IN THE SUPREME COURT OF FLORIDA
CASE NO.: SC15-2180

JEAN CHARLES, JR., as next Friend and duly appointed Guardian of his sister, MARIE CHARLES, and her minor children, ANGEL ALSTON, and JAZMIN HOUSTON, minors, and PERVIN ALSTON,

Appellants,

v.

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC. d/b/a Baptist Medical Center-South, KRISTIN FERNANDEZ, D.O., YUVAL Z. NAOT, M.D., SAFEER A. ASHRAF, M.D., INTEGRATED COMMUNITY ONCOLOGY NETWORK, LLC, a Florida limited liability corporation, ANDREW NAMEN, M.D., GREGORY J. SENGSTOCK, M.D., JOHN D. PENNINGTON, M.D., and EUGENE R. BEBEAU, M.D.,

Appellees.
_____/

L.T. Case Nos.: 1D15-0109
2012-CA-002677

ON APPEAL FROM THE DISTRICT COURT,
FIRST DISTRICT, STATE OF FLORIDA

INITIAL BRIEF OF APPELLANTS

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PRELIMINARY STATEMENT

The record consists of: (i) three volumes paginated by the clerk of the First District; (ii) three appendices at tabs A, B, and C; and (iii) five amicus briefs at tabs D, E, F, G, and H. The paginated volumes are cited, for example, as follows: (R. 100), with 100 referring to the page number. The three appendices are cited as follows. First, the Appendix to the Petition at tab A, filed on January 8, 2015, is cited as "Pet.'s App." Second, the Appendix to the Motion to Dismiss at Tab B, filed on January 20, 2015, is cited as "App. to Mot. to Dismiss." Third, the Supplemental Appendix at tab C, filed on April 27, 2015, is cited as "Supp. App." The numbers following each of these appendix citations refer to page numbers supplied by the parties. There are no citations herein to the amicus briefs at tabs D, E, F, G, and H. Finally, two citations are to the appendix filed in this Court on January 4, 2016, in support of Appellants' response to the motion to dismiss. *See infra* notes 13 & 18.

All emphases in quoted materials are supplied unless otherwise indicated.

STATEMENT OF THE CASE AND FACTS

The Charles family, the appellants, sued appellees for their medical malpractice that severely incapacitated the family's mother, Marie Charles. Her injuries require around-the-clock care and prevent her from caring for her children. (App. to Mot. to Dismiss 21-22, ¶¶ 31-33.) She incurred her injuries at the hospital of Appellee, Southern Baptist Hospital, Inc. (Baptist). (App. to Mot. to Dismiss 18, ¶15.) To prove liability, Ms. Charles exercised her rights under Article 10, section 25 of the Florida Constitution, commonly called Amendment 7, by requesting certain state-mandated records of adverse incidents. (Pet.'s App. 32-35.)

On federal preemption grounds, the First District invalidated the state constitutional rights of Ms. Charles and patients throughout Florida. (R. 478-80.) Specifically, it decided that the Patient Safety and Quality Improvement Act of 2005 (PSQIA or the Act) preempted Amendment 7. (*Id.*) Over 5.8 million Florida voters (80 plus percent of the electorate) approved Amendment 7 in 2004,[1] granting patients a broad constitutional right to access records of adverse medical incidents. (R. 466-67.) The First District, however, determined the PSQIA gave medical providers the "unilateral, unreviewable" discretion to make virtually any state-mandated record

[1] Fla. Dep't of State, Division of Elections, Patients' Right to Know About Adverse Medical Incidents, 03-07, located at http://dos.elections.myflorida.com/initiatives/initdetail.asp?account=35169&seqnum=3 (visited on Feb. 1, 2016).

privileged by voluntarily storing a record in a patient safety evaluation system (PSES) for reporting to a patient safety organization (PSO). (R. 476-79.)

The First District erred. *Infra* Argument at 29. To understand why, one must first understand the federal and state constitutional, statutory, and regulatory framework that governs Baptist's obligations and privileges with regard to reporting, recording, collecting, maintaining, and developing patient safety information. *Infra* Statement, Part I, at 2. Then, one must understand how Baptist operates its voluntary federal PSES and its state-mandated internal risk management program. *Infra* Statement, Part II, at 17. Finally, one must understand the other facts and procedural history of this case. *Infra* Statement, Part III, at 22.

I. The constitutional, statutory, and regulatory framework.

A. Patient Safety and Quality Improvement Act (PSQIA).

1. Plain text.

The PSQIA consists of six statutes in Part C of Subchapter VII, Chapter 6A of Title 42 of the United States Code. Pub. L. No. 109-41, 119 Stat. 424, codified at 42 U.S.C. §§ 299b-21 *et seq.* The Act provides for the creation and maintenance of a patient safety database of information reported to patient safety organizations (PSOs) by healthcare providers (including hospitals). *See* 42 U.S.C. § 299b-23. The Act does <u>not</u> require providers to report to PSOs; their decision to do so is voluntary. (R. 6, 8, 10.) PSOs are certified entities, separate from providers, which collect,

analyze, develop, disseminate, and utilize information to improve patient safety. *See* 42 U.S.C. §§ 299b-21(5), 299b-24. A related term of art is a patient safety evaluation system (PSES); it is defined as "the collection, management, or analysis of information for reporting to or by a [PSO]." *Id.* § 299b-21(6). The Act makes privileged certain information reported to PSOs. *Id.* § 299b-22.

Under the Act, information is broken down into two categories, defined by subparagraphs (A) and (B) under paragraph (7) of 42 U.S.C. §299b-21. The first category, "patient safety work product" (PSWP), is defined in subparagraph (A) and consists of certain information – "any data, reports, records, memorandum, analyses (such as root cause analyses), or written or oral statements" – that satisfy any one of three alternative criteria. *Id.* § 299b-21(7)(A). One of these criteria, information developed by a PSO, is not at issue in this case. *See id.* § 299b-21(7)(A)(i)(II). The two potentially applicable criteria are information that: (i) is "assembled or developed by a provider for reporting to a [PSO] and [is] reported to a [PSO];" or (ii) "identif[ies] or constitute[s] the deliberations or analysis of, or identif[ies] the fact of reporting pursuant to, a [PSES]." *Id.* § 299b-21(7)(A)(i)(I)&(ii). Information satisfying any one of these criteria is privileged PSWP, *see* 42 U.S.C. §299b-22, unless subparagraph (B) excludes it from the PSWP definition.

The second category, defined in subparagraph (B), consists of non-privileged information explicitly excluded from the PSWP definition in subparagraph (A). *See*

id. § 299b-21(7)(B). This category is broken down into two sub-categories. *Id.* § 299b-21(7)(B)(i)&(ii). One sub-category consists of "a patient's medical record, billing and discharge information, or any other original patient or provider record." *Id.* § 299b-21(7)(B)(i). This sub-category is not at issue in this case.

This case concerns the other sub-category of non-privileged information, defined in clause (ii) of subparagraph (B) and called "separate information":

> (ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a [PSES]. Such separate information or a copy thereof reported to a [PSO] shall not by reason of its reporting be considered [PSWP].

Id. § 299b-21(7)(B)(ii).

The First District concluded state-mandated information is "separate" under clause (ii), and not PSWP, only if a provider, in its "unilateral, unreviewable" discretion, decides not to store the information in its PSES. (R. 476-77.) In other words, information is PSWP if a provider places it into its PSES for reporting to a PSO and if it does not exist outside of the PSES; no further analysis is required according to the First District. (R. 478.) As argued *infra*, this interpretation renders meaningless clause (ii)'s second sentence. Argument I.C.1, at 41.

The final, third clause of subparagraph (B) preserves, rather than preempts, certain state-law obligations. It states that "nothing in [the PSQIA] shall be construed to limit" the following:

> (I) the discovery of or admissibility of information described in this subparagraph [(B)] in a criminal, civil, or administrative proceeding;
>
> (II) the reporting of information described in this subparagraph [(B)] 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 [(B)] under Federal, State, or local law.

42 U.S.C. § 299b-21(7)(B)(iii).[2] "[I]nformation described in this subparagraph" means non-privileged information described in subparagraph (B), ***not*** privileged PSWP information described in subparagraph (A).[3] Yet, the First District concluded a provider could use PSWP (defined by subparagraph (A)) instead of non-privileged information (defined by subparagraph (B)) to satisfy its state-law reporting and recordkeeping obligations. (R. 478.)

2. Federal regulations and HHS's guidance on the PSQIA.

In 2008, the U.S. Department of Health and Human Services (HHS) adopted rules to implement the PSQIA. *See* Patient Safety and Quality Improvement Act, 73

[2] Similarly, another PSQIA statute states that nothing in that statute should be construed "as preempting or otherwise affecting any State law requiring a provider to report information that is not [PSWP]." 42 U.S.C. §299b-22(g)(5).

[3] *See Koons Buick Pontiac GMC, Inc. v. Nigh*, 543 U.S. 50, 60-61 (2004) (noting that both the House and Senate legislative manuals designate paragraphs with Arabic numerals and subparagraphs with uppercase letters); *accord* M. Douglass Bellis, Deputy Legislative Counsel, U.S. House of Representatives, *Statutory Structure and Legislative Drafting Conventions: A Primer for Judges* 8-9 (Federal Judicial Center 2008) (http://www.fjc.gov/public/pdf.nsf/lookup/draftcon.pdf/$file/draftcon.pdf).

