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IN THE SUPREME COURT OF FLORIDA

JEAN CHARLES, JR., etc., *et al*.,

Appellants,

v.

Case No. SC15-2180
L.T. Case Nos. 1D15-109
2012-CA-2677

SOUTHERN BAPTIST HOSPITAL
OF FLORIDA, INC., etc., *et al*.,

Appellees.
_____/

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BRIEF OF AMICI CURIAE

The American Medical Association and the Florida Medical Association (the "**Association Amici**"); Clarity PSO, Vizient 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, Quantros Patient Safety Center, Quality Circle for Healthcare, Inc., PsychSafe, UHS Acute Care PSO, Midwest Alliance for Patient Safety, Alliance for Patient Medication Safety, American Medical Foundation Patient Safety Organization, Center for the Assessment of Radiological Sciences PSO, and MCIC Vermont PSO (the "**PSO Amici**"); and 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, and Adventist Health System/Sunbelt, Inc. (the "**Provider Amici**")

IN SUPPORT OF APPELLEE SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC.

Respectfully submitted by:
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IDENTITY AND INTEREST OF AMICI CURIAE

The American Medical Association ("AMA") and the Florida Medical Association ("FMA") (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.

Clarity PSO and the twenty-four 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"), and its implementing regulations, 42 C.F.R. Part 3 ("Final Rule"), 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 federal regulations, and (iii) protected from disclosure as patient safety work product ("PSWP"). Together, the PSO Amici serve thousands of member hospitals, individual physicians and physician groups, 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 for the purpose of improving health care services and reducing risk to all patients.

A number of the PSO Amici serve Florida-based health care providers. For example, UHS Acute Care PSO, PsychSafe, CHS PSO, LLC, Quality Circle for Healthcare, Inc., and Ascension Health PSO serve over 20 health care facilities in Florida, 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 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.

The foregoing amici have joined this brief to support the position of the Appellee and the holding of the First District Court of Appeal, both of which

accord with the clear intent of the PSQIA to create a means for health care providers to share information about patient safety events within a "protected legal environment" in order to improve patient safety and the quality of care nationwide. Patient Safety and Quality Improvement, 73 Fed. Reg. 70732, 70732 (Nov. 21, 2008) (hereinafter "Final Rule Preamble"). Requiring Appellee to produce documents which meet the statutory requirements for protection would invalidate the PSQIA and undermine the efforts of providers, federal and state governments and others in the health care industry to improve patient care and reduce risk.

SUMMARY OF ARGUMENT

As the First District recognized, the Final Rule was expressly intended to permit the very kind of recordkeeping system implemented by Baptist Hospital. A reversal of the First District's holding would contravene the Final Rule and effectively nullify the PSQIA in the State of Florida. Amendment 7, on the other hand, imposes no recordkeeping requirements of its own, and Appellants have no standing to allege noncompliance with recordkeeping requirements imposed by Florida hospital licensing statutes. While the preemption of Amendment 7 by the PSQIA would have no effect on the substantive rights of medical malpractice claimants, preemption of the PSQIA by Amendment 7 would drastically limit provider participation and negatively impact the important work of PSOs. Accordingly, the First District's opinion should be affirmed.

ARGUMENT

I. Appellants acknowledge the "no-duplication guidance" of HHS, but their analysis strips it of any meaning.

Appellants acknowledge that the Final Rule was intended by the Department of Health and Human Services ("HHS") to permit the collection of patient safety information within a single system unless and until a provider determines that certain information must be removed for reporting to the State. IB 6 (citing Final Rule Preamble at 70742), 42, 43-44, 46.[1] Yet Appellants also claim that Baptist's compliance with the Final Rule was "unlawful," and that information that Baptist must maintain (but not externally report) pursuant to State law must be kept separate from PSWP. Appellants rely on language in HHS's preamble to the Final Rule indicating that information cannot be PSWP if it is collected to comply with "external obligations." IB 6-7. However, reading "external obligations" to include *any* state-mandated recordkeeping obligations, as Appellants do, contravenes the purpose and intent of HHS's no-duplication guidance.

