[J-7-2021]
IN THE SUPREME COURT OF PENNSYLVANIA
WESTERN DISTRICT

BAER, C.J., SAYLOR, TODD, DONOHUE, DOUGHERTY, WECHT, MUNDY, JJ.

JAMES E. LEADBITTER AND TAMMY M. LEADBITTER, HIS WIFE	:	No. 19 WAP 2020
	:	Appeal from the Order of Superior Court
v.	:	entered on 2/12/20 at No. 1414 WDA 2018 affirming the order of the Court of Common Pleas of Allegheny County
KEYSTONE ANESTHESIA CONSULTANTS, LTD., A CORPORATION, CHRISTOPHER MERCK, D.O., AJOY KATARI, M.D., JOHN P. WELDON, M.D., LAURA V. MCNEILL, M.D., AND ST. CLAIR HOSPITAL	:	entered 9/17/18 at No. G.D. 16-10700
	:	ARGUED: March 9, 2021
v.	:	
CARMEN PETRAGLIA, M.D. AND SOUTH HILLS ORTHOPAEDIC SURGERY ASSOCIATES, A CORPORATION	:	
APPEAL OF: ST. CLAIR HOSPITAL	:	

OPINION

JUSTICE SAYLOR **DECIDED: AUGUST 17, 2021**

This discretionary appeal concerns discovery in a medical negligence lawsuit in which the patient suffered complications following surgery at a hospital. The issue is whether certain portions of the hospital's credentialing file for the doctor who performed the surgery are protected from discovery. The hospital claims protection under the Peer Review Protection Act and the federal Health Care Quality Improvement Act.

I. Background

In mid-2014, Carmen Petraglia, M.D., applied to be appointed to the medical staff of Appellant St. Clair Hospital (the "Hospital"). He also applied for orthopedic surgery clinical privileges. In considering these applications, the Hospital's credentials committee reviewed a variety of information and documentation, and it ultimately recommended that these requests be granted. In September 2014, Dr. Petraglia accepted appointment to the Hospital's medical staff with delineated clinical privileges in the Department of Surgery, Section of Orthopedic Surgery.[1]

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[1] In its pleadings, the Hospital asserted that Dr. Petraglia was not employed by the Hospital, but rather, maintained staff privileges there. *See* Answer and New Matter to Plaintiffs' First Amended Complaint at ¶18, *reprinted in* RR. 104a-105a.

Along these lines, this Court has observed that, "in most cases doctors with hospital privileges are not employees of the hospital, instead, they are independent contractors who must be granted permission to admit patients and make use of the hospital's resources." *Cooper v. Del. Valley Med. Ctr.*, 539 Pa. 620, 628, 654 A.2d 547, 551 (1995) (citing Timothy Stoltzfus Jost, *The Necessary & Proper Role of Regulation to Assure the Quality of Health Care*, 25 HOUS. L. REV. 525, 553 (1988)). *See generally* Craig W. Dallon, *Understanding Judicial Review of Hospitals' Physician Credentialing & Peer Review Decisions*, 73 TEMP. L. REV. 597, 599-604 (2000) (providing a brief sketch of the history of hospitals and professional staffing). One reference work explains that

> [t]he term medical staff in the context of a hospital refers to an organized body of licensed physicians . . ., dentists . . ., and other healthcare providers (including podiatrists and psychologists) who are authorized by state law and by a hospital through its medical staff Bylaws to provide medical care to patients within the hospital. Some hospitals include allied health professionals (e.g., nurse practitioners, physician assistants, surgical assistants, and doctors of pharmacy) and postgraduate trainees (e.g., residents and fellows) within the term medical staff . . .. Furthermore, although a significant portion of the hospital's medical staff may be employees of the hospital, the majority are not employees.

Mehrnaz Hadian, *et al.*, WHAT IS . . . MEDICAL STAFF PEER REVIEW §1.1, 2019 A.B.A. SEC. HEALTH LAW (footnote omitted, title ellipsis in original).

During the next few months, Dr. Petraglia examined plaintiff James Leadbitter and recommended spinal surgery. He performed the surgery during a two-day period at the Hospital in mid-January 2015. Shortly thereafter, Leadbitter suffered a series of strokes, resulting in numerous impairments including permanent brain damage.

Leadbitter and his wife ("Plaintiffs") filed a complaint raising, *inter alia*, claims of negligence against multiple defendants, including the Hospital, and vicarious liability and corporate negligence against the Hospital. In the latter claim, Plaintiffs alleged the Hospital's credentialing and privileging process was inadequate, and that it knew or should have known Dr. Petraglia lacked the expertise to be authorized to perform the surgery in question. *See* First Amended Complaint at ¶76, *reprinted in* RR. 88a-92a.

In March 2017, Plaintiffs served on the Hospital a first set of interrogatories and request for documents seeking the complete credentialing and/or privileging file for Dr. Petraglia. The Hospital responded by supplying much of the requested file, but it withheld or redacted several documents. After this Court decided *Reginelli v. Boggs*, 645 Pa. 470, 181 A.3d 293 (2018) – which held, among other things, that the evidentiary privilege set forth in Pennsylvania's Peer Review Protection Act (the "PRPA")[2] applies to the documents of a "review committee" but not to the documents of all "review organizations," *see id*. at 490, 181 A.3d at 305-06 – Plaintiffs asked the Hospital to produce the complete, unredacted file. In the event of incomplete production, Plaintiffs asked the Hospital to include with its response a privilege log identifying any documents withheld, the reasons they were withheld, and the reasons for any redactions appearing in the documents supplied. The Hospital responded by providing additional portions of the file, together with a privilege log.

[2] Act of July 20, 1974, P.L. 564, No. 193 (as amended 63 P.S. §§425.1-425.4).

According to the privilege log, the Hospital believed that five documents in Dr. Petraglia's file were non-discoverable: an OPPE (Ongoing Professional Practice Evaluation) Summary Report; a Professional Peer Review Reference and Competency Evaluation, which contained evaluations prepared by other physicians of Dr. Petraglia's performance; and three documents described as "National Data Bank Practitioner Query Response," based on queries submitted to the National Practitioner Data Bank (the "NPDB") in July 2014, December 2014, and January 2017. *See* Contents of Non-Discoverable Portions of Credentials File of Carmen Petraglia, M.D., *reprinted in* RR. 337a; *see also* Response in Opposition to Plaintiff's [sic] Motion to Compel Discovery, at ¶9, *reprinted in* RR. 360a. In addition to withholding these documents, the Hospital redacted from three documents that it provided to Plaintiffs information which the Hospital characterizes as professional opinions relating to Dr. Petraglia's competence. *See* Brief for Appellant at 14.

