

Chapter 3

Medical Staff Peer Review in the Credentialing and Privileging of Physicians

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MEDICAL STAFF PEER REVIEW

The purpose of credentialing medical staff is to maintain quality patient care. This is an ongoing process during which the physician's training, skill, experience, and clinical competence are evaluated to ensure that the privileges granted match the physician's expertise.¹ The application of "corporate liability" concepts to hospital malpractice lawsuits after the landmark case of *Darling v. Charleston Community Memorial Hospital*² led to more aggressive physician peer review because hospitals could no longer deny responsibility for acts and omissions by their staff physicians. To encourage more aggressive peer review by the medical staffs, many states have enacted immunity statutes to protect hospitals' peer review committees.³ In addition, federal law related to Medicare and Medicaid programs mandate some form of peer review if hospitals are to be compensated for services.⁴ Therefore federal and state laws, regulations, and case law all emphasize a hospital's duty to monitor patient care and serve as the impetus for credentialing.

The Joint Committee on Accreditation of Healthcare Organizations (JCAHO) also requires its member hospitals to have a credentialing process in place for accreditation and hold the hospital's governing board ultimately responsible for peer review by its medical staff.⁵

The Health Care Quality Improvement Act (HCQIA) of 1986 grants health care entities and peer review committees immunity from liability for credentialing and privileging activities as long as due process is afforded the affected physician. The HCQIA also established the National Practitioner Data Bank (NPDB), an information clearinghouse regarding licensure actions, malpractice payments, and final adverse actions taken by hospitals and other health care entities that restrict physicians' practice privileges for more than 30 days. Hospitals and other health care entities must also query the NPDB when credentialing physicians for appointment and reappointment to the medical staff.

CREDENTIALING

Case law regarding credentialing generally supports the premise that a hospital could be held liable for a patient injured by a staff physician because the hospital should have known of the physician's poor performance or incompetence and failed to investigate or take reasonable corrective action. After the *Darling* case, the Wisconsin Supreme Court ruled in *Johnson v. Misericordia Community Hospital*⁶ that the hospital had a duty to properly credential physicians on its staff even when the physician falsified his or her application for privileges. Similarly, in *Elam v. College Park Hospital*,⁷ the court held that the hospital may be responsible for the conduct of its physicians under the doctrine of corporate negligence. These cases underscore the need for ongoing peer review to maintain quality care.

All credentialing criteria must be clearly stated in the medical staff bylaws and communicated to members of the medical staff and new applicants. Any changes adopted by the medical staff must be approved by the hospital's governing body. The medical staff bylaws should clearly identify the mechanisms and procedures to be used in the credentialing processes for appointment and reappointment. Standards for the evaluation and verification of applicant information, the delineation of privileges, and the procedures for appealing adverse decisions should also be clearly documented in the bylaws or rules and regulations of the medical staff. Applicants should not be asked for information related to gender, nationality, race, creed, sexual orientation, age, religion, ethnic origin, or any other data that can be viewed as having a discriminatory purpose. Likewise, provisions of the Americans with Disabilities Act (ADA) protect rehabilitated drug or alcohol abusers; therefore information requested of applicants should address *current* alcohol or drug abuse that has not been rehabilitated.

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PRIVILEGING

The objective of the privileging decisions should be the delineation of the specific diagnostic and therapeutic procedures, whether medical or surgical, that may be performed in the hospital and the types of clinical situations to be managed by the physician. The JCAHO requires that privileges be granted before any care is provided to patients, noting that temporary privileges must be time limited. Physicians working in outpatient facilities owned or managed by JCAHO-approved health care entities are also subject to the credentialing and privileging process.

PROCTORING

For all new applicants for privileges (or additional privileges) and for physicians who may be returning to practice after a significant absence, proctoring is usually required for a time to ensure that the physician is competent to perform the procedures for which privileges are requested. Appropriate proctors should be selected and can include members of the medical staff who are noncompetitors, when possible, and senior active staff who have privileges in the same area of practice. The number of cases or length of proctoring and the method of proctoring (such as direct observation or prospective and retrospective review of cases) should be determined and communicated to the applicant in writing. The form of the proctor's report should be standardized and submitted to the department chair for periodic review. The physician being proctored should be apprised of his or her progress, including observed strengths and weaknesses, and should be given copies of any written evaluations submitted to the department chair. Final recommendations of the proctor should then be reviewed by the department chair and forwarded to the credentialing committee for final recommendation to the medical executive committee. Privileges approved by this committee should be formally granted by the governing board.