Fed. Reg. 70732 (Nov. 21, 2008) (codified at 42 C.F.R. Pt. 3). The public was given notice of the proposed rules and an opportunity to comment. *Id.* at 70733. HHS responded to the comments, modified the proposed rules, and provided guidance how it would implement and interpret the PSQIA. *Id.* at 70733-93.

a. The no-duplication guidance.

HHS addressed public comments concerning how reporting information to PSOs would work in conjunction with reporting information to state authorities:

> To address commenter concerns about the duplication of resources for similar patient safety efforts and the lack of protection upon collection, we have clarified the requirements for how information becomes [PSWP] when reported to a PSO. Generally, information may become [PSWP] when reported to a PSO. Information may also become [PSWP] upon collection within a [PSES]. Such information may be voluntarily removed from a [PSES] if it has not been reported and would no longer be [PSWP]. As a result, providers need not maintain duplicate systems to separate information to be reported to a PSO from information that may be required to fulfill state reporting obligations. All of this information, collected in one [PSES], is protected as [PSWP] unless the provider determines that certain information must be removed from the [PSES] for reporting to the state. Once removed from the [PSES], this information is no longer [PSWP].

Id. at 70742. The First District expressly cited this guidance. (R. 476.)

b. The PSQIA requires providers to use non-PSWP information to satisfy their external obligations.

Several lines after its no-duplication guidance, HHS interpreted § 299-21(7) to mean that external obligations had to be met with non-privileged information defined in subparagraph (B), not PSWP defined in subparagraph (A). *See* 73 Fed.

Reg. at 70742 ("Even when laws or regulations require the reporting of the information regarding the type of events also reported to PSOs, the [PSQIA] does not shield providers from their obligation to comply with such requirements. These external obligations must be met with information that is not [PSWP] . . . ."). Further, HHS stated that PSWP does not include information to which "oversight entities" had "access prior to the passage of the [PSQIA]" and directed that such entities "continue[d] to have access to this original information in the same manner as such entities have had access prior to the passage of the [PSQIA]." *Id.* HHS also clarified its no-duplication guidance was meant to provide "flexibility" to providers to protect "information as [PSWP] within their [PSES] while they consider whether the information is needed to meet external reporting obligations." *Id.* But HHS warned that providers "should carefully consider the need for this information to meet their external reporting or health oversight obligations." *Id.*

c. State-mandated information is separate and not PSWP.

HHS clarified that state-mandated "information collection activities" remained "separate" and "distinct" from systems established by the PSQIA:

> The [PSQIA] establishes a protected space or system that is separate, distinct, and resides alongside but does ***not*** replace other information collection activities mandated by laws, regulations, and accrediting and licensing requirements . . . .

Id. Critically, HHS stated: "Information is not [PSWP] if it is collected to comply with external obligations, such as: ***state incident reporting requirements***; . . .;

certification or licensing records for compliance with health oversight agency requirements; . . . ." *Id.* at 70742-43.

d. Information collected for a purpose other than reporting to a PSO does not become PSWP merely because a provider reports such information to a PSO.

HHS explained that, for information to be PSWP, it "must be collected or developed for the purpose of reporting to a [PSO]." *Id.* at 70739. HHS warned that information "collected for a purpose other than reporting to a PSO" was not PSWP:

> Providers should be cautioned to consider whether there are other purposes for which an analysis may be used to determine whether protection as [PSWP] is necessary or warranted. Further, the definition of [PSWP] is clear that information collected for a purpose other than for reporting to a PSO may not become [PSWP] only based upon the reporting of that information to a PSO.

Id. at 70744. In response to a comment that information collected for a PSO may be the same information that must be reported to a state agency, HHS said "that providers must comply with applicable regulatory requirements and that the protection of information as [PSWP] does not relieve a provider of any obligation to maintain information separately." *Id.* at 70743. Also, HHS noted, the Act "does not preempt state laws that require providers to report information that is not [PSWP]," though states "may not require that [PSWP] be disclosed." *Id.* at 70743-44.

3. PSQIA's legislative history.

Regarding the Act's legislative purpose and history, the First District stated:

> In 2005, Congress took action to improve patient safety in the healthcare industry as a whole with the passage of the [Act]. The Act was passed following a 1999 Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health System*, in which IOM estimated that at least 44,000 people and potentially as many as 98,000 people die in United States hospitals each year as a result of preventable medical errors. The IOM report recommended that legislation be passed to foster the development of a reporting system through which medical errors could be identified, analyzed, and utilized to prevent further medical errors. *See* S. Rep. No. 108-196, at 3-4 (2003)[4]; H.R. Rep. No. 109-197, at 9 (2005). Through passage of the Act and its privileges, Congress sought to "facilitate an environment in which health care providers are able to discuss errors openly and learn from them." H.R. Rep. No. 109-197, at 9 (2005). . . .The Act was intended to replace a "culture of blame" and punishment with a "culture of safety" that emphasizes communication and cooperation. *See* S. Rep. No. 108-196, at 2 (2003) . . .

(R. 467-68.) This description was incomplete.

The PSQIA was enacted with broad, bipartisan support (unanimous consent in the Senate; 428-3 in the House).[5] Senator Jeffords, an independent, was the sponsor in the 109th Congress (2005-06) of Senate Bill 544, which eventually was enacted into law as the PQSIA.[6] He spoke about the bill on the Senate floor on July

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[4] This Senate report "accompanie[d] a 2003 proposed version of the [PSQIA] that was not enacted." *Tibbs v. Bunnell*, 448 S.W. 3d 796, 802 (Ky. 2014); (R. 229-32).

[5] *Final Vote for Roll Call 434, at* http:// clerk.house.gov/evs/2005/roll434.xml (visited Feb. 1, 2016); *Bill Summary & Status, 109th Congress (2005-06), S. 544, All Congressional Actions*, The Library of Congress, Thomas, at http://thomas.loc.gov/cgi-bin/bdquery/z?d109:SN00544:@@@X (visited Feb. 1, 2016) (Supp. App 308-09.)

[6] *Bill Summary & Status, 109th Congress (2005-06), S. 544, All Congressional Actions*, The Library of Congress, Thomas, at http://thomas.loc.gov/cgi-bin/bdquery/z?d109:SN00544:@@@X (visited Feb. 1, 2016) (Supp. App. 308-09.)

22, 2005, the day after it was adopted by the Senate. 151 Cong. Rec. S8741-44 (daily ed. July 22, 2005) (located at Supp. App. 457-60). He promoted many of the same policies noted by the First District. *See id.* But, he conceded that the enacted bill "reflect[ed] difficult negotiations and many compromises over almost 5 years of consideration," and he commended his colleagues for "reconcil[ing] disagreements that have previously stopped th[e] legislation from moving forward." *Id.* at S8743-44; (*see* R. 229-32 (describing the compromise).) Notably, the bill that Senator Jeffords introduced in the 108th Congress – which never was enacted – had none of the language eventually enacted in subparagraph (B) of 42 U.S.C. § 299b-21(7).[7]

Senator Jeffords recognized the PSQIA would not "reduce or affect" any other legal requirements related to health information or alter any existing rights or remedies belonging to injured patients:

> This legislation does nothing to reduce or affect other Federal, State or local legal requirements pertaining to health related information. Nor does this bill alter any existing rights or remedies available to injured patients. The bottom line is that this legislation neither strengthens nor weakens the existing system of tort and liability law.

[7] *Compare* S. 720, 108th Cong. § 3, at 5-6, 9-10 (Mar. 26, 2003) (proposing to add §§ 921(2), 922(a)&(b) to Title IX of the Public Health Service Act (42 U.S.C. § 299 et seq.) (Supp. App. 328-29; 332-33), *with* Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, § 2, 119 Stat. 424, 426 (July 29, 2005) (adding § 921(7)(B) to Title IX of the Public Health Service Act (42 U.S.C. § 299 et seq.)) (Supp. App. 315.) Senator Jeffords' original bill broadly defined "Patient Safety Data" and made all such data privileged. (Supp. App. 328-29.)

Id. Rather than merge existing requirements into the new PSQIA system, Senator Jeffords intended for the PSQIA to "create[] a new, parallel system of information collection and analysis." *Id.* at S8744.

Senator Jeffords was not alone in this intent. Senator Enzi, the Republican chair of the committee reporting the bill, stated that information not privileged before the Act's enactment would be not privileged after the Act's enactment:

> It is not the intent of this legislation to establish a legal shield for information that is already currently collected or maintained separate from the new patient safety process, such as a patient's medical record. That is, information which is currently available to plaintiffs' attorneys or others will remain available just as it is today. Rather, what this legislation does is create a new zone of protection to assure that the assembly, deliberation, analysis, and reporting by providers to patient safety organizations of what we are calling "Patient Safety Work Product" will be treated as confidential and will be legally privileged.

