
4. In the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3). (42 U.S.C. § 11112(a))

A professional review action is presumed to have met these four standards unless the preponderance of evidence rebuts the presumption. As a result, the courts throw out most challenges to HCQIA immunity when defendant hospitals ask for summary judgment on the matter. (Summary judgment is a request by a party to throw out a lawsuit when he believes "there is no genuine issue of material fact and he is entitled to prevail as a matter of law."[2])

In the two decades since its enactment, HCQIA immunity has held up well when medical staff leaders act in good faith and when they adhere to the procedures outlined in their bylaws and peer review policies. Most medical staff bylaws and fair hearing plans are written to comply with HCQIA by providing for the due process steps outlined in the statute.

As mentioned above, HCQIA also established the National Practitioner Data Bank (NPDB) that has a number of reporting requirements that must be followed by healthcare entities that perform peer review. The NPDB serves as a clearinghouse of information for healthcare organizations throughout the nation.

Important HCQIA Definitions:

In order for credentialing or peer review decisions to qualify for immunity under HCQIA, they must be a "**professional review action,**" which is defined in 42 U.S.C. § 11151(9) as:

An action or recommendation of a professional review body which is taken or made in the conduct of professional review activity, which is based on the competence or professional conduct of an individual physician (whose conduct affects or could affect adversely the health or welfare of a patient or patients), and which affects (or may affect) adversely the clinical privileges…of the physician.

Under the HCQIA, a "**professional review body,**" which can be granted immunity from suits for damages, is defined as:

A healthcare entity and the governing body or any committee of a healthcare entity that conducts professional review activity, and includes any committee of the medical staff of such an entity when assisting the governing body in a professional review activity. (42 U.S.C. § 11151(11))

HCQIA describes the following as "**immunized participants**" in peer review:

a. Professional review bodies;

b. Any person acting as a member or staff to the professional review body;

c. Any person acting under a contract or other formal agreement with the professional review body; and

d. Any person who participates with or assists the professional review body.
(42 U.S.C. § 11111(a)(1))

[1]A copy of the legislation can be read at www.npdb-hipdb.hrsa.gov/legislation/title4.html.

[2]Black's Law Dictionary, Fifth Edition.

One objective of the NPDB is clearly to prevent problematic doctors from engaging in the age old "geographic cure." That is, when in trouble in one locale, pack up your bags and move to another where word of your difficulties has not yet reached.

It is important to note that healthcare bodies that do not make required reports to the NPDB forfeit the peer review immunities they would otherwise be entitled to under HCQIA. For an excellent review of those events that must be reported to the NPDB see the NPDB Guidebook.[3]

As important as it is to make a proper report to the NPDB when required, it is equally important to refrain from making reports when they are not required. Since a report to the NPDB makes the information it contains widely available, an inaccurate report (or one that is not required at all) can provide the grounds for a defamation lawsuit. For example, the NPDB requires that suspensions that last *more* than thirty days must be reported. Therefore, do not make the mistake of reporting a suspension at *thirty* days! Despite these cautions it is important to know that HCQIA grants immunity with respect to reports made to the NPDB by any person "without knowledge of the falsity of the information contained in the report" (42 U.S.C. §11137(c)).

HCQIA does not provide immunity from all types of lawsuits regarding peer review and it is important to understand the limitations on the statute's scope. HCQIA immunity does not apply to damages relating to the civil rights of any person under any federal or state civil rights law. Therefore, if a physician claims that an adverse peer review action resulted from illegal discriminatory bias, the practitioner may well get his or her day in court.

National Practitioner Data Bank Definitions

Adverse action: (1) an action taken against a practitioner's clinical privileges or medical staff membership in a healthcare entity, or (2) a licensure disciplinary action.

Healthcare entity: (1) a hospital; (2) an entity that provides healthcare services and follows a formal peer review process for the purpose of furthering quality healthcare; or (3) a professional society or a committee or agent thereof, including those at the national, state, or local level, of physicians, dentists, or other healthcare practitioners, that follows a formal peer review process for the purpose of furthering quality healthcare.

