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**IN THE SUPREME COURT OF PENNSYLVANIA
WESTERN DISTRICT**

19 WAP 2020

JAMES E. LEADBITTER AND TAMMY M. LEADBITTER
v.
KEYSTONE ANSETHESIA CONSULTANTS, LTD., A CORPORATION, CHRISTOPHER MERCK, D.O., AJOY KATARI, M.D., JOHN P. WELDON, M.D. AND ST. CLAIR HOSPITAL
v.
CARMEN PETRAGLIA, M.D. AND SOUTH HILLS ORTHOPAEDIC SURGERY ASSOCIATES, A CORPORATION
APPEAL OF: ST. CLAIR HOSPITAL

BRIEF *AMICUS CURIAE* OF THE AMERICAN MEDICAL ASSOCIATION AND THE PENNSYLVANIA MEDICAL SOCIETY

Appeal from the February 12, 2020 Order and Opinion of the Superior Court of Pennsylvania, at No. 1414 WDA 2018, affirming the Order entered September 17, 2018, in the Court of Common Pleas of Allegheny County, Civil Division, at Docket No. G.D. No. 14-10939

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I. **STATEMENT OF INTEREST OF *AMICUS CURIAE***

Amicus Curiae, the American Medical Association and the Pennsylvania Medical Society file this Brief in Support of St. Clair Hospital pursuant to Pa.R.A.P. 531(a).

Amicus Curiae, the American Medical Association (the "AMA"), is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all United States physicians, residents, and medical students are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every medical specialty area and in every state, including Pennsylvania.

Amicus Curiae, the Pennsylvania Medical Society (the "Medical Society"), is a Pennsylvania non-profit corporation that represents physicians of all specialties and is the Commonwealth's largest physician organization. The Medical Society regularly participates as *amicus curiae* before this Court in cases raising important health care issues, including issues that have the potential to adversely affect the quality of medical care.

The AMA and the Medical Society submit this brief on their own behalf and

as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state and the District of Columbia. Its purpose is to represent the viewpoint of organized medicine in the courts.

The above organizations have a unique and substantial interest in the issues presented by the instant case. They are concerned about the erosion of confidentiality of "peer review" procedures in medicine; they believe strongly in the need for transparency and accountability in peer review.

The AMA and the Medical Society submit that they are appropriate *amici* under Pa.R.A.P. 513(a) *Amici* urge this Honorable Court to consider seriously the legal and policy considerations advanced in this Brief *Amicus Curiae*, which compel the conclusion that the trial court's decision must be reversed.

II. FACTS

This case involves an appeal by St. Clair Hospital from a Superior Court decision affirming a trial court Order requiring the Hospital to produce the credentialing and privileging file of its on-staff physician, Dr. Carmen Petraglia. The file was created when Dr. Petraglia applied for orthopedic surgery clinical privileges and sought appointment to the Hospital's medical staff. Included in Dr. Petraglia's file were a "Professional Peer Review Reference and Competency Evaluation," completed by other physicians, as well as an "Ongoing Professional Practice Evaluation of St. Clair Hospital Summary Report," containing various data on Dr. Petraglia's performance.

Five months after the Hospital granted Dr. Petraglia's requests for appointment and privileges, Dr. Petraglia performed two surgeries on James Leadbitter. Plaintiffs (Mr. Leadbitter and his wife) claim that Dr. Petraglia performed the surgeries negligently and sued Dr. Petraglia, the Hospital, as well as other defendants, for medical malpractice.

During discovery, Plaintiffs moved to compel the Hospital's production of Dr. Petraglia's entire credentialing file, claiming that they were entitled to this information based on this Court's decision in *Reginelli v. Boggs*, 181 A.3d 293 (Pa. 2018). The Hospital opposed Plaintiffs' motion, arguing that: (i) Dr. Petraglia's professional opinions and performance evaluations were protected from discovery

under Pennsylvania's Peer Review Production Act (63 P.S. § 425.1, *et seq.*) ("PRPA"), and that (ii) information from the National Practitioners' Data Bank ("NPDB") was protected from disclosure by the Health Care Quality Improvement Act (42 U.S.C.A. § 11101) ("HCQIA").

