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

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC.,

Petitioner,

v.

Case No. 1D15-0109
L.T. Case No. 2012-CA-002677

JEAN CHARLES, JR., et al.,

Respondents.
_____/

# BRIEF OF *AMICI CURIAE*

Clarity PSO, Quality Alliance Patient Safety Organization, Schumacher Group Patient Safety Organization, Inc., UHC Safety Intelligence PSO, California Hospital Patient Safety Organization, CHS PSO, LLC, The PSO Advisory, LLC, Society of NeuroInterventional Surgery PSO, QA to QI LLC, Pascal Metrics, Inc., MEDNAX PSO, LLC, Child Health Patient Safety Organization, Inc., Missouri Center for Patient Safety, NC Quality Center PSO, American Data Network PSO, ECRI Institute PSO, Strategic Radiology Patient Safety Organization LLC, Ascension Health Patient Safety Organization, Verge Patient Safety Organization, Quantros Patient Safety Center, Quality Circle for Healthcare, Inc., PsychSafe, UHS Acute Care PSO, Midwest Alliance for Patient Safety (the "PSO Amici"), IASIS Healthcare LLC, Florida Health Sciences Center, Inc. d/b/a Tampa General Hospital, Crestview Hospital Corporation, Lake Wales Hospital Corporation, Manatee Memorial Hospital, L.P., La Amistad Residential Treatment Center, LLC, Adventist Health System/Sunbelt, Inc. (the "Provider Amici"), American Medical Association, Florida Medical Association, American College of Radiology, and American Society for Radiation Oncology (the "Association Amici")

**IN SUPPORT OF PETITIONER**
**SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC.**

Respectfully submitted by:

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## TABLE OF CONTENTS

## TABLE OF CITATIONS

### CASES

**STATUTES**



**RULES**



**OTHER AUTHORITIES**

## IDENTITY AND INTEREST OF AMICI CURIAE

Clarity PSO and the twenty-three other Patient Safety Organizations ("PSOs") who appear herein as amici curiae ("PSO Amici") were established in accordance with the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. § 299b-21 *et seq.* ("PSQIA"), for the purpose of gathering and analyzing information which is (i) critical to the improvement of patient safety and quality of care, (ii) submitted to PSOs in accordance with a carefully constructed federal regulatory framework, and (iii) protected from disclosure as privileged and confidential patient safety work product ("PSWP"). Together, the PSO Amici serve thousands of member hospitals, physicians, and other licensed health care providers throughout Florida and the United States who have relied on the aforementioned protections in implementing comprehensive information-gathering and reporting systems that meet the requirements of the PSQIA.

A number of the PSO Amici provide services to Florida-based health care providers. For example, UHS Acute Care PSO, PsychSafe, CHS PSO, LLC and Quality Circle for Healthcare, Inc. collectively serve over 20 health care facilities, including facilities operated by amici Manatee Memorial Hospital, L.P., La Amistad Residential Treatment Center, LLC, Crestview Hospital Corporation, Lake Wales Hospital Corporation, and Adventist Health System/Sunbelt, Inc.

In addition to the PSO Amici, multiple providers join in this brief, including IASIS Healthcare LLC, Florida Health Sciences Center, Inc. d/b/a Tampa General Hospital, and the providers mentioned in the preceding paragraph ("Provider Amici"). IASIS operates a national network of hospitals and other health care providers, and until October of 2013, operated three hospitals in the Tampa Bay area that were PSO members. Tampa General Hospital is an acute care hospital with 1,018 licensed beds, and has been a PSO member since 2009. Manatee Memorial Hospital, L.P., La Amistad Residential Treatment Center, LLC, Crestview Hospital Corporation, Lake Wales Hospital Corporation, and Adventist Health System/Sunbelt, Inc. collectively own multiple facilities throughout Florida that are also members of PSOs.

Finally, the American Medical Association ("AMA"), Florida Medical Association ("FMA"), American College of Radiology, and American Society for Radiation Oncology (collectively the "Association Amici") are professional associations representing physicians and other health care providers throughout Florida and nationally. The AMA and FMA join this brief in their own right and as representatives of the Litigation Center of the AMA and the State Medical Societies, which is a coalition of the AMA and the medical societies of each state and the District of Columbia, whose purpose is to represent the viewpoint of organized medicine in the courts.