First, the phrase "external obligations" is clearly intended by HHS to refer to "external *reporting* obligations," as seen throughout the preamble to the Final Rule. For example, at page 70739, the preamble states, "Providers must fulfill external *reporting* obligations with information that is not patient safety work

[1] Appellants' Initial Brief will be cited herein as "IB," and Appellee's Answer Brief will be cited as "AB."

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 Appellants should be read *in pari materia* with the rest of the preamble to refer to external *reporting* obligations, rather than to create a blanket exception to the PSQIA for *every* document maintained pursuant to *any* regulation.

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 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, in HHS's Notice of Proposed Rulemaking, it contemplated that "healthcare associated infections," which a hospital is required to track internally but not mandated to report to the state, would be reported to PSOs. *See* Patient Safety and Quality Improvement, 73 Fed. Reg. 8112, 8129 (Feb. 12, 2008) ("NPRM"). It would be contrary to the intent of the PSQIA to exclude from the scope of PSWP infection-related data that is collected for reporting to a PSO simply because it also satisfies the State's requirement for hospitals to have an infection control program (Rule 59A-3.250).

It is this overlap between the purposes of the PSQIA and other regulations that caused HHS to approve dual purpose document collection and maintenance. 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. 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." Final Rule Preamble at 70740. Providers indicated that "if duplication of information is required, [they] may opt to not participate due to costs and burdens." *Id*.

In response, HHS 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 ["PSE 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. 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 [PSE system], is protected as patient safety work product unless the provider determines that certain information must be removed from the [PSE system] for reporting to the state." *Id*. at 70742.[2]

This Court should give effect to HHS's express approval of PSE systems that serve a dual purpose under the PSQIA and other state and federal regulations. *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.").

II. Amendment 7 does not impose any recordkeeping requirements.

Appellants freely acknowledge that "Amendment 7 does not mandate that hospitals or providers create, collect or develop any particular information, reports, or records." IB 16. Yet in the very next sentence, Appellants contend that "Amendment 7 mandates that information be maintained in a manner that allows

[2] This modification was 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.

requesting patients access to it." *Id*. Appellants go on to criticize Baptist for asserting its legal right to prepayment for the cost of complying with Appellants' Amendment 7 request. IB 24, 43, 48. They claim that this cost is so high because Baptist needs to "separate the state-mandated information from the PSWP stored in the PSES," IB 24, a task they claim is necessitated by Baptist's supposedly "unlawful" merger of state-mandated information with PSWP.

As Appellants concede, Amendment 7 imposes no recordkeeping duties. It simply gives patients "a right to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident." Art. X, § 25(a), Fla. Const. If records have already "been made publicly available by publication or on the Internet," then Amendment 7 allows a provider to grant access to them by referring a patient to the "location at which the records are publicly available." *Id*. at § 25(c)(4). However, nothing in Amendment 7 requires that a provider "maintain" records in any particular "manner."

Appellants' argument that Amendment 7 imposes some particular manner of recordkeeping is belied both by its implementing statute and common sense. First, section 381.028(7)(c), Florida Statutes (2015) allows a provider to require prepayment of a fee for the "reasonable and actual cost" of complying with an Amendment 7 request, "including a reasonable charge for the staff time necessary

to search for records."[3] There would be no need to charge for time spent searching for responsive records if Amendment 7 required them to be maintained in some separate manner specifically calculated to make them more accessible to patients.

Moreover, Appellants' reading of Amendment 7 is contrary to common sense because it turns hospital recordkeeping practices on their head. Instead of maintaining records in the manner required by state or federal law or the manner best suited to hospitals' business and operational needs, Appellants would require hospitals to maintain records in a manner best suited to the convenience of medical malpractice litigants. Despite the preferences of those making Amendment 7 requests, hospitals do not maintain—and are not required to maintain—records in a manner that distinguishes and segregates "records of adverse medical incidents" as defined by Amendment 7. Amendment 7 may provide access to certain documents, but there is nothing in the constitutional provision itself or its ballot summary that suggests that Florida voters intended a radical alteration to the customary recordkeeping practices of hospitals.