Id.[8]

Senator Kennedy expressed a similar intent. On the day the Senate passed the bill, he said on the floor that the bill "does not accidentally shield persons who have negligently or intentionally caused harm to patients." 151 Cong. Rec. S8713 (daily

[8] Senator Enzi made virtually the same statement before the Act's passage:

> This legislation would not permit anyone to hide information about a medical mistake. Under the bill, lawyers could still access medical records and other information that would normally be discoverable in a legal proceeding. However, the bill would ensure that the analysis of that information by [PSOs] would take place on a separate track in a protected legal environment.

150 Cong. Rec. S8223 (daily ed. July 15, 2004)(located at Supp. App. 440).

ed. July 21, 2005) (located at Supp. App. 455). And, he remarked, the legislation "uph[eld] existing state laws on reporting patient safety information." *Id.*

The Senate report on which the First District relied also conveyed a congressional intent that the Act would not preempt state-law obligations to report and disclose information:

> [T]he adverse event or the medical error itself is not privileged; it is the analysis of and subsequent corrective actions related to the adverse event or medical errors that are privileged. The underlying information remains unprivileged and available for reporting to authorities under mandatory or voluntary reporting initiatives. . . . Because such information of adverse events or medical errors is available or can be collected or developed independent of the reporting system contemplated by this legislation, these protections ***do not preempt*** current or preclude future Federal, State or local requirements for the ***reporting or disclosure of information*** that ensures accountability or furthers informed consumer choice (e.g., hospital-acquired infections, medical errors, adverse or sentinel health care events, and medical outcomes) other than patient safety data. These protections do not provide a basis for providers to refuse to comply with such reporting requirements simply because they have reported the same or similar information through the reporting system contemplated by this legislation . . . . As long as there is another source of the information reported to the PSO–even if it is the same information as is reported–the protections in ***this legislation will not operate to prevent its release or disclosure*** because the information would come from the other sources, not from patient safety data.

S. Rep. No. 108-196, at 4. This report further noted that the Act would "not preempt Federal, State, or local law governing accountability for a health care professional's negligence, malfeasance, or criminal acts, or that requires the collection and reporting of underlying data on health care provider quality of care, other than

patient safety data." *Id.* at 8. It also clarified that the Act's systems would be "separate from and independent of mandatory or voluntary reporting systems that have been or may be established under Federal, State or local law or regulation." *Id.*

This intent not to shield previously available information also existed in the House. (R. 228.) The committee report stated the Act did not "prevent a provider from complying with authorized requests for information that has been collected, developed, maintained, or exists separately from a [PSES]." H.R. Rep. No. 109-197, at 9 (2005) (located at Pet.'s App. 834). It also stated, "In general, information that is available to the public today will continue to be available." *Id.*

B. Florida's recordkeeping and reporting laws.

To paraphrase the PSQIA, what "separate information" were hospitals required to "collect, maintain, or develop" under Florida's recordkeeping and reporting laws before Congress enacted the PSQIA and what is required today? *See* 42 U.S.C. § 299b-21(7)(B)(ii). And, what information was available to patients and state agencies before the PSQIA's enactment and what is available today? The answers to these questions are in statutes, regulations, and Amendment 7. Notably, these answers are the same today as they were before the PSQIA's enactment.[9]

[9] The only statutory amendments since 2005 were insignificant changes to the following provisions: §§ 395.0193(6), 395.0197(12), 766.101(1)(a)1.f-i., Fla. Stat. *See* Ch. 2014-209, § 73, Laws of Fla.; Ch. 2014-19, § 294, Laws of Fla.; Ch. 2009-132, § 50, Laws of Fla.; Ch. 2007-230, §§ 43-44, Laws of Fla.

1. Florida statutes and regulations.

In contrast to the voluntary reporting of information authorized (but not mandated) by the PSQIA, Florida law mandates that hospitals create, collect, maintain, and develop certain patient safety information, including records of adverse incidents. *See, e.g.*, § 395.0197, Fla. Stat. (2014). This information, discussed in Part I.B.1, is called "state-mandated information" throughout this brief.

a. Incident reports and state regulatory framework.

Under Florida law, incident reports are part of a hospital's mandatory internal risk management program. *See generally id*. This program must include "the investigation and analysis of the frequency and causes of . . . adverse incidents to patients" and the "development of appropriate measures to minimize the risk of adverse incidents to patients." § 395.0197(1)(a)&(b), Fla. Stat. (2014). This program also "must include a system for informing a patient" that she "was the subject of an adverse incident." *Id.* § 395.0197(1)(d). Most notably, a risk management program must include "an incident reporting system based upon the affirmative duty of all health care providers and all agents and employees of the [hospital] to report adverse incidents to the risk manager." *Id.* § 395.0197(1)(e).

Accordingly, a hospital's risk management program, under Florida law, must collect, maintain, and develop three types of incident reports. First, all hospital providers and employees must report an adverse incident to the hospital's risk

manager within three business days of the "occurrence;" these are called 3-day reports. *Id.* § 395.0197(1)(e). Second, a hospital must submit to the Agency for Health Care Administration (AHCA) its annual report, which summarizes the adverse incident reports. *Id.* §§395.002(2), 395.0197(6)(a). Third, a hospital must submit to AHCA reports of certain adverse incidents within fifteen days of the incident; these are called Code-15 reports. *Id.* § 395.0197(7).

While a hospital need not submit its 3-day reports to AHCA, it must give AHCA "access" to the reports. *See* Fla. Admin. Code R. 59A-10.0055(3)(b) (stating such reports "shall be made available for review to any authorized representative of [AHCA] upon request during normal working hours."); § 395.0197(13), Fla. Stat. (2014) ("[AHCA] shall have access to all licensed facility records necessary to carry out the provisions of this section."); *see also* 73 Fed. Reg. at 70741 (allowing providers to "report" information to PSOs by providing them "access" to records). The 3-day reports must contain specific information, including: a "clear and concise description of the incident;" a "statement of [the] physician's recommendations as to medical treatment;" and a "listing of all persons then known to be involved directly in the incident." Fla. Admin. Code R. 59A-10.0055(2).

b. Peer-review, medical review and root-cause analyses.

Under Florida law, a hospital must create and maintain certain documents related to a physician's peer reviews. § 395.0193, Fla. Stat. (2014). Baptist admitted

these documents are not PSWP. (R. 39.) Baptist also admitted that it must "establish medical-review committees," § 766.101, Fla. Stat. (2014), but, it argued, these committees are not required to create or maintain any documents. (R. 39-40.) The statute, however, refers to "complaints," an "advisory report," "factual findings," and a "judgment." § 766.101(7), Fla. Stat. (2014).[10] Finally, a hospital must conduct root-cause analyses. *See* § 395.0197(1)(a), Fla. Stat. (2014) (requiring a hospital's internal risk management program to include "[t]he investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents to patients."); (R. 42 (noting the Joint Commission requires root-cause analyses).)

2. Amendment 7.

Unlike the statutes and regulations, Amendment 7 does not mandate that hospitals or providers create, collect, or develop any particular information, reports, or records. *See* Fla. Const., Art. X, § 25. But, if records of adverse medical incidents are created, collected, or developed, then Amendment 7 mandates that information be maintained in a manner that allows requesting patients access to it. *See id.*

Under Amendment 7, patients have "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." *Id.* § 25(a). An "adverse medical incident"

[10] The statute also shields a committee's "records" from discovery, § 766.101(5), Fla. Stat. (2014), but that shield is unconstitutional under Amendment 7. *Fla. Hosp. Waterman, Inc. v. Buster*, 984 So. 2d 478, 491-92 (Fla. 2008).

includes "medical negligence" and "any other act, neglect, or default" of a hospital or provider "that caused or could have caused injury to or death of a patient." *Id.* § 25(b)(3). An "adverse medical incident" specifically includes "those incidents that are required by state or federal law to be reported to any governmental agency or body" or "that are reported to or reviewed by any health care facility peer review, risk management, quality assurance, credentials, or similar committee, or any representative of any such committees."[11] *Id.* These records must be made available for inspection to a requesting patient. *See id.* § 25(a) & (c)(4).

Amendment 7's purpose was to do away with restrictions on a patient's right to know information about adverse medical incidents. *Fla. Hosp. Waterman, Inc. v. Buster*, 984 So. 2d 478, 489 (Fla. 2008). Accordingly, a patient may obtain records of adverse medical incidents even if: the records are not relevant to the patient's suit; production would be burdensome; or such records are purportedly protected by a state privilege or the work product doctrine. *See, e.g., Baldwin v. Shands Teaching Hosp. and Clinics, Inc*., 45 So. 3d 119, 124 (Fla. 1st DCA 2010); *Lakeland Reg'l Med. Ctr. v. Neely*, 8 So. 3d 1268, 1269-70 (Fla. 2d DCA 2009).

[11] Below, Baptist noted that the definition for "adverse medical incidents" under Amendment 7 is different than the definition for "adverse incident" in section 395.0197(5), Florida Statutes (2014). (*E.g.* Pet.'s App. 420 ¶ 14; 491, p. 61, lines 8-21.) The difference is immaterial. Amendment 7's definition expressly includes records falling under the statutory definition. Fla. Const., Art. X, § 25(b)(3).

II. Baptist's federal PSES and state internal risk management program.

Baptist bears the burden of establishing its privilege claim. *Infra* Argument at 29. Affidavits of Baptist's agents are a part of the record. (Pet's App. 266-70, 417-24; Supp. App. 143-59.) This Part II is based on those affidavits.

