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AMBULATORY SURGERY CENTERS—MEDICAL CLINICS AND THE NATIONAL PRACTITIONER DATA BANK

ROBERT E. KUELTHAU*

With the advent of ambulatory surgery centers and the accelerating tendency of physicians, dentists, and related health care providers to coalesce into larger combinations and clinics, uncertainty has developed as to whether those entities are subject to the mandatory reporting provisions of, or are eligible for, the civil damage immunities granted by the Health Care Quality Improvement Act of 19861 ("HCQIA" or the "Act") and the regulations established pursuant to the Act.2 Those regulations, which became effective on October 17, 1989, established an information clearing house known as the National Practitioner Data Bank For Adverse Information on Physicians and Other Health Care Practitioners ("NPDB"). The Act generally requires hospitals, state medical boards, professional liability insurers, and specified other nonhospital health care entities to report to the NPDB certain disciplinary measures taken or payments made due to unprofessional or poor quality health care rendered by physicians and other health care practitioners. In Wisconsin, the uncertainty that has developed is evidenced by the failure of the Wisconsin Board of Medical Examiners (the board to which any reports required under the Act are to be sent) to receive its first Adverse Action Report from any such non-hospital entity, even though it is highly probable that at least some reportable adverse actions against physicians or dentists have been taken by such surgery centers and larger clinics in the more than four years since the NPDB was established.3

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2. 45 C.F.R. § 60 (1994).
3. Nationwide, in the period from September 1, 1990 (when the NPDB commenced operation) until March 31, 1995, the NPDB had received 114,455 Adverse Action and Malpractice Payment Reports, of which only 290 were from group medical practices. Since no separate reporting category for ambulatory surgery centers has been established, it is
Although the Act and the NPDB regulations have detailed provisions concerning state medical and dental boards, medical malpractice insurers, professional societies, and hospitals, as well as other health care entities and health care practitioners, the focus of this Article will be on whether provisions of the Act and the NPDB regulations are applicable to medical clinics and ambulatory surgery centers, and if they are, how they might affect the operation of those entities.

The HCQIA was enacted by Congress in response to a perceived need to improve the quality of medical care nationwide. It attempts to promote that goal by establishing mandatory reporting of certain licensure disciplinary actions and virtually all payments in settlement of any malpractice claim to the NPDB, and by encouraging more effective professional peer review of physicians, dentists, and other health care practitioners. These requirements are intended:

to improve the quality of health care by encouraging physicians, dentists and other health care practitioners to identify and discipline those who engage in unprofessional behavior and to restrict the ability of incompetent physicians, dentists, and other health care practitioners to move from State to State without disclosure or discovery of the practitioners' previous damaging or incompetent performances.4

The threat of private money damage liability under federal laws, including possible treble damages under applicable antitrust laws, was believed to discourage effective professional peer review and imposition of appropriate discipline. In response, the Act provides that professional review bodies of hospitals, professional societies, and other health care entities that follow the guidelines and procedures set forth in the Act

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assumed that reports from those entities have been included in the 6608 reports from Non U.S. Government hospitals and possibly also in the 1582 reports from Other Entities, Non U.S. Government. DIVISION OF QUALITY ASSURANCE, BUREAU OF HEALTH PROFESSIONS, HEALTH RESOURCES AND SERV. ADMIN., U.S. DEPT. OF HEALTH & HUMAN SERVS. (May 22, 1995).

It is interesting to note that in the period from September 1, 1990, through December 31, 1993, only 23% of Wisconsin's 143 hospitals submitted any Adverse Action Reports (which is only 2.1 reports per 1,000 hospital beds). OFFICE OF INSPECTOR GEN., U. S. DEP'T. OF HEALTH & HUMAN SERVS., HOSPITAL REPORTING TO THE NATIONAL PRACTITIONERS DATA BANK (Feb. 1995).