Professional review activity: an activity of a healthcare entity with respect to an individual physician, dentist, or other healthcare practitioner: (1) to determine whether the physician, dentist, or other healthcare practitioner may have clinical privileges with respect to, or membership in, the entity; (2) to determine the scope or conditions of such privileges or membership; or (3) to change or modify such privileges or membership.

(From the NPDB Guidebook Glossary, www.npdb-hipdb.hrsa.gov/npdbguidebook.html.)

However, it will usually take more than a simple allegation to achieve this, and the physician will need to provide at least some evidence to support the claim of discrimination or the courts won't allow the litigation to proceed.

It should also be noted that, although HCQIA immunity will protect against a private antitrust claim, it does not apply to governmental antitrust prosecutions such as those brought by the Federal Trade Commission (FTC).

As more and more non-physician practitioners join hospitals, it is important for medical staff leaders to be aware of another limitation of the HCQIA. This legislation was passed in the mid-1980s when it was relatively rare to grant privileges to anyone other than physicians and dentists. Only these latter professions are mentioned in HCQIA and the immunity and reporting provisions do not clearly apply to nurse practitioners, physician assistants, chiropractors, podiatrists, and others who may be on your medical staff or be granted privileges at your hospital. Similarly, most state laws protecting peer review work were written decades ago and focus on physicians and dentists while making no reference to other allied health practitioners (AHPs). Without legal protections, there are no evidentiary protection incentives to diligently review the credentials of AHPs since the peer review work done is usually discoverable.

In most states, HCQIA also provides protection against claims made by physicians based on state law. Examples of such claims are breach of contract, defamation, and tortious interference with business relationships.

[3] Available at www.npdb-hipdb.hrsa.gov/npdbguidebook.html.

Patient Safety and Quality Improvement Act

On July 29, 2005, President Bush signed the Patient Safety and Quality Improvement Act of 2005 (S. 544/Pub. L. No. 109-41) into law. The Act amends the Public Health Service Act by establishing broad confidentiality and privilege protections for information pertaining to medical errors and other quality information that is created for reporting to, and that is voluntarily reported to, so-called patient safety organizations (PSOs).

In part, this statute is an effort to address the glaring hole in peer review protections created by the absence of a federal peer review privilege. Regulations implementing this law have been slow in coming, but some counselors to medical staffs have recommended they become designated patient safety organizations in order to gain the additional protections provided by this statute. The possibility of becoming a PSO is worthy of discussion with legal counsel for your hospital or medical staff.

Legal Terms Relating to Peer Review Confidentiality

Discovery: "the pre-trial devices that can be used by one party to obtain facts and information about the case from the other party in order to assist the party's preparation for trial." (From Black's Law Dictionary, Fifth Edition.)

Admissibility: whether certain evidence may be introduced at trial for consideration by the judge or the jury.

Privilege: in the context of peer review, it is a legal recognition of a special interest in confidentiality that the law has determined appropriate to protect. State laws establish the extent of this privilege.

State Laws

It is important for physician leaders to be familiar with their own state laws governing peer review activities. When HCQIA was enacted it included an "opt out" option for states that were willing to pass their own statutes that incorporated, at a minimum, the protections contained in the federal statute.

Nearly all states have their own statues that grant immunity from damages to individuals and entities involved in peer review proceedings in certain circumstances. These provisions typically provide a qualified immunity from damages for actions taken in good faith, without malice, or under some other standard.

It is important to note that these immunity statutes are not uniform so you should become familiar with the law in the state where you serve as a medical staff leader. For example, some states have immunity provisions that apply to individuals involved in peer review processes but not to hospitals. State statutes may adopt an absolute immunity from damages standard, a "good faith" standard, a "without malice standard," or some other standard.

With regard to immunity from declaratory and injunctive relief (which are not covered by HCQIA) a state may impose procedural conditions for peer review that are more burdensome than those required by HCQIA. As a result, when fashioning peer review policies for your medical staff, it is important to understand the requirements of both HCQIA and your own state law.