A. Baptist purports to meet its state-law obligations for 3-day reports by use of "occurrence reports" stored in its privileged PSES.

Baptist has merged significant parts of its state-mandated internal risk management program with its PSES. Indeed, Baptist's risk manager attested that its PSES was "a component of [Baptist's] comprehensive risk management program." (Pet.'s App. 420, ¶ 15.) As the ensuing discussion shows, Baptist purports to satisfy its state-law obligations to create, collect, maintain, and develop 3-day adverse incident reports by using "occurrence reports" stored in its PSES that cannot be accessed by either patients (as Amendment 7 requires) or state agencies (as required by a state regulation and statute).

Baptist voluntarily established a PSES in late 2005, then joined a PSO, and in 2011 began reporting information collected in its PSES to a PSO. (Pet.'s App. 419, ¶¶ 7-12.) At one time, the website of Baptist's PSO stated: "Information that is collected for multiple purposes can be shared with a PSO as a 'copy,' but it cannot become PSWP." (Pet.'s App. 279.) This statement was later removed from the website after the Charles family's counsel noted it at a hearing. (Pet.'s App. 369, p. 45; Pet.'s App. 679, p. 15.)

By March 2013, Baptist had collected 52,000 "occurrence reports" in its PSES. (Pet.'s App. 268, ¶ 15.) According to Baptist, occurrence reports record "events that are not consistent with the routine operations of the hospital or routine care of a patient or that could result in an injury." (Pet.'s App. 419-20 ¶ 13.) These events include falls, injuries, unexpected returns to the hospital or operating room, surgical complications, device malfunctions, unexpected cardiopulmonary events or deaths, medication errors, and delay in care. (*Id.*)

Baptist's records of adverse medical incidents exist solely in its PSES, according to its risk manager. (Supp. App. 144 ¶ 4.a.) The PSES occurrence reports may report on "adverse medical incidents" or "adverse incidents," as those terms are defined in Amendment 7 and section 395.0197(5), Florida Statutes, and Baptist admitted some of the PSES occurrence reports, in fact, do report on adverse incidents. (Pet.'s App. 420, ¶¶ 14, 20; R. 18.) Baptist also conceded below that "[t]he events described in the 'incident reports' that the State requires Baptist to create constitute a small subset of the events captured and reported internally in the occurrence reports that Baptist collects." (R. 18.) However, Baptist asserted, most occurrence reports do not concern adverse medical incidents. (Supp. App. 153, ¶ 14.)

Baptist also claimed below that it could satisfy its "state-law obligation to create and maintain records of adverse incidents" by way of the occurrence reports stored in its privileged PSES. (R. 18-19 (noting that "some occurrence reports satisfy

Baptist's state-law obligation to create and maintain records of adverse incidents"); R. 22 (noting that "[i]ts occurrence reports . . . did not exist separately from the PSE System . . . . [and] [t]hat some occurrence reports also satisfied Baptist's state-law obligation to maintain records of adverse incidents"); Pet.'s App. 421, ¶ 17 (testimony by Baptist's risk manager that "occurrence reports are . . .maintained by the hospital as described in [Fla. Stat.] § 395.0197(4)[12]").) Under Baptist's view, it may use privileged PSWP, stored in its PSES, to satisfy its state-law obligations, rather than use the non-privileged information defined in subparagraph (B) of § 299-21(7) to satisfy these obligations. (Pet.'s App. 419-22, ¶¶ 13-14, 17, 22.)

Despite its claim that the occurrence reports satisfied its state-law obligations, Baptist asserted no state agency was permitted to review these reports. (R. 34.) Baptist's risk manager attested that the occurrence reports "are not required to be submitted or reported to any state agency, and these occurrence reports are not submitted or reported to any state agency and have not been disclosed or produced to any state agency." (Pet.'s App. 421 ¶ 17; *see also* R. 15, 17-18, 22, 34-35.) To the extent Florida law granted patients and state agencies the right to inspect these state-mandated reports, Baptist argued that Florida law had to "yield" to the Act. (R. 33.)

[12] Section 395.0197(4) states in part, "Each internal risk management program shall include the use of incident reports to be filed with [the risk manager] . . . ."

B. Baptist maintains its annual reports and Code-15 reports differently than it maintains its 3-day reports.

Recall, under Florida law, hospitals must create and maintain: (i) 3-day reports, (ii) annual reports, and (iii) Code-15 reports. *See supra* at 14. Unlike the 3-day reports, Baptist does not store the latter two types of reports in its PSES and does not claim they are privileged under the PSQIA. (R. 478 n.2.; R. 19, 21; Pet.'s App. 422-23, ¶¶ 23-25.) Baptist distinguishes between the annual/Code-15 reports and 3-day reports. It argues that state law requires the annual/Code-15 reports be "submitted" to state agencies, whereas state law requires that state agencies merely have "access" to the 3-day reports. (R. 19, 35, 291.)

Baptist conceded below that it would contravene the PSQIA's reporting sub-clause (§ 299b-21(7)(B)(iii)(II)) if it stored the mandatory annual/Code-15 reports in the privileged PSES and refused to report them to the State. (R. 291.) Baptist, however, never acknowledged below that, by refusing to grant patients and state agencies access to the mandatory 3-day reports, it would contravene the reporting sub-clause, the similarly-worded recordkeeping sub-clause (§ 299b-21(7)(B)(iii)(III)) or the separate-information clause (§ 299b-21(7)(B)(ii)). As argued *infra*, these positions are irreconcilable. *Infra* Argument I.B, at 36.

C. Baptist's peer-review, medical-review, and root-cause analyses.

Baptist admits that its peer-review and medical committees "review records of adverse medical incidents in the course of their established functions," but it

denies that these committees are required to create or preserve any records. (Supp. App. 145 ¶ 6.) Baptist's affiants have been silent as to whether the committees, in fact, create or maintain such records or whether any such records are stored within or outside of the PSES. (Pet's App. 266-70, 417-24; Supp. App. 143-59.) However, Baptist does submit all root-cause analyses to its PSO. (Supp. App. 146, ¶ 9.)

III. Facts and proceedings in this case.

A. The Charles family's claims in their complaint.

Ms. Charles presented in February 2010, to Baptist, suffering from iron deficiency anemia and thrombocytosis. (App. To Mot. To Dismiss 18 ¶ 16.) The standard of care required medication, not surgery. (*Id.* at 18, 19 ¶¶ 17, 20.) Baptist's physicians/agents performed surgery and committed other acts of negligence. (*Id.* at 19-21 ¶¶ 21-29.) They caused Ms. Charles to suffer a massive stroke. (*Id.* at 21-22 ¶¶ 30-31.) The Charles family sued Baptist and its physicians. (*Id.* at 15-18 ¶¶ 2-14.) They alleged that Baptist failed to: have sufficient stroke protocols; follow or timely invoke stroke protocols; and retain and adequately train personnel to implement stroke protocols. (*Id.* at 23-24 ¶¶ 36-42.)

B. Baptist's resistance to the Charles family's Amendment 7 request.

In July 2013, the family requested from Baptist "all documents considered adverse incident documents under the Florida Constitution" for the three-year period preceding Ms. Charles' incident. (Supp. App. 8-11.) Importantly, this request was

limited to documents "created" or "maintained" by Baptist "pursuant to any obligation or requirement in any state or federal law, rule, or regulation." (*Id.*) In other words, information that Baptist voluntarily created, collected, or developed solely for reporting to a PSO was not requested. (*See id.*)

Baptist's extensive efforts to resist this discovery request were fully recited to the trial court. (Pet.'s App. 51-55, 432-37.) Over eleven months, the trial court held eight hearings where the request was argued. (Pet.'s App. 282-91, 293-97, 354-55, 364-76, 386-88, 477-91, 674-87, 690-707.) Baptist repeatedly denied that it had any incident reports relating to Ms. Charles' incident. (Pet.'s App. 37-38, 43, 45-48.) After seven months of denials, Baptist finally removed from its PSES, and produced, two 2-page occurrence reports relating to Ms. Charles' incident. (Pet.'s App. 433; Supp. App. 1-4.) Baptist has never attested whether it has stored in its PSES additional, non-produced reports on Ms. Charles' incident. Its risk manager merely attested, "[n]o other risk management documents involving Marie Charles exist separately from the hospital's PSES." (Pet.'s App. 423 ¶ 26.)

In producing these two reports, Baptist was clear that its decision to do so was voluntary and could not be ordered by the courts (Pet.'s App. 423, ¶¶ 25, 27; Pet.'s App. 433, 488-90). Baptist argued that its PSES was so secretive that a court, under the PSQIA, could not require a privilege log to enable the court to evaluate the

validity of the privilege claims. (Pet.'s App. 488-90.) Baptist's trial counsel did indicate that perhaps an *in camera* review would be possible. (Pet.'s App. 490.)

Baptist has not produced: (i) any 3-day incident reports other than the two involving Ms. Charles; (ii) any reports on strokes that occurred at Baptist; (iii) any documents from its medical or peer review committees; or (iv) any root causes analyses. Baptist has merely produced its annual/Code-15 reports (less than 300 pages[13]), Ms. Charles' medical records, and the two occurrence reports. Baptist has also demanded that the Charles family pre-pay between $143,000 and $326,000 for the research costs to separate the state-mandated information from the PSWP stored in the PSES. (Supp. App. 142, 155, 159.)