DUE PROCESS

In the context of medical staff peer review in credentialing and privileging, *due process* refers to the fair and consistent treatment of physicians who first apply for privileges or who reapply for privileges that were involuntarily restricted, suspended, or revoked. Clearly written due process procedures must be established, understood, and properly implemented by the hospital because physicians have legal rights to protect their careers. In government-owned hospitals, these rights may be found under the due process provisions of the United States and in state constitutions, but in privately operated hospitals, constitutional rights may not apply.⁸

Cases in which the power of the medical staff was abused for discriminatory or other improper motives have led some states' courts and legislatures to gradually extend legal protections to physicians whose staff privileges are attacked. Since the 1950s, the trend has been toward upholding the physician's right to fully practice his or her

profession, a right that has in some states been considered "fundamental" for purposes of extending constitutional protections.⁹ This view mandates fair procedures in disciplinary actions for medical staff.¹⁰ Fair procedure includes, at a minimum, adequate notice of the charges on which the action is based and the opportunity to present evidence on one's own behalf to an unbiased decision-maker.¹¹ However, other protections usually found in civil and criminal actions, such as the right to cross-examine adverse witnesses and the right to be represented by counsel, have generally not been accorded in disciplinary hearings.

State laws provide for the right to legally challenge a decision restricting or terminating medical staff privileges, but judicial review may be limited by numerous factors, including the requirement that one must fully exhaust all available administrative remedies before seeking redress in the courts. Courts have traditionally shown a great deal of deference to the decisions of administrative bodies such as hospital boards and committees, even when due process may have been lacking at the administrative level, and are loathe to interfere in what is viewed as the exclusive bailiwick of hospitals and physicians.

Although many states have begun to address these issues, there is wide variance in the extent to which physicians' rights to practice in the hospital can be protected under the law. Most states, however, have done nothing to address similar problems created by managed care organizations, medical societies, and other entities that perform peer review and credentialing functions but that are not necessarily required by law to have an organized and independent medical staff.

PHYSICIAN RIGHTS UNDER MANAGED CARE

In California, the law applying to hospitals extends by statute to state medical societies, but only recently have the courts begun to extend the same protections in cases involving private insurers, health maintenance organizations, and managed care payors.¹² These cases hold that entities controlling "important economic interests" may not arbitrarily deprive a physician of privileges or contract rights without providing a fair hearing procedure, even if existing law requires that the action be reported to the state medical board or to the NPDB.¹³

In the seminal *Delta Dental* case, the court determined that the managed care organization had a duty to accord its member dentists the right to common law fair procedure in a dispute over a reduction in the payment rates because the plan was "the largest dental health plan in California, covering over 8 million individuals."¹⁴ Thus the court apparently viewed the importance of the defendant's market power in general, rather than its impact on the plaintiff's business in particular, as controlling.

In the *Ambrosino* case that followed *Delta Dental*, the plaintiff podiatrist was terminated from participation in a managed care plan on the basis of "a short-term chemical

dependency problem” that he claimed did not render him impaired to practice.¹⁵ The plan refused to grant him a hearing because under its contract, any history of substance abuse was considered grounds for termination. The court first cited *Delta Dental* for the proposition that “[t]he common law right to fair procedures has recently been held to extend to health care providers’ membership in provider networks such as that operated by defendant because managed care providers control substantial economic interests.”¹⁶ Then in determining that the *Delta Dental* criteria had been met, the court noted that approximately 15% of the plaintiff’s patients were insured by defendant and concluded that therefore the plaintiff “had a common law right to fair procedures, including the right not to be expelled from membership for reasons which are arbitrary, capricious and/or contrary to public policy,” notwithstanding the termination-at-will clause in the participation contract.¹⁷

These two cases were hailed by many as opening a new era in the law relating to managed care and physicians’ rights. However, there was ample support for the *Ambrosino* decision in long-standing California case law, including the 1974 *Ascherman* case.¹⁸ The true significance of the *Delta Dental* case seems to be that the common law right to fair procedure was accorded there despite the fact that no issue of the plaintiff’s competence, fitness, or quality of care was raised; the decision to reduce payments under the plan was purely economic. The retroactive nature of the action, and consequently its effect on previously “vested” rights, also seems to have been an important factor. The California Supreme Court has recently extended the fair procedure doctrine to cases of “economic credentialing,” wherein a hospital or managed care entity terminates participation on a physician plan for purely business reasons without according the affected physicians notice or a fair hearing.¹⁹ Whether the courts will be willing to extend this doctrine to hospital privilege cases is uncertain.