The trial court rejected both of the Hospital's arguments and ordered the Hospital to turn over to Plaintiffs the entire credentialing file in unredacted form. In so doing, the trial court held that the PRPA does not protect professional opinions and evaluations obtained by the Hospital's credentialing committee and that the NPDB responses are not protected from discovery by federal law. After the trial court granted Plaintiffs' Motion to Compel, the Hospital appealed the Order, under Pa.R.A.P. 313, to the Pennsylvania Superior Court.

The Superior Court affirmed the trial court's decision based solely on its conclusion that this Court's decision in *Reginelli* requires disclosure of peer review material created by a "review organization," even where the documents in question are "peer review" documents. Slip. Op., at 8.

The Superior Court expressed serious reservations about its holding, however. Recognizing that the documents in Dr. Petraglia's credentialing file were clearly "peer review" in nature, the Superior Court asked this Court for guidance. *See* Slip. Op. at 9, n.7 ("In light of the fact that the Supreme Court assumed that documents in a credentialing file are not peer review documents and, in this case, the documents

at issue are peer review documents, it would be helpful for the Supreme Court to grant allocator and address this issue directly.”).

The Hospital filed a Petition for Allowance of Appeal which this Court granted.

This Court accepted the following two issues for review:

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*, 181 A.3d 293 (Pa. 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?

III. SUMMARY OF ARGUMENT

The Superior Court's decision compelling complete and unredacted disclosure of a physician's credentialing file containing peer review material is unprecedented. If left to stand, the Court's decision will seriously undermine and erode efforts by the medical community to create a safer health care environment in this Commonwealth by way of the peer review process.

Peer review is critical to the practice of medicine. Every state has a peer review statute intended to balance the health and safety of patients with the need for confidential and candid peer review and credentialing discussions. The principles underlying the framework for peer review are simple, basic, and sound. To be effective, peer review requires open, frank and candid discussion between and among physicians about other physicians. However, to succeed, peer review also requires strict confidentiality. Recognizing that the need for candor is inextricably intertwined with the need for confidentiality, all peer review statutes, including Pennsylvania's statute, provide assurance to physicians and hospitals who participate in the process that information generated during the peer review process will remain protected, confidential and out of public view.

In Dr. Petraglia's case, the Superior Court ignored these important and practical policies in favor of a decision requiring disclosure of the full, unredacted, evaluations of Dr. Petraglia set forth in his credentialing file. Critically, the Superior

Court came to this conclusion, in a triumph of semantics over reality, based on the label given to the structure involved—namely that, in the Court's view, the documents were in a credentialing file, such that review was performed by an organization, not a committee. *Amici* submit that the Superior Court's decision inappropriately elevates form over function, threatens to chill candid peer review discussion, and, if left to stand, will adversely affect the quality of health care.

Amici submit that the Court's decision requiring disclosure of material obtained from the NPDB also requires reversal by this Court. Federal law prohibits the production of the NPDB query responses; moreover, to the extent there is any discrepancy between state and federal law, federal law must control.

For the reasons set forth below, *Amici* urge this Court to adopt Appellants' arguments, overturn the Superior Court's decision, and make clear to the bench and bar that any peer review documents contained within the physician's credentialing files are protected from discovery under Pennsylvania law.

IV. ARGUMENT

A. Peer Review Protections Are Necessary to Promote Public Policy and Interest in Improving Health Care.

Amici have considerable experience, a keen understanding, and unique perspective on the issue of peer review. As health care providers, they understand the need for open and honest dialogue in the peer review setting as well as the overarching need for confidentiality with regard to these discussions. Indeed, the importance of confidentiality in the peer review setting cannot be overstated. While some physicians may feel compelled to report critically on peers even in the absence of protection, a great many are likely to be deterred unless they are assured that their report will not be made public, for fear of censure and retaliation, or because they are conflict-averse and do not wish to face, or be held accountable by, the peer who is the subject of their report. Given the myriad of such human factors involved in peer review, state statutes generally give broad protections to peer review materials.