Unsatisfied with the Hospital's response, Plaintiffs filed a motion to compel, seeking the entire, unredacted file. In its responsive pleading, the Hospital alleged it had withheld or redacted materials that were privileged or did not pertain to the time period encompassed by the request. The Hospital claimed such materials were protected from disclosure under the PRPA or, in the case of the NPDB query responses, by the federal Health Care Quality Improvement Act of 1986 (the "HCQIA").[3]

After oral argument on the motion, the county court granted it, expressly relying on *Reginelli*, and directing the Hospital to produce Dr. Petraglia's credentialing file in full and without redactions. In its Rule 1925(a) opinion, *see* Pa.R.A.P. 1925(a), the court stated that, per its reading of *Reginelli*, files relating to a doctor's membership or

[3] Pub. L. 99-660, Title IV, §§402-432 (as amended 42 U.S.C. §§11101-11152). The HCQIA is discussed in Part III of this opinion.

continued membership on a hospital's medical staff constitute credential-review files (as opposed to peer-review files) and, as such, are not protected by the PRPA. It also concluded that, because the information requested from the NPDB was part of that same file, it too was unprotected. *See Leadbitter v. Keystone Anesthesia Consultants, Ltd.*, No. GD 16-10700, *slip op*. at 2-3 (C.P. Allegheny Nov. 26, 2018).

The Hospital filed an interlocutory appeal, arguing that the trial court erred in finding that PRPA does not protect from disclosure the professional opinions and performance evaluations that the credentials committee reviewed, reasoning that the materials constitute peer-review documents subject to PRPA's protection. The Hospital also asserted that the court mistakenly compelled it to produce the NPDB query responses notwithstanding HCQIA's protections.

The Superior Court affirmed in a published decision. *See Leadbitter v. Keystone Anesthesia Consultants, Ltd.*, 229 A.3d 292 (Pa. Super. 2020). The court indicated that the documents at issue constituted professional evaluations that the committee considered before granting Dr. Petraglia surgery privileges – and, as such, that they fit the PRPA's definition of peer-review documents. *See id*. at 296 (citing 63 P.S. §425.2). However, the court understood *Reginelli* as holding that only documents of a "review committee" enjoyed the statutory protection, and not documents kept by a "review organization," regardless of the nature of such documents. Thus, the court found that, as the credentials committee was a review organization, the PRPA did not shield any portion of its file on Dr. Petraglia from discovery. *See id*. It added that this Court may wish to grant review to address the propriety of its analysis on this point because, in the Superior Court's view, *Reginelli* "assumed that documents in a credentialing file are not peer review documents." *Id*. at 297 n.7.

As for the NPDB information, the court largely tracked the reasoning of the common pleas court, stating that because no aspect of the committee's file was protected under the PRPA, the NPDB documents were similarly unprotected under the HCQIA. In reaching this holding, the Superior Court relied on a provision of the HCQIA which indicates that nothing in its conferral of confidentiality is meant to prevent disclosure, by a party which is otherwise authorized under state law to make such disclosure, of information reported pursuant to the HCQIA. *See id*. at 297-98 (quoting 42 U.S.C. §11137(b)(1); 45 C.F.R. §60.20(a)).

This Court allowed further review to consider the following issues as framed by the Hospital:

> (1) Whether the Superior Court's holding directly conflicts with the Pennsylvania Peer Review Protection Act, 69 P.S. §§ 425.1, *et seq.*, and misapplies *Reginelli v. Boggs*, 645 Pa. 470, 181 A.3d 293 (2018), by ordering the production of acknowledged "peer review documents" solely because they were maintained in a physician's credentialing file?
>
> (2) Whether the Superior Court's holding directly conflicts with the Federal Healthcare Quality Improvement Act, 42 U.S.C. § 11137(B)(1), and federal regulations which protect from disclosure, responses to statutorily-required inquiries of the national practitioner data bank, by ordering the production of such documents solely because they were maintained in physician's credentialing file?

Leadbitter v. Keystone Anesthesia Consultants, Ltd., ___ Pa. ___, ___, 239 A.3d 11, 12 (2020) (*per curiam*).

II. The PRPA

Before discussing the reasons the Hospital believes the Superior Court erred, it is helpful to review certain aspects of the PRPA and the *Reginelli* decision.

The purpose underlying the PRPA has been articulated in prior decisions. Briefly, the enactment stems from the dual observations that: the practice of medicine

is highly complex and, as such, the medical profession is in the best position to police itself, *see Reginelli*, 645 Pa. at 481, 181 A.3d at 300; and, the profession's self-regulation is accomplished, at least in part, through a peer-review mechanism undertaken to determine whether a particular physician should be given clinical privileges to perform a certain type of medical activity at a hospital, *see Cooper v. Del. Valley Med. Ctr.*, 539 Pa. 620, 628, 654 A.2d 547, 551 (1995); *see also id*. ("The purpose of this privilege system is to improve the quality of health care . . .. Thus, it is beyond question that peer review committees play a critical role in the effort to maintain high professional standards in the medical practice.").

Against this background, the PRPA is designed to foster candor and frankness in the creation and consideration of peer-review data by conferring immunity from liability, as well as confidentiality – all with the objectives of improving the quality of care, reducing mortality and morbidity, and controlling costs. *See McClellan v. HMO of Pa.*, 546 Pa. 463, 472, 686 A.2d 801, 805 (1996) (Opinion in Support of Affirmance) (quoting *Robinson v. Magovern*, 83 F.R.D. 79, 87 (W.D. Pa. 1979)); *accord Reginelli*, 645 Pa. at 481, 181 A.3d at 300. *See generally* 63 P.S. §425.2 (definition of "Review Organization"); Act 193 of 1974, Title (indicating that the PRPA is an act "[p]roviding for the increased use of peer review groups by giving protection to individuals and data who report to any review group"). These types of protections are viewed as helpful in fostering effective peer review because of the perceived reluctance of members of the medical community to criticize their peers and take corrective action. One court has explained that physicians

> seem to be reluctant to engage in strict peer review due to a number of apprehensions: loss of referrals, respect, and friends, possible retaliations, vulnerability to torts, and fear of malpractice actions in which the records of the peer review proceedings might be used. It is this

> ambivalence that lawmakers seek to avert and eliminate by shielding peer review deliberations from legal attacks.

Cruver v. Love, 599 So. 2d 111, 115 (Fla. 1992) (quoting Gregory G. Gosfield, *Medical Peer Review Protection in the Health Care Industry*, 52 TEMP. L.Q. 552, 558 (1979)). Additionally, absent such protections medical practitioners may fear antitrust claims by a sanctioned doctor, as peer-reviewers may be actual or potential competitors with the doctors they review. *See* James F. Blumstein & Frank A. Sloan, *Antitrust & Hosp. Peer Review*, 51 LAW & CONTEMPORARY PROBLEMS 7, 15 (1988).

Beyond its short-title provision, *see* 63 P.S. §425.1, the PRPA has a definitional section, *see id*. §425.2, and two substantive-protection provisions: an immunity-from-liability provision, *see id*. §425.3 (granting immunity from civil and criminal liability to persons who provide information to review organizations), and a confidentiality-and-testimonial-privilege provision, *see id*. §425.4. The definitional section defines four terms: "peer review," "professional health care provider," "professional society," and "review organization."[4] The definition of "review organization," and the confidentiality aspect of the statute, were primarily at issue in *Reginelli*, and they are primarily at issue in this dispute. Accordingly, these provisions are set forth below:

> **"Review organization"** means [(1)] any committee engaging in peer review, including a hospital utilization review committee, a hospital tissue committee, a health insurance review committee, a hospital plan corporation review committee, a professional health service plan review committee, a dental review committee, a physicians' advisory committee, a veterinary review committee, a nursing advisory committee, any committee established pursuant to the medical assistance program, and any committee established by one or more State or local professional societies, to gather and review information relating to the care and treatment of patients for the purposes of (i) evaluating and improving the quality of health care rendered; (ii) reducing morbidity or mortality; or (iii) establishing and enforcing guidelines designed to keep within reasonable

[4] Although the PRPA defines "professional society," it does not use that term.

