SUPREME COURT OF FLORIDA

Case No. SC15-2180
L.T. Case Nos. 1D15-109; 162012CA002677XXXXMA

JEAN CHARLES, JR., ETC., ET AL.

Appellants,

v.

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC., ETC., ET AL.

Appellees.

AMICUS CURIAE BRIEF OF THE PATIENT SAFETY ORGANIZATION OF FLORIDA AND ECRI INSTITUTE PSO

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STATEMENT OF IDENTITY AND INTEREST OF *AMICUS CURIAE*

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 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.

SUMMARY OF 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. The Act created a voluntary system that allowed health care providers to collect data related to patient safety and submit it for analysis to Patient Safety Organizations. In order to encourage participation and to achieve the goal of improving health care for patients nationwide, the Act included privilege and confidentiality provisions to protect the work product of the providers. According to the terms of the Act, data that is collected and remains within a provider's Patient Safety Evaluation System for the purpose of reporting to a Patient Safety Organization is privileged, confidential and not subject to forced production. Contrary state laws relating to disclosure are preempted by the Act's confidentiality provisions in order to promote candid and effective reporting by providers so that the goal of improved patient care is achieved. While the Act offers unequivocal protection that preempts contrary state laws, it does so in a manner that allows providers the ability to maintain a single database from which the provider can voluntarily remove documents to be used for a separate purpose such as complying with state record keeping requirements without jeopardizing the confidentiality and privilege of the materials that remain in the system/database.

ARGUMENT

THE PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005

The Patient Safety and Quality Improvement Act of 2005 ("PSQIA") was passed by unanimous vote of the Senate and nearly unanimous vote of the House of Representatives with the stated purpose of "improving patient safety and the quality of [health]care nationwide." The Act established a "Patient Safety Evaluation System" ("PSES") that was to be developed by health care providers permitting the provider to share information, relating to patient safety events with Patient Safety Organizations ("PSO"). In passing the Act, Congress recognized an effective system that encouraged provider participation and achieved meaningful results, required the creation of a privilege for the information collected by providers. 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) at 2. 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 PSOs "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 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."

Although the system is voluntary, providers are encouraged to participate. Since the passage of the PSQIA, Congress has even shown the preference that hospitals utilize Patient Safety Evaluation Systems in their passage of other legislation. For example, in the sweeping legislation on health care insurance reform known as the Affordable Care Act, Congress required that any hospital with greater than fifty beds, that wishes to contract with statewide health care exchanges and accept plans under the Affordable Care Act, will only be permitted to do so if the hospital "utilizes a patient safety evaluation system as described in [the PSQIA]." Patient Protection and Affordable Care Act §1311(h)(1)(A)(i). To that end, the 20-member hospital and health care organizations of PSO Florida and the over 1,000 health care provider organizations working through ECRI have undertaken the arduous task of building IT infrastructures at their facilities, created

patient safety evaluation systems and have submitted thousands of documents to their respective PSOs. This allows members to share information not only with other hospitals in their state, but also with PSO members nationwide to accomplish the goal of making the health care provided to patients safer. In exchange for their participation, the PSQIA provided assurances to members that their self-critical analysis would be protected from forced disclosure and use in civil actions against them. §299b-22(a)-(b).

The definitions of PSWP are broad and include a variety of documents commonly created by hospitals in evaluating outcomes for quality. Specifically, the PSWP includes, "any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" that (1) are assembled or developed by a provider for reporting to a PSO; (2) are in fact reported to a PSO; and (3) could result in improved patient safety, health care quality, or health care outcomes. Id. §299b-21(7)(A)(i). PSWP also includes "any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" from the deliberations or analysis of a PSES, or which identify the fact of reporting pursuant to a PSES. Id. §299b-21(7)(A)(ii).

Congress also specifically defined what PSWP is not. Original records such as a patient's medical chart, nursing notes, billing information and "information that is collected, maintained, or developed separately, or exists separately," from

the PSES does not enjoy the privilege created under the PSQIA. Id. §299b-21(7)(B)(ii). While disclosing the documentation to third parties typically removes the document from the required sequestration in the PSES, Congress identified third parties who can receive PSWP from providers without destroying the privilege attached to the documents. For example, Subsection 922(d) states that providers are permitted to disclose the materials to any organization in connection with accreditation and still maintain the absolute privilege against forced disclosure of the documents.

I. ANY DOCUMENT CREATED WITHIN A PROVIDER'S PATIENT SAFETY EVALUATION SYSTEM IS PRIVILEGED AND CONFIDENTIAL AND THE PSQIA DOES NOT PROHIBIT A DOCUMENT FROM SIMULTANEOUSLY BEING PATIENT SAFETY WORK PRODUCT AND MEETING STATE REPORTING REQUIREMENTS

The central premise of the arguments advanced by the Appellant and its Amici is that because the PSQIA preserves the obligation of state record keeping and reporting, any document that may eventually be reported must be deemed to exist separate from the Patient Safety Evaluation System and therefore cannot be PSWP. Such an interpretation is atextual and ignores the plain language of the Act.