As this Court is aware, "peer review" is a fluid process that presents in many forms. Generally, it is the process or procedure that physicians and hospitals use to critically analyze and review the performance and capability of individual physicians and other health care professionals. Peer review generally occurs both on a periodic basis or when health care professionals seek to join a medical staff of a hospital or other health care organization. Peer review can occur in a formalized committee-based procedure in a major hospital, or in a process of critical evaluation of one

physician by a supervisor or directly by a colleague. The purpose of peer review is to ensure the highest quality of health care within an organization by allowing colleagues to critically analyze, in the most robust fashion, medical services performed by other physicians. *See* Kenneth Kohlberg, *The Medical Peer Review Privilege: A Linchpin for Patient Safety Measures*, 86 Mass. L. Rev. 157 (2002).

The need for both candid discussion and confidentiality in the peer review process was eloquently explained in the often-cited decision in *Bredice v. Doctors Hosp., Inc*., 50 F.R.D. 249, 250 (D.D.C. 1970). In *Bredice*, the District of Columbia Court articulated the important policy concerns undergirding peer review statutes: "[c]andid and conscientious evaluation of clinical practices is the sine qua non of adequate hospital care…[c]onstructive professional criticism cannot occur in an atmosphere of apprehension that one doctor's suggestion will be used as a denunciation of a colleague's conduct in a malpractice suit." *Id.* Importantly, as the court also recognized:

> To subject these discussions and deliberations to the discovery process, without a showing of exceptional necessity, would result in terminating such deliberations. Constructive professional criticism cannot occur in an atmosphere of apprehension that one doctor's suggestion will be used as a denunciation of a colleague's conduct in a malpractice suit. The purpose of these staff meetings is the improvement, through self-analysis, of the efficiency of medical procedures and techniques. They are not a part of current patient care but are in the nature of a retrospective review of the effectiveness of certain medical procedures. The value of these discussions and reviews in the education of the doctors who participate, and the medical students who sit in, is undeniable. This value would be

destroyed if the meetings and the names of those participating were to be opened to the discovery process.

Id. Every state and the District of Columbia has recognized the importance of peer review, as well as the need for immunity and confidentiality for the individuals and documents involved therein. As a result, all states have enacted some type of statutory limitation on the disclosure and use of peer review materials, and have extended protection to peer review committee reports, records, proceedings and testimony. *See KD ex rel. Dieffenbach v. United States*, 715 F. Supp. 2d 587, 594-93 (D. Del. 2010) ("… all 50 states, as well as the District of Columbia, have created an evidentiary privilege for medical peer review information. These statutes share a common purpose in encouraging physician candidness by eliminating the fear that peer review information will be used against them in subsequent litigation.").

Pennsylvania's legislature first created protection for peer review organizations in 1974.[1] The PRPA, later amended in 1978, provides guidance in connection with evaluations of patient care, for quality control purposes as well as limited immunity for those who are involved in the peer review process. The purpose of Pennsylvania's statute been described as one aiming to "improve the quality of care," *Robinson v. Macgovern*, 83 F.R.D. 79 (W.D. Pa. 1979), to help "keep health

[1] Peer review is required by the Joint Commission on Accreditation of Health Care Organizations ("JCAHO") and the American Osteopathic Association ("AOA"), private bodies by which hospitals and other health care organizations may receive accreditation which is useful for federal certification for Medicare and state licensing purposes.

care costs within reasonable bounds," *id.*, and to encourage "free and frank discussion by review organizations." *Sanderson v. Frank S. Bryan, M.D., Ltd.*, 522 A.2d 1138, 1139 (Pa. Super. 1987).