4. U.S. DEP'T OF HEALTH & HUMAN SERVS., NATIONAL PRACTITIONER DATA BANK GUIDEBOOK A-2 (hereinafter NPDB Guidebook). The original NPDB Guidebook was published by the U.S. Dep't of Health & Human Services shortly after the HCQIA regulations became effective. In August 1992, a Guidebook Supplement (NPDB GUIDEBOOK SUPPLEMENT) was issued, and in October 1994, a 1994 edition of the Guidebook (NPDB 1994 GUIDEBOOK) was published.
and the NPDB regulations will be immune from damages (except damages relating to the civil rights of any person or arising out of a government-commenced antitrust action) in private civil suits under both federal and state laws when disciplining a physician, if the disciplinary action taken as a result thereof is promptly reported to the NPDB. Should a professional society, hospital, or other health care entity fail to comply with the reporting requirements of the Act or not follow the guidelines and procedures prescribed by the Act, all persons connected with the peer review process lose their civil damage immunity for a three-year period.

It is important to note that "immunity from civil damages" is not synonymous with "immunity from civil suit." Thus, a disgruntled physician who believes that he she was damaged by an adverse professional review action could commence a lawsuit claiming a breach of some federal or state law or requesting an injunction or a declaratory judgment. However, if it is determined that the health care entity's professional review action did comply with the minimum standards for civil immunity, no civil damages could be assessed against that entity. Furthermore, if it is found that the entity complied with the statutory criteria and standards for its professional review action, and the entity substantially prevails in the lawsuit, and if the court finds that the "claim, or the claimant's conduct during the litigation of the claim was frivolous, unreasonable, without foundation, or in bad faith," the court may award


9. Austin v. McNamara, 979 F.2d 728, 733 (9th Cir. 1992).
to the prevailing entity “the cost of the suit attributable to such claim, including a reasonable attorney’s fee.”

For an ambulatory surgery center or medical clinic to be subject to the terms of the Act and the NPDB regulations, it must come within the definition of a “health care entity.” As defined by the United States Code, “health care entities” include “hospital[s] that [are] licensed to provide health care services by the State in which [they are] located,” and “an entity (including a . . . group medical practice) that provides health care services and that follows a formal peer review process for the purpose of furthering quality health care.” A “hospital” is further defined as an institution primarily engaged in providing physician-supervised medical care to persons on an “in-patient” basis. A “formal peer review process” is defined as the “conduct[ing] of professional review activities through formally adopted written procedures which provide for adequate notice and an opportunity for a hearing.” A “professional review activity” is defined to mean:

- an activity of a health care entity with respect to an individual physician—
  - (A) to determine whether the physician may have clinical privileges with respect to, or membership in, the entity,
  - (B) to determine the scope or conditions of such privileges or membership, or
  - (C) to change or modify such privileges or membership.

Since, by definition, ambulatory surgery centers serve patients who do not require overnight hospital care, they are not institutions primarily engaged in providing physician-supervised health care services to “in-patients” and, therefore, are not “hospitals” as defined within the Act.

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10. 42 U.S.C. § 11113 (1986). See Smith v. Ricks, 31 F.3d 1478 (9th Cir. 1994), where the hospital was awarded approximately $300,000 in attorneys fees and costs incurred in defending a physician’s meritless challenge to his medical staff termination.
13. 45 C.F.R. § 60.3 (1994).
14. 42 U.S.C. § 11151(10) (1988). It should be noted that 42 U.S.C. § 11151(8) defines and limits the term “physician” to include a “doctor of medicine or osteopathy or a doctor of dental surgery or medical dentistry.” However, the NPDB regulations erroneously attempt to expand the definition of a “professional review activity” to include an activity with respect to “other health care practitioners.” 45 C.F.R. § 60.3 (1994). “Health care practitioners” is separately defined at 41 U.S.C. § 11151(6) (1986).
Nevertheless, all ambulatory surgery centers and medical clinics are entities that provide health care services. The question, then, is whether those health care entities utilize a formal review process and engage in professional review activities that provide for “adequate notice” to the physician involved and an opportunity for that person to have a “hearing” if requested. The adequate notice and hearing requirements, set forth in detail in the Act, generally require that the physician or practitioner be given notice of any adverse action that has been proposed to be taken against the person, and that the notice set forth the reasons for that proposed action. The person must have at least thirty days to request a hearing and be given a summary of his or her rights. Persons who request a hearing must be given at least thirty days notice of the time, date, and place of the hearing. He or she must also be given a list of witnesses expected to testify at the hearing on behalf of the review body and has the right to be represented by an attorney or another person of his or her choice. It is important to note that although the Act does not require that an entity adopt the procedural guidelines set forth in the Act for adequate notice and hearing, if those guidelines are followed, the health care entity is deemed to have given adequate notice and hearing. If other notice and hearing procedures are used in connection with a peer review action, they will have no presumption of adequacy and will be subject to court review to determine whether the physician’s due process rights have been adequately protected.