APPLICATION OF DUE PROCESS PRINCIPLES

Due process requires that the right to practice medicine not be infringed on in an arbitrary or capricious manner.²⁰ The critical question concerns what procedures will suffice to satisfy due process requirements. Unfortunately there is no one answer to this query; due process varies according to the facts and circumstances of each case and according to the law of each jurisdiction where it is applied. The California Supreme Court has stated that:

*Due process is flexible and calls for such procedural protections as the particular situation demands. Consideration of what procedures due process may require under any given set of circumstances must begin with a determination of the precise nature of the government function involved as well as of the private interest that has been affected by governmental action.*²⁰

The nature and extent of the private interest involved are necessarily fact-based determinations based in most cases on the application of state law. A flexible formula suggests that the type of hearing afforded may vary from case to case. Clearly, however, due process requires “some form of hearing” before an individual may be deprived of a protected interest.²¹ Furthermore, it is generally accepted that “in a highly technical occupation (like the practice of medicine), the members of the profession should have the power to set their own standards. Due process requires that the evaluations of whether one gets along and meets the standards not be made in bad faith or arbitrarily and capriciously.”²² On the other hand, there is no constitutional requirement that physicians be given a formal adversarial hearing, nor even that the decision-makers be completely uninvolved in the underlying matter.²³ “The common law requirement of a fair procedure does not compel formal proceedings with all the embellishment of a court trial, nor adherence to a single mode of due process. It may be satisfied by any one of a variety of procedures which afford a fair opportunity for an applicant to present his position.”²⁴

Under the HCQIA, peer review participants are immune from civil liability in connection with the peer review action if the affected physician is given a fair procedure under the terms outlined in the statute.²⁵ Various elements constitute “fair procedure” or “due process” under the law, depending on the particular jurisdiction’s legislative and judicial history of providing protection in this area. California offers what is probably the most comprehensive legislative scheme protecting the medical staff privileges of physicians (and similar property interests), as well as judicial interpretation and application of the law. For example, in California, the required hearing procedures include an unbiased hearing officer; an unbiased trier of fact, whether composed of a panel of peers or an arbitrator (or arbitrators); notice of the nature of the proposed action, the right to a hearing, and the time in which to request a hearing; notice of the reasons for the proposed action and of the fact that the action will be reported when final; and the right to inspect and copy documents to be used in support of the adverse action and to learn the identity of witnesses to be called by the representatives of the medical staff.²⁶

The precise methods to be followed may vary according to the rules and regulations of the institution. Although medical staff bylaws vary from one institution to the next, most are similar in providing for an initial investigation by a credentials committee or similar body, during which the physician generally has few (if any) procedural rights but may be required to appear and answer questions in the matter; a hearing, including the basic elements previously discussed; and an appeal to the governing board of the hospital, medical society, or other institution. Medical societies have promulgated model medical staff bylaws prescribing procedures for each of these steps, and these models are generally geared toward ensuring a fair procedure for the physician whose privileges are under review.²⁷ Model bylaws are an excellent resource for attorneys and administrators involved in drafting and updating bylaws in any jurisdiction.

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The final element of due process in adverse actions affecting staff privileges is that of judicial review. This right also varies considerably from one jurisdiction to another, again depending on each state's interpretation of *due process*, the property or liberty rights recognized, and the extent to which the courts have been willing to intervene in what have traditionally been considered private, or semipublic, concerns. Nevertheless, the majority of jurisdictions now recognize the right to obtain redress in the courts when due process is not provided by the institution with respect to medical staff privileges. Judicial review may be limited to a review of the written record of proceedings held by the peer review body or may encompass a full evidentiary hearing *de novo*, although the latter may be available only under limited circumstances.

