IN THE DISTRICT COURT OF APPEAL
FIRST DISTRICT, STATE OF FLORIDA

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC.,

Petitioner,

v. Case No. 1D15-109

JEAN CHARLES, JR., as next friend and duly appointed guardian of his sister, MARIE CHARLES, and her children, ANGEL ALSTON and JAZMIN HOUSTON, minors, and ERVIN ALSTON; KRISTIN FERNANDEZ, D.O.; YUVAL Z. NAOT, M.D.; SAFEER A. ASHRAF, M.D.; INTEGRATED COMMUNITY ONCOLOGY NETWORK, LLC; ANDREW NAMEN, M.D.; GREGORY J. SENGSTOCK, M.D.; JOHN D. PENNINGTON, M.D.; and EUGENE R. BEBEAU, M.D.; and ROBERT E. ROSEMUND, M.D.,

Respondents.

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 complimentary 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.

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 like Southern Baptist Hospital of Florida 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. 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).

As noted above, in order allow candid participation by providers and achieve meaningful analysis of the data collected, the PSQIA declared all PSWP to be

privileged and confidential. §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.

THE TRIAL COURT ERRED BY ORDERING THE PRODUCTION OF DOCUMENTS THAT FALL WITHIN THE DEFINITION OF PATIENT SAFETY WORK PRODUCT

The central questions that should be considered by the Court when reviewing a request for information that is claimed to be PSWP is (1) were the documents created within the PSES and (2) did they remain isolated within the System, designated as privileged work product to be sent to a PSO. If it is determined that the documents were created within the PSES and have not been reported to any other non-exempt entity or agency outside of the PSES, the plain language of the Act demands that the documents receive protection from forced disclosure.

In the present matter, the Plaintiff put forth no arguments that the requested reports fell outside the definition of PSWP. Instead, the Plaintiff advanced the argument that the documents lost their privilege because they were created for "multiple purposes," namely for compliance with Chapter 395 of the Florida Statutes. App. 282, p. 5; 288, p. 31 The Court agreed, ordered production of the documents and in doing so, committed error.

It is important to note at the outset that although the phrases "dual purpose" and "multiple purposes" were used by the Plaintiff and apparently considered by the Court, that nomenclature does not exist in the PSQIA. Nowhere within the Act does the plain language state that if the reports created within the PSES by the provider also satisfy some concurrent state requirement, then the PSWP loses its privileged status. During argument on the underlying motion, Plaintiff relied upon a "Frequently Asked Questions" section of the PSO website. App. 282, p. 5; 288, p. 31. That section of the website used the phrase "multiple purposes" and attempted, perhaps inartfully, to address questions regarding the use of PSES documentation for legal defense against claims.[1] However, this "FAQ" section of the website is neither law nor controlling precedent of any kind. In evaluating Plaintiff's claims the trial court was required to evaluate the plain language of the statute regarding whether documents within the PSES lose privilege if they can also arguably satisfy other state imposed obligations. The PSQIA is clear in the protections PSWP documents enjoy from the date of creation and the very narrow instances in which, *through declassification by the provider*, the document is no longer considered PSWP.

In fact, the framework of the PSQIA was developed, and later clarified by the United States Department of Health and Human Services ("HHS"), to ensure

[1] The Frequently Asked Questions section of the PSO Florida website has since been changed to use citation from the Federal Register to clarify this issue. http://www.psoflorida.org/faq.html

that hospitals could participate in a PSO, receive the full benefit of the privileges Congress deemed vital to the success of the Act, and still meet the obligations of regulation by the home state of the provider.

In 2008, HHS published final regulations under the Act. These regulations provide two very important pieces of guidance that show how the PSQIA provides an immediate and overarching privilege to documents created within the PSES.

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 70741. 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 was physically transmitted to the PSO or that any other person or entity can lay claim to the document prior to the attachment of the privilege. The immediacy of the privilege also removes any perceived burden upon the hospital to immediately transmit to the PSO any document it creates relating to patient safety.

Second, the regulations disposed of any notion that providers would be required to maintain separate, duplicative recordkeeping systems to collect PSWP and report it to PSOs while at the same time satisfying state reporting requirements. 73 Fed. Reg. at 70740-41. The regulations provided that all information is permitted to be initially collected in the PSES and, as noted above,

immediately enjoy the protections of the privilege. The provider can then review the collection of materials and declassify any document the provider feels must be disclosed to state agencies. Id. at 70741-42. Any information that is declassified is no longer considered PSWP. 42 C.F.R. §3.20; 42 U.S.C. §299b-21(7)(B)(ii). The regulations therefore illustrate how only the actual disclosure of the document to an outside body or agency, through intentional declassification and use by the provider, 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 ruling of the Court suggests that documents must be created *exclusively for* the purpose of reporting to the PSO, a requirement that is not found anywhere within the text of the ACT. To allow the Order to stand based upon this premise would not only destroy the very purpose of the PSQIA, 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 Plaintiff, and indeed the Court also improperly relied 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…"

as a basis to conclude 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. Nevertheless, the trial court misapplied section 299b-21(7)(B)(iii) in its Order and impermissibly expanded its breadth. The Order suggests that if concurrent obligations exist for reporting and/or recordkeeping, the privilege for PSWP is voided as to all documents created by the hospital related to quality evaluation regardless of whether they have actually been used for that purpose and disclosed to any third party. The interpretation by the Court is well outside the plain language contained

within the clause and violates the tenants of statutory construction in Florida. 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).