> bounds the cost of health care. [(2)] It shall also mean any hospital board, committee or individual reviewing the professional qualifications or activities of its medical staff or applicants for admission thereto. [(3)] It shall also mean a committee of an association of professional health care providers reviewing the operation of hospitals, nursing homes, convalescent homes or other health care facilities.

63 P.S. §425.2. As can be seen, the definition is set forth in three distinct sentences which contemplate three different types of bodies. Confidentiality in relation to records held by review committees is conferred by Section 4 of the act as follows:

> **§425.4. Confidentiality of a review organization's records**
>
> The proceedings and records of a review committee shall be held in confidence and shall not be subject to discovery or introduction into evidence in any civil action against a professional health care provider arising out of the matters which are the subject of evaluation and review by such committee and no person who was in attendance at a meeting of such committee shall be permitted or required to testify in any such civil action as to any evidence or other matters produced or presented during the proceedings of such committee or as to any findings, recommendations, evaluations, opinions or other actions of such committee or any members thereof: Provided, however, [t]hat information, documents or records otherwise available from original sources are not to be construed as immune from discovery or used [sic, use] in any such civil action merely because they were presented during proceedings of such committee, nor should any person who testifies before such committee or who is a member of such committee be prevented from testifying as to matters within his knowledge, but the said witness cannot be asked about his testimony before such a committee or opinions formed by him as a result of said committee hearings.

63 P.S. §425.4.

Although the section's title suggests it pertains to *review organizations*,[5] the substantive text sets forth confidentiality mandates and testimonial privileges relating to the work and records of *review committees*. It may be observed that the term "review

[5] Other than the Purdon's section number (425.4), the section title as it appears above was included in the bill passed by the General Assembly in 1974. *See* PRPA §4.

committee" as it is used in the above provision is not textually limited to peer-review committees, and that various types of committees which engage in some sort of review are mentioned in all three sentences of the definition of "review organization." Still, the majority holding in *Reginelli* was based on the concept that "review committee" as the term appears in Section 4 is limited to committees which engage in peer review, *see Reginelli*, 645 Pa. at 486 n.8, 488, 181 A.3d at 303 n.8, 304, and the parties do not presently ask this Court to reconsider that facet of the decision.

The distinction between a "review organization" and the entity referred to in Section 4 as a "review committee" came into focus in *Reginelli*. In that matter, the Court addressed an argument by Monongahela Valley Hospital ("MVH") that an individual doctor, Dr. Walther, who served as the director of MVH's emergency department – and who prepared and maintained records concerning the subject physician – was either a "review committee" or a "review organization" in and of herself. MVH noted that the PRPA's definition of "review organization" includes "any hospital board, committee *or individual* reviewing the professional qualifications or activities of its medical staff or applicants for admission thereto." 63 P.S. §425.2 ("review organization" definition, Sentence 2) (emphasis added).

This Court acknowledged that Dr. Walther may have been a review organization per Sentence 2 of the definition, but it made two salient observations. First, "individuals" and "committees" are distinct entities as contemplated by the statutory text which lists both words as examples of a "review organization" in Sentence 2. Because the confidentiality directive of Section 4 expressly applies to review committees but not more broadly to all review organizations, even if Dr. Walther could be considered a review organization (again, per Sentence 2), this alone would be insufficient to invoke Section 4's protections. *See Reginelli*, 645 Pa. at 489-90, 181 A.3d at 305-06.

Second, the Court highlighted a distinction between what it termed *credentials* review – *i.e.*, analyzing a person's "professional qualifications or activities," 63 P.S. §425.2 ("review organization" definition, Sentence 2) so as to decide whether to appoint (or reappoint) that person to a hospital's medical staff – and *peer* review as that term is referred to in Sentence 1 of the definition of a "review organization."[6] Expressing that peer review is "limited to the evaluation of the 'quality and efficiency of services ordered or performed' by a professional health care provider," *Reginelli*, 645 Pa. at 490, 181 A.3d at 305 (quoting 63 P.S. §425.2 ("Peer review" definition)), the Court continued that such actions are "markedly different" from credentials review as contemplated by Sentence 2. *Reginelli*, 645 Pa. at 490, 181 A.3d at 305.[7]

Notably, since *Reginelli* was decided, the Superior Court has tended to focus on the type of committee whose records are being sought when deciding whether the

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[6] PRPA defines "peer review," in relevant part, as

> the procedure for evaluation by professional health care providers of the quality and efficiency of services ordered or performed by other professional health care providers, including practice analysis, inpatient hospital and extended care facility utilization review, medical audit, ambulatory care review, claims review, and the compliance of a hospital, nursing home or convalescent home or other health care facility operated by a professional health care provider with the standards set by an association of health care providers and with applicable laws, rules and regulations.

63 P.S. §425.2.

[7] Because credentials review analyzes a person's "professional qualifications or activities," implicit in the above distinction is the premise that a doctor's "professional activities" do not include the "services" he or she performs, as such services are, by definition, the subject of peer review. *See* 63 P.S. §425.2 ("Peer review" definition). The dissent suggested that "professional activities" includes health care delivery, and hence, "professional qualifications and activities" is not limited to professional credentials. *See Reginelli*, 645 Pa. at 504, 181 A.3d at 314 (Wecht, J., dissenting).

PRPA's protections apply. *See Leadbitter*, 229 A.3d at 296 ("[T]o determine the applicability of the PRPA privilege, we must consider whether a 'review organization' or a 'review committee' reviewed the professional evaluations of Dr. Petraglia."); *Ungurian v. Beyzman*, 232 A.3d 786, 800-01 (Pa. Super. 2020) (holding the PRPA's protections did not apply because the entity possessing the documents in question was a credentialing committee); *Estate of Krappa v. Lyons*, 211 A.3d 869, 875 (Pa. Super.) (expressing that the "PRPA's protections do not extend to the credentialing committee's materials, because this entity does not qualify as a 'review committee.'"), *allocatur denied*, ___ Pa. ___, 222 A.3d 372 (2019) (*per curiam*).

Turning to the present controversy, the Hospital's central position is that the work of a credentials committees is multi-faceted and it includes peer review. The Hospital proffers that medical malpractice lawsuits in which the treatment took place at a hospital routinely involve a claim of corporate negligence against the hospital, which has a non-delegable duty to ensure that the doctors who deliver health care within its walls are competent. *See* Brief for Appellant at 51. *See generally Thompson v. Nason Hosp.*, 527 Pa. 330, 339-40, 591 A.2d 703, 707 (1992). The Hospital continues that, in light of that duty, a hospital's review for appointment or re-appointment to its medical staff with delineated clinical privileges will necessarily include both verification of the applicant's objective credentials (such as academic degrees, state-level licensure, and board certifications) and peer review of the applicant's work in practice. As a result, the Hospital states, its records are privileged under the PRPA to the extent they reflect the credentials committee's activities which are in the nature of peer review – as the credentials committee will then have been a committee engaged in peer review as understood by *Reginelli*.