C. The trial court's ruling.

In granting the family's motion to compel, the trial court ordered Baptist to produce "[a]ll reports of adverse medical incidents, as defined by Amendment 7, which are created, or maintained pursuant to any statutory, regulatory, licensing, or accreditation requirements." (Pet.'s App. 503.) The court reasoned:

> Documents are not PSWP if those documents were collected or maintained for a purpose other than submission to a PSO or for a dual purposes. Any documents that are collected pursuant to a healthcare provider's obligation to comply with federal, state, or local laws, or accrediting or licensing requirements are not privileged under the PSQIA, and such documents do not gain privilege by being submitted to the PSO.

[13] See pages 271-541of the appendix to Appellants' response, filed in this Court on January 4, 2016, opposing Appellee's motion to dismiss.

(Pet.'s App. 501.)

D. Proceedings in the First District and this Court.

Baptist petitioned the First District for a writ of certiorari. In response, the Charles family argued: "[Baptist] effectively has merged its mandatory data collection and reporting requirements under Florida law with its voluntary reporting system under the PSQIA. This merger is unlawful." (R. 250.) Nevertheless, the First District's opinion asserted that the family had not alleged any failure by Baptist to comply with reporting or recordkeeping requirements. (R. 477.)

The family also argued that this "unlawful merger" violated HHS guidance and the PSQIA's legislative intent. (R. 250-51.) Congress did not intend to diminish a provider's state-law obligations. (R. 250-51.) Those obligations, the family explained, included obligations to create and maintain certain reports and records pursuant to state statutes and regulations and to allow state agencies and patients access to such records and reports. (R. 215-19, 244, 247-48.)

In construing the Act, the First District concluded that, if Baptist places a document into its PSES for reporting to a PSO, then the document is PSWP. (R. 478.) That these documents, stored in the PSES, may be relied upon by Baptist to satisfy its state reporting or recordkeeping obligations was not relevant, according to the court. (*Id.*) The court reasoned, "[n]owhere does the definition state that a

document may not simultaneously be PSWP and also meet a state reporting requirement." (R. 476.) Additionally, the court concluded:

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

(R. 476-77.)

The First District acknowledged its decision could encourage a provider to exercise its "unilateral, unreviewable" discretion to "dump everything into its [PSES], rendering it privileged and confidential, in an effort to thwart to discovery." (R. 477.) The court concluded, however, that such "gamesmanship" was "unlikely" because the PSQIA "clearly define[d] what can and cannot constitute PSWP." (*Id.*) But if gamesmanship did occur, the "remedy would not be for the trial court to 'rummage through'" Baptist's PSES "in search of documents that could possibly serve a 'dual purpose.'" (*Id.* (citing *Tibbs v. Bunnell*, 448 S.W.3d 796, 809 (Ky. 2014) (Abramson, J., dissenting).) Instead, the First District reasoned, the remedy would be to address the noncompliance of recordkeeping or reporting obligations itself in the same manner as it could have been addressed before the PSQIA. (*Id.*)

The First District declared the PSQIA "preempted" Amendment 7. (R. 479-80.) The Charles family appealed, invoking this Court's mandatory appellate

jurisdiction (Fla. Const. Art. V, § 3(b)(3); *State v. Harden*, 938 So. 2d 480, 495-96 (Fla. 2006)), or alternatively discretionary review, as the decision below construed constitutional provisions or expressly and directly conflicted with a Fourth District decision (Fla. Const. Art. V, § 3(b)(3); *Bethesda Hosp., Inc. v. Gomez-Colombo*, Case No. 4D15-1080, Order (Fla. 4th DCA April 22, 2015)). (Notice of Appeal.) On February 5, 2016, this Court denied Baptist's motion to dismiss this appeal.

SUMMARY OF ARGUMENT

This case requires this Court both to: (i) interpret a federal statute that creates a privilege and (ii) determine a provider's reporting and recordkeeping obligations under Florida law. The federal and state legal issues are intertwined. The federal statute in subparagraph (A) broadly defines the scope of the PSWP privilege to include many types of patient safety information. 42 U.S.C. § 299b-21(7)(A). But the ensuing subparagraph (B) expressly preserves state-law reporting and recordkeeping obligations to limit the privilege's scope and ensure that information that was available to regulators, patients, and plaintiffs before the PSQIA's enactment continues to be available to them today. *See id.* 299b-21(7)(B)(ii) & (iii)(II) & (III).

The First District erred because it read the PSQIA as granting providers, like Baptist, the "unilateral, unreviewable" discretion to decide the limits on what information is privileged. The Act neither expressly nor implicitly grants such

unfettered, unprecedented discretion to providers. Instead, the privilege is limited by a provider's reporting and recordkeeping obligations under state, local, and other federal laws, all of which the PSQIA expressly preserves. If these non-PSQIA laws, like Florida law, mandate that a provider collect, maintain, or develop specified information separately from a privileged database, then providers must comply with those non-PSQIA laws. That information is "separate" and thus not privileged, although a provider may still report this separate, non-privileged information to a PSO for use in a patient safety database. Conversely, other information – the collection, maintenance, and development of which is not mandated by state law and other non-PSQIA laws – may be assembled or developed by a provider for reporting to a PSO and become privileged PSWP.

Accordingly, the Charles family's arguments can be summarized as follows:

1. Baptist's storage in a privileged database of state-mandated information – that is, information that Baptist must collect, maintain, or develop under Florida law – does not comply with Baptist's state-law reporting and recordkeeping obligations, which are expressly preserved by the PSQIA. Those state-law obligations require Baptist to maintain all state-mandated information separately from any privileged database, so it is accessible to patients and state agencies. Although the PSQIA permits this separate, state-mandated information to be stored also in a PSES and reported to a PSO, that mere reporting does not transform the

state-mandated information into privileged PSWP. The PSQIA's plain text, regulatory guidance, and legislative history do not suggest otherwise.

2. Because Baptist has not complied with its state-law reporting and recordkeeping obligations, Ms. Charles has suffered a constitutional wrong. An appropriate remedy must be ordered. The trial court determined that Baptist must remove from its PSES any information on adverse medical incidents mandated by state and other non-PSQIA laws and disclose that information to Ms. Charles. That was the correct remedy. The First District erred in concluding otherwise. However, alternative remedies used for spoliation of evidence also may be appropriate. The trial court should be instructed to consider these alternatives on remand.

ARGUMENT

Issues presented.

I. To comply with the PSQIA and state-law reporting and recordkeeping obligations, may a provider store state-mandated information on adverse medical incidents exclusively in its privileged PSES, or must it maintain this state-mandated information separately from the PSES, so it is accessible to patients and state agencies?

II. If a Florida provider unlawfully stores its state-mandated patient information exclusively in a privileged PSES to deny a patient her state constitutional right to inspect this information, what remedy should a court impose to protect a patient's constitutional right?

Preliminary matters.

i. Jurisdiction. To establish this Court's jurisdiction, the Charles family relies on their response, filed on January 4, 2016, opposing Appellee's motion to dismiss, which this Court denied on February 5, 2016.

ii. Standard of review. A reviewing court may issue a writ of certiorari only if the lower tribunal's order: (i) departs from the essential requirements of law, and (ii) results in material injury that cannot be corrected on post-judgment appeal. *E.g., Citizens Prop. Ins. Corp. v. San Perdido Ass'n, Inc.*, 104 So. 3d 344, 351 (Fla. 2012). The former prong is "something that is more than just a legal error." *Id.*

iii. The *Chevron* doctrine, the federal rules of statutory construction, and the burden of establishing a privilege. The PSQIA's interpretation is a question of federal law governed by the federal rules of statutory construction. *See State v. Joseph*, 94 So. 3d 672, 674 (Fla. 1st DCA 2012); *Snavely Siesta Associates, LLC v. Senker*, 34 So. 3d 813, 816-17 (Fla. 2d DCA 2010). The primary rule of construction for this case is the *Chevron* doctrine. *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). *Chevron* is binding on state courts when interpreting federal statutes administered and interpreted by federal

agencies.[14] *See Smiley v. Citibank (S. Dakota), N.A.*, 517 U.S. 735, 737-39 (1996) (applying *Chevron* to resolve conflict amongst state courts construing a federal act).

Under *Chevron*, courts must accept a federal agency's reasonable construction of an ambiguous statute that falls within the agency's jurisdiction to administer. *E.g.*, *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980, 982 (2005). *Chevron* established a two-step procedure. *Id.* at 986. First, a court must ask whether the statute's plain terms "directly address the precise question at issue." *Id.* (internal quotations omitted). Second, if the statute is ambiguous, the court must defer to the agency's interpretation "so long as the construction is a reasonable policy choice for the agency to make."[15] *Id.* (internal quotations omitted). Moreover, if a statute is ambiguous, legislative history may be consulted when it has "clear evidence of congressional intent" that "illuminate[s] [the] ambiguous text."[16] *Milner v. Dep't of Navy*, 562 U.S. 562, 572 (2011).