State peer review statutes often address an issue on which the federal HCQIA is silent—the discoverability of peer review documents. This protection or "privilege" prevents peer review documents from being accessed by lawyers seeking to bring lawsuits against hospitals and participants in the peer review or credentialing process.

The degree of protection afforded by these statutes is literally all over the map. Some states have excellent peer review privilege rules while others put up few barriers to the discovery of peer review material. Therefore, it is imperative to review the legal realities in your state with a knowledgeable local attorney. Regardless of what evidentiary privilege your state law grants to peer review information, if litigation around peer review enters the federal courts, no protection from discovery exists under the Federal Rules of Civil Procedure and the Federal Rules of Evidence.

Physician leaders should be aware that they might lose a privilege against discovery under their state peer review statute if they do not maintain appropriate confidentiality of peer review material. Specific peer review information that you wish to be kept privileged (i.e., non-discoverable) should not be shared beyond participants in the formal "peer review process" as defined in medical staff bylaws or associated policies and procedures. State laws sometimes specifically impose a duty on peer review participants to maintain confidentiality and both immunity and privilege may be lost under state law if peer review information is shared inappropriately. *The medical staff should have a confidentiality policy to which physician leaders are regularly oriented and to which they rigorously adhere.*

LEGAL LANDMINES: SPECIFIC DANGER ZONES FOR PHYSICIAN LEADERS

While it is helpful to know there are protections in place to support the work of physician leaders, it is always prudent to avoid missteps that can encourage litigation. The best preventative approach is to engage in accepted "best" or recommended practices when performing medical staff work. A review of such practices is beyond the scope of this white paper. However, the following pages highlight some high-risk areas and actions that can be characterized as "legal landmines."

CREDENTIALING

The major activities engaged in by medical staff leaders are credentialing and peer review. In recent decades the regulations addressing these activities have become much more rigorous. Notorious lapses in good credentialing and peer review practices have received wide publicity and provided the impetus for these heightened expectations on the part of regulators, governments, and the public. Today it is vitally important that medical staff leaders perform credentialing and peer review meticulously and conform to those practices that have been widely adopted by the industry.

In years past, tort actions against community hospitals were unusual and these institutions were protected by the legal doctrine of "charitable immunity." The premise of this doctrine was that organizations working on behalf of the community should not suffer legal exposure for their good works. If injured parties were able to sue hospitals, the charitable resources donated to it could be depleted and the mission of the hospital seriously impaired.

By the 1940s courts began to explicitly reject the charitable immunity doctrine, making hospitals liable for their own negligent acts and the negligent acts of their employees. The concept of corporate liability for negligent credentialing moved forcefully into the world of community hospitals in 1965 with the landmark decision of the Illinois Supreme Court in *Darling v. Charlestown Community Memorial Hospital* (33 Ill. 2nd 326, 211 N.E.2nd 253).

In this case, an eighteen year old broke his leg in a college football game and was taken to the emergency room of Charleston Community Memorial Hospital. The patient was treated by the general practitioner on emergency call and admitted to the hospital. The doctor applied a cast too tightly and the ultimate consequence was a partial amputation of the patient's leg. The patient sued the hospital for allowing the doctor to do orthopedic work despite his lack of training and experience is this area. The hospital defended itself arguing that it could not control the treatment delivered by the independent doctor. However, the hospital was found by the court to have an independent duty to monitor and supervise its medical staff and to properly select and retain medical staff members.

As the court noted, "The conception that the hospital does not undertake to treat the patient, does not undertake to act through its doctors and nurses, but undertakes instead simply to procure them to act upon their own responsibility, no longer reflects the fact. Present day hospitals, as their manner of operation plainly demonstrates, do far more than furnish facilities for treatment."[4]

In another notable case, *Johnson v. Miseracordia Community Hospital*, a 1981 Wisconsin case, the court said, "…we hold that a hospital owes a duty to its patients to exercise reasonable care in the selection of its medical staff and in granting specialized privileges." Later in its ruling, the court also noted that "this is not to say that hospitals are insurers of the competence of their medical staff, for a hospital will not be negligent if it exercises the noted standard of care in selecting its staff." In *Johnson v. Miseracordia* it became clear that the medical staff/hospital had failed to do even a cursory background check on the physician who treated Jimmy Johnson and inadvertently severed his femoral nerve and artery. The patient was left with permanent paralysis of part of his leg. If the hospital/medical staff had done a background check on the surgeon they would have learned that the physician had made misstatements about his qualifications on his medical staff application, had his privileges restricted/removed elsewhere, and had a slew of malpractice judgments.