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. *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, the Plaintiff's arguments and thus the Court's Order, confusingly migrate between the obligations of Chapter 395 of the Florida Statutes and the Florida Constitution, Article X, Section 25, which is often cited as the "Patient's Right to Know About Adverse Medical Incidents." The Plaintiff requested "adverse incident materials" under the Article X, Section 25. The Court in ordering the production of the documents at issue also used the constitutional definition of "adverse incident." App. 400 ¶ 1. The Court then uses the obligations purportedly

imposed under Chapter 395 as the basis for the determination that the documents in question are created for a "separate" purpose and are therefore not protected as PSWP. However, the Florida Constitution and Chapter 395 have different definitions of the term "adverse incidents." Chapter 395 narrowly defines "adverse incidents" as those incidents that involve:

[395.0197(5)]

> 1. Death;
> 2. Brain or spinal damage;
> 3. Permanent disfigurement;
> 4. Fracture or dislocation of bones or joints;
> 5. A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility;
> 6. Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or
> 7. Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;
>
> (b) Was the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;
>
> (c) Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or
>
> (d) Was a procedure to remove unplanned foreign objects remaining from a surgical procedure.

Article X, Section 25 of the Florida Constitution contains a much more broad definition of the term and includes any and all incidents that "caused or

could have caused harm to a patient." Florida Hosp. Waterman, Inc. v. Buster, 984 So.2d 478 (Fla. 2008). If the Court intended to order the production of reports allegedly created to satisfy the requirements of Chapter 395, the plain language of the definitions contained in that Chapter dictate a far more narrow scope of documents than what was ordered by the Court. The Florida Constitution does not require the creation of any document by healthcare providers whatsoever. Rather, under Article X, Section 25, it allows Plaintiffs to now view quality assurance documents already created that were once strictly protected by the Florida Statutes. Chapter 395 requires the disclosure of only two types of documents – reports of incidents as defined under 395.0176(5) and annual summary reports of the incidents listed in that section. Thus, when the Trial Court relied upon the risk management provisions of Chapter 395 to order the production of all documents as defined by the Florida Constitution in Article X, Section 25, the Court impermissibly interjected and expanded the scope of the record making and record keeping obligations of the hospital under Chapter 395.

Likewise the Court incorrectly concluded that the reference contained within §395.0197(4) that hospitals be required to "use" and "maintain" incident reports as part of their risk management program created a record keeping obligation that removed any such report from the protections enjoyed by PSWP. App. 391-400. That conclusion is unsupported by the Act's final regulations. The HHS sought to

specifically alleviate provider concerns that two separate, duplicative collections of documents were required[2]. 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. This practice is illustrated by the actions of Southern Baptist Hospital of Florida Inc. in the underlying case. Southern Baptist established, and the Court accepted as fact, 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 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. As a result, according the plain language of the PSQIA, the reports are not subject to forced disclosure.

The fact that the State may hold a "right" to inspect certain documents likewise does not trump the privilege afforded those documents. The trial Court, at the urging of Plaintiff's counsel, incorrectly concluded that Section 395.0197(13),

[2] The concerns surrounding a potential requirement to maintain two record keeping systems was reported to be the "most significant areas of comment" on the proposed regulations. *See* 73 Fed. Reg. at 70740-41 Additionally, 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 70741.

authorizing state regulators to inspect "all records" created under Chapter 395, necessarily meant that the hospital was maintaining the records for "multiple purposes." First and foremost, and as discussed above, the proper inquiry is not whether the reports satisfy multiple purposes, but instead whether the reports were maintained separate and a part of the hospital's PSES. Second, the Act's mandated confidentiality for PSWP pre-empts state law and negates the state's authority to inspect records that are PSWP. If instead the Act's confidentiality provisions were secondary to a State law right to inspect, each State could 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. 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. Therefore, to interpret any section of the of the PSQIA as yielding to state law requirements as the trial Court did in the case at bar, 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).

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. The trial court's Orders should be quashed in accordance with the express provisions of the PSQIA and 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 February 4, 2015.

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CERTIFICATION OF FONT SIZE AND STYLE

I HEREBY CERTIFY that this Petitioner'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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