Pennsylvania's statute also provides immunity and confidentiality protections for individuals and documents involved in the peer review process. Indeed, the legislature made this clear when it identified the statute's purpose; it noted that "the purpose of the bill is to provide protection to those persons who give testimony to peer review organizations." *Id.*, at 496 (citing Hearing on H.B. No. 1729, 158 Pa. Legis. J. House at 4438 (1974) (statement of Representative Wells)). The Act's prefatory language echoes this sentiment: "Providing for the increased use of peer review groups by giving protection to individuals and data who report to any review group." *Id.* (citing H.B. 1729, Act of July 20, 1974, P.L. 564, No. 193.) *See also Steel v. Weisberg*, 500 A.2d 428, 430 (Pa. Super. 1985) ("[t]hrough these immunity and confidentiality provisions. . . the Legislature has sought to foster free and frank discussion by review organizations.").

B. Proper Application of the Federal and State Statutes Compels the Conclusion that Information in the Credentialing File Is Peer Review Information that Should Be Protected.

1. The Superior Court's Reliance on *Reginelli dicta* Was Misplaced.

In this case, notwithstanding these important policy concerns, the Superior Court affirmed the trial court's disclosure Order based solely on this Court's decision

in *Reginelli*. *See* Slip. Op. at 8 (noting, that, under *Reginelli,* "since St. Clair Hospital's credentialing committee is a committee that reviewed the professional qualifications and activities of Dr. Petraglia following his application for hospital privileges at St. Clair Hospital, the credentialing committee is a review 'organization.' Therefore, the PRPA privilege does not apply to the documents that the credentialing committee reviewed.").

Amici submit that the Superior Court's conclusion that *Reginelli* required disclosure of the documents in this case is incorrect. Specifically, *Amici* respectfully submit that this Honorable Court was not asked in *Reginelli* to decide, and, thus, did not decide, whether specific peer review information contained in credentialing files is discoverable. Instead, *Amici* submit, this Court's holding in *Reginelli* turned in large part on the fact that the independent contractor who provided emergency room staffing to a hospital did not qualify as a "professional health care provider;" hence, evaluations in the contractor's files by a physician-supervisor of a physician-employee were not protected under the PRPA, and an individual physician employee of a staffing company, who had reviewed the performance of a colleague, could not be considered a "review committee" under the PRPA. (181 A.3d 304-05). *Amici* submit that any reference in *Reginelli* to the fact that a physician's credentialing file *may* be subject to discovery is *dicta* in circumstances where this Court was not asked to address that specific issue, which had neither been briefed nor argued. Moreover,

this Court's distinction between peer review information compiled by "committees" versus "organizations" or individuals was unnecessary to reach its holding that the reviewing body must be qualified as a "professional health care provider."

Because the Superior Court improperly relied on this Court's *dicta* in *Reginelli*, without considering the specific language or addressing the question in the context of the canons of statutory construction, *Amici* submit that the Superior Court erred and that its decision should be reversed.

2. PRPA's Plain Language and Structure Demonstrate that It Is the Nature of the Documents Not the Label of "Committee" or "Organization" that Should Control.

Amici submit that analysis of the issue under statutory construction principles favors Defendants' interpretation that peer review documents in a credentialing file are protected from discovery.

Before Pennsylvania passed the PRPA, Pennsylvania did not have a peer review statute. The General Assembly was motivated to pass the statute, in part, out of concern for confidentiality. In light of this expressed concern, as well as the fact, identified by Justice Wecht in his dissenting opinion in *Reginelli,* that this is a statutory privilege created by the legislature for which additional exceptions should not be created by "judicial fiat," 181 A. 3d. at 310, there is no reason to conclude that the legislature intended to create two classes of peer review documents—those created by a peer review organization and those created by a peer review committee—and to then subject each to different treatment. The legislature would have recognized that making such a distinction would have had a dramatic effect on the way in which peer review is conducted, and, likely would have undermined the legislature's goal in protecting from disclosure the candid and robust reviews peer review engenders.