Where hospitals follow sound and accepted practices they can defend themselves against claims of negligence. But the negligence suits still come, and under a variety of appellations: corporate negligence, negligent credentialing, negligent peer review, institutional negligence, negligent selection, negligent supervision, and so forth. Many plaintiffs who believe they have a valid claim of negligent credentialing will sue not only the hospital, but also its medical staff and physician leaders, management executives, and board members. In general, corporate officers and directors, including medical staff leaders, are insulated from liability where their actions are taken in good faith and in furtherance of the mission and appropriate objectives of the institution. Liability typically falls upon the hospital and not upon individual players. However, courts occasionally have found otherwise and this is usually when there have been particularly egregious failures on the part of specific individuals.

Courts have imposed a duty on hospitals to:

- Exercise ordinary care in the selection of physicians (*Darling v. Charleston Community Memorial Hospital,* 211 N.E. 2nd 252, Illinois, 1965).
- Make a reasonable investigation into a physician's background before granting him privileges (*Johnson v. Miseracordia Community Hospital,* 293 N.W. 2nd 501, Wisconsin, 1980).
- Monitor medical staff performance (*Burnes v. Forsyth County Hospital Authority*, 344 S.W. 2d 839, NC App., 1986).
- Take corrective action where the hospital is aware of physician incompetence (*Insinga v. LaBella*, 534 SO. 2d 209, Fla., 1989).

[4] *Darling* at p. 257.

Recommended Practices in Credentialing

Today, hospitals and medical staffs are almost routinely named in negligent credentialing lawsuits whenever a malpractice suit is filed against a medical staff member. The defense against these suits is adherence to good credentialing practices, compliance with your medical staff bylaws and related policies, and good record keeping. Here are some suggestions to avoid litigation or assure the best possible defense when negligent credentialing litigation ensues:

- Insist that your hospital provides physician leaders with adequate education on modern credentialing and peer review practices. Acquiring adequate knowledge is a potent safeguard against mistakes that could land you in court.
- Never engage in credentialing shortcuts! Verify submitted data, follow up on every "red flag," and consistently follow all the steps in your bylaws and credentialing policies.
- Make sure applicants have signed all appropriate waivers, consents, authorizations, and releases.
- Always demand information that an applicant fails to provide or refuses to make available if it is relevant to vet his or her credentials.
- Never hold a vote at a department meeting on recommendations regarding an applicant for membership or privileges. Such an action can appear to be a conspiracy of competitors trying to restrain competition.
- Always document interactions with the applicant and all requests for information. In addition document all decisions/actions taken regarding an applicant and the reason(s) for the decision/action.
- Review your policies with your attorney before asking applicants for specific information about their health. Some jurisdictions have held that the Americans with Disabilities Act applies to independent physicians on the medical staff or those who are applying to the staff.
- If you have a conflict of interest regarding an applicant in the credentialing process, make the conflict known and recuse yourself from voting on matters involving that applicant.
- If a legal concern arises, consult a knowledgeable healthcare attorney.
- Keep all credentialing information and discussions confidential as appropriate. This means no discussions with your partner when you return to the office, or with your spouse over dinner! Keep credentials files in a locked office or cabinet and have clear policies about who can access them.
- Remember that the hospital board and not physician leaders make all final decisions regarding medical staff appointment and grants of privileges. Therefore, communicate these decisions over the signature of the board chair or designee and not over that of a medical staff officer.