All of the foregoing amicus parties have joined this brief because the effect of the trial court's decision is to significantly undermine and frustrate the clear intent of PSQIA as set forth in the preamble to the implementing regulation:

> The Patient Safety Act focuses on creating a voluntary program through which health care providers can share information relating to patient safety events with PSOs, with the aim of improving patient safety and the quality of care nationwide. 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.

Patient Safety and Quality Improvement, 73 Fed. Reg. 70732, 70732, (Nov. 21, 2008) (hereinafter "Final Rule") (emphasis added). The trial court's decision misinterprets the PSQIA by requiring the Petitioner to produce documents which meet the statutory requirements for protection. Indeed, the court's finding that incident reports, analyses and other documents reported to PSOs are discoverable effectively nullifies the PSQIA and would undermine the efforts of providers, federal and state governments and other health care industry participants to improve patient care and reduce risk through collective action.

## SUMMARY OF ARGUMENT

The trial court improperly grafted onto the PSQIA a limitation on the privilege which appears nowhere in the statute or Final Rule, finding that any

document which is collected or maintained to fulfill a regulatory requirement is not protected, when in fact, the Final Rule expressly allows documents created pursuant to external obligations to be maintained in a privileged patient safety evaluation system unless and until they must be reported to an agency. By contradicting the express language of the Final Rule, the court has eviscerated the PSQIA and contravened the intent of Congress to create a protected environment in which providers can share information without fear of liability. The decision also ignores the preemptive effect of the PSQIA and threatens to reverse the progress that has been made in encouraging open and collegial quality improvement activities. For these reasons, the court's order should be quashed.

## ARGUMENT

### I. The trial court's creation of an exception for documents "collected" or "maintained" pursuant to federal, state or local regulations contradicts the express language and intent of the PSQIA and Final Rule.

The trial court found that "information collected, maintained, or developed to fulfill obligations under federal, state or local law does not constitute PSWP." Petitioner's App. at 0499-0500. In support of its ruling, the court repeatedly cited language from the preamble to the Final Rule, which states: "Information is not patient safety work product if it is collected to comply with external obligations…." *See id.* at 0500, 0502 (citing 73 Fed. Reg. at 70742). The court misconstrued the phrase "external obligations" to include *any* obligations imposed

by a governmental entity, rather than limiting it to external *reporting* obligations, which is the intent indicated throughout the preamble and regulations. The court also erroneously found that "[d]ocuments are not PSWP if those documents were collected or maintained … for a dual purpose," *id*. at 0501, when the Final Rule expressly allows documents to be collected and maintained for dual purposes.

First, the trial court ignored the fact that the words "external obligations" refer to "external *reporting* obligations," a phrase that is used repeatedly throughout the preamble. For example, at page 70739, the preamble states, "Providers must fulfill external *reporting* obligations with information that is not patient safety work product" (emphasis added). The preamble uses this phrase again on page 70740, multiple times on page 70742, and again on page 70744. The language cited by the trial court should be read *in pari materia* with the rest of the preamble, which addresses the effect of external *reporting* obligations, rather than creating a blanket exception to the PSQIA for every document maintained pursuant to any regulatory requirement, which would render the PSQIA nugatory.

The trial court's finding that any documents "collected *pursuant to* a healthcare provider's obligation to comply with federal, state, or local laws" (Petitioner's App. at 0501 (emphasis added)) is particularly problematic due to the breadth of the term "pursuant to." This Court has noted that "pursuant to" can be used to mean "(1) in accordance with; (2) under; (3) as authorized by; or (4) in

carrying out." *State v. Phillips*, 852 So. 2d 922, 923 (Fla. 1st DCA 2003) (quoting Bryan A. Garner, *A Dictionary of Modern Legal Usage* 721 (2d ed. 1995)).[1] Similarly, the Fourth District has defined "pursuant to" as "acting or done in consequence or in prosecution (of anything); hence, agreeable; conformable; following; according." *LaChance v. Sagumeri*, 537 So. 2d 665, 666 (Fla. 4th DCA 1989) (quoting *Old Colony Trust Co. v. Comm'r of Int'l Revenue*, 301 U.S. 379 (1937)). Certainly, Congress could not have intended to exclude from the definition of PSWP literally *any*thing collected or maintained by a hospital or other health care provider in "carrying out" *any* regulatory obligation.