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[14] Alternatively, this Court must give a federal agency's interpretation substantial deference under the *Skidmore* doctrine. *See United States v. Mead Corp.*, 533 U.S. 218, 234 (2001) (discussing *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)).

[15] Baptist may criticize our reliance on the regulatory "preamble." This criticism is unwarranted for two reasons. First, the First District and Baptist relied on this same preamble, even though they unduly focused on the no-duplication guidance while ignoring other parts. (R. 476.) Second, a court may rely on a regulatory preamble as an interpretative aid even when regulations are unambiguous. *Ramos v. Baldor Specialty Foods, Inc.*, 687 F.3d 554, 559 & n.3 (2d Cir. 2012).

[16] Baptist may criticize our reliance on floor statements by two senators made one day after the Senate passed the bill, but before the House did. These floor statements, however, were consistent with the PSQIA's text and its pre-enactment history, including the committee reports on which Baptist and the First District relied.

Finally, a statute granting a privilege, like the PSQIA, must "be strictly construed so as to avoid a construction that would suppress otherwise competent evidence." *Baldrige v. Shapiro*, 455 U.S. 345, 360 (1982) (internal quotations omitted). This strict construction lies in the "fundamental maxim," grounded in the common law, that the public "has a right to every man's evidence." *United States v. Bryan*, 339 U.S. 323, 331 (1950). Baptist, the party claiming the privilege, bears a "heavy" burden to establish its applicability. *E.g., In re Grand Jury Subpoenas Dated March 19, 2002 & August 2, 2002*, 318 F.3d 379, 384 (2d Cir. 2003).

Merits.

I. Under Florida law, state-mandated information must be maintained separately from a privileged database. The PSQIA preserves this Florida law and makes this information non-PSWP. Baptist may not transform non-PSWP to PSWP simply by storing it in the PSES.

The PSQIA's plain language expressly preserves – rather than preempts – reporting and recordkeeping obligations under state law (and other non-PSQIA laws). 42 U.S.C. § 299b-21(7)(B)(iii)(II) & (III); *see id.* § 299b-22(g)(5); *see also W. Florida Reg'l Med. Ctr., Inc. v. See*, 79 So. 3d 1, 19-20 (Fla. 2012) (relying on provision preserving state law in another federal act to determine that federal act did not preempt Amendment 7). Accordingly, as interpreted by the HHS, the PSQIA establishes systems that are "separate" and "distinct" from, but "do[] not replace," the "other information collection activities mandated by [state] laws, regulations, and accrediting and licensing requirements." 73 Fed. Reg. 70732, 7042-43. The

PSQIA's legislative history is in agreement. *See supra* Statement, Part I.A.3, at 8. Given that the PSQIA expressly preserves state-law reporting and recordkeeping obligations, HHS has correctly determined that nothing about the Act "relieve[s] a provider of any [state-law] obligation to maintain information separately." 73 Fed. Reg. at 7043. And, the PSQIA plainly states that the PSWP privilege does not apply to "information that is collected, maintained, or developed separately, or exists separately, from a [PSES]." 42 U.S.C. §299b-21(7)(B)(ii).

Accordingly, the proper analysis under this first issue requires this Court to answer three questions. First, does a provider like Baptist have obligations, under Florida law, to collect, maintain, or develop specified information on adverse medical incidents separately from a privileged database? The answer is yes. *Infra* Argument I.A., at 32. Second, under the PSQIA, is this state-mandated information privileged PSWP or non-privileged "separate information?" It is non-privileged "separate information." *Infra* Argument I.B., at 36. Third, does the PSQIA authorize a provider to make this separate, state-mandated information privileged PSWP by simply storing that information in the privileged PSES for reporting to a PSO? The answer is no. *Infra* Argument I.C., at 41.

A. Florida law mandates that Baptist collect, maintain, or develop certain information on adverse medical incidents separately from a privileged database.

As discussed above, various Florida statutes and regulations mandate that hospitals (like Baptist) collect, maintain, or develop specified information on adverse medical incidents – referred to as "state-mandated information." *See supra* Statement, Part I.B.1, at 14. Under Florida statutory law, hospitals must collect, maintain, and develop specific information on adverse medical incidents in three types of incident reports (3-day, Code-15, and annual reports), *supra* Statement, Part I.B.1.a, at 14; § 395.1097, Fla. Stat. (2014), as well as, in other records pertaining to peer review, medical review committees, and root-cause analyses, *supra* Statement Part I.B.1.b, at 15. Under Florida regulatory law, hospitals must collect, maintain, and develop specific information when completing the 3-day incident reports. *Supra id.* Part I.B.1.a, at 14; Fla. Admin. Code R. 59A-10.0055(2).

There can be little doubt that under Florida reporting and recordkeeping laws, hospitals must collect, maintain, or develop all the state-mandated information (including the 3-day reports) "separately" from a privileged database. *See* 42 U.S.C. § 299b-21(7)(B)(ii). Stated another way, Florida law requires this information to "exist[] separately" from a privileged database. *See id.* This is so because: (i) a state statute and regulation expressly grant AHCA access to the state-mandated information, § 395.0197(13), Fla. Stat. (2014); Fla. Admin. Code R. 59A-

10.0055(3)(b), and (ii) a state constitutional provision, Amendment 7, expressly grants patients the right to access this state-mandated information to the extent it relates to an adverse medical incident, Fla. Const., Art. X, § 25; *supra* Statement, Part I.B.2, at 16. Maintaining state-mandated information exclusively in a privileged database, to which patients and state agencies are denied access, violates a hospital's reporting and recordkeeping obligations under Florida law. *See* Fla. Const., Art. X, § 25; § 395.0197(13), Fla. Stat. (2014); Fla. Admin. Code R. 59A-10.0055(3)(b).

Enforcing these state-law reporting and recordkeeping obligations will not annul, or conflict with, federal law. The First District and Baptist were wrong to say otherwise. (R. 289-90, 478-79). Indeed, the federal Act expressly preserves and incorporates these obligations. 42 U.S.C. § 299b-21(7)(B)(iii)(II) & (III); *see also id.* §299b-22(g)(5). Moreover, enforcement of these obligations will not mean that all PSES information is disclosed. Only information that state law (or some other law) mandates must be collected, maintained, or developed separately, or exist separately, from a privileged database is subject to disclosure. *See id* § 299b-21(7)(B)(ii). Baptist is free to voluntarily collect, maintain, or develop other information not required by state (or other) laws and store that information in its privileged PSES. For example, Baptist claims most of the 52,000 occurrence reports in the PSES do not relate to adverse incidents and thus do not contain state-mandated

information. (Supp. App. 153, ¶ 14.) If Baptist is correct (which the Charles family does not assume), then much of the PSES information may be privileged.

B. State-mandated information is "separate" and not PSWP.

Clause (ii) of subparagraph (B) of § 299-21(7) expressly states: "[I]nformation that is collected, maintained, or developed separately, or exists separately, from a [PSES]" is not privileged PSWP. State-mandated information that must be collected, maintained, or developed separately, or exists separately, from a privileged database (such as the state incident reports) qualifies as "separate information" under § 299-21(7)(B)(ii). *See supra* Statement, Part I.B.1, at 14. Thus, it is not privileged PSWP.

HHS agrees that state-mandated information is not PSWP. In interpreting the Act, HHS has stated: "Information is not [PSWP] if it is collected to comply with external obligations," including "state incident reporting requirements." 73 Fed. Reg. at 7042-43. The legislative history supports this interpretation. *See supra* Statement, Part I.A.3, at 8. Both floor statements and committee reports repeatedly emphasized that information available to regulators, patients, and their attorneys before the PSQIA's enactment – which was true of information in Florida's incident reporting system, *see id*., Part I.B & n.9 at 13 – would continue to be available after its enactment. *See id.*, Part I.A.3, at 8.

Even Baptist agrees, to a point, that some state-mandated information is not PSWP. Baptist conceded below that two types of state incident reports (annual and Code-15 reports) were not PSWP.[17] (R. 19, 35, 291; App. 423 ¶ 25.) But it distinguished the two non-PSWP incident reports from the 3-day incident reports, which it contended were PSWP. (R. 17-19.) Although Baptist conceded that Florida law required it to "create and maintain" the 3-day reports, it asserted these reports could be PSWP because Florida law did not require them to be "report[ed]" – that is, actually submitted – to the State. (R. 17-18.) Thus, Baptist contended below, it could satsify its state-law recordkeeping obligation – as it must do under the recordkeeping sub-clause, § 299-21(7)(B)(iii)(III) – by maintaining the information required for a 3-day report in an "occurrence report" stored in its privileged PSES. (*See* R. 17-18.) On the other hand, Baptist contended the reporting sub-clause, § 299-21(7)(B)(iii)(II), prevented it from treating the annual/Code-15 reports as PSWP because those reports had to be submitted to the State. (*See* R. 19, 291.)

Baptist's arguments, and its distiction between 3-day and annual/Code-15 reports, do not withstand scrutiny for several reasons. First, maintaining the information required for the 3-day reports (and other state-mandated information) in a privilege database does not satsify Florida's reporting and recordkeeping

[17] Baptist also admitted peer-review materials were not privileged (R. 39), but it has not produced any such materials.

obligations. *See supra* Argument I.A., at 34. Of course, this Court (not Baptist) conclusively interprets Florida's reporting and recordkeeping obligations. *See, e.g.*, *Gonzalez v. State*, 617 So. 2d 847, 849 (Fla. 4th DCA 1993).

