No. 16-1446

IN THE
Supreme Court of the United States

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC.,
Petitioner,
v.
JEAN CHARLES, JR., as next friend and duly appointed guardian of his sister, MARIE CHARLES, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the Florida Supreme Court

BRIEF OF *AMICUS CURIAE* PSO FLORIDA, ECRI INSTITUTE PSO, TRINITY HEALTHCARE CORPORATION, NCH HEALTHCARE SYSTEM, BAYCARE HEALTH SYSTEMS, ADVENTIST HEALTH SYSTEM AND HOLY CROSS HOSPITAL, INC. IN SUPPORT OF PETITIONER

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July 3, 2017

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STATEMENT OF IDENTITY AND INTEREST OF *AMICUS CURIAE*[1]

PSO Florida was established to assist hospitals, health systems, physicians, and other healthcare providers in providing the safest, highest quality of care to their patients. Its mission is to improve the safety and quality of healthcare delivery through the application of science and implementation of best-practice evidence with the objective of preventing patient injury or death. PSO Florida has 20 member hospitals and healthcare organizations throughout the state of Florida.

ECRI Institute PSO is a component of ECRI Institute. ECRI Institute PSO's mission is to achieve the highest levels of safety, quality, and cost-effectiveness of healthcare by collecting and analyzing patient safety information and sharing lessons learned and best practices. The primary activity of ECRI Institute PSO is to conduct activities designed to improve patient safety and the quality of health care delivery. To achieve its mission, ECRI Institute PSO collects, aggregates and analyzes reports of adverse events, near misses and hazards; conducts investigations and studies; and disseminates best practices, tools and lessons learned that are gleaned from the data to encourage a culture of safety and to minimize patient risk. ECRI Institute PSO collaborates formally with 13 other PSOs and works with over 1,000 healthcare provider organizations on making care safer.

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[1] In accordance with Rule 37.6, amici state that no counsel for either party has authored this brief in whole or in part, and no person or entity, other than amici, has made a monetary contribution to the preparation or submission of this brief. In accordance to Rule 37.2, all parties were notified 10 days prior to the filing of the brief of the Amicus' intention to file. All parties have consented to the filing of this brief.

PSO Florida and ECRI Institute PSO are patient-safety organizations created under the express provisions of the PSQIA at issue, which implement Congress' aim of facilitating the sharing and studying of patient-safety information in a protected environment, see 42 USC 299b-21.

Trinity Healthcare Corporation, Holy Cross Hospital, Inc., NCH Healthcare System, BayCare Health Systems and Adventist Health System are health care organizations that operate 44 hospitals and hundreds of other healthcare facilities in the state of Florida. These healthcare organizations are members of Patient Safety Organizations and participate in quality improvement through Patient Safety Evaluation Systems under the Patient Safety Quality Improvement Act.

Additionally, Trinity Healthcare Corporation and Adventist Health System operate hundreds of hospitals and care centers nationwide which will be subjected to different applications of the privileges under the Patient Safety Quality Improvement Act as a result of the split of authority across state lines.

Holy Cross Hospital, Inc., a member of Trinity Healthcare Corporation, is a non-profit, 557-bed hospital that participates in a Patient Safety Organization created under the express provisions of the Federal statutory scheme at issue.

SUMMARY OF THE ARGUMENT

The Patient Safety and Quality Improvement Act of 2005 was passed for the purpose of improving the quality of medical care and patient safety. Congress recognized that achieving this worthy goal required that privilege and confidentiality attach to the work product of the providers. The fear of liability created

by participation in quality improvement activities chills candid disclosure and discussion of medical errors and eliminates the ability to implement effective change.

The decision below by the Florida Supreme Court undermines the intent of Congress by suggesting that existing State laws do not give way to this Federal legislation. If the decision is allowed to stand, in the law regarding the privilege and confidentiality afforded to quality improvement documentation. Providers will be unwilling to share information about medical errors and near misses: an outcome diametrically opposed to Congress' aim. Without active and candid participation by providers, Patient Safety Organizations become incapable of raising the level of care in hospitals.

The breadth of the incorrect decision by the Florida Supreme Court results in immediate damage to PSO members by removing privileges providers relied upon. The uncertainty for PSO members moving forward is as troubling. PSO members with facilities in Florida and other states will be placed in the untenable position of prohibiting their Florida facilities from enjoying the benefits of PSO participation or encouraging them to create documents that will be used against them in medical malpractice litigation.