PEER REVIEW AND CORRECTIVE ACTION

Once practitioners have joined the medical staff or received privileges at the hospital, physician leaders must assure that they practice safely and competently. Failure to monitor performance adequately or allowing poor practice to occur can subject hospitals and their staffs to litigation for negligent peer review/supervision/monitoring/oversight.

Once again the best barrier to such suits is an excellent peer review/performance improvement program by your medical staff. Physician leaders should be familiar with the accreditation standards regarding peer review as provided by their accrediting agency (e.g., the Healthcare Facilities Accreditation Program or the Joint Commission).

The most dangerous activity physician leaders engage in with regards to peer review involves the corrective action process. Corrective action refers to the steps taken to decide on a recommendation to the hospital board on membership termination or privilege restriction of a medical staff member.

Recommended Practices in Peer Review

The following are some suggestions to avoid litigation or assure the best possible defense when negligent peer review litigation ensues:

- Always provide the practitioner feedback concerning peer review findings and give him/her the opportunity to comment.
- Have a medical staff policy on external peer review (EPR) and use EPR when appropriate.
- When a collegial intervention is warranted by peer review findings, always look for the least burdensome intervention that is likely to be effective.
- When using a collegial intervention to improve the performance of a colleague, always follow up to be sure the intended result is achieved.
- When discussing peer review findings or collegial interventions to improve performance, always document all interactions with the practitioner. It is good practice to send one copy of this documentation to the confidential peer review file and another copy to the practitioner.
- When peer review discussions with a practitioner are expected to be difficult, consider having at least two physician leaders present. This is especially helpful when confronting a "disruptive" colleague about unprofessional conduct.
- Keep peer review matters confidential at all times. Remember the WWII admonition, "Loose lips sink ships!"
- When you initiate or engage in the corrective action process, always do so with extreme care. Follow the bylaws meticulously and consider working with legal counsel as you move through the process.
- Always think twice before imposing a summary or precautionary suspension. Make sure you have undertaken less burdensome collegial interventions before resorting to suspension if patient safety will not be jeopardized.

- When imposing a suspension under the medical staff bylaws (as an authorized physician leader), always have it ratified by the medical executive committee as quickly as possible. Summary suspensions reported to the NPDB after thirty days must be an entity's action, as opposed to the action of an individual.
- Make sure your bylaws contain a "bright line" definition of what constitutes an investigation. This term is often used without rigor but the NPDB requires that practitioners who resign while under investigation be reported. Be careful to distinguish an "investigation" from collegial focused peer review.
- Never report a practitioner to the NPDB unnecessarily. For example, do not report suspensions that do not exceed thirty days. Do not report a practitioner if she resigns while being scrutinized by collegial focused peer review but has not been the subject of a formal investigation.
- When votes are taken regarding corrective action, recuse yourself if you are a direct competitor or partner of the party involved.
- Keep minutes of peer review committee meetings and document all decisions and actions including interventions, responses from the practitioner involved, follow-ups, and so forth. In general, minutes should not quote or relate specific comments from individuals participating in the meeting. If you are in a state with poor protection for peer review documents, consider using numbers to identify practitioners, rather than names.
- When pursuing corrective action, it is usually good practice to allow the practitioner to address the medical executive committee and state his or her position regarding the corrective action steps being considered.
- In pursuing corrective action, if you find that you have inadvertently failed to follow some step in your bylaws, correct the oversight as quickly as possible. Courts generally don't require the corrective action process to be perfect, but they will review your actions to make sure they appear fair and have offered reasonable due process to the member being affected.
- When sharing information about peer review findings with third parties, always try to obtain a specific release from the practitioner. This is especially valuable if the findings raise concerns about competence or conduct.

DEALING WITH CONFLICTS OF INTEREST

All types of conflicts of interest can occur on medical staffs and with physician leaders. Conflicts of interest are not necessarily problematic, but it is sensible to anticipate as many as possible and address them in medical staff conflict-of-interest policies.