Second, the PSQIA itself suggests, and HHS's guidance expressly states, that a provider may not use privileged PSWP to satisfy state-law reporting and recordkeeping obligations. The First District was wrong to conclude otherwise. (R. 476.) In preserving state-law obligations, the PSQIA expressly referred to non-privileged information rather than privileged PSWP. *See* 42 U.S.C. § 299-21(7)(B)(iii)(II) & (III) (referring to "information described in this subparagraph [(B)]," which describes non-privileged information, as opposed to subparagraph (A), which describes PSWP). Accordingly, HHS has instructed providers that they must meet their "external obligations" with "information that is not [PSWP]." 73 Fed. Reg. at 7042. Had Congress intended to allow providers to use PSWP to comply with state-law obligations, it would have expressly said so by a reference to paragraph (7) of the statute, which describes both PSWP and non-privileged information. *See Koons*, 543 U.S. at 60-61 (2004) (describing "paragraphs" and "subparagraphs" in federal statutes). Baptist's current practice of using PSWP to purportedly meet its state-law obligations is unlawful. *See* 73 Fed. Reg. at 7042.

Third, though Baptist was correct to admit that the state-mandated information in the annual/Code-15 reports was not PSWP, it failed to recognize the correct

provision that made these reports not PSWP. It is true, as Baptist noted below, that the reporting sub-clause prohibited Baptist from "refus[ing] to report to the State records that must be reported [under state law]." (R. 291 (citing § 299-21(7)(B)(iii)(II)).) Moreover, the reporting and recordkeeping sub-clauses are relevant to determining what is and is not PSWP. But, neither the reporting nor recordkeeping sub-clauses define non-PSWP information. Instead, as Baptist correctly recognized below, only the first two clauses of subparagraph (B) – clauses (i) and (ii) – define the exceptions to PSWP. (R. 288.) The first clause (i), describing original patient records, does not apply to any of the incident reports. 42 U.S.C. § 299b-21(7)(B)(i). The second clause (ii), describing "separate information," does apply to the annual/Code-15 and 3-day incident reports because all these reports record and report information that, under state law, must be "collected, maintained or developed separately, or exists separately" from a privileged database. *See id.* § 299b-21(7)(B)(ii); *supra* Argument I.A., at 34.

Fourth, the distinction drawn by Baptist – between information submitted to the State (annual/Code 15 reports) and to which the State has a right to access (3-day reports) – does not matter under clause (ii). Irrespective of whether or not a report is submitted to the State, information in a report is "separate" under clause (ii), and not PSWP, if state law mandates that the information be "collected, maintained, or developed separately, or exist separately, from" a privileged database

like the PSES. *See* 42 U.S.C. § 299b-21(7)(B)(ii). Under Florida law, a hospital must provide patients and AHCA access to all three types of incident reports and must maintain all three reports separately from a privileged database. *See* Fla. Const., Art. X, § 25; § 395.0197(13), Fla. Stat. (2014); Fla. Admin. Code R. 59A-10.0055(3)(b); *supra* Argument I.A, at 34. The only distinction is that a hospital has sole custody of the 3-day reports, while the annual/Code-15 reports are held by AHCA and the hospital. This distinction is meaningless.

Fifth, allowing hospitals to keep state-mandated reports in a secret database is absurd. Why would any state mandate the collection, maintenance, and development of information if it was powerless to inspect this information to ensure the regulated entity was complying with the state's mandate? Congress never intended such an absurd result. *See supra* Statement, Part I.A.3, at 8; *see also Armstrong Paint & Varnish Works v. Nu-Enamel Corp.*, 305 U.S. 315, 333 (1938) (holding that it is a "judicial function" to construe a statute in such a manner so as to avoid an absurd result). HHS agrees. *See* 73 Fed. Reg. at 70742 (noting that PSWP does not include information to which oversight entities had access before the PSQIA).

In summary, the information in the 3-day reports and the other state-mandated information qualifies as "separate information" under § 299b-21(7)(B)(ii) and thus is not PSWP. Any arguments to the contrary are unpersuasive.

C. Baptist cannot transform separate, non-privileged information, such as the state-mandated information, to PSWP simply by storing or "dumping" it in a PSES for reporting to a PSO.

1. The First District's conclusion that a provider has "unreviewable" power ignored clause (ii)'s plain text and legislative intent.

The second sentence of clause (ii) of subparagraph (B) of § 299b-21(7) states: "Such separate information or a copy thereof reported to a [PSO] shall not by reason of its reporting be considered [PSWP]." A PSES's purpose, by definition, is "for reporting to or by a [PSO]." 42 U.S.C. § 299b-21(6). Thus, under the statute's plain language, Baptist's decision to store "separate information," such as state-mandated information, in its PSES for reporting to a PSO does not transform the non-privileged, separate information into privileged PSWP. *Cf. Falsone v. U.S.*, 205 F.2d 734, 739 (5th Cir. 1953) (noting the administration of justice could be easily defeated if a party could withhold evidence by simply transferring it to his counsel).

Remarkably, however, the First District concluded that "[t]he Act is clear" that the provider "determines how information is stored and reported" and that this purportedly "unreviewable" discretion could allow a provider to "potentially dump everything into its [PSES], rendering [all the dumped information] privileged and confidential, in an effort to thwart discovery." (R. 477.) The First District failed to cite any statutory text to support its extraordinary interpretation of the Act. Indeed,

no such text exists in the PSQIA. And, the First District never addressed or analyzed clause (ii)'s second sentence; it just ignored it. (R. 473-80.)

The First District's interpretation contradicts the plain language of clause (ii)'s second sentence. While a provider may store non-PSWP information in its PSES, the decision to store it there does not make it PSWP. 42 U.S.C. § 299b-21(B)(ii). The First District has drained clause (ii) of any meaning. *But see Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991) (holding a statute must be construed, if possible, to avoid rendering any part of it superfluous).

The First District's interpretation contravenes legislative intent because it grants unprecedented, unchecked power to providers to conceal information. It empowers a provider to unilaterally transform virtually any information – collected, maintained, or developed pursuant to a non-PSQIA law – into privileged PSWP by simply reporting that information to the PSO. This was not Congress's intent. *Supra* Statement, Part I.A.3, at 8. For example, the Senate report stated, the Act does not allow "providers to refuse to comply with [non-PSQIA] reporting requirements simply because they have reported the same or similar information through the reporting system contemplated by [the Act]." S. Rep. No. 108-196, at 4.

This Court also should reject a premise of the First District's interpretation – that is, its rank speculation that providers are "unlikely" to engage in "gamesmanship" when exercising "unreviewable" power to decide what is

privileged. (R. 477.) Baptist is already engaged in gamesmanship. It conveniently discloses the reports that it must submit to AHCA, which has the power to revoke its license, § 395.003(1)(a), Fla. Stat. (2014). But when a patient, like Ms. Charles (who lacks the power of license revocation) requests other incident reports under her state constitutional right, Baptist initially denies the existence of any incident reports relating to her stroke, never comes clean on whether additional such reports exist, makes a meaningless distinction between the 3-day and annual/Code-15 reports to obstruct evidence on other adverse stroke incidents, and demands $143,000 to $326,000 from Ms. Charles to extract from its PSES the state-mandated information that it was required to maintain separately. *Supra* Statement, Part III.B, at 22. Baptist's annual/Code-15 reports also show gamesmanship; Baptist repeatedly has failed to complete the initial adverse incident reports required by section 395.0197, Florida Statutes.[18] By comparison, Baptist completed over 52,000 occurrence reports for its privileged PSES. (Pet.'s App. 268, ¶ 15.).

2. HHS's guidance does not support the First District's decision.

The First District cited HHS's no-duplication guidance, *see supra* Statement, Part I.A.2, at 5, as purportedly supporting its interpretation of the Act. (R. 476.)

[18] See pages 288, 299, 305, 309, 312, 316, 325, 342, 346, 350, 353, 357, 360, 383, 387, 390-391, 394-395, 398-399, 406-407, 411, 415, 419, 423, 427, 431, 435, 439, 443, 447, 467, 475, 478, 481, 484, 488, 491, 495, 498, 504, 521, 525, 529, 532, 536, and 539 of Appellant's appendix, filed in this Court on January 4, 2016, in support of Appellant's response opposing Appellee's motion to dismiss.

Reading this guidance in context, it is clear that HHS merely recognized that, at the time of data collection, a provider may not know whether data was necessary for state-law and other non-PSQIA obligations. Thus, HHS granted providers "flexibility" to place collected information in the PSES while "they consider whether the information is needed to meet external reporting obligations." 73 Fed. Reg. at 70742. But HHS warned providers to "carefully consider" whether information it placed in a PSES was needed "to meet their external reporting or health oversight obligations," and it further warned that information was not PSWP if it was "collected to comply with external obligations." *Id.*

While the HHS guidance did indicate providers have discretion to "determine[] [whether] certain information must be removed from the [PSES] for reporting to the state," the HHS never suggested – as the First District has held – that such discretion was "unreviewable," "unilateral," and beyond the purview of any judicial or executive power to ensure a provider is complying with non-PSQIA laws. The HHS could not suggest this because, to reiterate, the Act expressly preserves, rather than pre-empts, non-PSQIA reporting and recordkeeping obligations, like those in Florida law. *See* 42 U.S.C. § 299b-21(7)(B)(iii)(II) & (III). Indeed, had the HHS construed the PSQIA to give providers the broad, unreviewable power granted to them by the First District, HHS's construction would be invalid as "unreasonable" under *Chevron*. *See supra* at 30-31 (discussing *Chevron* doctrine).