Indeed, Florida hospitals are governed by a wide variety of regulations covering everything from surgery and anesthesia services (Rule 59A-3.2085(3), (4), Fla. Admin. Code) to paint and plumbing (*id.* at 59A-3.276(1)(c), (e)). Given the pervasive regulation of hospitals, it would be absurd to exclude from the definition of PSWP every document created pursuant to any state or federal regulation. *See Fla. Dep't of Envtl. Prot. v. ContractPoint Fla. Parks, LLC*, 986 So. 2d 1260, 1270 (Fla. 2008) ("the Court should not interpret a statute in a manner resulting in unreasonable, harsh, or absurd consequences"). For example, the Department of Health and Human Services' ("HHS") Notice of Proposed

[1] As further noted by the Court, "Because the phrase means so many things, it is rarely—if ever—useful. Lawyers are nearly the only ones who use the phrase, and they often use it imprecisely." *Id.* at 923 (quoting the *Dictionary*).

Rulemaking ("NPRM"), expressly contemplated the reporting of "healthcare associated infections" to PSOs. *See* Patient Safety and Quality Improvement, 73 Fed. Reg. 8112, 8129 (Feb. 12, 2008). It would contravene the intent of the PSQIA to exclude from the definition of PSWP infection-related data and analysis that is collected for reporting to a PSO, simply because it also satisfies the Florida requirement for hospitals to have an infection control program (Rule 59A-3.250).

In contrast to regulatory requirements generally, the number of external *reporting* requirements are relatively few, including the "Code 15" Reports and Annual Reports referenced in Southern Baptist Hospital's Petition for Certiorari. *See* Pet. at 14. These are reported to the government, so their exclusion from the definition of PSWP makes sense, i.e., they can hardly be considered to reside in a "protected legal environment," free from the "threat that the information will be used against the subject providers." 73 Fed. Reg. at 70739. Internal incident reports, by contrast, must be *maintained* pursuant to section 395.0197, Florida Statutes and Rule 59A-10.0055 of the Florida Administrative Code, but are not subject to external *reporting*. Rather, the Florida Legislature intended that they be used for the same kind of quality improvement that lies at the heart of PSQIA. *See* § 395.0197(4), Fla. Stat. (2014) ("incident reports shall be used to develop categories of incidents which identify problem areas," and "once identified, procedures shall be adjusted to correct the problem areas").

It is this overlap between the purposes of the PSQIA and other regulations that caused the Department to approve dual purpose document collection and maintenance, in lieu of requiring hospitals to collect and maintain two sets of the same documents. The NPRM, published on February 12, 2008, was generally viewed as requiring parallel and redundant patient safety and quality improvement systems, one for satisfying regulatory requirements and one for reporting to a PSO. The preamble to the Final Rule recounts that comments on the NPRM "raised significant and substantial concerns regarding … how existing patient safety processes will occur given the protections for patient safety work product, and the likelihood that providers may need to maintain separate systems with substantially duplicate information." 73 Fed. Reg. at 70740. A number of providers indicated that "if duplication of information is required, providers may opt to not participate due to costs and burdens." *Id.* The Department characterized this as "[o]ne of the most significant areas of comment." *Id.*