Thus, according to the Hospital, denying confidentiality to peer-review materials based solely on a committee's label as a credentials committee fails to comport with a realistic understanding of how such bodies operate, and fails to protect the confidentiality of peer-review materials as intended by the General Assembly. In this latter regard, the Hospital advances that the peer-review aspect of credentials review would be undermined, to the detriment of patient safety and quality of care, if the hospital could not rely on candid and accurate assessments, by a physician's peers, of the doctor's past performance. It maintains that the possibility such assessments could be chilled if peer-level reviewers knew their evaluations might be disclosed during litigation is among the very considerations that motivated the Legislature to enact the PRPA in the first instance. *See* Brief for Appellant at 21-31 & n.3, 35, 37, 47-51; Reply Brief for Appellant at 11-13.

With this background, the Hospital frames the question before this Court as whether a credentials committee is entitled to the PRPA's protections to the extent it performs a peer-review function – and, in particular, whether the Hospital's credentials committee was engaged in peer review when it reviewed the specific materials relating to Dr. Petraglia which it redacted or withheld as set forth in the privilege log. The Hospital endorses an affirmative answer to both questions. *See id*. at 32, 35.

Plaintiffs agree that protecting patient safety is a paramount goal of hospital credentials committees, but they warn against giving too much secrecy to the procedures used by such committees when deciding whether to grant clinical privileges to specific physicians. Plaintiffs suggest that shielding peer review materials understood in an overly broad sense could lead to hospitals acting unethically by granting privileges to less-than-competent practitioners based on those individuals' personal connections or potential to generate revenue for the hospital – which, they

argue, would jeopardize patient safety as much as would chilling peer review through under-protection. *See* Brief for Appellees at 37-39;[8] *cf.* Blumstein & Sloan, *Antitrust & Hosp. Peer Review*, 51 LAW & CONTEMPORARY PROBLEMS at 14 (stating that potential civil liability from alleged medical malpractice provides hospitals with an incentive to monitor quality effectively).

Further, Plaintiffs assert that the party claiming a privilege bears the burden of demonstrating that it applies, and they highlight that the definition of "peer review" is limited to the procedure for evaluation, by professional health care providers who are licensed in Pennsylvania, of the quality and efficiency of services ordered or performed by other professional health care providers who are licensed to practice, or otherwise regulated to practice or operate in the health care field, under Pennsylvania law. In terms of the precedent set by *Reginelli*, Plaintiffs read that decision as establishing a bright-line rule that the PRPA's protections do not apply to the credentialing process and are "not available to hospital boards, committees, or individuals engaged in the process of credentialing and privileging members of its medical staff or applicants thereto," regardless of whether those entities undertake peer review in their decision-making process. Brief for Appellees at 16.

Beyond this, Plaintiffs focus on the nature of the documents in question, and they contend that the record does not support the Hospital's invocation of the PRPA privilege as to any of them. Plaintiffs take issue with the redactions appearing on three

[8] *See generally* American Medical Association Code of Medical Ethics, Council on Ethical and Judicial Affairs, Opinion 9.5.2 (as renumbered in 2016) (indicating that a grant of privileges should be grounded on the candidate's training, experience, and demonstrated competence, the availability of facilities, and "the overall medical needs of the community, the hospital, and especially patients" – and that it should not be based on any of the following: the number of patients the candidate has admitted to the facility; the economic or insurance status of the patients admitted by the candidate; or "personal friendships, antagonisms, jurisdictional disputes, or fear of competition").

documents and the withholding of five additional documents. In terms of the former, Plaintiffs contest redactions on: page 3 of Dr. Petraglia's application for appointment to the Hospital's medical staff, *see* R.R. 131a, 204a (showing redactions of peer-reference identities); a printout of a page from the Hospital's credential-tracking computer system, which shows affiliations, employment, and peer references, *see* RR. 260a (reflecting redactions of various portions of the printout); and the Hospital's Initial Applicant Interview Report form, which memorializes the results of a telephone interview with Dr. Petraglia, as well as a file review, conducted by Brett Perricelli, M.D., *see* RR. 150a, 223a (displaying redactions of contents under the labels, "Topics Reviewed," "Adequacy of Answers," and "Additional Comments").

As for the five withheld documents, the three NPDB query responses are discussed in Part III below. The other two, as noted, are a Professional Peer Review Reference and Competency Evaluation and an OPPE Summary Report. *See* RR. 337a. In a portion of their argument which seems to apply to some of the redactions and the competency evaluation, Plaintiffs argue the Hospital has not established the letters of reference or Dr. Perricelli's comments concerning the interview and file review were produced by a peer-review committee, were written or submitted by physicians licensed in Pennsylvania, or purport to evaluate services ordered or performed by Dr. Petraglia. They argue that, in any event, Dr. Petraglia had not yet completed his surgery residency and fellowship in Maryland at the time, and hence, the health care services to which these items pertain could not have been delivered in Pennsylvania. *See* Brief for Appellees at 20-21; *see also id*. at 21-22 (suggesting the PRPA privilege doesn't protect documents relating to the treatment of patients outside Pennsylvania).

In terms of the OPPE report, Plaintiffs aver that this type of document contains performance metrics which are compiled as a means of complying with healthcare-

accreditation standards developed by the Joint Commission – a process they portray as substantially broader than peer review. *See id*. at 22-23.[9] They state it is unclear who authored the report and whether it is a record of a committee involved in peer review. As the report allegedly relates to performance metrics, Plaintiffs suggest it may embody a "continuum looking at data collected over time," *id*. at 24, and they express skepticism that it evaluates the care provided to specific patients. Instead, they maintain, it is the type of document kept by a "review organization" as defined in Sentence 2 of that term's definition, and, as such, it is not protected under *Reginelli*. *See id*. at 24-25.[10]

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[9] Founded in 1951, the Joint Commission is a private, non-profit organization which accredits over 22,000 health-care organizations in the United States. *See* https://www.jointcommission.org/about-us/facts-about-the-joint-commission/history-of-the-joint-commission/ (last viewed Aug. 11, 2021). It was previously known as the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), and before that, the Joint Commission on Accreditation of Hospitals ("JCAH"). *See* ***Dep't of Pub. Welfare v. Forbes Health Sys.***, 492 Pa. 77, 86 & n.10, 422 A.3d 480, 485 & n.10 (1980).

Among its activities, the Joint Commission develops standards which are recognized by governmental entities. *See, e.g.*, 50 P.S. §7105 (as part of the Mental Health Procedures Act, requiring that the Department of Human Service's standards for certain mental-health treatment facilities be at least as stringent as those of, *inter alia*, the Joint Commission); 35 P.S. §448.806(c) (as part of the Health Care Facilities Act, mandating that the Department of Health adopt standards relating to fire or other emergencies, providing they are not "more stringent than those required of hospitals by the Joint Commission . . . or such national accreditation organizations as the department may find appropriate"); *id*. §6944.2(a). The standards focus on patient safety and quality of care. *See* https://www.jointcommission.org/about-us/facts-about-the-joint-commission/joint-commission-faqs/ (last viewed Aug. 11, 2021).

[10] The Pennsylvania Association for Justice has filed an *amicus* brief favoring affirmance. Several *amici* have submitted briefs favoring reversal (some of which are joint briefs), including: the American Medical Association, the Pennsylvania Medical Society, the Chester County Medical Society, the Delaware County Medical Society, the Pennsylvania Coalition for Civil Justice Reform, Curi, UPMC, The Doctors Company, the Pennsylvania Orthopaedic Society, and the Hospital and Healthsystem Association of Pennsylvania.