Moreover, as Justice Wecht pointed out, PRPA *as a whole* negates the conclusion that the legislature intended to draw a distinction between a review

organization and a review committee. *Id*. at 314 ("[t]he bright line that the Majority seeks to draw between a review organization and a review committee cannot be sustained by the statutory text read holistically"). *Amici* agree with Justice Wecht's observation that any reading that concludes that no record is confidential unless it pertains to reviews by review organizations described as "committees" would be unreasonable, in light of the title of the statute and the fact that the intent of the Act was to provide confidentiality to such documents. *See Id.* at 312.

Moreover, *Amici* submit, had the legislature intended to provide greater guidance to alert physicians and hospitals that reviews created by groups under a certain label are protected, it would have reflected that point somewhere in the statutory language. *See Kmonk-Sullivan v. State Farm Mut. Auto. Ins. Co*., 788 A.2d 955, 962 (Pa. 2001) (citations omitted) (as "a matter of statutory interpretation, although one is admonished to listen attentively to what a statute says … [o]ne must also listen attentively to what it does not say."). Where the legislature easily could have included language expressly making this distinction, and did not do so, courts should not add or create distinctions where they do not exist. *See Commonwealth v. Wright*, 14 A.3d 798, 814 (Pa. 2011) (when General Assembly enacts a clear statute and purposely excludes language it could easily have incorporated, "it is not for the courts to add, by interpretation, to [the] statute, a requirement which the legislature did not see fit to include"). Thus, for this reason as well, this Court should find that

the legislature did not intend to create a distinction with regard to "peer review organizations" and "peer review committees" as the Superior Court held, and that the peer review documents in Dr. Petraglia's credentialing file are, in fact, protected by the PRPA.

3. The Superior Court's Decision Elevates Form Over Function.

As a practical matter, the Superior Court's decision must be set aside because its decision to disqualify documents in a "credentialing" file from confidentiality protections elevates form over function. Peer review may take different forms—it may be an official peer review committee commenced only to address peer review issues *or* it may be an individual supervising physician, a committee, or peers charged with assessing an individual physician's qualifications or any of the foregoing reviewing that physician's evaluations by his or her peers. Thus, where a credentialing committee "wears two hats," the portion of the committee's records that simply reflect a physician's objective qualifications, education or board certifications may be discoverable, but the portion that reflects peer review should be protected. Otherwise, the entire purpose of the PRPA will be undermined. *See Reginelli,* 181 A. 3d. at 315 (Wecht, dissenting) ("In addition to evaluating documentary evidence of a physician's qualifications—licensure, education, experience etc.—credential's committees assess qualitative aspects of the care provided by staff physicians.) *Amici* submit that the latter category is, as the Hospital

maintains, quintessentially peer review material that must be protected from discovery to protect the integrity of the process and participants.

Accordingly, *Amici* believe that all peer review documents—in whatever form and regardless of the label given to the creating force, should be protected from discovery. Otherwise, the presumption—long shared in this Commonwealth by physicians, the bench and bar, that *all* peer review is generally protected from discovery—will no longer be applicable, the confusion will discourage practitioners from engaging in peer review of any sort, and the quality of health care in this Commonwealth will be dramatically diminished.

C. The Superior Court's Holding Requiring Release of Data Bank Reports Directly Conflicts with Federal Law.

Amici also urge this Court to adopt Appellants' position that the Superior Court's holding also directly conflicts with the HCQIA and the regulations interpreting it which specifically protect from disclosure responses to statutorily-required inquiries of the NPDB. Here, the Court ordered release of reports made to the Data Bank regarding Dr. Petraglia, notwithstanding that those reports are deemed confidential and may only be released upon certain conditions that clearly are not satisfied here.