The Court should grant the Petition to reinstate the full complement of benefits under the PSQIA to PSO members, resolve the uncertainty in the law and conflict between the courts regarding the protections under the PSQIA and reestablish the supremacy of Federal law in Florida.

ARGUMENT

I. THE PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005

The Patient Safety and Quality Improvement Act of 2005 ("PSQIA") was created with patient safety at its core. When it was passed by unanimous vote of the Senate and nearly unanimous vote of the House of Representatives, its stated purpose was "improving patient safety and the quality of [health]care nationwide." The drafters of the Act were responding in large part to findings contained in the Institute of Medicine's groundbreaking study, Institute of Medicine, *To Err Is Human: Building A Safer Health System* 27 (Nov. 1999). The report not only highlighted the $17-$29 billion dollar costs of medical errors, but recognized that changing the culture of quality improvement in the healthcare industry was essential. Specifically, the Institute noted that providers needed to retreat from the "culture of blame" and instead focus on "systemic breakdowns" which caused the majority of costly medical errors. *Id.* at 51-53.

Congress recognized the warning by the Institute and designed the PSQIA to protect the documents created during self-critical analysis. The legislative history of the Act clearly recognizes that providers who contribute to quality improvement in our nation's hospitals can only do so candidly and effectively if they are assured that their efforts to improve patient safety are not used against them in civil litigation. The Senate Committee Report on the bill noted that "society's long-standing reliance on the threat of malpractice litigation discourages health care professionals and organizations from disclosing, sharing and discussing information about medical errors." S. Rep. No. 108-196, at 2 (2003). To "engender the trust

and cooperation of health care providers" in this "confidential and nonpunitive system . . . ," Congress created "broad confidentiality and legal protections" for information collected and reported to Patient Safety Organizations ("PSOs"). The Act encouraged such reporting "for the purpose of improving the quality of medical care and patient safety." *Id*. at 4; See also *KD ex rel. Dieffenbach v. United States*, 715 F.Supp.2d 587, 595 (D.Del.2010) (The Patient Safety Act "announces a more general approval of the medical peer review process and more sweeping evidentiary protections for materials used therein."). The Act established a "Patient Safety Evaluation System" ("PSES") that was to be developed by health care providers permitting the provider to share information, known as Patient Safety Work Product ("PSWP"), relating to patient safety events with PSOs. The preamble to the implementation language of the Act summarizes the importance of the protections Congress intended:

> The statute attaches privilege and confidentiality protections to this information, termed 'patient safety work product,' to encourage providers to share this information without fear of liability and creates PSOs to receive this protected information and analyze patient safety events. These protections will enable all health care providers, including multi-facility health care systems, to share data within a protected legal environment, both within and across states, without the threat that the information will be used against the subject providers.

From the Act's inception, providers were strongly encouraged to participate. Congress even showed the

preference that hospitals utilize Patient Safety Evaluation Systems in their passage of other legislation. For example, in drafting the Affordable Care Act ("ACA"), Congress prohibited any hospital with greater than fifty beds from participating in statewide health care exchanges and accepting ACA health plans unless they "utilize[d] a patient safety evaluation system as described in [the PSQIA]." Patient Protection and Affordable Care Act, § 1311(h)(1)(A)(i), Pub. L. No. 111-148, 124 Stat. 180 (2010). While later revisions to the ACA opened participation to hospitals that implemented other evidence based quality improvement measures, the importance placed on effective quality improvement by Congress should not be overlooked.

Effective quality improvement requires the protections set forth in the PSQIA. The *Charles* decision eliminates them. Patient Safety Organizations have already begun to provide significant benefits to their members. Analyzing data submitted from providers nationwide has provided unique and never before seen insights into ways hospitals can deliver safer patient care. See ECRI Institute online at https://www.ecri.org/resource-center/Pages/Key-Learnings-from-ECRI-Institute-Patient-Safety-Organization.aspx. For example, ECRI Institute PSO has completed a "deep dive" analysis of a patient safety topic each year. Deep Dive topics have included errors related to the use of health care information technology, Care Coordination, Laboratory Events, Medication Safety, and reducing the risk of wrong-patient errors during the multitude of patient encounters occurring daily in health care settings. Thousands of events are shared on these topics from hundreds of hospitals nationwide. The results of the studies are then made available to all PSO members. See ECRI Institute online at https://www.ecri.org/Pages/Patient-Identification-Deep-

Dive.aspx. The information, analysis, advice and support from these studies allows participants in the PSO to prevent future occurrences and learn from other healthcare organizations across the country. This type of analysis is only possible if PSO members trust that sharing their data will not ultimately lead to its use in medical malpractice litigation. That trust, earned by Congress through the passage of the PSQIA, is violated by the ruling of the Florida Supreme Court.