CONFIDENTIALITY AND PEER REVIEW PRIVILEGE

Generally, records of peer review actions and proceedings are exempted from discovery and evidentiary use in civil actions. This may be expressed as an "immunity" from discovery, as an evidentiary "peer review privilege," or both. Exceptions may be found in cases in which a plaintiff has made a *bona fide, prima facie* case against the hospital for negligently credentialing the physician or in which the litigation concerns the physician's rights against the institution (as opposed to a malpractice claim). Some courts have upheld the protection against discovery in such actions, and some have not. There is also an open question as to whether, and in what circumstances, a peer review participant otherwise entitled to claim a privilege may waive it by voluntarily disclosing the records or facts pertaining to the peer review action; at least one court has held that a participant in the peer review process who may not be compelled to testify to the "privileged" matters may nevertheless do so of his own free will.²⁸

Confidentiality may be ensured by means other than the law. Medical staff bylaws often require members involved in peer review proceedings to hold confidential all information and records relating to the proceedings or otherwise be subjected themselves to disciplinary action. The author is unaware of any case challenging such a provision. However, it is important to keep in mind that in some states the bylaws may be considered a binding contract, whereas in others the courts have not adopted that view.

Numerous instances continue to exist in which a physician's medical staff privileges may be revoked or withdrawn and due process protections cannot be invoked, such as when a hospital acts for purely business or economic reasons or some other cause that does not relate to the quality of care practiced by the physician or his or her fitness to practice. For example, courts have held that a hospital may close its staff or a particular service, such as radiology or anesthesiology, or award an exclusive contract to one physician or group while excluding all others (including those already on staff). Although such actions

have occasionally been challenged on both due process and antitrust theories, these cases have failed to produce decisions limiting the hospital's discretion to make such decisions, even when the resulting effects on individual physicians are harmful or seemingly anticompetitive.²⁹

PEER REVIEW CORRECTIVE ACTION: AN UNFAIR PROCESS?

Most physicians must carry hospital staff privileges in one or more facilities. The medical staff is self-policing and is independent of the hospital.³⁰ Its functions include reviewing the care provided by its physician members to patients and acting as a liaison between the hospital administration and individual physicians. As a peer review body, the medical staff is responsible for shielding patients from incompetent or unstable physicians; at the same time, by controlling physicians' access to both the patients and the facilities, the medical staff wields considerable power over physicians, and when that power is abused, the physician's professional reputation, standing, and license to practice may be disrupted and damaged.

Despite a growing trend toward protecting physicians' fundamental rights and interests in medical staff privileges, medical staffs continue to operate independently, without strict controls, when determining which physicians are granted credentials and which physicians should lose their credentials. At every stage of the disciplinary process, the affected physician is at a disadvantage. The disciplinary hearing under medical staff bylaws is like a malpractice action against the affected physician with one's own colleagues acting as witnesses, prosecutors, and judges. Dozens of charges involving the care of numerous patients may be leveled at one time. If the physician loses, he or she will probably have no insurance coverage against either the costs of defense or the economic impact on his or her medical practice.

There is little opportunity to obtain discovery of evidence before it is presented. The chairman of the medical executive committee usually selects the jury panel members and hearing officer (sometimes subject to the physician's challenges for bias, which may be overruled). There may be use of hearsay evidence, including medical opinions of experts who cannot be compelled to appear and be cross-examined. Frequently, the physician is denied the assistance of counsel in the hearing room and must represent himself or herself or depend on a medical colleague to act in a representative capacity. Other procedural protections, such as the right to subpoena witnesses or documents, are usually lacking, and witnesses in a peer review hearing may enjoy absolute immunity from civil suits for slander or malicious injury, even if their testimony is false.³¹ The hospital and medical staff members are also immune from suit under federal law unless it is proved that they acted in bad faith when taking the peer review action.³²

An adverse outcome for the physician may destroy his or her career. Actions adversely affecting medical staff privileges must be reported by the hospital to the state

medical board, as well as the NPDB and the Healthcare Integrity and Protection Data Bank, nationwide databases accessible to hospitals and managed care organizations.³³ The state medical board may then commence an investigation, finding the physician an easy target because damning evidence has already been compiled in the medical staff hearing. Although the state medical board may decide not to prosecute, in almost all cases it can do nothing to aid the physician to clear his or her name, regain staff privileges, or obtain redress for the economic, professional, and emotional injuries sustained. The physician's reputation and career may be ruined, and his or her legal recourse is extremely limited. Although physicians have sued for deprivation of hospital staff privileges on any number of legal theories, including breach of contract, various tort theories, and antitrust, these suits are difficult, costly, and rarely successful.