Most, if not all, ambulatory surgery centers do have a formal peer review process included in their medical staff bylaws, which is utilized for determining initial and continued eligibility for medical staff membership and for the determination of the nature and scope of privileges to be granted to individual medical staff members. If the terms of the surgery center’s formal peer review process are sufficient to satisfy the minimum standards set forth in the Act, those ambulatory surgery centers would

17. Smith v. Ricks, 31 F.3d 1478, 1486 (9th Cir. 1994).

It is significant to note that even if the professional peer review groups’ activities do not satisfy the Act’s due process requirements, the Act does not provide for, and the courts will not imply, a private action against that peer review group by a physician claiming he or she was denied due process. Hancock v. Blue Cross-Blue Shield of Kan., Inc., 21 F.3d 373 (10th Cir. 1994); Goldsmith v. Harding Hosp., Inc., 762 F. Supp. 187 (S.D. Ohio 1991).
come within the statutory definition of a "health care entity." Thus, they would be subject to the provisions of the Act and the NPDB regulations and eligible for the immunity protection afforded by them.

Because of the great diversity in the size, organizational structure, and operating procedures of individual medical clinics, however, it is not safe to assume that all medical clinics are "health care entities" that are subject to and protected by the Act. Likewise, it cannot be assumed that all peer review or quality improvement programs of any individual clinic would sufficiently satisfy the procedural and notice requirements of the Act so that the persons participating in those programs would be eligible for the immunities granted thereby.

If a medical clinic or an ambulatory surgery center has in place and utilizes a formally adopted peer review policy that provides for adequate notice and hearing procedures, then the governing body and any committees of that entity which conduct a professional review activity in accordance with the NPDB regulations are eligible for immunity from civil damages in any private legal action based upon that peer review activity and any adverse "professional review action" resulting from it.19 This is also true in regard to any committee of the medical staff of that entity who assist in that review activity, any person acting as member or staff to that body, any person under a contract with the body, and any person who participates with or assists the body with respect to the activity.20 It should be noted that the "adequate notice and hearing procedures" do not have to be followed to obtain civil damage immunity during the investigation phase of a professional peer review activity21 where no adverse professional review action is taken against the physician, or if there is a suspension or restriction of clinical privileges for a period of not longer than fourteen days during which an investigation is being conducted to determine whether a professional review action is needed.22 In addition, the notice and hearing provisions of the Act do not preclude "an immediate suspension or restriction of clinical privileges, subject to subsequent notice and hearing or other adequate

19. 42 U.S.C. §§ 11111(a)(1), 11151(11) (1986). Federal and state civil damage immunity is also granted to any person "providing information to a professional review body regarding the competence or professional conduct of a physician . . . unless such information is false and the person providing it knew that such information was false." § 11111(a)(2).
A "professional review action" is defined 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 (which conduct affects or could affect adversely the health or welfare of a patient . . .), and which affects (or may affect) adversely the clinical privileges, . . . of the physician."24 If the professional review action taken by a professional review body was taken:

1) [in] the reasonable belief that the action was in furtherance of quality health care, (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 . . ., and (4) in the reasonable belief that the action was warranted by the facts known . . .,

then immunity from civil damages is granted. A review action is not considered to be based on the competence or professional conduct of a physician if the action is primarily based on any matter that does not relate to the professional competence or professional conduct of the physician involved.26

If an ambulatory surgery center or clinic has a formal peer review policy meeting the statutory minimum requirements, the question then becomes: What professional review actions taken in the implementation of that policy are required to be reported and to whom and when is the report to be submitted? The Act provides that an eligible health care entity must report the following professional review actions which are adverse to the physician:

[An] action based on the physician’s or dentist’s professional competence or professional conduct that adversely affects his or her clinical privileges for a period of more than 30 days.