II. THE FLORIDA SUPREME COURT'S DECISION WARRANTS THIS COURT'S REVIEW

If the decision below is permitted to stand, PSO members in the state of Florida will suffer present and ongoing harm. Further, the Florida Supreme Court's decision will reach beyond the borders of the state. Any suggestion by the respondent that this writ should be denied as moot is contradicted by the present and ongoing harm suffered by Patient Safety Organizations and their members. Indeed, the very decision of the Florida Supreme Court to issue an opinion in the underlying case itself belies the argument that this case is moot. The Florida Court exercised its discretion to ignore the attempt by the parties to dismiss the appeal and retained jurisdiction over the case, recognizing that this very issue is a matter of great public importance and is likely to recur. *Pino v. Bank of N.Y.,* 76 So. 3d 927 (Fla. 2011).

This Court has similar authority. The definition of the "case or controversy" requirement for jurisdiction pursuant to Article III of the Constitution simply requires that litigants demonstrate that the challenged ruling will have ongoing consequences in the suit. *Camreta v. Greene,* 563 U.S. 692, 131 S. Ct. 2020, 179 L. Ed. 2d 1118 (2011). There is no doubt that

Patient Safety Organization members will suffer ongoing adverse consequences if the incorrect decision of the Florida Supreme Court is allowed to become concrete. PSO members would experience shrinking quality assurance participation, less frequent post-incident analysis and rulings by trial courts following the rule of the decision below.

A. PSO Members in the State of Florida Suffer Present and Ongoing Harm as a Result of the Decision Below

In joining a Patient Safety Organization, members undertook the arduous task of creating patient safety evaluation systems and building IT infrastructures to transmit data to PSOs. PSO members submitted thousands of documents to their respective PSOs. In reliance upon the PSQIA, these health care organizations provided assurances to participating providers that their self-critical analysis would be protected from forced disclosure and used in civil actions. 42 U.S.C. § 299b-22(a)-(b). If the *Charles* decision is allowed to stand, health care providers that dedicated their efforts to improve patient care and safety will see the Federal protections they relied upon retroactively stripped away, as documents that were protected at the time of creation are now subject to disclosure.

PSO members like Southern Baptist Hospital of Florida have been stripped of privileges that were previously conferred by Federal statute. Quality improvement activities that were encouraged and protected by the PSQIA have now been undermined and severely limited. The full benefits of the Federal Legislation designed to improve patient care in Florida hospitals have now been removed.

If the opinion of the Florida Supreme Court is left unaddressed trial courts throughout the state will undoubtedly feel compelled to order the production of documents that once enjoyed absolute privilege and confidentiality. Discovery orders will ultimately lead to inconsistent application of the Patient Safety Quality Improvement Act across state lines. Hospitals in Florida will be compelled to produce documents that fellow PSO members in neighboring states will be entitled to protect. The uneven application will be more pronounced and even more problematic when health care organizations have facilities in Florida and other states. In that scenario, a health system that is sharing information across their own organization and ultimately with their PSO, could see the same document protected in one state and subject to disclosure and use in civil litigation in Florida.

Due to the Florida Supreme Court's ruling, organizations that use quality improvement reports across their system may be forced to wall off their Florida facilities, prohibiting them from contributing data to the PSO in order to shield them from the adverse effect of discovery in civil litigation. Clearly, preventing facilities from engaging in activities designed to enhance patient safety frustrates the very purpose of the PSQIA. Avoidance of system review and enhancement due to the threat of litigation returns Florida hospitals to the same "culture of blame" the Institute of Health warned against and that the PSQIA was designed to prevent.

The inconsistent treatment of PSO members in Florida highlights the need for a uniform national system that was intended by Congress in their passage of the PSQIA. Without this Court's review, each state will continue inconsistent and conflicting applications

of the PSQIA. See *Baptist Health Richmond, Inc. v. Clouse*, 497 S.W.3d 759 (Ky. 2016)(holding that a provider "may collect information within its Patient Safety Evaluation System that complies with the Act and that also complies with state statutory and regulatory requirements; *Department of Financial & Professional Regulation v. Walgreen Co.*, 970 N.E.2d 552(Ill. App. Ct. 2012)(shielding reports subpoenaed by a state agency because the reports had been submitted by a PSO.