Although the objective of peer review is to ensure the quality of care and retention of competent medical staff, peer review functions are performed by physician staff members who are uncompensated for their efforts and retain the risk of being sued by the affected physician despite immunity statutes. In addition, peer review immunity may not necessarily be extended if a federal claim, such as antitrust or unlawful discrimination, is proved.

Clearly, there is a continuing need for improvement in the credentialing and peer review processes. Extension of procedural due process principles to all facets of peer review must be accomplished with due respect to the realities of the health care environment and marketplace. Credentialing and peer review remain important functions of the organized medical staff. The courts and legislatures are increasingly involved in the process. Physicians and hospitals should continuously assess their peer review processes in light of the evolution of the law.

Acknowledgment

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Endnotes

1. See generally F.A. Rozovsky, L.E. Rozovsky & L.M. Harpster, *Medical Staff Credentialing: A Practical Guide* (American Medical Association, Chicago, 1994).
2. Darling v. Charleston Community Memorial Hospital, 211 N.E. 2d 253, 260 (1965).
3. See Hammock, *The Antitrust Laws and the Medical Peer Review Process*, 9 J. Contemp. Health Law Policy 419 (1993).
4. Blum, *Medical Peer Review*, 38 J. Legal Educ. 525 at 531 (1988).
5. ECRI, *Medical Staff Credentialing*, in *Healthcare Risk Control. Risk Analysis: Medical Staff I*, Volume 3 (ECRI, Plymouth Meeting, Penn. Reissued January 1996).
6. *Johnson v. Misericordia Community Hospital*, 301 N.W. 2d 156 (Wis. 1981).
7. *Elam v. College Park Hospital*, 132 Cal. App. 3d 332, 183 Cal. Rptr. 2d 156 (1982).
8. Most states' laws still distinguish between public and private hospitals in determining whether, or to what extent, a physician is entitled to due process in respect to the termination or restriction of medical staff privileges. Others have largely eliminated this distinction, either by finding "state action" in the hospital's acceptance of federal funds, such as Hill-Burton Act payments, or by focusing on the quasi-public character of a hospital's business. See, e.g., *Ascherman v. San Francisco Medical Society*, 114 Cal. Rptr. 681 (Cal. App. 1974); *Silver v. Castle Memorial Hospital*, 497 P. 2d 564 (Hawaii 1972) (*cert. denied*, 409 U.S. 1048, *reh'g denied* 409 U.S. 1131); *Peterson v. Tucson General Hospital, Inc.*, 559 P. 2d 186 (Ariz. Ct. App. 1976). In California the courts have expressly held that a common law doctrine of "common law fair procedure" exists and requires the same elements of fair procedure as would be required under a due process analysis. *Applebaum v. Board of Directors of Barton Memorial Hospital*, 104 Cal. App. 3d 648, 163 Cal. Rptr. 831 (1980).
9. See, e.g., *Ascherman v. San Francisco Medical Society*, *supra* note 8.
10. California's statutory scheme governing procedures in medical staff privileges disciplinary hearings may be found in Cal. Bus. Prof. Code, §§809, *et seq.*
11. *Applebaum*, *supra* note 8.
12. *Potvin v. Metropolitan Life Insurance Company*, 22 Cal. 4th 1060, 997 P. 2d 1153, 95 Cal. Rptr. 2d 496 (2000); *Delta Dental Plan of California v. Banasky*, 33 Cal. Rptr. 2d 381 (Cal. App. 1994); *Ambrosino v. Metropolitan Life Insurance Company*, 899 F. Supp. 438 (N.D. Cal. 1995); *Hallis & Nopoletano v. CIGNA Health Care of Connecticut, Inc.* (1996), 680 A. 2d 127, *cert. denied*, 137 L.Ed. 2d 308; *Paul J. Harper, M.D. v. Healthsource New Hampshire, Inc.*, 674 A. 2d 962 (1995).
13. *Supra* note 9.
14. *Supra* note 12, 33 Cal. Rptr. 381, 385.
15. *Supra* note 12, 899 F. Supp. 438, 440.
16. *Id.* 899 F. Supp. 445.
17. *Id.*
18. *Supra* note 8.
19. *Potvin v. Metropolitan Life Insurance Company*, 22 Cal. 4th 1060, 997 P. 2d 1153, 95 Cal. Rptr. 2d 496 (2000), reaffirms *Ambrosino* by stating that the key issue in determining whether a payor entity must accord a fair procedure hearing to its members is the defendant's ability to control significant economic interests, following *Ascherman* and other existing case law.
20. *Anton v. San Antonio Community Hospital*, 19 Cal. 3d 802, 823, 567 P. 2d 1162, 140 Cal. Rptr. 442 (1977); see also *Anton v. San Antonio Community Hospital*, 132 Cal. App. 3d 638, 183 Cal. Rptr. 423 (1982).
21. *Mathews v. Eldridge*, 424 U.S. 319, 335 96 S.Ct. 893, 963, 47 L.Ed. 2d 68 (1975).
22. *Stretten v. Wadsworth Veterans Hospital*, 537 F. 2d 361, 369, n.18 (9th Cir. 1976).
23. *Arnett v. Kennedy*, 416 U.S. 134, 94 S.Ct. 1633, 40 L.Ed. 2d 15.
24. *Pinsker v. Pacific Coast Society of Orthodontists*, 12 Cal. 3d 541, 555, 526 P. 2d 253, 116 Cal. Rptr. 245 (1974). See also *Tiholiz v. Northridge Hospital Foundation*, 151 Cal. App. 3d 1197, 11203, 199 Cal. Rptr. 338 (1984) (procedures must ensure physician is "treated fairly"); *Cipriotti v. Board of Directors*, 147 Cal. App. 3d 144, 152, 196 Cal. Rptr. 367 (1983) (procedural protections are designed to give the physician "an opportunity to confront the witnesses and evidence against him and to present his defense").
25. 42 U.S.C. §11112(b).
26. Cal. Bus. Prof. Code §809, *et seq.*
27. See, e.g., California Medical Association Model Medical Staff Bylaws.
28. See, e.g., *West Covina Hospital v. Superior Court (Tyus)*, 226 Cal. Rptr. 132 (1986), a California Supreme Court decision narrowly