The First District Court of Appeal correctly recognized that the argument of the Appellant was specifically contradicted in the Health and Human Services final rule guidance. As noted in the lower court's opinion, the rules, "specifically

address this scenario by assuring providers that they may place information into their PSE system with the expectation of protection and may later remove the information if the provider determines that it must be reported to the State." *Southern Baptist Hosp. of Fla., Inc. v. Charles*, 178 So.3d 102, 109, (Fla. 1st DCA 2015), *citing* 73 Fed. Reg. at 70,742.

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 position the Appellant asks this Court to take.

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 as is suggested by the Appellant.

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 First District, 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." *See Southern Baptist Hosp. of Fla., Inc. v. Charles*, 178 So.3d 102, 109, (Fla. 1st DCA 2015). The regulations 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 hospitals 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. App. 423 ¶ 25. Conversely, all other reports remained segregated within the PSES. No state regulator or other third party is or ever has been privy to those documents. App. 423 ¶ 25-426.

The position of the Appellant, 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 by PSO members, but would impermissibly abrogate the powers of Congress by adding words and additional meaning to a Federal statute. *See Bay Holdings, Inc. v. 2000 Island Blvd. Condo. Ass'n*, 895 So.2d 1197 Fla. 3d DCA (2005), (Court is not at liberty to add words to statutes

that were not placed there by the legislature; to do so, would be an abrogation of legislative power.); *Chaffee v. Miami Transfer Co., Inc.,* 288 So.2d 209 (Fla. 1974), (Court in construing statute cannot invoke a limitation or add words to the statute not placed there by the legislature.

The Appellant bases their position 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..." *Horowitz v. Plantation General Hosp. Ltd. Partnership,* 959 So.2d 176 (Fla. 2007). In fact, no attempt to alter, interpret or decipher the PSQIA is necessary. As the First District explained, "the Act is Clear"

and such clear language must be used as the "starting point and guidepost" for any decision. *See Southern Baptist Hosp. of Fla., Inc. v. Charles*, 178 So.3d 102, 107-108 (Fla. 1st DCA 2015). It would also 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. *See McKibben v. Mallory*, 293 So.2d 48 (Fla. 1974), (Construction of a statute which would lead to an absurd result should be avoided).

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 they would have done so by including such documents in this section.

II. THE PRINCIPLES OF FEDERAL PREEMPTION CONTRADICT THE POSITION OF THE APPELLANT

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. R. at 70743, 70744. To interpret any section of the PSQIA as yielding to state law requirements is to impermissibly read conflict and disharmony into the law itself. *See Forsythe v. Longboat Key Beach Erosion Control Dist*., 604 So.2d 452 (Fla. 1992) (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 Appellants' approach of looking at first at State law to construe it in a manner that escapes Federal law would allow each State to overcome the preemptive effect of the PSQIA by passing a law allowing regulators to inspect a

provider's documents, thus destroying 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 in opposite to the law of Federal preemption. The dispositive question should be whether the documents at issue were created and maintained within the PSES. If that question can be answered in the affirmative, then Federal law mandates protection of the documents and, as noted by the First District, there is "no need for the court to consider whether the documents at issue simultaneously satisfy any state law obligations." *Southern Baptist Hosp. of Fla., Inc. v. Charles*, 178 So.3d 102, 110, (Fla. 1st DCA 2015).

The nullification 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 29 (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 rebuffed arguments by the State that the reports

were maintained "separate" from the PSES, on the strength of affidavits indicating that the reports in questions were created within the PSES and remained sequestered in the system. Accepting those affidavits as fact, just as the affidavits of Southern Baptist Hospital were accepted in the present matter, the Court in *Walgreen* ceased the inquiry, determining that the records created within the PSES and maintained there, were confidential and preempted the state's right to inspect. *Id.* at 558. The PSWP, in the present matter, created and maintained at all times within the PSES of the hospital, should likewise be protected.

CONCLUSION

If a document is created within the PSES for reporting to a PSO and does not exist separately from the provider's PSES, it is privileged and confidential under the express terms of the PSQIA of 2005. The documents created within the PSES, which are covered by privilege upon creation, do not lose their confidential status regardless of whether the document also concurrently satisfies a state requirement to create or maintain records. The PSQIA was created with patient safety at its core. The drafters of the Act recognized that providers who participate in a system of self-critical analysis 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. Therefore, the members of PSO Florida and ECRI respectfully urge this

Court to uphold the express provisions of the PSQIA and to support their participation in furtherance of the Act's worthy goals.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U. S. Mail to the individuals identified on the attached Service List on May 2, 2016.

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CERTIFICATION OF FONT SIZE AND STYLE

I HEREBY CERTIFY that this Appellant's INITIAL BRIEF has been typed using the 14 point Times New Roman font as required by Rule 9.210(a) and 9.210(a)(2), Florida Rules of Appellate Procedure.

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