Acceptance of the surrender or restriction of clinical privileges while the physician or dentist is under investigation or in return for not conducting [such] an investigation by the health care

23. Id. § 11112(c)(2).
24. Id. § 11151(9). Here again, the NPDB regulations erroneously attempt to expand the definition of a "professional review action" to include an action based on the conduct of other “health care practitioners.” 42 C.F.R. § 60.3 (1994).
entity relating to possible professional incompetence or improper professional conduct.\textsuperscript{27}

The term "adversely affects" is defined to include any actions which reduce, restrict, suspend, revoke, deny, or fail to renew clinical privileges or membership in a health care entity.\textsuperscript{28} Adverse actions involving censures, reprimands, or admonishments are not to be reported.\textsuperscript{29} The Guidebook published by the NPDB provides examples of reportable and non-reportable review actions including the following:

\textbf{Reportable Actions:}

A physician's application for medical staff appointment is denied based on the professional competence or conduct. (However, a denial based upon failure to meet the initial credentialing criteria applied to all medical staff or clinical privilege applicants is not reportable.)

A physician's request for clinical privileges is denied or restricted, based upon an assessment of his or her current clinical competence as defined by the health care entity.

A physician voluntarily restricts or surrenders his clinical privileges while his professional competence or conduct is under investigation, or in return for an agreement not to conduct an investigation of his professional competence and/or conduct.

Based on an assessment of his professional conduct, a proctor is assigned to a physician and the physician must be granted approval by the proctor before certain medical care is administered.

Although not specifically set forth as an example in the Guidebook, it is likely that the denial of membership in a medical clinic based on professional competence or conduct would also be a reportable action.

\textbf{Non-Reportable Actions:}

Based on an assessment of his professional competence, a proctor is assigned to supervise a physician, but a proctor is not required to grant approval before medical care is provided by the physician.

If a physician voluntarily restricts or surrenders his clinical privileges for personal reasons when his professional competence and/or conduct is not under investigation.

If a physician is denied medical staff appointment or clinical privileges because the health care entity already has too many

\textsuperscript{27} 42 U.S.C. § 11133(a)(1) (1986); NPDB GUIDEBOOK \textit{supra} note 4, at 25.

\textsuperscript{28} \textit{Id.} § 11151(1).

\textsuperscript{29} NPDB 1994 GUIDEBOOK, \textit{supra} note 4, at E-18.
specialists in the individual’s discipline.
If a physician’s privileges are suspended because of failure to complete a patient’s chart in accordance with the health care entity’s policy.\(^\text{30}\) Any revisions to previously reported adverse actions must also be reported.\(^\text{31}\)

For each reportable professional review action, the name of the physician involved and a description of the acts or omissions or other reasons for the action or, if known, for the surrender of privileges, must be submitted within fifteen days after the reportable action is taken. This information must be submitted in an NPDB Adverse Action Report Form to the appropriate board designated by the state for the purpose of monitoring and disciplining physicians and dentists. The state board is then responsible for submitting that report directly to the NPDB, and to the appropriate state licensing board, if necessary, within fifteen days from the date of its receipt of the report.\(^\text{32}\) If a health care entity fails to submit the required adverse action report, then, after notice and an opportunity to cure that failure, that health care entity will lose its peer review immunity protection for professional review actions it takes against physicians and dentists for three years.\(^\text{33}\)

The peer review policies and activities of ambulatory surgery centers and clinics are primarily concerned with the professional competence and conduct of their physicians. Nevertheless, there are undoubtedly occasions when the professional competence and conduct of one of their nonphysician licensed health care practitioners is reviewed and some adverse action is taken affecting that person’s clinical privileges and his or her continued membership in that surgery center or clinic. As defined in the Act, a “licensed health care practitioner” is “an individual (other than a physician) who is licensed or otherwise authorized by the State to provide health care services.”\(^\text{34}\) Any adverse professional review action taken pursuant to a formal peer review process which the health care entity would be required to report if the practitioner was a physician may be reported in the case of a licensed health care practitioner who is not a physician.\(^\text{35}\) It is important to note, however, that while the peer review body will be immune from any damages which might result from