From a liability perspective, the most worrisome conflicts are those where credentialing and privileging decisions are being made and a practitioner's ability to practice is being limited. As a general rule, physician leaders should recuse themselves from votes that will involve direct competitors or direct partners. This does not mean that a leader could not engage in peer review or in some discussions concerning a partner or competitor. On a small staff it may be impossible to have reasonable peer review done by anyone else. But if the findings lead to a vote of some kind, it is better to let a multi-disciplinary body (e.g., credentials or medical executive committee) handle the matter and have direct competitors/partners abstain from the committee deliberations and actions. In situations where such conflicts exist, consider the use of external peer review to assure objectivity.

Another example where such conflicts might arise is around "turf battles" over privileges. If the credentials committee is considering the resolution of these professional disputes over privileging criteria, conflicted parties should recuse themselves from the deliberations and votes. Failure to do so could lead to allegations of anti-competitive behavior (see below).

If a physician leader sits on the board of the hospital, it is important that he/she discloses all pertinent conflicts of interest when board discussions move to topics where such conflicts exist. Failure to do so may be a violation of the fiduciary responsibilities the physician has as a board member. Such a failure could subject that physician to legal action under certain circumstances.

DEFAMATION

Physician leaders who participate in credentialing and peer review activities are frequently anxious about sharing any information when asked to do so by healthcare organizations with a legitimate need to know about an applicant's performance. This is especially true when there is information that might raise concerns that would lead the inquiring organization to reject an application for membership or credentials.

Physicians who are found through the peer review process to have clinical or behavioral problems often threaten defamation lawsuits if any of this information is shared without their explicit consent. As discussed earlier in this document, it is always prudent to obtain consent or a release from that individual before sharing information about him or her with a third party. Nevertheless, fears of a defamation judgment are usually overblown. In order to make headway, the plaintiff in a defamation case usually has to show that the shared information was inaccurate, that the revealing party knew it was inaccurate, and that is was communicated to a third party with malice rather than in good faith.

When sharing credentialing/peer review information with appropriate third parties, always keep strictly to the facts. Don't make any subjective comments or assumptions, disparaging remarks, or sweeping conclusions. When making a report to the NPDB, it can be a good tactic to negotiate with the party about whom you are reporting exactly what you will submit to the federal database. This way, they cannot come back to you later and complain that the reporting was inaccurate and defamatory. Also remember that when you report to the NPDB, you should do so only if the statute requires it. As explained above, HCQIA says that suspensions that last for more than thirty days must be reported, even if they are not final actions. Since the language of the statute is clear (though frequently misread), a plaintiff might impute intentional malice to a report submitted at thirty days—and see it as an act of defamation. This being said, it is worth reiterating that general immunity for NPDB reporting is well established and HCQIA specifically provides such immunity as long as the person reporting is "without knowledge of the falsity of the information contained in the report."

Physician leaders should take care not to let fear of defamation litigation keep them from doing the right thing. Hospitals and medical staffs rely on information from other healthcare entities in order to carry out effective credentialing. In a well-publicized, recent lawsuit, Kadlec Hospital in Washington State sued a Louisiana hospital and physician practice for failing to give complete information when Kadlec inquired about a *locum tenens* physician who was applying for a position on its staff. The hospital and physicians in Louisiana failed to mention that the doctor had been found diverting drugs in their facilities and had a drug impairment problem. The doctor joined the staff at Kadlec and his unresolved impairment led to negligent care, which put a young woman in a coma. Kadlec argued that if the impairment information had been shared the patient would not have been put in harms way. It is hard to disagree even though the courts ultimately did not find liability on the part of the Louisiana hospital. The right thing to do is share relevant performance information with appropriate third parties. Done properly, defamation should never be a significant concern.

ANTITRUST CONCERNS

The antitrust laws are meant to prevent anti-competitive behavior in the marketplace. Prior to the mid-1970s it was widely believed that the healthcare industry was not subject to the federal antitrust laws because it was a learned profession that was regulated by the states. Beginning in 1975, however, the Supreme Court made it clear that healthcare providers can be subject to the federal antitrust laws and no exemption would be made for learned professions.