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holding that the state's evidence code prohibition against discovery of peer review proceedings was no bar to a participant's *voluntary* testimony (i.e., that the privilege to protect such information could be waived).

29. See, e.g., *Jefferson Parish v. Hyde*, 466 U.S. 2 (1984); *Eszpeleta v. Sisters of Mercy Health Corp.*, 800 F.2d 119 (7th Cir. 1986); *Beard v. Parkview Hosp.*, 912 F.2d 138 (6th Cir. 1990); *Capital Imaging Associates v. Mohawk Valley Medical Association*, 791 F. Supp. 956 (N.D.N.Y. 1992); *Anne Arundel Gen. Hosp. v. O'Brien*, 432 A.2d 483 (Md. App. 1981); *Holt v. Good Samaritan Hosp.*, 590 N.E.2d 1318 (Ohio App. 1990); *Caine v. Hardy*, 943 F.2d 1406 (5th Cir. 1991).
30. The Joint Commission on Accreditation of Healthcare Organizations is one source of the requirement that medical staffs be self-governing. State laws also may require that the hospital not only recognize but also require independent governance of its professional staff. See, e.g., 22 Cal. Code Regs. §70701.
31. California provides such an absolute immunity to witnesses in a peer review proceeding (Cal. Civil Code §47(b)) and a qualified immunity to all participants who act without malice in the reasonable belief that the action is warranted by the facts (Cal. Civil Code §43.7). Federal law extends essentially the same protections under the Health Care Quality Improvement Act, 42 U.S.C. §11111, *et seq.*
32. Immunity is provided under the "safe harbor" provisions of the federal Health Care Quality Improvement Act of 1986 (42 U.S.C. §11111, *et seq.*) when the peer review body observes certain minimal standards for fair procedure and acts in good faith for the purpose of furthering quality health care. 42 U.S.C. §11112(a).
33. The NPDB was created by the Health Care Quality Improvement Act of 1986. Hospitals and other entities responsible for credentialing physicians are required not only to report to the NPDB when taking peer review actions, 42 U.S.C. §11132, but also to query the NPDB when granting or renewing a physician's privileges, 42 U.S.C. §11135. The Healthcare Integrity and Protection Data Bank was recently established under the provisions of the Health Insurance Portability and Accountability Act of 1996, 45 C.F.R. §61.1.