B. The Decision by the Florida Supreme Court is in Error

The central premise of the decision by the Florida Supreme Court is that because the PSQIA preserves the obligation of state record keeping and reporting, any document that may potentially be reported must be deemed to exist separate from the Patient Safety Evaluation System and therefore cannot be Patient Safety Work Product. Such an interpretation is a textual and ignores the plain language of the Act. This interpretation was specifically contradicted in the Health and Human Services ("HHS") rule guidance. Those rules addressed this scenario by assuring providers that they may place information into their PSES with the expectation of protection and may later remove the information if the provider determines that it must be reported to the State." 73 Fed. Reg. at 70,732, 70,742 (Nov. 21, 2008).

The final regulations under the Act, published by the HHS in 2008 in fact provide two very important pieces of guidance that plainly rebut the conclusion reached by the Florida Supreme Court.

First, privilege attaches to materials created within the PSES immediately upon collection of the information and not at the time that the information is sent to the PSO. 73 Fed. Reg. at 70,741. Thus, the genesis of the privilege is at the time the data is first collected, preventing any argument that the document loses its privilege at any point before it is physically transmitted to the PSO. More importantly however, it removes the claim that any entity, including a State agency or regulatory body, can lay claim to the document prior to the attachment of the privilege.

Second, as noted above, the regulations disposed of any notion that providers would be required to maintain separate, duplicative recordkeeping systems to collect PSWP while at the same time satisfying state reporting requirements. 73 Fed. Reg. at 70,740-41. The concern surrounding the potential that two record keeping systems would be required was reported to be the "most significant area of comment" on the proposed regulations. See 73 Fed. Reg. at 70,740-41. HHS was concerned that if dual systems to participate in a PSO and comply with State obligations were required, providers "may opt to not participate . . . due to costs and burdens." 73 Fed. Reg. at 70,741. The HHS sought to specifically alleviate provider concerns that two separate, duplicative collections of documents were required. The regulations state that the provider makes the ultimate determination whether any of the documents created within the PSES need to be disclosed to State or Federal regulators and provided a mechanism to declassify those documents. As was concisely and accurately stated by the Florida First District Court of Appeal, the HHS' rules give providers the

> "flexibility to collect and maintain its information in the manner it chooses with the caution that nothing should be construed to limit any reporting or recordkeeping requirements under State or Federal law. The Act is clear that it is the provider who determines how information is stored and reported, and the provider must face any consequences of noncompliance with State or Federal reporting or recordkeeping requirements."

Pet. App. 46a

The regulations also illustrate how only the actual disclosure of the document to an outside body or agency can remove the cloak of confidentiality afforded under the PSQIA. Unless and until the document is actually used for a purpose outside of the PSES, and thus "exists separately" from the PSES, the privileges and protections afforded to the documents remain and such protections preempt any State law that would otherwise require disclosure. The practice contemplated by the PSQIA was illustrated by the actions of Southern Baptist Hospital of Florida Inc. in the underlying case. Southern Baptist established that all incident reports were created within the Hospital's PSES. The only reports that were removed from the PSES and disclosed to any third party were the Hospital's Code 15 and Annual reports. The Hospital voluntarily agreed to produce those reports because they existed outside of and separate from the PSES.

Suggesting that documents must be created exclusively for the purpose of reporting to the PSO, imposes a requirement that is not found anywhere within the text of the Act. Using this premise would not only destroy the very purpose of the PSQIA, thereby eliminating the incentive of creating a greater culture

of safety, but would impermissibly abrogate the powers of Congress by adding words and additional meaning to a Federal statute. See *Johnson v. Royal Caribbean Cruises, Ltd.,* 449 F. App'x 846, 848 (11th Cir. 2011).

The Florida Supreme Court based its opinion in part on Section 42 U.S.C. § 299b-21(7)(B)(iii), which states in pertinent part:

> (iii) Nothing in this [Act] shall be construed to limit—. . . (II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or (III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law . . .

and concludes that concurrent obligations destroy the privilege afforded to PSWP. Such an interpretation is misplaced. This clause clearly and simply states that providers may not use the Act to escape the requirements imposed by the State or Federal government pertaining to record creation or retention. Notably absent in this section however, is any reference to the destruction of the privilege afforded to PSWP simply by the existence of concurrent state law obligations. Courts are "without power to construe an unambiguous statute in a way which would extend, modify, or limit, its express terms . . ." *Glass v. Captain Katanna's, Inc.,* 950 F. Supp. 2d 1235, 1242 (M.D. Fla. 2013) (quoting *Bennett v. St. Vincent's Med. Ctr., Inc.*, 71 So. 3d 828, 838 (Fla. 2011)). In fact, no attempt to alter, interpret or decipher the PSQIA is necessary. The Act is clear and such clear language must be used as the "starting point" for any decision. *Good Samaritan*

Hosp. v. Shalala, 508 U.S. 402, 409, 113 S. Ct. 2151, 2157, 124 L. Ed. 2d 368 (1993).