Furthermore, the extraordinarily burdensome and expensive search that Baptist would be required to undertake would be necessary whether or not it had a PSE system or was a member of a PSO. As Baptist points out, it maintains

[3] This Court has expressly approved the prepayment provision of section 381.028. *See Fla. Hosp. Waterman, Inc. v. Buster*, 984 So. 2d 478, 493 (Fla. 2008); *see also W. Fla. Reg'l Med. Ctr., Inc. v. See*, 79 So. 3d 1, 14 (Fla. 2012) (noting approval of this provision in *Buster*).

occurrence reports on a wide variety of unanticipated events, whether or not they constitute "adverse incidents" under Amendment 7 or any Florida state regulatory scheme, and whether or not they "caused or could have caused injury to or death of a patient." Art. X, § 25(3), Fla. Const.; AB 5-7. Therefore, Baptist would necessarily be required to review all documents potentially responsive to an Amendment 7 request to determine whether any particular document constitutes a "record of an adverse medical incident" under Amendment 7. The fact that Baptist has chosen to maintain its occurrence reports in a PSE system does nothing to increase the burden of sorting Amendment 7 from non-Amendment 7 documents.

Broad-based "incident" or "occurrence" reporting systems like the one used by Baptist are common among Florida hospitals. For example, a hospital employee may report a theft or sexual assault—events which obviously impact patient safety but do not constitute a "record of an adverse medical incident" under Amendment 7. Incident reporting systems are intended to sweep broadly to draw in as much data as possible, and thus best serve the Legislature's purpose of identifying and minimizing risks to patients. *See* § 395.0197(1)(b), Fla. Stat. (2015). This purpose is further served by incorporating the reporting system into a privileged database that assures providers that their reports will remain confidential and will not be used against them. *See* NPRM at 8113 ("These protections will enable all health care providers … to share data within a protected legal environment … without the

threat of information being used against the subject providers."). Contrary to Appellants' claims, the privileges and protections of the PSQIA are consistent with, and indeed further, the policies underlying State risk management regulations; it is Appellants' interpretation that would undermine those policies.

III. Appellants lack standing to criticize Baptist's alleged regulatory noncompliance.

Baptist's alleged noncompliance with Florida state regulations supposedly imposing separate recordkeeping requirements is the linchpin of Appellants' argument. However, it is indisputable that the regulations cited by Appellants—in particular the provisions of section 395.0197 and its corresponding administrative code—are part of the state regulatory scheme governing the licensure and operation of hospitals. Section 395.001, Florida Statutes (2015), states that the purpose of chapter 395 is to "provide for the protection of public health and safety in the establishment, construction, maintenance, and operation of hospitals … by providing for licensure of same and for the development, establishment, and enforcement of minimum standards with respect thereto." Nothing in chapter 395 evidences a Legislative intent to bestow a private right of action on medical malpractice plaintiffs to assert claims for regulatory noncompliance.

In fact, the Legislature expressly conferred upon the Agency for Health Care Administration (AHCA) the sole authority to discipline hospitals for violations of chapter 395. Section 395.1065(2)(a), Florida Statutes (2015) allows AHCA to

"impose an administrative fine, not to exceed $1,000 per violation, per day, for the violation of any provision of this part … or applicable rules." AHCA may also "impose an immediate moratorium on elective admissions to any licensed facility … when [AHCA] determines that any condition in the facility presents a threat to public health or safety." § 395.1065(4), Fla. Stat. AHCA's exclusive authority to remedy violations of chapter 395—including violations of section 395.0197 and the other regulations relied upon by Appellants—necessarily implies the lack of any privately enforceable right.[4] The undersigned are not aware of AHCA imposing any such fines on Baptist for alleged violations of chapter 395, or claiming that Baptist has wrongfully treated the documents in dispute as PSWP.