II. The trial court correctly ordered Baptist to produce all records of state-mandated information on adverse medical incidents. The First District erred in holding otherwise. Alternatively, this Court should consider other remedies for Baptist's violation of non-preempted state law.

A. The trial court's order imposed the correct remedy for Baptist's non-compliance with its state-law obligations.

Baptist has violated non-preempted Florida law. Florida's reporting and recordkeeping laws, preserved by the federal Act, required Baptist to collect, maintain, or develop specified information on adverse incidents separately from any privileged database. *Supra* Argument I.A., 34. Baptist unlawfully stored this state-mandated information exclusively in a privileged database and denied a patient, Ms. Charles, her state constitutional right to inspect this information. *Supra* Statement, Parts II.A, III.B, at 18, 22. Accordingly, Baptist wronged Ms. Charles.

"The law guarantees every person a remedy when [s]he has been wronged. *Fla. Pub. Utils. Co. v. Wester*, 7 So. 2d 788, 790 (Fla. 1942); *accord Marbury v. Madison*, 5 U.S. 137, 163 (1803). For discovery wrongs, trial courts have wide discretion to impose remedies, including sanctions. *See, e.g.*, *Mercer v. Raine*, 443 So. 2d 944, 945-46 (Fla. 1983) (citing *National Hockey League v. Metropolitan Hockey Club, Inc.*, 427 U.S. 639, 643 (1976)). Here, the trial court ordered a mild remedy. It ordered Baptist to produce "[a]ll reports of adverse medical incidents, as defined by Amendment 7, which [were] created, or maintained pursuant to any statutory, regulatory, licensing, or accreditation requirements." (Pet.'s App. 503.)

While the trial court's ruling will require Baptist to remove from its PSES state-mandated separate information on adverse medical incidents, Baptist is in no position to complain. Baptist acted unlawfully. Now, the trial court is compelling Baptist to act lawfully. Baptist simply must do what it should have always done. That is, it must comply with state reporting and recordkeeping laws, preserved by the Act, that require Baptist to collect, maintain, or develop state-mandated information on adverse medical incidents separately from a privileged database.

It does not matter that HHS's guidance may have permitted Baptist to store state-mandated information in its PSES until Baptist determined that information had to be removed to satisfy state-law obligations. 73 Fed. Reg. at 70742. The discretion granted Baptist did not include the discretion to act unlawfully, violate reporting and recordkeeping laws, or conceal non-PSWP information. Parties granted discretion under a constitution, statute, regulation, or other source of law must exercise their discretion lawfully. When they fail to do so, courts may compel the non-compliant party to follow the law. *Cf. Pleus v. Crist*, 14 So. 3d 941, 945 (Fla. 2009) (directing the Governor to exercise his "inherently discretionary" power to appoint judges in a manner compliant with the state constitution).

The remedy compelled by the trial court was in accord with a remedy ordered by the Supreme Court of Kentucky, the only state supreme court to address a similar issue under the PSQIA. *Tibbs v. Bunnell*, 448 S.W.3d 796 (Ky. 2014). There, the

provider "intermingled" PSWP and non-privileged, state-mandated incident reports; the *Tibbs* court directed the trial court, *in camera*, to separate the non-privileged incident reports from the PSWP. *Id.* at 809. Likewise, here, Baptist has unlawfully merged non-PSWP information with PSWP. The trial court ordered Baptist to unwind its unlawful merger. This was a sound exercise of judicial discretion.

B. The First District's discussion on remedies was flawed.

In quashing the trial court's order, the First District agreed with the *Tibbs* dissent, expressing a concern with any remedy that allowed courts to "rummage through" a provider's PSES to separate the state-mandated information from the PSWP. (R. 477 (citing *Tibbs*, 448 S.W.3d at 809 (Abramson, J. dissenting).) The remedy, the First District reasoned, should be directed at correcting the provider's non-compliance of its recordkeeping and reporting obligations. (*Id.*) The *Tibbs* dissent, for example, opined that a provider "could be compelled to prepare the incident report required by state law." 448 S.W.3d at 816 (Abramson, J. dissenting). Under the mistaken belief that no reporting or recordkeeping violations had been alleged (*but see* R. 250-51), the First District did nothing to remedy Baptist's unlawful merger of its state-mandated information into the PSES. (R. 477-78.)

The First District's reasoning was flawed for several reasons. First, the fault for any "rummaging" lies with Baptist. Had Baptist followed the law by maintaining its state-mandated information separately from its PSES, no rummaging would be

necessary. Ms. Charles would prefer not to rummage to obtain the records to which she has a constitutional right. Indeed, Baptist is using its unlawful merger as a purported justification to charge Ms. Charles between $143,000 and $326,000. (Supp. App. 142, 155, 159.) This charge allegedly covers the research costs for Baptist to separate its state-mandated information from its PSES (*id.* 142-59), something that Baptist was already obligated to do under Florida law.

Second, while any remedy should be directed at correcting Baptist's unlawful conduct, the First District overlooked that Baptist's merger of its state-mandated reporting system with the PSES was the unlawful conduct that needed to be corrected. The trial court fashioned a reasonable remedy by requiring Baptist to unwind this merger and remove from the PSES state-mandated information that Baptist should have separated on its own in the first instance.

Third, the remedy proposed by the First District and the *Tibbs* dissent is unworkable. The First District's opinion and the *Tibbs* dissent suggest that Ms. Charles should identify specific adverse medical incidents and request that Baptist be compelled to complete an incident report for each incident. But, no patient, including Ms. Charles, is able to identify the hundreds or thousands of adverse medical or stroke incidents that occurred at Baptist's hospital. The mandatory incident reports are required to do this. Moreover, like many patients, Ms. Charles cannot identify all the adverse medical incidents that may have occurred in her case

during her multi-day stay at the hospital; after all, she was not conscious for much of that time. That is why providers must inform a patient when he or she has been the subject of an adverse incident. § 395.0197(1)(d), Fla. Stat. (2014). Finally, a 3-day incident report cannot be easily re-created, if at all, years after the incident; memories and evidence fade away. Extracting information from the PSES likely is the only practical way for Baptist to provide the state-mandated information.

In sum, the trial court's remedy was the right remedy. The First District got it wrong when it fashioned no remedy for Baptist's unlawful concealment of information to which Ms. Charles had a state constitutional right to access. However, if this Court, like the First District, disapproves of the trial court's remedy, then this Court should order some type of remedy and not follow the First District's example of doing nothing. *See Wester*, 7 So. 2d at 790 (guaranteeing "every person a remedy when [s]he has been wronged"). Next, alternative remedies are suggested.

C. Alternatively, on remand, the trial court should be instructed to consider other remedies for Baptist's unlawful conduct.

Baptist has violated its state-law duty to preserve evidence: Baptist has not collected, maintained, or developed state-mandated information separately from the PSES. It claims that it is unable or unwilling to remove that information from the PSES and will not honor Ms. Charles' state constitutional right to inspect that information. Thus, Baptist has spoiled evidence. To remedy this wrong, Baptist should be sanctioned like any other party who spoils evidence.

This Court recently spoke to the remedies for spoliation of evidence:

> Even in the absence of a legal duty, . . . the spoliation of evidence [may] result in an adverse inference against the party that discarded or destroyed the evidence. . . . Florida courts may impose sanctions, including striking pleadings, against a party that intentionally lost, misplaced, or destroyed evidence, and a jury could infer under such circumstances that the evidence would have contained indications of liability. If the evidence was negligently destroyed, a rebuttable presumption of liability may arise. . . . [A]n adverse inference may arise . . . where potentially self-damaging evidence is in the possession of a party and that party either loses or destroys the evidence.

League of Women Voters of Fla. v. Detzner, 172 So. 3d 363, 391 (Fla. 2015) (internal citations and quotations omitted).

Unlike in *Detzner*, Baptist had a clear legal duty to separately preserve and maintain state-mandated information on adverse medical incidents. *Infra* Statement, Part I.B., at 13; Argument I.A., at 34. Baptist's breach of this duty may make it practically impossible for Ms. Charles to inspect the evidence. It may be too difficult or expensive to separate the evidence from the PSES. If so, Baptist should be sanctioned. The courts in this case should consider the remedies noted in *Detzner* and the cases cited therein, and any other remedy allowed under the law or in equity.

CONCLUSION

This Court should reverse the First District's decision and reinstate the trial court's quashed order. Alternatively, on remand, the trial court should be instructed to consider appropriate sanctions and remedies for Baptist's non-compliance with its state-law recordkeeping and reporting obligations.

Respectfully submitted,

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I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished, via electronic mail, to the following on this 10th day of February, 2016:

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