In Pennsylvania, every hospital has a medical staff which is accountable to the hospital's governing body and is responsible for the quality of care provided to patients. *See* 28 Pa. Code §107.1. The staff may be organized into departments as necessitated by the hospital's complexity. *See id*. §107.22. The medical staff operates pursuant to a set of bylaws which, among other things, specify the functions assigned to its various standing committees. *See id*. §107.12(9). The bylaws also reflect the requirements for a practitioner's admission to the medical staff, and for the delineation and retention of clinical privileges. *See id*. §§107.2, 107.11, 107.12(2). Notably, beyond requiring that each medical staff have a medical executive committee (the "MEC"), *see id*. §107.25, Pennsylvania's regulations allow each hospital to choose – by way of its medical staff bylaws – the particular identities and titles of committees which perform evaluations and make recommendations to the governing body concerning such matters.[11] That being the case, the by-laws are not required to specify which committees undertake peer review or evaluate peer-review documents.[12]

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[11] One author explains that it is advisable that the decision of whether to grant or deny a practitioner's application be made by the hospital's governing body (such its board of trustees) rather than by the credentials committee or even the MEC. The reason is that individuals on the governing body are not in direct competition with the applicant and, as such, they do not risk being accused of restraining free trade or otherwise engaging in anti-competitive practices. *See* MARK A. SMITH, THE CREDENTIALS COMMITTEE HANDBOOK 3-4 (2016) (hereinafter, "CREDENTIALS COMMITTEE HANDBOOK").

[12] In the regulations governing health facilities, peer review is only mentioned expressly in three limited settings. *See* 28 Pa. Code. §136.12 (requiring that the supporting medical staff for open-heart surgical services include a board-certified medical cardiologist "with subspecialty certification in cardiovascular disease or who has demonstrated competence as determined by peer review"); *id*. §138.17(b) (mandating that a "rigorous mechanism for valid peer review" be "ongoing in a hospital offering PTCA [percutaneous transluminal coronary angioplasty] services"); *id*. §555.3(b) (insofar as ambulatory surgical facilities are concerned, providing that medical-staff privileges should reflect peer review or utilization review specific to ambulatory surgery).

When a physician applies for appointment to a hospital's medical staff, the physician is ordinarily seeking, not only the political rights that come with staff membership – such as participation in meetings, voting, or holding office – but hospital privileges as well. *See id*. §107.4. This is distinguished from the scenario addressed in *Reginelli*, which, the Court explained, only involved review of "professional qualifications or activities" as referenced in Sentence 2 of the definition of review organization. *See Reginelli*, 645 Pa. at 489-90, 181 A.3d at 305. *Reginelli*'s discussion was thus expressly limited to credentialing review for purposes of appointment to a hospital's medical staff, *see id*., and it concomitantly disapproved Superior Court decisions which held that "credentialing review is entitled to protection from disclosure under the PRPA's evidentiary privilege." *Id*. at 490 n.13, 181 A.3d at 306 n.13. That being the case, *Reginelli* did not purport to analyze review for delineated hospital privileges, a process known as privileging. Privileging is distinct from credentialing as it involves giving the physician permission to treat patients at the hospital, and not merely to exercise political rights in relation to staff and committee meetings. The regulations recognize this distinction, as they specify that the medical staff must define in its bylaws the requirements both for admission to staff membership *and* for the delineation and retention of clinical privileges. *See* 28 Pa. Code §107.2. The regulations also provide that privileges, in particular, may only be given "commensurate with [the applicant's] qualifications, experience, and present capabilities." *Id*. §107.3(b).[13]

The Hospital emphasizes that privileging evaluations – *i.e.*, an assessment of the applicant's experience, capabilities, and competence – inherently involve peer review

[13] Re-appointment to the medical staff and re-privileging must take place at least once every two years. *See id*. §107.5(c); *cf.* 42 U.S.C. §11135(a)(2) (requiring each hospital to request NPDB information for each practitioner on its medical staff at least once every two years).

regardless of whether the committee that performs them is named the "credentials committee" and regardless of whether the same committee also does credentialing review, *i.e.*, reviews objective criteria such as the applicant's academic degrees, board certifications, and licensure status and history. *See, e.g.*, Brief for Appellant at 44 (expressing that the Hospital's credentials committee engaged in peer review in addition to its review of professional qualifications). In this vein, one practice manual explains:

> When the credentials committee considers an application, that application contains two parts. The first is for membership in the medical staff. Criteria for such membership may include type of licensure, education, training, and experience. The second part is for privileges, which define the scope of clinical care that an applicant can administer and should be matched to that applicant's current clinical competency. There are certain criteria that applicants must meet in order to exercise particular privileges in the organization. These criteria may overlap with criteria for membership on the medical staff, but those for privileges tend to be more specific.

CREDENTIALS COMMITTEE HANDBOOK at 11. Thus, it is possible that a credentials committee may undertake review necessary for the granting of privileges, and nothing in the laws and regulations governing such activities preclude this. *Accord id*. at 5-6 (explaining that, for credentialing and privileging, including items involving peer review, the MEC ordinarily delegates responsibility to the credentials committee).[14]

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[14] *See also id*. at 13-14 (describing areas of competency reviewed by credentials committees in relation to a request for privileges, and observing that the review includes an assessment of whether the practitioner has performed well in recent practice, which in turn entails peer review); Arthur Shorr, HOSPITAL NEGLIGENCE: LEGAL & ADMINISTRATIVE ISSUES §3.10 (June 2020) (noting a hospital's credentials committee reviews all elements of a complete application including the applicant's history at other hospitals, peer references, and licensure and malpractice litigation history); *Leadbitter*, 229 A.3d at 297 ("It is crucial that a committee considering whether to authorize a physician to practice at its hospital has the opportunity to obtain candid and accurate evaluations of the physician before the physician practices at its hospital.").

In the present matter, as noted, the Hospital's credentials committee handled Dr. Petraglia's request for delineated hospital privileges – a process which, again, is asserted to have included peer review.

With this background, we return to Section 4 of the PRPA, *see* 63 P.S. §425.4, which is quoted above. Per that provision, discovery is precluded with regard to "proceedings and records of a review committee."[15] The term, "review committee," is not expressly defined by the PRPA, but *Reginelli* attributed to it a definition which subsumes any committee that undertakes peer review, *see Reginelli*, 645 Pa. at 486 n.8, 181 A.3d at 303 n.8 (indicating that "review committee" means "any committee engaged in peer review"), and that definition is not challenged here. Moreover, this conception of a review committee as encompassing various types of committees which engage in peer review is consistent with Sentence 1 of the definition of "Review organization," which specifies that a review organization is "any committee engaging in peer review," and then lists eleven non-exclusive examples.[16] Notably, none of these examples is expressly termed a "peer review committee."[17]

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[15] As discussed, the substantive text does not align with the title: while the title relates to the records of a review *organization* the text speaks in terms of review *committees*. This same feature is also at variance with the only other protective facet of the act: Section 3, which grants immunity from liability and whose text is framed in terms of review organizations. *See* 65 P.S. §425.3.