The HCQIA was passed by Congress to "improve the quality of medical care by encouraging physicians to identify and discipline physicians who are incompetent or who engage in unprofessional behavior." *Mathews v. Lancaster Gen. Hosp.*, 87

F.3d 624, 632 (3d Cir. 1996) (*quoting* H.R. Rep. No. 903, 99th Cong., 2d Sess. 2 (1986), reprinted in 1986 U.S.C.C.A.N. 6287, 6384). HCQIA specifically immunizes hospitals and physicians who participate in peer review proceedings properly conducted by a professional review body. A "professional review body" is defined as a health care entity and the governing body or any committee of a health care entity which conducts professional review activity, and includes any committee of the medical staff of such an entity when assisting the governing body in a professional review activity. 42 U.S.C.A. § 11151(1). If deemed a professional review action, immunity under HCQIA is available if the action was taken:

> (1) in a reasonable belief that the actions were in furtherance of a 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 or after such other procedures as are fair to the physician under the circumstances; and
> (4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirements of paragraph (3).

Id., at § 11112(a). The NPDB is a creation of HCQIA intended to bolster the integrity of the peer review process by "accumulating and disseminating data pertaining to adverse peer review actions which have an impact on the clinical privileges of physicians and other staff members." Karen S. Rieger, *et al.*, *Healthcare Entity Bylaws and Related Documents: Navigating the Medical Staff/Healthcare Entity Relationship;* § 1.1, at 2 (3d ed. 2011); Gayland Hethcoat, *Terminating the Hospital-*

Physician Employment Relationship: Navigating Conflicts Arising from the Physician's Dual Roles as Employee and Medical Staff Member, 23 U. Miami Bus. L. Rev. 425 (2014).

Unlike attorney discipline, which is reported and *may* be reviewed by a client or potential employer, every hospital has an affirmative *duty* to request the information contained in the NPDB file for every physician who applies for a position on its medical staff. 42 U.S.C.A. § 11135.

It is clear from the NPBD statute and the regulations interpreting it, that information contained in NPDB reports is considered confidential, and may not be disclosed except as specified in NPDB regulations. The confidentiality provisions of Title IV, Section 1921, and Section 1128E allow an eligible entity receiving information from the NPDB to disclose the information to others who are part of the investigation or peer review process, as long as the information is used for the purpose for which it was provided. An organization that requests information for credentialing purposes must only use the information retrieved for credentialing purposes. Moreover, "[s]haring query responses and any accompanying reports with individuals or organizations outside of the querying organization's review process is prohibited. The strong security rules and limited access exist to not only protect the privacy of the individuals whose information resides within the NPDB, but also to

help ensure the integrity of the information reported to the NPDB."[2] Because the HCQIA is a federal statute that *prohibits the production of the NPDB query responses*, to the extent there is any discrepancy between state and federal law, federal law must control.

Courts have identified three different ways in which federal law may preempt state law: (1) where Congress has expressly preempted state action (express preemption); (2) where Congress has implemented a comprehensive regulatory scheme in an area, thus removing the entire field from state realm (implied field preemption) such that courts may reasonably infer that Congress left no room for state action; or (3) where state action actually conflicts with federal law (implied conflict preemption) such that a particular state law presents an obstacle to the accomplishment of congressional purposes and objectives, or where it is impossible for a private party to comply with both state and federal requirements. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992); *English v. General Electric Co.*, 496 U.S. 72, 78-79 (1990).

The issue of preemption has come up in the context of NPDB reports in other states and in those cases, courts have always erred on the side of non-disclosure. For example, in *Diaz v. Provena Hosp.*, 817 N.E.2d 206, 212 (Ill. 2004), an appellate court in Illinois was asked to address a trial court order holding the defendant

[2] National Practitioner Data Bank, 78 Fed. Reg 20473, 20483 (April 5, 2013).

hospital in contempt for failing to *retract* a report made to the Data Bank, which the Hospital maintained was required when the plaintiff physician voluntarily surrendered her privileges during a peer review action. *Id.* at 208-210. Because the Court recognized that the hospital was unable to serve two masters—it could not satisfy its obligations under HCQIA to keep the information confidential while abiding by a court order requiring it to retract reporting it had made—the appellate court held that HCQIA preempted state law and that the report should remain.