Generally speaking, "a statute that does not purport to establish civil liability but merely makes provision to secure the safety or welfare of the public as an entity"—such as hospital licensing and regulatory statutes—"will not be construed as establishing a civil liability." *Horowitz v. Plantation Gen. Hosp. Ltd. P'ship*, 959 So. 2d 176, 182 (Fla. 2007) (quoting *Murthy v. N. Sinha Corp.*, 644 So. 2d 983, 986 (Fla. 1994)). Indeed, the Legislature's express provision of administrative remedies for regulatory noncompliance, without providing any equivalent civil penalties, implies that it did not intend to create a private right of action. In the

[4] Amendment 7 confers certain rights on Appellants, but not a right to a specific manner of hospital recordkeeping. Conversely, chapter 395 imposes specific recordkeeping obligations, but confers no rights on Appellants.

absence of any private right of action to enforce the regulatory requirements of chapter 395, Appellants lack standing to criticize Baptist's supposed noncompliance in this Court. *See City of Sarasota v. Windom*, 736 So. 2d 741, 742 (Fla. 2d DCA 1999) ("the plaintiffs possess no private cause of action and, accordingly, lack standing to institute such a claim").[5]

IV. Amendment 7 does nothing to further—and the PSQIA does nothing to curtail—the substantive rights of medical malpractice litigants.

Appellants claim that they exercised their rights under Amendment 7 in order to "prove liability," IB 1, and they spend a substantial portion of their brief reciting "legislative history" indicating that the PSQIA was not intended to alter "existing rights and remedies available to injured patients." IB 10 (quoting statement by Senator Jeffords). The statements of individual legislators cited by Appellants generally suggest that information "currently available" to prove medical negligence (in 2005) would still be available post-enactment. IB 11. Though not expressly argued, Appellants imply by their recitation of this purported legislative history that the First District's interpretation of the PSQIA would somehow thwart their substantive right to a remedy under medical malpractice law.

[5] Appellants also assert that it is job of this Court to "conclusively interpret[] Florida's reporting and recordkeeping obligations." IB 38. While this Court does indeed have the final say on matters of state law, *Gonzalez v. State*, 617 So. 2d 847, 849 (Fla. 4th DCA 1993), it is not the primary authority for interpreting hospitals' regulatory obligations. Rather, that task belongs to AHCA, § 395.1055(1), Fla. Stat. (2015), which has not intervened in this action or objected to Baptist's maintenance of occurrence reports within its privileged PSE system.

What Appellants merely suggest, amicus curiae AARP outright states: that Amendment 7 is intended to ensure "that victims of medical harm can access the information needed to hold negligent health care providers accountable," and that the First District's decision will have a "draconian effect on victims of medical harm or neglect." Br. of Amicus Curiae AARP 2-3. The AARP claims that Amendment 7 "gives citizens the constitutional right to access information critical to pursuing a successful tort action," and therefore preemption of Amendment 7 by the PSQIA "significantly hampers malpractice victims' ability to sue by blocking access to essential evidence." *Id*. at 14, 16. The AARP vastly overstates the significance of Amendment 7 as it relates to medical malpractice.

Medical malpractice actions generally involve a "battle of the experts," in which deviations from the standard of care are determined from the medical record and the personal knowledge of witnesses to the patient's medical care—both of which are as available after the passage of the PSQIA as they were before. On the other hand, patient safety and quality improvement materials, including incident reports, peer review, and credentialing records, were not admissible in 2005 and still are not admissible in medical malpractice claims. *See* §§766.101(5), 395.0191(8), 395.0193(8), Fla. Stat. (2015) (barring such materials from "introduction into evidence"); 395.0197(4), Fla. Stat. (making incident reports "not admissible as evidence in court"). Amendment 7, by its terms, grants only a "right

to have access," i.e. discovery. It does not expressly or impliedly override evidentiary privileges. Because none of the materials customarily sought by plaintiffs pursuant to Amendment 7 would be admissible in court, the privileges provided by the PSQIA do not hinder their cases.