In response, the Department modified the regulations to "permit[] providers to maximize organizational and system efficiencies and lessen[] the need to maintain duplicate information for different needs." *Id.* at 70741. This was accomplished by "allowing providers the flexibility to collect and review information within a patient safety evaluation system to determine if the information is needed to fulfill external reporting obligations," at which point it

can be removed from the system and reported. *Id*. at 70744.[2] The Department's modification eliminated the need for providers to "maintain duplicate systems to separate information to be reported to a PSO from information that may be required to fulfill state reporting obligations." *Id*. at 70742. As a result, *all* patient safety information, "collected in one patient safety evaluation system, is protected as patient safety work product unless the provider determines that certain information must be removed from the patient safety evaluation system for reporting to the state." *Id*. at 70742.[3] This modification was specifically intended to encourage participation by providers that have "mature patient safety efforts"—like hospitals with long-standing state-mandated patient safety and quality improvement programs. *Id*. at 70744. The reference to removing information from the patient safety evaluation system in order to meet an external reporting requirement recognizes that information within the system remains protected under the PSQIA, while information removed from the system and reported externally does not. The trial court entirely missed this critical point.

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[2] This emphasis on "flexibility" is evident elsewhere in the Final Rule. *See, e.g., id*. at 70742 ("Providers have the flexibility to protect this information as patient safety work product within their patient safety evaluation system while they consider whether the information is needed to meet external reporting obligations.").

[3] In fact, Petitioner was able to remove two incident reports and produce them to Plaintiff because they had not yet been reported to its PSO. Pet. at 16.

Given the Department's substantial revision of the implementing regulation and its express approval of patient safety evaluation systems that serve a dual purpose under the PSQIA and other federal and state regulations, the trial court's ruling that "dual purpose" documents cannot be PSWP is simply untenable. The incident reports at issue in this case need not be reported externally and can be maintained on a privileged and confidential basis in the hospital's patient safety evaluation system.[4]

The Department's endorsement of dual-purpose systems is entitled to deference by this Court. *See Pan Am. World Airways, Inc. v. Fla. Pub. Serv. Comm'n*, 427 So. 2d 716, 719 (Fla. 1983) ("We have long recognized that the administrative construction of a statute by an agency or body responsible for the statute's administration is entitled to great weight and should not be overturned unless clearly erroneous."); *Republic Media, Inc. v. Dep't of Transp., State of Fla.*, 714 So. 2d 1203, 1205 (Fla. 5th DCA 1998) ("A reviewing court must defer to any statutory interpretation by an agency which is within the range of possible and reasonable."); *Natelson v. Dept. of Ins.*, 454 So. 2d 31, 32 (Fla. 1st DCA 1984) (reviewing court should defer to any agency interpretation that is "within the range of *possible* interpretation").

[4] Based on the preamble to the Final Rule, even information that may ultimately be needed for external reporting can be maintained in the patient safety evaluation system until the provider determines that it must be removed and reported. 73 Fed. Reg. at 70751.

## II. The trial court's order did not sufficiently address the fact that PSQIA protections expressly and impliedly preempt Amendment 7.

The trial court generally glossed over the issue of federal preemption. The PSQIA expressly preempts Article X, Section 25 of the Florida Constitution ("Amendment 7") to the extent that a document—like the incident reports at issue in this case—constitutes both "patient safety work product" and a "record of an adverse medical incident." *See* 42 U.S.C. § 299b-22(a) (PSWP is privileged "[n]otwithstanding any other provision of Federal, State or local law"); *Ford Motor Co. v. Ins. Comm'r of Pa.*, 874 F.2d 926, 937 (3d Cir. 2002) (finding express preemption in the phrase "[n]otwithstanding any provision of the laws or constitutions of any State or any provision of Federal law").

Congress recognized the need to implement more uniform and broad protections for all health care providers under the PSQIA by specifically preempting any state law which would require disclosure of PSWP or which does not otherwise provide the same level of protections available under the Act. The importance of these protections is reflected in the preamble to the Final Rule:

> Proposed Subpart C sought to balance key objectives of the Patient Safety Act. First, the proposal sought to address concerns about the potential for damage from unauthorized release of information, including the potential for the information to serve as a roadmap to provider liability from negative patient outcomes. It also promoted the sharing of information about adverse patient safety events among providers and PSOs for the purpose of learning from those events to improve patient safety and quality of care. To achieve those objectives, Subpart C proposed that patient safety work product would

> be privileged and confidential, except in the certain limited circumstances identified by the Patient Safety Act and as needed by the Department to implement and enforce the Patient Safety Act. . .