\(^\text{30}\) Id. at E-22-23.
\(^\text{31}\) 45 C.F.R. § 60.6(b) (1994); NPDB 1994 GUIDEBOOK, supra note 4, at E-6.
\(^\text{32}\) 45 C.F.R. § 60.5(c) (1994).
\(^\text{33}\) 42 U.S.C. § 11111(b) (1986).
\(^\text{34}\) Id. § 11151(6).
\(^\text{35}\) Id. § 11133(a)(2).
the submission of that report, the HCQIA does not provide civil damage immunity for any action taken by that body against the licensed health care practitioner.\textsuperscript{36}

To further facilitate the availability to hospitals and other health care entities of any adverse information concerning the professional incompetence of health care providers, the Act has established other requirements as well. It mandates that any entity (regardless of whether they are otherwise subject to any provisions of the Act or the NPDB regulations) that makes any payment for the benefit of a physician, dentist, or licensed health care practitioner in settlement of, or in satisfaction of, a written complaint or claim for payment of monetary damages against such person based on that person’s provision, or failure to provide, health care services, must simultaneously report that payment to the National Practitioner Data Bank and the appropriate state board.\textsuperscript{37} Such payment must be reported within thirty days after the date the payment was made.\textsuperscript{38}

Most malpractice claims are settled and paid directly to the claimant by an entity's malpractice insurer who then reports such payments. Still,

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  \item \textsuperscript{37} 42 U.S.C. §§ 11131(a), 11134 (1986). It should be noted that, while the initial NPDB regulations, 45 C.F.R. §§ 50.1, 60.7(a) (1994) required reporting of such payments by “individuals” and “any person or entity,” the Act, 42 U.S.C. § 11131(a) (1986), refers only to an “entity” that makes such a payment for the benefit of a physician. Moreover, a United States district court held that “entity” as used therein refers only to groups and organizations, and does not extend to individual physicians or dentists. American Dental Ass'n v. Shalala. 3 F.3d 445, 446-47 (D.C. Cir. 1993). The revised NPDB 1994 Guidebook, issued in October 1994, at page E-10, citing that decision, acknowledges that, despite the language of the initial regulation, individual practitioners no longer will be required to report to the NPDB any payments they make on their own behalf. As a result of that decision, §§ 60.2 and 60.7 of the initial regulations were amended effective as of December 1, 1994, “to require reporting only by entities which make medical malpractice payments, deleting the reference to reporting by persons (individuals).” 59 Fed. Reg. 61,554 (1994).
  \item Also, although 42 U.S.C. § 11131(b) requires that the report of a malpractice payment include “the name of any physician or licensed health care practitioner for whose benefit the payment is made,” through various artifices group medical practices and other medical corporations frequently omit the names of the physician for whom malpractice payments are made.
  \item The Health Resources and Services Administration, however, has drafted legislation, which thus far has not been introduced, that would restrict the impact of the Shalala decision by expressly requiring individual physicians and dentists to report payments made by them in settling malpractice claims or judgments, including fee refunds, and by requiring all reporting entities to identify the practitioner for whom a malpractice payment is made if it is reasonably possible to do so. 3 Health Rep. (BNA) 5 (Jan. 6, 1994).
  \item 42 U.S.C. §§ 11131(a), 11134(1986).
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in instances where a claim may be settled for amounts less than the entity’s insurance deductible, individual health care entities may settle claims and make payments directly to or for the benefit of a claimant without involving the entity’s insurance carrier. Under those circumstances, and in instances where the health care entity pays the insurance deductible portion of larger settlement amounts directly to the malpractice claimant, the entity making the payment must report any such payments. Those reports must be filed regardless of whether the payment was as a result of an out-of-court settlement, arbitration, or court judgment, and even though the settlement or court judgment includes a stipulation that the terms thereof be kept confidential. Failure to promptly report any such payment can result in a civil penalty of up to $10,000.00 for each failure.

Surgery centers and large clinics should also be cognizant of the fact that all information reported to and received from the NPDB is considered to be confidential and cannot be disclosed except as specified in the NPDB regulations. Therefore, appropriate action must be taken by surgery centers and clinics to ensure that any reports to, or information received from, the NPDB on their physicians, dentists, or licensed health care practitioners are utilized only for purposes of carrying out a professional review activity within that entity. That information can be disclosed to professionals involved in a peer review activity, but those individuals, and all persons and entities who receive NPDB information, directly or indirectly, are subject to the confidentiality provisions of the Act. Disclosure of such information, even in response to a court-ordered subpoena, is considered to be an improper disclosure and a violation of the confidentiality provisions of the Act. For each violation of confidence, a civil penalty of up to $10,000.00 can be imposed upon each individual or entity responsible for the improper disclosure of that information.