Even as a discovery tool, Amendment 7 does not broadly override any and all discovery privileges for patient safety and quality improvement materials. First, it applies only to records of "adverse medical incidents." It does not apply to policies and procedures, or to credentialing and recredentialing records that do not specifically involve adverse medical incidents. *See Bartow HMA, LLC v. Kirkland*, 171 So. 3d 783, 786 (Fla. 2d DCA 2015); *Morton Plant Hosp. Ass'n, Inc. v. Shahbas*, 960 So. 2d 820, 826-827 (Fla. 2d DCA 2007). Moreover, contrary to Appellants' suggestion, Amendment 7 does not require a hospital to produce analyses regarding the "frequency and causes of general categories and specific types of adverse incidents," IB 16, § 395.0197(1)(a), Fla. Stat., since such general, statistical information does not pertain to a "specific incident involving a specific patient that caused or could have caused injury to or the death of that patient." *W. Fla. Reg'l Med. Ctr., Inc. v. See*, 18 So. 3d 676, 690 (Fla. 1st DCA 2009).

Finally, even if the PSQIA somehow impacted medical negligence claimants in the presentation of their cases, this would be neither unusual nor cause for criticism. As this Court long ago recognized with respect to peer review privilege,

"[i]nevitably, such a discovery privilege will impinge upon the rights of some civil litigants to discovery of information which might be helpful, or even essential, to their causes." *Holly v. Auld*, 450 So. 2d 217, 220 (Fla. 1984). Nevertheless, the legislature—in this case Congress—has carried out a balancing test and determined that the benefits of such protections outweigh the detriments. This kind of policy judgment is exclusively within the province of the legislature. *See id*.

V. Appellants' 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*, 450 So. 2d at 220; *Dade County Med. Ass'n v. Hlis*, 372 So. 2d 117, 119-120 (Fla. 3d DCA 1979). This broad protection was intended to promote open deliberation and criticism among healthcare providers, which would be chilled if it were subject to discovery. *Hlis*, 372 So. 2d at 120; *Cruger v. Love*, 599 So. 2d 111, 115 (Fla. 1992).[6]

Notwithstanding 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…." *Fla. Hosp. Waterman, Inc. v.*

[6] 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* NPRM at 8113.

Buster, 984 So. 2d 478, 489 (Fla. 2008). 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 the risk of public exposure 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 patient safety and quality improvement activities. This Court's reversal of the First District's ruling in this case would undo the progress made to date and undermine the valuable work that has been done by PSOs and their member health care providers. Patients, who are the ultimate beneficiaries of the PSQIA, would suffer.

VI. The privileges conferred by the PSQIA are vital to PSOs in meeting their statutory duties 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 "data, reports, records, memoranda, [and] analyses (such as root cause analyses)" relating to patient safety activities within their respective PSE 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 70732), 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 81 federally listed PSOs. 66 were previously delisted by AHRQ, most voluntarily, based on the extensive statutory obligations placed on PSOs (www.pso.ahrq.gov/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 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 confidentially 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.

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.[7] These aggregated and de-identified studies

[7] 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

would not be possible without the receipt of confidential information currently being collected, reported to and analyzed by PSOs.[8] 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 the PSQIA, a reversal of the First District's holding would 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

In recognition of the important work done by PSOs and the vital interests served by the PSQIA, this Court should affirm the First District's holding that the PSQIA preempts Amendment 7 and that PSWP properly maintained by Baptist in its PSE system is not discoverable.

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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 https://www.childrenshospitals.org/Quality-and-Performance/Patient-Safety/Patient-Safety-Action-Alerts. 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 examples of the important work being done by PSOs to improve patient safety and health care quality.

[8] 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 May 2, 2016, 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