Particularly as "review committee" is not a defined term, Section 4's use of this phrase gives rise to interpretive difficulties. Still, it would be improper for this Court to resolve such difficulties by assuming the text was intended to apply to review organizations as a whole. *See Burke v. Independence Blue Cross*, 628 Pa. 147, 158-59, 103 A.3d 1267, 1274 (2014) (noting courts may not rewrite statutory text under the guise of statutory construction). *See generally Reginelli*, 645 Pa. at 489, 181 A.3d at 305 (observing that review committee and review organization are distinct terms under the PRPA).

[16] We have no present occasion to consider when committees described by Sentence 3 may be considered review committees entitled to Section 4's protections. As for (continued…)

Therefore, we agree with the Hospital's core position that a committee which performs a peer-review function, although it may not be specifically entitled a "peer review committee," constitutes a review committee whose proceedings and records are protected under Section 4 of the act. *Accord Trinity Med. Ctr. v. Holum*, 544 N.W.2d 148, 155 (N.D. 1996) (indicating that the scope of a peer-review protection act should not be limited "by the name employed to describe the committee and to thereby contradict legislative intent"); *Babcock v. Bridgeport Hosp.*, 742 A.2d 322, 342 (Conn. 1999) (explaining that the privilege does not depend on the nature of the committee, but on whether it was engaged in peer review). Sentence 1 of the PRPA's definition of "review organization" makes that conclusion inevitable because, as noted, it subsumes "*any* committee engaging in peer review," 63 P.S. §425.2 (emphasis added), and nothing in either that definition or in *Reginelli* suggests the committee must engage *exclusively* in peer review to qualify as a review committee. It follows that a hospital's credentials committee enjoys such protection if (and only if) it engages in peer review. *See generally Memorial Hosp. – The Woodlands v. McCown*, 927 S.W.2d 1, 5 (Tex. 1996) (finding that, because the initial credentialing process involves the review of

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(…continued)
Sentence 2, *Reginelli* established that: an individual is not a review committee under that provision; and an entity whose review is limited to objective professional criteria such as board certifications and licensure is also not a review committee under PRPA.

[17] The examples are: (1) a hospital utilization review committee; (2) a hospital tissue committee; (3) a health insurance review committee; (4) a hospital plan corporation review committee; (5) a professional health service plan review committee; (6) a dental review committee; (7) a physicians' advisory committee; (8) a veterinary review committee; (9) a nursing advisory committee; (10) any committee established pursuant to the medical assistance program; and (11) any committee established by one or more state or local professional societies, to gather and review information relating to the care and treatment of patients. *See* 63 P.S. §425.2 (definition of "Review Organization," Sentence 1).

professional-competence and ethical-practice information, it is subject to the protections afforded by the Texas peer-review protection act). Assessing this type of situation, one court has stated that:

> In essence, the [subject hospital's] Credentials Committee is really a specialized quality assurance committee, charged with assuring the competence of physicians authorized to practice at [the hospital]. It performs this function by maintaining files and reviewing the performance on each physician authorized to practice at [the hospital]. . . . Thus, the concerns about, and the objective to assure, open and honest physician participation in the peer review process emphasized in the legislative history support application of the privilege to the Credentials Committee.

Trinity, 544 N.W.2d at 155.[18]

We recognize that the statutory privilege as thus understood may prevent civil plaintiffs from obtaining some documents tending to show that their injuries were caused by the defendant's negligence, whether it be that of the physician or the facility at which he or she maintains privileges. However, the legislative body is presumed to have balanced that consideration against others, discussed above, which may be in tension with it, and to have intentionally used language applying to a variety of committees whose proceedings and records involve peer review. *See Vine v. State Emps. Ret. Bd.*, 607 Pa. 648, 667, 9 A.3d 1150, 1161 (2010) (observing that this Court does not weigh competing societal interests against one another, but assumes the General Assembly, as a policy-making body, has already done so in enacting legislation (citing *Program Admin. Servs., Inc. v. Dauphin Cty. Gen. Auth.*, 593 Pa. 184, 192, 928 A.2d 1013, 1017-18 (2007))). In this respect, the Hospital cogently notes that

> [t]he convergence of medicine and litigation at times brings about discordant results: the furtherance of one end may commensurately

[18] This, then, is an example of the situation described above, in which the name of the committee is not dispositive of whether it performs peer review.

> disadvantage the other. All privileges necessarily hinder to some degree the information available to opposing litigants. Similarly, assigning paramount status to a plaintiff's pursuit of a legal remedy can strike a fatal blow to a procedural framework erected to enhance patient safety. The General Assembly, in enacting Section 425.4, clearly voiced an intention to allow for the confidentiality necessary for meaningful [peer] review.

Brief for Appellant at 52.

Consequently, the information redacted by the Hospital, and the documents it withheld, are not discoverable by Plaintiffs if they constitute peer review "proceedings" or "records," 63 P.S. §425.4, in accordance with the PRPA's definition of peer review. *See id*. §425.2, *quoted in supra* note 6.[19] The record does not include the withheld documents reflected in the privilege log or the unredacted versions of the papers in question that were supplied to Plaintiffs. Hence, it will be for the common pleas court on remand to review such information *in camera* and make a determination as to whether they are protected as peer-review materials pursuant to the statutory definition of "peer review." In this latter regard, we acknowledge Plaintiffs' argument that the statutory definition of "peer review" is framed in terms of "professional health care providers" – which, in turn, is limited to "individuals or organizations who are approved, licensed or otherwise regulated to practice or operate in the health care field" under Pennsylvania

[19] Section 4 of the PRPA facially protects "[t]he proceedings and records of a review committee[.]" 63 P.S. §425.4. The Hospital's position in the present controversy is essentially that its credentials committee functioned as a review committee (as defined above) to the degree it considered peer-review documents. That being the case, only peer-review documents are at issue, and not the committee's documents more broadly. Further, *Reginelli* held that Section 4's protective scope is limited to documents of a review committee "that it utilized when it engaged in peer review," *Reginelli*, 645 Pa. at 486 n.8, 181 A.3d at 303 n.8; *accord Babcock*, 742 A.2d at 342 (applying similar statutory text), and the Hospital does not seek any amendment to that holding.

law. 63 P.S. §425.2 (definitions of "Peer review" and "Professional health care provider"). This definition should be utilized by the county court on remand.[20]

Finally, we clarify that the above applies only to the redactions and the withheld documents identified in the privilege log as the Professional Peer Review Reference and Competency Evaluation, and the OPPE Summary Report. The NPDB query responses stand on a different footing, as they are governed by federal law as discussed in Part III.

III. The HCQIA

Concerned about a lack of communication among hospitals and the ability of incompetent doctors to move from state to state without disclosing their track records, Congress enacted the HCQIA in 1986 to improve health-care quality by addressing such concerns and facilitating effective peer review. *See* 42 U.S.C. §11101 (relating to Congress's findings); *Manzetti v. Mercy Hosp. of Pittsburgh*, 565 Pa. 471, 483, 776 A.2d 938, 945 (2001); *Omar v. Jewish Hosp. Healthcare Servs., Inc.*, 153 S.W.3d 845, 847 (Ky. 2004). The HCQIA envisioned a centralized, national reporting system that was ultimately realized in 1990 with the promulgation of regulations by the Department of Health and Human Services (the "Department"), establishing the NPDB as a central repository for such information. *See* 45 C.F.R. §60.1. The NPDB regulations are set forth as Part 60 of Title 45 of the Code of Federal Regulations. *See* 45 C.F.R. §§60.1-60.22. *See generally* Jeanne Darricades, *Medical Peer Review: How is it Protected by the Health Care Quality Improvement Act of 1986?*, 18 J. CONTEMP. L. 263, 274-75 (1992) (citing 55 Fed. Reg. 31,239 (1990)).