73 Fed. Reg. at 70771 (emphasis added). On the subject of preemption, the preamble states: "While the Patient Safety Act does not preempt state laws that require providers to report information that is not patient safety work product, the state may not require that patient safety work product be disclosed." *Id*. at 70743, 70744 (emphasis added). Furthermore, in response to questions concerning preemption, the Department stated that:

> [P]atient safety work product protections provided under the statute generally preempt state and other laws that would permit or require disclosure of information contained within patient safety work product. However, State laws that provide for greater protection of patient safety work product are not preempted and continue to apply.

*Id.* at 70774. In summary, the PSQIA preempts conflicting state law and specifically bars Respondent's efforts to force disclosure of Petitioner's incident reports because they were collected within its patient safety evaluation system for reporting to a PSO and therefore constitute protected PSWP.

An analogous application of this preemption principle involving the State of Florida can be found in *OPIS Management Resources, LLC vs. Secretary, Florida Agency for Health Care Administration*, 713 F.3d 1291 (11th Cir. 2013), which involved a group of Florida nursing facilities that refused to turn over medical records of deceased nursing home residents to spouses or their attorneys-in-fact

because the records were protected under the Health Insurance Portability and Accountability Act ("HIPAA"). The State of Florida argued that the facilities had breached Section 400.145, Florida Statutes, which required disclosure. In holding that HIPAA's protections preempted state disclosure requirements, the Eleventh Circuit provided an excellent summary of the law of preemption:

> We begin our analysis with the bedrock principle that the Constitution designates the laws of the United States as the supreme law of the land, requiring that "all conflicting state provisions be without effect." … Accordingly, where state and federal law directly conflict, "state law must give way." … In addition, "[t]here is no doubt that Congress may withdraw specified powers from the States by enacting a statute containing an express preemption provision." … As the Supreme Court has explained, "[w]hen a federal law contains an express preemption clause, we focus on the plain wording of the clause," as the plain language of the text is "the best evidence of Congress' preemptive intent." …

*Id*. at 1294 (citations omitted). Based on the HIPAA preemption clause and the fact that HIPAA provided greater confidentiality protections than the contrary Florida statute, the nursing homes were not required to produce the records. *See also U.S. v. Lot 5, Fox Grove, Alachua County, Fla.*, 23 F.3d 359 (11th Cir. 1994) (Florida state constitutional provision preempted by conflicting federal statute); *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691 (1984) ("Federal regulations have no less preemptive effect than federal statutes.").

In addition to running afoul of the express preemption provision of the PSQIA, the trial court's ruling runs counter to the principle of implied or "conflict"

preemption. "Conflict preemption exists … where the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Irving v. Mazda Motor Corp.*, 136 F.3d 764, 768 (11th Cir. 1998).[5] Because nearly every document in a hospital is collected or maintained "pursuant" to some regulatory requirement, excluding such documents from the definition of PSWP would mean that very little could be protected. This clearly would present an obstacle to accomplishing the purposes of Congress.

The purposes of the PSQIA were discussed at length in the NPRM, which noted that "[t]raditional state-based legal protections for such health care quality improvement activities, collectively known as peer review protections, are limited in scope" and "do not exist in all states."[6] 73 Fed. Reg. at 8113. The NPRM went on to state, "[f]or the first time, there will now be a uniform set of Federal protections that will be available in all states and U.S. territories and that extend to all health care practitioners and institutional providers." *Id*. Allowing a patchwork of state recordkeeping obligations to undermine the expressed purpose of achieving national uniformity would be clearly contrary to Congressional intent.

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[5] "The existence of an express preemption clause does not necessarily preclude the presence of implied preemption." *Id.*

[6] Although not expressly mentioned in the NPRM, the Department may have had in mind states like Florida, which had passed Amendment 7 only months before the passage of the PSQIA.

## III. The trial court's interpretation of the PSQIA would reverse the positive movement from a "culture of blame" to a "culture of safety."