Moreover, at 42 U.S.C. § 299b-21(7)(B)(i)-(ii), Congress identified the items it intended to exclude from the definition of PSWP:

> (i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other patient or provider record.
>
> (ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

If Congress had the intent to exclude documents that may ultimately be reported to the state from the definition of patient safety work product it would have done so by including such documents in this section.

C. The Florida Supreme Court Incorrectly Ruled that State Law is Not Preempted by the PSQIA

The Florida Supreme Court also created a troubling roadmap for other States who wish to circumvent the PSQIA. In its opinion, the Florida Supreme Court ruled that state reporting and discovery laws were not preempted by the PSQIA. Pet. App. 32a.

This suggests that any State, who presently has, or who chooses to pass legislation that requires the creation or maintenance of certain documents by hospitals, can simply avoid the effect and intent of the

PSQIA and avoid pre-emption of established Federal law. It would be illogical and counterproductive if Congress included the requirement that providers meet concurrent state obligations in the PSQIA with the intention of excluding any such document from being considered PSWP. The Court should avoid any such construction of the law that would completely undermine the purpose of the Act by allowing states to pass law that create concurrent record keeping obligations and thereby strip the Federal Legislature of their power to create a confidential system in which providers can improve patient safety. *Haggar Co. v. Helvering,* 308 U.S. 389, 394, 60 S. Ct. 337, 339, 84 L. Ed. 340 (1940) (A literal reading which would lead to absurd results is to be avoided when statutes can be given a reasonable application consistent with their words and with legislative purpose).

Federal preemption demands a different result. The United States Constitution designates the laws of the United States as the supreme law of the land, requiring that all conflicting state provisions be without effect. *Murphy v. Dulay*, 768 F.3d 1360 (11th Cir. 2014). The PSQIA clearly states its intention to preempt any state laws requiring disclosure of PSWP. 42 U.S.C. § 299b-22(a)-(b); 73 Fed. Reg. at 70,743-44. To interpret any section of the PSQIA as yielding to state law requirements is to impermissibly read conflict and disharmony into the law itself. *Allen v. USAA Cas. Ins. Co.,* 790 F.3d 1274, 1280 (11th Cir. 2015) (All parts of statute must be read together in order to achieve a consistent whole; where possible, a court must give full effect to all statutory provisions and construe related statutory provisions in harmony with one another). Thus, the proper lens through which to view any request for documents that may enjoy privilege under the PSQIA is to evaluate Federal

law and its preemption first before turning to State law to determine what survives that preemption. The Florida Supreme Court's approach of looking first at State law to construe it in a manner that escapes Federal preemption would allow each State to overcome the effect of the PSQIA by passing recordkeeping and retention laws to destroy the Act's confidentiality provisions. To allow a state to pass a law that could be later interpreted to require disclosure of PSWP would be in direct contravention to the Act and run inapposite to the law of Federal preemption.

A guiding example of the preemptive effect of the PSQIA of a State law right to inspect by the PSQIA was demonstrated in *Department of Financial and Professional Regulation v. Walgreen Co.*, 970 N.E.2d 552 (Ill. App. Ct. 2d 2012). Illinois state law authorized regulators to "subpoena and compel the production of documents, papers, files, books, and records in connection with any hearing or investigation" carried out by state regulators. *Id*. at 558. However, the Court held that the Act protected the documents at issue. *Id*. The Court also demonstrated the appropriate inquiry into whether a document was being maintained "separately" from a PSES so as to lose its confidential status. The Court did not look to the concurrent state law obligations or rights, but instead ruled that because the reports in question were created within a PSES and remained sequestered in the system, the reports were protected. Likewise, this Court should restore the preemptive effect of the PSQIA by granting the Petition of Southern Baptist Hospital of Florida.

CONCLUSION

For the foregoing reasons and those in the petition, the petition for writ of certiorari should be granted.

Respectfully submitted,

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