[20] With that said, and contrary to Plaintiffs' suggestion, nothing in the PRPA requires, as a prerequisite to confidentiality, that the health-care services which are the subject of the peer review materials at issue were delivered in Pennsylvania.

The HCQIA comprises Chapter 117 of Title 42 of the United States Code. In addition to the congressional findings set forth in Section 11101, it is divided into three subchapters: Subchapter I relates to the promotion of professional review activities, *see* 42 U.S.C. §§11111-11115; Subchapter II pertains to the reporting, disclosure, and correction of information in the NPDB, *see id*. §§11131-11137; and Subchapter III defines terms and mandates that certain reports to Congress be made and certain memoranda of understanding be entered into between the Secretary and other federal agencies, *see id*. §§11151-11152.[21]

Subchapter II is the facet of the enactment presently in focus. It requires health care entities to report any professional review action which adversely affects a doctor's clinical privileges for more than 30 days. *See* 42 U.S.C. §11133(a)(1), 11134(a). Such reports are to be made to the Secretary or to an agency designated by the Secretary – *i.e.*, the NPDB. *See id*. §11134(b). Subchapter II also mandates that certain other reports be made to the NPDB, such as those relating to medical malpractice payments stemming from the doctor's negligence, *see id*. §11131, as well as actions taken by a state board of medical examiners. *See id*. §11132(a); *see also id*. §11152(c) (relating to the Drug Enforcement Agency's duty to report to the NPDB information concerning doctors whose registration to dispense controlled substances has been affected). *See generally Imperial v. Suburban Hosp. Ass'n*, 37 F.3d 1026, 1028 (4th Cir. 1994). In turn, hospitals have a duty to request NPDB information about practitioners who apply for membership on the hospital's medical staff or for clinical privileges at the hospital. *See id*. §11135(a).

[21] As used in the HCQIA, the "Secretary" is the Secretary of the United States Department of Health and Human Services. *See* 42 U.S.C. §11151(12).

The statute requires disclosure by the NPDB of the information it collects, upon request, to certain persons or entities, including the practitioner who is the subject of the information, *see id*. §11136, state licensing boards, *see id*. §11134(c), and hospitals or other health care entities. *See id*. §11137(a) (directing that such information be provided, upon request, "to State licensing boards, to hospitals, and to other health care entities . . . that have entered (or may be entering) into an employment or affiliation relationship with the physician or practitioner or to which the physician or practitioner has applied for clinical privileges or appointment to the medical staff"). Overall, then, there is a two-way flow of information between hospitals and the NPDB, with state licensing boards also receiving or providing information as needed.

Under the HCQIA, the information stored in the NPDB – most notably for present purposes, the data reported to it concerning physicians – is confidential; it "may be accessed only by permitted entities, and by health care providers who may self-query." *Satgunam v. Mich. State Univ.*, 556 Fed. Appx. 456, 460 n.2 (6th Cir. 2014). Thus, Section 11137(b)(3) indicates that the information "is intended to be used solely with respect to activities in the furtherance of the quality of health care," 42 U.S.C. §11137(b)(3), and any violation of this mandate carries a potentially heavy penalty. *See id*. §11137(b)(2) (imposing a fine up to $10,000 for each violation). The substantive provision conferring confidentiality, which is at the heart of the present issue, states:

> Information reported under [Subchapter II] is considered confidential and shall not be disclosed (other than to the physician or practitioner involved) except with respect to professional review activity, as necessary to carry out [the objective of the Data Bank to inform hospitals concerning an applicant for medical staff appointment or hospital privileges] (as specified in regulations by the Secretary), or in accordance with regulations of the Secretary promulgated pursuant to subsection (a) [relating to the providing of data to state licensing boards, hospitals, and other health-care entities]. *Nothing in this subsection shall prevent the disclosure of such information*

> *by a party which is otherwise authorized, under applicable State law, to make such disclosure*.

Id. §11137(b)(1) (emphasis added). Under the first sentence above, disclosure in discovery of information reported to the NPDB is prohibited as this would exceed the purposes of the enactment. This facet of the HCQIA has been referred to as the "federal statutory peer review privilege." *Wei v. Bodner*, 127 F.R.D. 91, 99 (D.N.J. 1989). The privilege is qualified, however, by the emphasized language, which is in the nature of a proviso. The scope of this statutory proviso is in dispute.

The trial and intermediate courts expressed that any absence of confidentiality under state law, such as the PRPA, gives rise to an identical gap in confidentiality under the HCQIA. *See Leadbitter*, 229 A.3d at 298 (indicating that "the confidentiality provisions of [the HCQIA] follow state law"); *Leadbitter*, No. GD 16-10700, *slip op*. at 3 (indicating that the NPDB responses were discoverable per federal law because they were unprotected by PRPA). Plaintiffs echo that position. *See* Brief for Appellees at 41. They argue that the NPDB responses are relevant to their corporate-negligence claim and, as such, their discovery is authorized under the civil rules. *See id*. at 44 (quoting Pa.R.C.P. No. 4003.1(a)). It follows, in Plaintiffs' view, that the NPDB query responses are made discoverable by the above statutory proviso.

For its part, the Hospital views the proviso as relating solely to the reports sent *to* the NPDB, and not to the information provided *by* the NPDB to hospitals. Thus, they view the statute's confidentiality mandate with regard to information provided by the NPDB as unaffected by the proviso. *See* Brief for Appellant at 55-57.

We believe the Hospital has the better argument for the reasons set forth below.[22] Preliminarily, however, we note that, in drafting the HCQIA, Congress was

[22] One difficulty with Plaintiffs' position is that the civil procedural rule which they view as authorizing disclosure of the NPDB responses does not apply to privileged materials. (continued…)

careful to refer to information the NPDB (or a licensing board) receives from health-care entities as being "reported" to it (or to the licensing board), or as comprising "reports." By contrast, the information the NPDB furnishes to health-care entities upon request, such as responses to NPDB inquiries, is portrayed as being "disclosed" or "provided" to the requester.[23] It is helpful to bear this distinction in mind when reviewing the enactment's substantive provisions, as litigants sometimes refer to the NPDB query

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(…continued)
See Pa.R.C.P. No. 4003.1(a) (allowing for "discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action"). Thus, Plaintiffs' contention is, essentially, that the confidentiality which would otherwise have been required by the HCQIA is inapplicable in view of the civil rule which permits discovery of non-privileged materials. This plainly is a circular argument and, as such, it is unpersuasive. We need not rest our holding on that basis, however, in light of our interpretation of the HCQIA and its implementing regulations as developed herein.