Florida's protections for patient safety and quality improvement activities have historically been interpreted broadly and upheld rigorously in litigation against providers. *See, e.g., Holly v. Auld*, 450 So. 2d 217, 220 (Fla. 1984) (accepting that peer review privilege would "impinge upon the rights of some civil litigants to discovery of information which might be helpful, or even essential, to their causes"); *Dade County Medical Association v. Hlis*, 372 So. 2d 117, 119-120 (Fla. 3d DCA 1979) (extending peer review protection even beyond the scope of statute due to "overwhelming public interest in maintaining the confidentiality" of such records). This broad protection was intended to promote open deliberation and criticism among healthcare providers, which would be chilled if it were subject to discovery. *See Hlis*, 372 So. 2d at 120 ("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." (quoting *Bredice v. Doctors Hosp., Inc.*, 50 F.R.D. 249, 250 (D.D.C. 1970)); *Cruger v. Love*, 599 So. 2d 111, 115 (Fla. 1992) (noting the apprehensions that make doctors reluctant to engage in strict peer review).[7]

[7] The PSQIA was motivated by a similar concern that providers would be "reluctant to participate in quality review activities for fear of liability, professional sanctions, or injury to their reputations." *See* 73 Fed. Reg. at 8113.

Contrary to the widely recognized public policy supporting the confidentiality of quality improvement activities, Amendment 7 was passed in order to "do away with existing restrictions on a patient's right to access a medical provider's history of adverse medical incidents and to provide a clear path to access those records." *Florida Hosp. Waterman, Inc. v. Buster*, 984 So. 2d 478, 489 (Fla. 2008). In addition to spawning a flood of litigation and thus further driving up the cost of health care,[8] the abrogation of privilege and confidentiality adversely impacted risk management and quality improvement processes in the years following the passage of Amendment 7. Many health care providers became concerned about the potential adverse consequences of open and collegial dialogue. Although they continued to perform required review, they grew reluctant to create a detailed written record that could be subject to discovery under Amendment 7. Potential discoverability and increased risk of liability threatened to detract from the important work of patient safety and quality improvement.

The passage of the PSQIA and its implementation by numerous Florida healthcare providers, including the Provider Amici, has largely alleviated these concerns by promoting and protecting from discovery more robust and essential patient safety and quality improvement activities. The trial court's decision threatens to undo this progress and undermine the valuable work that has been

[8] The appellate decisions involving Amendment 7 are numerous.

done by PSOs and their member health care providers. Patients, who are the ultimate beneficiaries of the PSQIA, will suffer.

## IV. The trial court's decision conflicts with the statutory duties and efforts of PSOs to assist providers in improving patient care.

In order for providers in Florida and all other states to access the confidentiality and privilege protections of the PSQIA, they must collect and assemble identified "data, reports, records, memoranda, [and] analyses (such as root cause analyses)" relating to patient safety activities within their respective patient safety evaluation systems for reporting to a PSO. *See generally* 42 C.F.R. §§ 3.20, 3.204, 3.206. PSOs, in turn, have multiple statutory duties, including a duty to conduct activities "to improve patient safety and the quality of health care delivery," to maintain bona fide contracts with providers "for the purpose of receiving patient safety work product," to "collect patient safety work product from providers. . . that permits valid comparisons of cases among similar providers," and to "utilize patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk." 42 C.F.R. § 3.102(b)(2)(F), (G). PSOs that cannot demonstrate compliance are subject to a fine and loss of certification. *See* 42 C.F.R. Part 3, Subpart D.

In order to assist PSOs, the Agency for Healthcare Research and Quality ("AHRQ"), which is the HHS agency tasked with the certification and listing of PSOs (73 Fed. Reg. at 70774), published a "Compliance Self-assessment Guide"

("Guide") in September 2009. The Guide identifies what AHRQ will examine and what the PSO should be documenting to demonstrate compliance with these and other duties under the PSQIA, and to obtain and maintain certification. (www.pso.ahrq.gov/legislation/assessment). There are currently 82 federally listed PSOs. 59 were previously delisted by AHRQ, most voluntarily, based on the extensive statutory obligations placed on PSOs (www.pso.ahrq/listed/delisted).