The world of healthcare has become highly competitive in recent decades and allegations of illegal anti-competitive actions are not infrequently levied at physician leaders. The denial of staff privileges historically has accounted for the greatest amount of antirust litigation involving hospitals and physicians. A physician denied such privileges may allege a group boycott to deny him/her access to the hospital.

The antitrust allegations usually assert one of four combinations of players: (1) the medical staff and the hospital, (2) the individual members of the staff conspiring among themselves, (3) individual staff members conspiring with the hospital, and (4) the hospital entering into an exclusive contract with a physician or group. To establish concerted action amounting to a group boycott, the plaintiff must show an agreement between two or more separate entities.

Physician leaders should always avoid the appearance of anti-competitive conspiracy—thus the recommendation made above that clinical departments (usually grouped by specialty) avoid taking votes or holding discussions on the applications of new practitioners to the staff. For the same reason, departments or medical staff committees should generally not discuss exclusive contracts. The granting of exclusive contracts is a *board activity* because the lay members of the board are not competitors or potential competitors. Physician leaders who sit on the board should recuse themselves from votes on exclusive contracts if they have any connection with the practitioners involved. (Note that it is acceptable for the MEC to discuss the performance expectations it would like to see in an exclusive contract or to provide the board with feedback on the performance of a party that is holding an exclusive contract.)

Practitioners subject to corrective action will often allege anti-competitive behavior on the part of the leaders who are driving the process. This is why it is so important to *follow your policies closely*. Always consider the use of external peer review in these circumstances to demonstrate your intent to have as much objective data as possible. Remember that HCQIA due process requirements state that no member of a fair hearing panel can be a direct competitor of the physician who is the subject of its deliberations. Deciding exactly who is a direct competitor is sometimes a matter of opinion. Whenever possible, document that the physician under review has no objection to the members of the hearing panel so he cannot later claim they were a biased group assigned as part of an anticompetitive conspiracy to remove his privileges.

Physician leaders who work on medical staff bylaws should be careful when they make decisions about what categories of practitioners may serve on the staff or hold privileges. In years past, efforts by some allopathic physicians to keep osteopaths off their staffs were seen as anti-competitive actions. Today, an ever-expanding panoply of practitioners (acupuncturists, psychologists, chiropractors, and so forth) is looking to hold hospital privileges. While medical staff leaders can make recommendations to the board regarding the types of practitioners they would like to see on the medical staff, these decisions should be left to the hospital governing body. Physician leaders should avoid appearances that they are colluding with board members to stifle competition from classes of practitioners who want hospital access.

ADDITIONAL AREAS OF CONCERN

The scope of health law is quite broad. Physician leaders must have at least a cursory familiarity with many of its facets. An expanded list of additional legal issues with which physician leaders should become familiar appears below:

- Anti-kickback and anti-fraud laws/Stark laws & regulations
- HIPAA and other privacy regulations
- Medical malpractice law
- The law of contracts
- Insurance laws
- Medical ethics controversies
- Patient competence & consent matters
- Medical records requirements
- Laws governing research and experimentation

CONCLUSION

Healthcare is delivered in a litigious world, as every physician is well aware. Nevertheless, the work of physician leaders is too important to be impaired by the constant fear of lawsuits. In reality, medical staff work performed properly poses little risk to those who step up into leadership roles. This white paper has tried to enumerate the many protections that exist to shield physician leaders from liability. A bit of knowledge about the legal process and relevant statutes and regulations, coupled with prudence and good intentions should keep the plaintiff attorneys at bay in most cases. When litigation does ensue, quickly securing competent counsel will provide leaders with the guidance they need to successfully navigate the rough waters.

This work only touches on the legal matters raised in its pages. The reference list has additional sources of information for those seeking more in-depth knowledge of the law and its interaction with medical practice. As in so many worthwhile endeavors, to really understand the best risk management approaches to medical leadership, it is necessary to constantly seek new information, ask questions, and seek the counsel of those more knowledgeable and experienced than yourself. In the world of physician leaders, such effort is always worthwhile. Be safe out there!

RESOURCES

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