Separately, Plaintiffs reference a provision indicating that nothing in the HCQIA "shall be construed as affecting in any manner the rights and remedies afforded patients under any provision of Federal or State law to seek redress for any harm or injury suffered as a result of negligent treatment or care by any physician, health care practitioner, or health care entity, or as limiting any defenses or immunities available to any physician, health care practitioner, or health care entity." 42 U.S.C. §11115(d), *quoted in* Brief for Appellees at 42. However, the general rule set forth by Section 11115(d) relating to the rights and remedies otherwise available to patients does not overcome the core protections established by the statute.

[23] *See, e.g.*, 42 U.S.C. §§11131, 11132, 11134(b), 11136 (referring to information "reported to" the Secretary of Health and Human Services, as well as the "disclosure of the information" to the subject practitioner), 11137(a) (requiring the Secretary to "provide" certain information to hospitals upon request), 11137(b)(4) (authorizing the Secretary to establish reasonable fees to reimburse the Data Bank for the costs of processing the requests for "disclosure" and of "providing" such information), 11137(c) (providing immunity from liability for "any report made under" the HCQIA).

The statute does direct the Secretary to "report to Congress" on certain topics. *See id*. §§11131(d), 11152. But this use of the word "report" stands apart from the rest of the enactment and involves an entirely different circumstance.

responses as "reports" – a usage which tends to confuse matters. *See, e.g.*, Brief for Appellant at 2 (advancing that the HCQIA prohibits disclosure of "Data Bank reports" and, as such, they were properly withheld from discovery in the present case); *id*. at 55 (asserting that "[r]eports received from the NPDB are protected from disclosure by federal law"); Brief for Appellees at 43 (maintaining that the "reports of the NPDB are not protected by [the] PRPA," and hence, they are not protected by federal law).

Returning to the statutory language, a plain-text reading of the above paragraph, in the context of the HCQIA as a whole, suggests the statutory proviso's permissive disclosure based on state-law authorization relates to the information reported *by* a party *to* the Data Bank, and not to information divulged by the Data Bank in response to a query. This is because "such information" refers back to "Information reported under [Subchapter II]," set forth in the first sentence. Information reported under Subchapter II, in turn – and as discussed – means information reported to the Data Bank. *Accord Comm'r of Pub. Health v. Freedom of Info. Comm'n*, 86 A.3d 1044, 1053 (Conn. 2014) ("When read in context, 'such information' [as that phrase is used in the statutory proviso] appears to refer to information reported to the Practitioner Data Bank, meaning from the party's own files.").

It also seems unlikely Congress intended to condition the federal peer review privilege upon the availability of a state-law privilege covering the same materials. Reading the statutory proviso in that way could render the federal privilege largely superfluous and unnecessary. This, in turn, would undermine Congress's aim of incentivizing the reporting of adverse professional review information to the NPDB in the interest of promoting effective peer review. *See* 42 U.S.C. §11101(3)-(5). As the Connecticut court noted, moreover, it would lead to an anomalous result allowing public

disclosure of information submitted to the NPDB "from a state whose law would bar public disclosure of that information." *Comm'r of Pub. Health*, 86 A.3d at 1053.

Finally, our understanding is consistent with the views of the Department – the federal agency responsible for implementing the HCQIA. Those views are embodied in the regulations implementing the HCQIA, which state, in pertinent part:

> (a) Limitations on disclosure. Information reported to the NPDB is considered confidential and shall not be disclosed outside the Department of Health and Human Services [subject to certain exceptions].[24] Persons and entities receiving information from the NPDB, either directly or from another party, must use it solely with respect to the purpose for which it was provided. *The Data Bank report may not be disclosed, but nothing in this section will prevent the disclosure of information by a party from its own files used to create such reports where disclosure is otherwise authorized under applicable state or Federal law*.

45 C.F.R. §60.20(a) (emphasis added).

This provision refers to information concerning a practitioner that is supplied to the NPDB as a "Data Bank report," since it was "reported to" the NPDB. *Id*.[25] It makes three essential points: (1) information reported to the NPDB is confidential and may not be disclosed extrinsic to the Department, except as necessary to fulfill the NPDB's purposes; (2) where hospitals or any other entities or persons receive such information (either directly from the NPDB or indirectly), they may only use it for the purpose for

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[24] These exceptions, which are not presently relevant, include disclosures as noted in the statutory provision which are necessary for the Data Bank to fulfill its objectives.

[25] Under the regulation's text, the term "Data Bank report" cannot mean a report created by the NPDB and sent to a recipient. After mentioning "The Data Bank report," the regulation refers to information in a party's "own files used to create such reports." Thus, it is clear that the language emphasized above pertains to reports created by parties, and not by the NPDB. This is consistent with the statutory use of the term "report," as discussed above. More broadly, the Part 60 regulations follow the same convention as the HCQIA in their use of the word "report." *See supra* note 23 and associated text.

which it was provided to them; and (3) if a party contains information in its own files that was used to create a report it previously sent to the NPDB, the regulation does not prevent *that* information from being disclosed to the extent authorized by state or federal law. Notably, nothing in the regulation contemplates disclosure to third parties of responses to NPDB queries; to the contrary, under point (2) above, the regulation specifies that information which health-care facilities receive from the NPDB may only be used for the purposes for which the NPDB provided it.[26]

In sum, then, the HCQIA and its regulations treat as privileged the information the NPDB provides to hospitals in response to requests concerning a specific practitioner. This privilege, moreover, subsists regardless of any aspect of state law to the contrary. *See generally* U.S. CONST. art. VI, cl. 2 (indicating that federal law trumps contrary aspects of state law); *Office of Disciplinary Counsel v. Marcone*, 579 Pa. 1, 17, 855 A.2d 654, 664 (2004) (same). Finally, the civil procedural rule Plaintiffs rely upon does not allow for discovery of privileged material. *See* Pa.R.C.P. No. 4003.1(a).

In light of the above, the three documents listed in the Hospital's privilege log as "Results from NDBP [sic, NPDB] Query," are not discoverable.

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[26] This understanding of the regulation is confirmed by the Department's "Final Rule" revising NPDB regulations under the HCQIA and Social Security Act to incorporate requirements imposed by the Patient Protection and Affordable Care Act of 2010. *See National Practitioner Data Bank*, 78 Fed. Reg. 20473, 20483 (Apr. 5, 2013) (explaining the purport of the regulation's text). Plaintiffs do not discuss this regulation. Instead, they quote an outdated regulation, previously set forth at 45 C.F.R. §60.13(a), that lacks the clarifying language emphasized above. *See* Brief for Appellees at 41. Plaintiffs' argument also proceeds from a premise we have rejected – that the PRPA does not protect any part of the files of the Hospital's credentials committee. *See id*. at 42-43.

IV. Conclusion

We answer the questions presented as follows: (1) a hospital's credentials committee qualifies as a "review committee" for purposes of Section 4 of the Peer Review Protection Act to the extent it undertakes peer review; and (2) the federal Health Care Quality Improvement Act protects from disclosure the responses given by the National Practitioner Data Bank to queries submitted to it – and this protection exists regardless of any contrary aspect of state law.

Accordingly, the order of the Superior Court is reversed insofar as it ordered discovery of the NPDB query responses. It is vacated in all other respects and the matter is remanded for further proceedings consistent with this opinion.

Chief Justice Baer and Justices Todd, Donohue, Dougherty and Mundy join the opinion.

Justice Wecht files a concurring opinion.