An Alabama court reached a similar conclusion in *Ex parte Alabama State Board of Pharmacy*, 253 So. 3d 972, 974 (Ala. Civ. App. 2017). There, the Alabama State Board of Pharmacy challenged a lower court's decision directing the Board to "void" a report the Board had made to the NPDB after the Board suspended a pharmacist's license and placed specific pharmacies on probation. The Board argued that the applicable federal law preempted the lower court's order requiring removal of language submitted to the NPDB providing notice of the suspension of the pharmacist's license and of the pharmacies' probation. Recognizing that state law action is preempted under the Supremacy Clause if the intent of Congress to preempt state law is clear and explicit in the statute, *English v. General Elec. Co.,* 496 U.S. 72, (1990), the Alabama Court of Civil Appeals concluded that the court had exceeded its authority ordering the Board to void the report. *See also Brown v. Medical College of Ohio*, 79 F. Supp. 2d 840, 843 (N.D. Ohio 1999) (regulations

accompanying the HCQIA set out a comprehensive administrative scheme for challenging the accuracy of a report; thus, granting physician's request for an injunction prohibiting a hospital from reporting his resignation to the NPDB until the completion of the "professional review action process" would undermine the scheme of decision-making that Congress has created under the HCQIA).

Here, the Superior Court concluded that information that was reported to the NPDB may be disclosed (and, hence, is not protected by the HCQIA) because it was permitted to be released by state law. Respectfully, this conclusion is unsupportable.

First, it is only the "original documents or records from which the reported information is obtained"—not the report itself—that HCQIA exempts from its confidentiality provisions. *See National Practitioners' Data Bank*, 78 Fed. Reg. 20473, 20483 (April 5, 2013). Indeed, the regulations make clear that "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). Thus, the exception to HCQIA's broad protection for information reported to the NPDB is only for documents used to create the Data Bank report, not the report itself.

Second, there is *no state law* that authorizes release of information provided to the NPDB. The issue clearly is not addressed by the PRPA, and there is no state statute that authorizes such release.

Third, the *Reginelli* decision cannot be considered a "state law" that allows release of information made confidential by federal law. A decision from this Court declining to apply a privilege to information contained within a contractor/employer's files is not the same as an affirmative "law" requiring disclosure of confidential Data Bank reports. Thus, because there is no state law that authorizes the release of this highly confidential information, the federal statute controls, and the Superior Court erred in ordering its disclosure.

V. <u>CONCLUSION</u>

The decision to allow wholesale disclosure of the peer review documents at issue in this case will undermine, rather than facilitate, better quality health care. If those who participate in peer review discussions cannot be assured that their communications will remain confidential and used only for this purpose, they will no longer willingly participate, or, if forced to participate, will be exceedingly circumscribed in the assessment and criticisms they provide.

This Court should clarify—once and for all—that: (i) peer review documents, including those created as part of the credentialing of a physician, are fully protected from discovery by the Peer Review Protection Act; and (ii) National Practitioners' Database documents are protected from discovery under federal law and may not be disclosed.

WHEREFORE, for the foregoing reasons, *Amici Curiae* respectfully request that this Court VACATE and REVERSE the decision of the Superior Court of Pennsylvania.

Respectfully submitted,

LAMB McERLANE PC

Dated: November 9, 2020

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CERTIFICATE OF COMPLIANCE

I certify that this filing complies with the provisions of the Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts that require filing confidential information and documents differently than non-confidential information and documents.

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IN THE SUPREME COURT OF PENNSYLVANIA

James E. Leadbitter and Tammy M. Leadbitter, his wife	:	19 WAP 2020
	:	
v.	:	
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		
v.		
Carmen Petraglia, M.D. and South Hills Orthopaedic Surgery Associates, a Corporation		
Appeal of: St. Clair Hospital		

PROOF OF SERVICE

I hereby certify that this 9th day of November, 2020, I have served the attached document(s) to the persons on the date(s) and in the manner(s) stated below, which service satisfies the requirements of Pa.R.A.P. 121:

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IN THE SUPREME COURT OF PENNSYLVANIA

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