The PSQIA, the Final Rule and the Guide make it very clear that PSOs are not merely receptacles for privileged PSWP submitted by participating providers. PSOs are required to collect, analyze and make "valid comparisons" among providers and provide "direct feedback and assistance to providers to effectively manage patient risk." These important responsibilities cannot be accomplished, however, unless providers are able to submit patient safety data reports and related information on a confidential basis to their PSOs. The information submitted by providers to PSOs around the country includes incident reports, root cause analyses, peer review and other patient safety information that is not required to be reported externally. Yet, under the trial court's reasoning, these documents are not protected if they were "created, or maintained pursuant to any statutory, regulatory, licensing or accreditation requirement…." (Emphasis added).[9] In one fell swoop,

[9] *See* Petitioner's App. at 0503. Thus, for example, even though the PSQIA specifically identifies root cause analyses as PSWP, and even though they need not

the trial court has sought to eliminate major categories of documents that qualify for protection under PSQIA.

Using patient safety information submitted by providers pursuant to the PSQIA, the PSO Amici and other PSOs around the country have been able to provide safety alerts, identify best practices, and prepare comparative and benchmarking studies as well as other confidential and public reports which have greatly assisted providers and the entire health care industry in efforts to reduce risk and improve care. PSOs have provided vital feedback on health information technology ("HIT"), pressure ulcers, medication safety, surgical errors, fall prevention, and a host of other issues.[10] These aggregated and de-identified studies would not be possible without the receipt of confidential information currently

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be reported to the state or federal government or any hospital accrediting body, the trial court has ruled that such information cannot be protected under the PSQIA.

[10] Links to publically available materials from amicus ECRI Institute PSO regarding HIT, pressure ulcers, medication safety, and other issues are available at https://www.ecri.org/resource-center/Pages/Key-Learnings-from-ECRI-Institute-Patient-Safety-Organization.aspx. Amicus Child Health Patient Safety Organization has similarly published online "Patient Safety Action Alerts" in the areas of sustained/extended release medication fill and administration errors, fingertip amputation, cutaneous fungal outbreak associated with hospital linens, wrong-size tracheostomy selection, and blind pediatric NG tube placements at http://www.childrenshospitals.net/AM/Template.cfm?Section=Patient_Safety_Action_Alerts&Template=/CM/HTMLDisplay.cfm&ContentID=71013. Amicus Clarity PSO has published materials on surgical errors, medication dosing omissions, fall prevention, HIT, and other issues at http://www.claritygrp.com/clarity-patient-safety-organization/learning-library/pso-learning-series. These are just a few publically available examples of the important work being done by PSOs across the nation to improve patient safety and health care quality.

being collected, reported to and analyzed by PSOs.[11] By eliminating the flow of this information, which will no longer be reported by hospitals, physicians and other providers to PSOs if not protected under PSQIA, the trial court's ruling threatens to preclude the important analysis and study of shared information by PSOs, thereby diminishing efforts to improve quality and reduce risk and reversing the progress that has been made since the passage of the PSQIA.

## CONCLUSION

The trial court's order misconstrues the PSQIA and Final Rule, is inconsistent with the Congressional intent to foster a culture of safety through well-defined and reliable privilege protections, ignores the preemptive effect of the PSQIA, and threatens vital patient safety and quality improvement efforts on the part of PSOs and providers. Accordingly, it should be quashed.

[11] In addition to these studies which are publically available and based on aggregated data, PSOs also participate in reviews and analysis with individual providers and systems which are not publically shared but are treated as PSWP.

## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I electronically filed the foregoing on February 4, 2015, with the Clerk of Court by using the eFiling Portal, and served a copy by email upon the attorneys listed on the attached service list.

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## CERTIFICATE OF COMPLIANCE

I HEREBY CERTIFY that the foregoing brief is in Times New Roman 14-point font and complies with the font requirements of Rule 9.210(a)(2), Florida Rules of Appellate Procedure.

/s/ Joshua P. Welsh
Joshua P. Welsh