39. NPDB Guidebook, supra note 4, at 42.
41. Id. § 11137(b)(1), (3). It is important to note that only information actually reported to and received from the NPDB is declared to be confidential and cannot be disclosed. In the absence of a reporting of information to the NPDB, information from peer review proceedings is not privileged under the Act. (However, it may be privileged and nondiscoverable under applicable state law. Wis. Stat. § 146.38 (1993-94)). It has been held that even information reported to the NPDB is discoverable in federal antitrust actions. Wei v. Bodner, 127 F.R.D. 91, 99 (D.N.J. 1989), aff'd, 983 F.2d 1054 (3d Cir. 1992).
42. 45 C.F.R. § 60.13 (1994); NPDB 1994 GUIDEBOOK, supra note 4, at A-4.
43. NPDB GUIDEBOOK SUPPLEMENT, supra note 4, at 29.
Presently, ambulatory surgery centers and clinics in Wisconsin and most states have to be concerned only with their limited obligations under federal law to report questionable professional competence and conduct of health care practitioners. That may not be true in the future, however. At least one state, Minnesota, has a very broad statute that requires all health care institutions and organizations to report to their state board "any action taken by the institution or organization or any of its committees . . . to revoke, suspend, restrict, or condition a physician's privilege to practice or treat patients in the institution, or as part of the organization, any denial of privileges, or any other disciplinary action." All such reports are confidential, and the person making the report is given immunity to civil liability and criminal prosecution.

In discussions of those professional reporting requirements with the personnel of the Wisconsin Medical Examining Board, this author has been informed that a law similar to the above-quoted Minnesota statute was proposed for adoption in the 1995 session of the Wisconsin legislature.

Until Wisconsin imposes more stringent reporting requirements on all health care professionals, and based upon the foregoing analysis of the HCQIA and the NPDB regulations, it is likely that most ambulatory surgery centers and large medical clinics, because of their peer review policies, are required to comply with the somewhat more limited, but still quite substantial, requirements of the HCQIA and the NPDB regulations. Thus, those entities should consider a review of all their professional quality review policies and procedures to determine whether they should be revised to include the formalities specified in the Act and the NPDB regulations so as to be eligible for civil damage immunity in connection with actions taken pursuant to those policies. For their own protection, they should also consider querying the NPDB about adverse reports on any physician, dentist, or health care practitioner when they are about to enter into an employment or affiliation relationship with the person or when such a person applies for medical staff appointment or

45. MINN. STAT. §147.111(2) (1985). Another subsection of that statute, 147.111(4), imposes a similar obligation on each individually licensed health care professional by requiring that they report to their state board "personal knowledge of any conduct which the person reasonably believes constitutes grounds for disciplinary action . . . by any physician, . . . including any conduct indicating that the person may be medically incompetent, or may have engaged in unprofessional conduct or may be medically or physically unable to engage safely in the practice of medicine."

46. MINN. STAT. § 147.121 (1985).
Finally, if those entities want to obtain the civil immunities granted by the Act and avoid potential substantial civil penalties, they should report specified professionally adverse actions taken against a physician or a dentist and any and all amounts paid in settlement of a claim against one of their physicians, dentists, or other health care practitioners. They should also maintain as confidential all reports made by them to, and all information received by them from, the NPDB.

47. At present, ambulatory surgery centers and medical clinics have no duty under the Act to request information from the NPDB about a physician or other licensed health care practitioner who is being considered for membership in, or staff privileges at, that entity. However, at least one commentator has suggested that, because of the readily available information concerning the person’s professional background through the NPDB and the minimal cost of obtaining said information, the courts might find those entities negligent for not requesting any available NPDB information on said person before granting membership or staff privileges. Pugsley, Implementing the Health Care Quality Improvement Act, 23 J. HEALTH & HOSP. L. 42, 50 (1990).